Health Evidence Review Commission's Value-based Benefits Subcommittee

August 13, 2020

8:00 AM - 1:00 PM

Virtual Meeting

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Section 1.0

Call to Order

AGENDA
VALUE-BASED BENEFITS SUBCOMMITTEE
8/13/2020
8:00am - 1:00pm
Virtual meeting
https://www.zoomgov.com/j/1619721537?pwd=cy84Vnd1a3I4aGEvM21kUXVSMEdSdz09
All times are approximate

I. Call to Order, Roll Call, Approval of Minutes – Kevin Olson **8:00 AM**

II. Staff report – Jason Gingerich, Ariel Smits **8:05 AM**
- **A.** Addition of standing yearly item to update outside guideline references

III. Straightforward/Consent agenda – Ariel Smits **8:15 AM**
- **A.** Straightforward updates to GN172 and GN173
- **B.** Consent table
- **C.** Straightforward guideline updates
- **D.** Menstrual bleeding disorders guideline update
- **E.** Straightforward nasal fracture coding correction
- **F.** Update of cervical cancer screening and cervical dysplasia guidelines

IV. 2021 ICD-10 Code review **8:30 AM**
- **A.** Codes requiring review
- **B.** Consent table

V. 2022 Biennial Review **9:00 AM**
- **A.** Polydactyly of the foot, flat foot, and tarsal coalition
- **B.** Back and neck pain
    - A. Surgical guideline
        1. Artificial disc replacement
        2. Diagnostic spinal injections
        3. General surgical guideline revision
    - B. Medical guideline
        1. Massage
        2. Low level laser therapy
        3. General medical guideline revision
    - C. Opioid guideline

Break **10:30 AM**

VI. COVID-19 changes effective August 2020 Prioritized List **10:40 AM**
- **A.** Affirming previous COVID-19 coding and guideline changes
- **B.** SARS-CoV-2 diagnostic testing guideline
- **C.** Telemedicine guideline

VII.	**New discussion items** **A.** Cologuard for colon cancer screening **B.** Nerve allografts **C.** Combined kidney liver transplants	**11:10 AM**
	Break	**11:35 AM**
VIII.	**Coverage guidances** **A.** Out of hospital birth	**11:45 AM**
IX.	**Public comment**	**12:55 PM**
X.	**Adjournment – Kevin Olson**	**1:00 PM**

Note: Impromptu testimony will not be allowed at the meeting. If you think you want to testify, please complete the survey to sign up at https://www.surveymonkey.com/r/herc-public-comment by Tuesday, 8/11/2020, noon.

Value-based Benefits Subcommittee Recommendations Summary
For Presentation to:
Health Evidence Review Commission on March 12, 2020

For specific coding recommendations and guideline wording, please see the text of the 3/12/2020 VbBS minutes.

RECOMMENDED CODE MOVEMENT (changes to the 10/1/2020 Prioritized List unless otherwise noted)

- Add bone marrow transplant as a treatment for sickle cell disease with a new guideline
- Add procedure codes for peripheral nerve ablations to an unfunded line
- Recommend to HSD that procedure codes for bone grafts are placed on the Ancillary File
- Add acupuncture procedure codes to all cancer lines with a guideline note entry to the acupuncture guideline
- Move the female genital mutilation status codes from an unfunded line to a funded line
- Remove a telehealth store-and-forward code from many lines and place on unfunded line
- Make various straightforward code and guideline note changes

ITEMS CONSIDERED BUT NO RECOMMENDATIONS FOR CHANGES MADE

- None

RECOMMENDED GUIDELINE CHANGES (changes to the 10/1/2020 Prioritized List unless otherwise noted)

- Update the psoriasis guideline to include validated quality of life assessment tools
- Adopt a new guideline on female genital mutilation
- Update the telehealth guideline (effective as soon as feasible due to the COVID-19 emergency)
- Adopt a new statement of intent about telephone services in an outbreak

2022 BIENNIAL REVIEW (changes to the 1/1/2022 Prioritized List)

- Combine the medical and surgical chronic pancreatitis lines and prioritize to a line above the funding line
- Rescore the line for treatment of foreign bodies in the ear and nose to a higher priority line
- Rescore the line for treatment of Meniere's disease to a lower priority line

VALUE-BASED BENEFITS SUBCOMMITTEE
Clackamas Community College
Wilsonville Training Center, Rooms 111-112
Wilsonville, Oregon
March 12, 2020
9:00 AM – 1:00 PM

Members Present: Kevin Olson, MD, Chair; Holly Jo Hodges, MD, MBA, Vice-chair; Gary Allen, DMD; Kathryn Schabel, MD; Brian Duty, MD (arrived 9:15); Mike Collins (arrived 10:25 via phone); Adriane Irwin, PharmD.

Members Absent: None.

Staff Present: Jason Gingerich; Ariel Smits, MD, MPH; Cat Livingston, MD, MPH; Daphne Peck, Jaime Taylor.

Also Attending: Regina Dehen, ND, LAc (via phone); Maria Rodriguez, MD (OHSU, via phone).

- **Roll Call/Minutes Approval/Staff Report**

  The meeting was called to order at 9:00 am and roll was called. A quorum of members was present at the meeting. Minutes from the January 16, 2020 VbBS meeting were reviewed and approved with no suggested changes.

  Gingerich introduced the nominated VbBS member Regina Dehen, ND, LAc and welcomed her to the subcommittee. Her position was officially voted on at the HERC meeting later on March 12th.

  Smits reviewed the errata document. She also discussed HERC staff efforts to ensure COVID-19 testing and treatment are covered. Gingerich requested that members who become aware of any coverage related issues having to do with COVID-19 should bring these issues to HERC staff's attention immediately. Gingerich announced that an updated version of the Prioritized List will be published very soon with the telehealth guideline update to highlight coverage of visits with synchronous audio and video, as part of a broader public health measure.

- **Topic: Straightforward/Consent Agenda**

  Discussion: There was no discussion about the consent agenda items.

  Recommended Actions:
  1) Remove 31090 (Sinusotomy, unilateral, 3 or more paranasal sinuses (frontal, maxillary, ethmoid, sphenoid)) from line 364 ACUTE SINUSITIS
  2) Add 27709 (Osteotomy; tibia and fibula) to line 359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS
  3) Remove CPT 58565 (Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants) from lines 1 PREGNANCY and 6 REPRODUCTIVE SERVICES
  4) Remove CPT 58340 (Catheterization and introduction of saline or contrast material for saline infusion sonohysterography (SIS)) and 74740 (hysterosalpingography) from line 6 REPRODUCTIVE SERVICES
     a. Advise HSD to add to the Excluded File as an infertility procedure
  5) Delete GN68 as shown in Appendix A

  MOTION: To approve the recommendations stated in the consent agenda. CARRIES 5-0. *(Absent: Collins)*

- **Topic: Female genital mutilation treatment**

  Discussion: Livingston reviewed the summary document. Dr. Maria Rodriguez from OHSU Gynecology was available by phone as an expert. A member expressed surprise that this topic had not come up before and others said it would likely have been covered via exception.

  Recommended Actions:
  1) Add the female genital mutilation status codes N90.810-N90.818 Line 120 ABUSE AND NEGLECT
  2) Delete N90.81X from Line 658 GENITOURINARY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
  3) Add these CPT codes to Line 120

13131	Repair, complex, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; 1.1 cm to 2.5 cm
56441	Lysis of labial adhesions

  4) Add a new guideline SURGERIES RELATED TO FEMALE GENITAL MUTILATION as shown in Appendix B
  5) Rename line 629 BENIGN ~~CERVICAL~~ GYNECOLOGICAL CONDITIONS

  MOTION: To approve the coding and guideline recommendations as presented. CARRIES 5-0. *(Absent: Collins)*

- **Topic: Biennial review: overall discussion of topics**

  Discussion: Smits gave a presentation on prioritization and the Biennial Review. Smits reviewed suggested topics to date. Members questions were all answered. There were no action items.

- **Topic: Biennial review: Surgical treatment of chronic pancreatitis**

  Discussion: Smits reviewed the summary document. There was minimal discussion.

  Recommended Actions:
  1) Combine the medical and surgical lines for chronic pancreatitis and maintain prioritization at line 250
  2) Change the treatment description of line 250 to "MEDICAL AND SURGICAL THERAPY"
  3) Add all CPT codes from line 599 to line 250 that do not currently appear there

  MOTION: To recommend the line changes as presented. CARRIES 6-0.

- **Topic: Biennial review: foreign body in the ear and nose**

  Discussion: Smits reviewed the summary document. There was minimal discussion.

  Recommended Actions:
  1) Rescore the line for foreign bodies in the ear and nose as shown below

     Line XXX FOREIGN BODY IN EAR AND NOSE
     Line prioritization (no current scores—line hand placed previously. Scores proposed below are based on the scoring for line 499 CERUMEN IMPACTION with suffering changed from 0 to 1; tertiary prevention changed from 0 to 1 and need for treatment changed from 0.9 to 1)
     Category: 7
     Healthy life years: 1
     Suffering: 1
     Population effects: 0
     Vulnerable population: 1
     Tertiary prevention: 1
     Effectiveness: 4
     Need for treatment: 1
     Net cost: 4
     Score: 320
     Line placement: 428 (current funding line 471)

  MOTION: To recommend the line scoring changes as presented. CARRIES 6-0.

- **Topic: Biennial review: Meniere's disease**

  Discussion: Smits reviewed the summary document. There was minimal discussion.

Recommended Actions:

1) Rescore the Meniere's line as shown below

Reprioritization of MENIERE'S DISEASE Treatment: MEDICAL AND SURGICAL TREATMENT

(Current scores for line 417 shown in parentheses)

Category: 7 (7)
Healthy life years: 4 (4)
Suffering: 2 (2)
Population effects: 0
Vulnerable population: 0
Tertiary prevention: 0
Effectiveness: 1 (3)
Need for treatment: 1 (1)
Net cost: 3 (3)
Score: 120 (360)
Line placement: 520 (417)

MOTION: To recommend the line changes as presented. CARRIES 6-0.

- **Topic: Bone marrow transplant for sickle cell disease**

Discussion: Smits reviewed the summary document. There was minimal discussion.

Recommended Actions:

1) Add the ICD-10 D57.0 series (sickle cell disease with crisis) and D57.1 (Sickle-cell disease without crisis) to line 113 APLASTIC ANEMIAS; AGRANULOCYTOSIS Treatment: BONE MARROW TRANSPLANT
2) Modify the line title of line 113 to APLASTIC ANEMIAS; AGRANULOCYTOSIS; SICKLE CELL DISEASE
3) Add a guideline to line 113 as shown in Appendix B

MOTION: To recommend the code, line title, guideline note changes as presented. CARRIES 6-0.

- **Topic: Peripheral nerve ablation**

Discussion: Smits reviewed the summary document. There was minimal discussion.

Recommended Actions:

1) Add CPT 64640 (Destruction by neurolytic agent; other peripheral nerve or branch) to line 662/GN173 with a guideline entry as shown in Appendix A
    a. Advise HSD to remove CPT 64640 from the Ancillary File
2) Add CPT 64632 (Destruction by neurolytic agent; plantar common digital nerve) to line 662/GN173 with a guideline entry as shown in Appendix A
    a. Remove CPT 64632 from line 539 LESION OF PLANTAR NERVE; PLANTAR FASCIAL FIBROMATOSIS.

MOTION: To recommend the code and guideline note changes as presented. CARRIES 6-0.

- **Topic: Bone grafts**

Discussion: Smits reviewed the summary document. There was minimal discussion.

Recommended Actions:

1) Remove CPT 20955-20973 (bone grafts/osteocutaneous grafts) from all current lines on the Prioritized List
2) Advise HSD to place CPT 20955-20973 on the Ancillary Procedures File

MOTION: To recommend the code changes as presented. CARRIES 6-0.

- **Topic: Cranial electrical stimulation guideline entry update**

Discussion: Smits reviewed the summary document. A member noticed that the date of last review for cranial electrical stimulation was incorrect; the date was changed to the correct date.

Recommended Actions:

1) Modify GN173 as shown in Appendix A

MOTION: To recommend the guideline note changes as modified. CARRIES 6-0.

- **Topic: Acupuncture for cancer related pain**

Discussion: Smits reviewed the summary document. There was discussion about whether coverage of acupuncture should be limited to "active" cancer patients, or whether patients "in remission" with continued pain should be included. There was discussion about a desire to cover neuropathic pain resulting from cancer treatment. The decision of the group was to approve the guideline note entry as proposed by staff, limiting to "active" cancer; this decision can be readdressed in the future if needed.

Recommended Actions:

1) Add acupuncture (CPT 97810-97814) to any line with ICD-10 G89.3 (Neoplasm related pain (acute) (chronic))
2) Modify GN92 as shown in Appendix A

MOTION: To recommend the code and guideline note changes as presented. CARRIES 6-0.

- **Topic: Psoriasis guideline update**

Discussion: Smits reviewed the summary document. There was discussion that a statement of "other validated tools" be added. It was pointed out that the tool scores in the staff proposal needed to be slightly modified to meet the "severe" definition in those scoring tools.

Recommended Actions:

1) Modify GN21 as shown in Appendix A

MOTION: To recommend the guideline note changes as modified. CARRIES 6-0.

- **Topic: Telehealth guideline**

Discussion: Livingston and Gingerich reviewed a presentation that described different areas of telehealth and Livingston introduced the summary document. Hodges queried why telehealth codes would not just be allowed to be wide open and members addressed the potential role of telehealth in the current COVID-19 pandemic. Schabel stated there is a role for tiers of telehealth, based on complexity or time. Members discussed whether or not there would be potential for overuse. One example was that specialty care is usually rationed to ensure appropriate use and that self-referral could be problematic.

Livingston discussed specific language to consider and Hodges raised the concern about language limiting the role of telehealth. For example, that not all primary care clinics can be PCPCHs and that would be a barrier, particularly in rural areas. The goal of expansion of telehealth would need to be much more open to enable rural areas and small doc shops to also be able to offer access. If limitations are placed on telehealth then it defeats purpose of increasing access. Schabel raised a devil's advocate perspective of potential abuse of this through working at home and seeing patients all day but avoiding providing in person clinical care. Hodges stated that through the credentialing process plans could make sure that in-person primary care was also being delivered, that telehealth only providers would not be credentialed by CCOs. Adler raised concern about the meaning of urgent care, particularly in rural areas. Olson spoke about the differences between urgent, emergent, and on-demand care. Hodges pointed out that plans can contractually manage this, for example, if excess on-demand care was seen. Olson and Schabel discussed other factors that might affect overutilization.

Irwin raised a concern about whether the guideline would be able to address pharmacist expanding role and provision of health services and their consultation with clinicians. She gave examples such as naloxone, PrEP, rapid flu testing and the difficulty of the pharmacy business model so closely tied to drug distribution. Members discussed that this topic is important, and complex, and needs to be addressed separately from the scope of the telehealth guideline currently under discussion. Staff agreed to meet with Irwin to discuss this issue further.

The conversation shifted back to whether concerns about overutilization justified a need for language limiting use of telehealth. Members discussed that there is a workforce shortage and an underserved population. While the evidence Livingston presented demonstrated some overuse in direct-to-consumer telehealth, it was felt to not be relevant to the OHP population. Olson gave an example that one expensive cancer drug would cover 2000 RVU codes that will be overbilled and fundamentally access is important. Members agreed that they wanted the new guideline to not be restrictive of telehealth and to go into effect as quickly as possible. This is an emergently developing issue in their clinical settings.

The conversation shifted to reimbursement rates and members discussed how that felt different than HERC's typical process and seemed more appropriate for a policy statement. Members and HERC staff felt it was appropriate to address the direction of the HERC in a statement of intent while others are navigating the policy pieces in other parts of the agency.

Duty gave an example from his clinical setting that patients are offered audio/visual appointments or telephone appointments and that the vast majority of them choose telephone. There was discussion about this unusual time (COVID-19 pandemic) and the need to not limit, as well as concerns about low reimbursement and administrative burden. Members raised concerns that OHP patients frequently experience various difficulties accessing care and this will help to reduce them. If overutilization is seen, there is the ability to implement changes to the guidelines down the road and it is better to err on the side of overpaying for access.

Recommended Actions:

1) Modify Ancillary Guideline A5 as shown in Appendix A.
2) Remove G2010 from 600+ lines and place it on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
3) Adopt a new Statement of Intent as shown in Appendix C.

MOTION: To recommend the code and guideline note changes as modified and adopt a new Statement of Intent. CARRIES 5-0. (Absent: Duty)

- **Public Comment:**

  No additional public comment was received.

- **Issues for next meeting:**
  There were no outstanding topics

- **Next meeting:**

  May 21, 2020 at Clackamas Community College, Wilsonville Training Center, Wilsonville Oregon, Rooms 111-112.

- **Adjournment:**

  The meeting adjourned at 12:55 PM.

Appendix A
Revised Guideline Notes

GUIDELINE NOTE 21, SEVERE INFLAMMATORY SKIN DISEASE

Lines 424,480,502,530,539,654

Inflammatory skin conditions included in this guideline are:

A) Psoriasis
B) Atopic dermatitis
C) Darier disease
D) Pityriasis rubra pilaris
E) Discoid lupus

The conditions above are included on Line 424 if severe, defined as having functional impairment as indicated by Dermatology Life Quality Index (DLQI) ≥ 11 or Children's Dermatology Life Quality Index (CDLQI) ≥ 13 (or severe score on other validated tool) ~~e.g. inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction)~~ AND one or more of the following:

A) At least 10% of body surface area involved
B) Hand, foot or mucous membrane involvement.

Otherwise, these conditions above are included on Lines 480, 502, 530, 539 and 654.

For severe psoriasis, first line agents include topical agents, phototherapy and methotrexate. Second line agents include other systemic agents and oral retinoids and should be limited to those who fail, or have contraindications to, or do not have access to first line agents. Biologics are included on this line only for the indication of severe plaque psoriasis; after documented failure of first line agents and failure of (or contraindications to) a second line agent.

For severe atopic dermatitis/eczema, first-line agents include topical moderate- to high- potency corticosteroids and narrowband UVB. Second line agents include topical calcineurin inhibitors (e.g. pimecrolimus, tacrolimus), topical phosphodiesterase (PDE)-4 inhibitors (e.g. crisaborole), and oral immunomodulatory therapy (e.g. cyclosporine, methotrexate, azathioprine, mycophenolate mofetil, or oral corticosteroids). Use of the topical second line agents (e.g. calcineurin inhibitors and phosphodiesterase (PDE)-4 inhibitors) should be limited to those who fail or have contraindications to first line agents. Biologic agents are included on this line for atopic dermatitis only after failure of or contraindications to at least one agent from each of the following three classes: 1) moderate to high potency topical corticosteroids, 2) topical calcineurin inhibitors or topical phosphodiesterase (PDE)-4 inhibitors, and 3) oral immunomodulator therapy.

~~**GUIDELINE NOTE 68, HYSTEROSCOPIC BILATERAL FALLOPIAN TUBE OCCLUSION**~~

~~*Line 6*~~

~~Placement of permanent implants in the fallopian tubes to induce bilateral occlusion (CPT code 58565) is covered only if the procedure is done in the office setting, not in the ambulatory surgical center or hospital setting.~~

Appendix A
Revised Guideline Notes

~~Hysterosalpingography (58340, 74740) is covered only for the follow-up testing after placement of permanent implants in the fallopian tubes to induce bilateral occlusion.~~

GUIDELINE NOTE 92, ACUPUNCTURE

Lines 1,5, 92,111,112,114,125,129,133,135,157,158,191,199,200,202,361, 208,210,214,215,229,234,237,238,258,259,261,262,271,276,286,287,294,314,315,316,329,342, 372,396,397,401,409, 420,434,461,538, 558

Inclusion of acupuncture (CPT 97810-97814) on the Prioritized List has the following limitations:

Line 1 PREGNANCY

Acupuncture pairs on Line 1 for the following conditions and codes.

Hyperemesis gravidarum

ICD-10-CM: O21.0, O21.1

Acupuncture pairs with hyperemesis gravidarum when a diagnosis is made by the maternity care provider and referred for acupuncture treatment for up to 12 sessions of acupressure/acupuncture per pregnancy.

Breech presentation

ICD-10-CM: O32.1

Acupuncture (and moxibustion) is paired with breech presentation when a referral with a diagnosis of breech presentation is made by the maternity care provider, the patient is between 33 and 38 weeks gestation, for up to 6 session per pregnancy.

Back and pelvic pain of pregnancy

ICD-10-CM: O99.89

Acupuncture is paired with back and pelvic pain of pregnancy when referred by maternity care provider/primary care provider for up to 12 sessions per pregnancy.

Line 5 TOBACCO DEPENDENCE

Acupuncture is included on this line for a maximum of 12 sessions per quit attempt up to two quit attempts per year; additional sessions may be authorized if medically appropriate.

Line 92 and all other cancer-related lines

Acupuncture is paired only with the ICD-10 code G89.3 (Neoplasm related pain (acute) (chronic)) when there is active cancer and limited to 12 total sessions per year; patients may have additional visits authorized beyond these limits if medically appropriate.

Line 202 CHRONIC ORGANIC MENTAL DISORDERS INCLUDING DEMENTIAS

Acupuncture is paired with the treatment of post-stroke depression only. Treatments may be billed to a maximum of 30 minutes face-to-face time and limited to 12 total sessions per year, with documentation of meaningful improvement; patients may have additional visits authorized beyond these limits if medically appropriate.

Line 361 SCOLIOSIS

Acupuncture is included on this line with visit limitations as in Guideline Note 56 NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE.

Line 401 CONDITIONS OF THE BACK AND SPINE

Acupuncture is included on this line with visit limitations as in Guideline Note 56 NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE.

Line 409 MIGRAINE HEADACHES

Appendix A
Revised Guideline Notes

Acupuncture pairs on Line 409 for migraine (ICD-10-CM G43.0, G43.1, G43.5, G43.7, G43.8, G43.9), for up to 12 sessions per year.

Line 461 OSTEOARTHRITIS AND ALLIED DISORDERS

Acupuncture pairs on Line 461 for osteoarthritis of the knee only (ICD-10-CM M17), for up to 12 sessions per year.

*Line 538 TENSION HEADACHES

Acupuncture is included on Line 538 for treatment of tension headaches (ICD-10-CM G44.2), for up to 12 sessions per year.

The development of this guideline note was informed by a HERC coverage guidance. See https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx.

*Below the current funding line.

GUIDELINE NOTE 173, INTERVENTIONS THAT ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS

Line 662

The following Interventions are prioritized on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:

Procedure Code	Intervention Description	Rationale	Last Review
K1002	Cranial electrotherapy stimulation system (CES)	No clinically important benefit (of CES) for chronic pain; insufficient evidence of effectiveness for all other indications	March 2020
64632	Destruction by neurolytic agent; plantar common digital nerve	Insufficient evidence of effectiveness	March 2020
64640	Destruction by neurolytic agent; other peripheral nerve or branch	Insufficient evidence of effectiveness	March 2020
97014, 97032, 0278T, E0720, E0730, G0283	Transcutaneous electrical nerve stimulation (TENS), frequency specific microcurrent therapy, microcurrent electrical stimulation, and all similar therapies; Scrambler therapy; ~~Cranial electrical stimulation;~~ all similar transcutaneous electrical neurostimulation therapies	~~No clinically important benefit (CES) or insufficient evidence of effectiveness (all other) for chronic pain; insufficient evidence of effectiveness for all other indications~~ Insufficient evidence of effectiveness for chronic pain and all other	January 2020

Appendix A
Revised Guideline Notes

		indications	

GUIDELINE A5, TELEHEALTH, TELECONSULTATIONS AND ELECTRONIC/TELEPHONIC SERVICES[1]

Telehealth (Synchronous audio/video visits)

Telehealth visits are defined as synchronous visits with both audio and video capability. The patient may be at home or in a health care setting. The originating site code Q3014 may only be used by appropriate health care sites. Codes eligible for telehealth services include 90785, 90791, 90792, 90832-90834, 90836, 90837-90840, 90846, 90847, 90951, 90952, 90954, 90955, 90957, 90958, 90960, 90961, 90963, 90964-90970, 96116, ~~96150-96154~~, 96156-96171, 97802-4, 99201-99205, 99211-99215, 99231-99233, 99307-99310, 99354-99357, 99406-99407, 99495-99498, G0108-G0109, G0270, G0296, G0396, G0397, G0406-G0408, G0420, G0421, G0425-G0427, G0436-G0439, G0442-G0447, G0459, G0506, G0508, G0509, G0513, G0514, G2086-G2088.

Telehealth visits are covered for inpatient and outpatient services for new or established patients.

Telehealth consultations are covered for emergency and inpatient services.

Billing for telehealth visits requires the same level of documentation, medical necessity and coverage determinations as in-person visits.

Patient to Clinician Services (via telephone or electronic)
Telephonic and electronic services, including services related to diagnostic workup (CPT 98966-98968, 99441-99443, 99421-99423, 98970-98972, G2012, G2061-G2063) between a patient and clinician must meet the following criteria:

A) Ensure pre-existing relationship as demonstrated by at least one prior office visit within the past 36 months.
B) Documentation must:
    1) model SOAP charting, or be as described in program's OAR;
    2) include patient history, provider assessment, treatment plan and follow-up instructions;
    3) support the assessment and plan;
    4) be retained in the patient's medical record and be retrievable.
C) Medical decision making (or behavioral health intervention/ psychotherapy) is necessary.
D) Ensure permanent storage (electronic or hard copy) of the encounter.
E) Meet HIPAA standards for privacy.
F) Include a patient-clinician agreement of informed consent, which is discussed with and signed by the patient and documented in the medical record.
G) Not be billed when the same services are billed as care plan oversight or anticoagulation management (CPT codes 99339-99340, 99374-99380 or 99363-99364).

[1] This guideline was later revised based on authority given to staff at the HERC meeting; for the latest version see the March 13, 2020 Prioritized List.

Appendix A
Revised Guideline Notes

H) When a telephone or electronic service refers to an E/M service performed and billed by the physician within the previous seven days, it is not separately billable, regardless of whether it is the result of patient-initiated or physician-requested follow-up.
I) This service is not billed if the service results in the patient being seen within 24 hours or the next available appointment.
J) If the service relates to and takes place within the postoperative period of a procedure provided by the physician, the service is considered part of the procedure and is not be billed separately.

Examples of reimbursable telephone or electronic services include but are not limited to:

A) Extended counseling when person-to-person contact would involve an unwise delay.
B) Treatment of relapses that require significant investment of provider time and judgment.
C) Counseling and education for patients with complex chronic conditions.

Examples of non-reimbursable telephone/electronic consultations include but are not limited to:

A) Prescription renewal.
B) Scheduling a test.
C) Reporting normal test results.
D) Requesting a referral.
E) Follow up of medical procedure to confirm stable condition, without indication of complication or new condition.
F) Brief discussion to confirm stability of chronic problem and continuity of present management.

Clinician-to-Clinician Consultations (telephonic and electronic)

Requirements for coverage of electronic or telephonic interprofessional consultation are as follows:

Consulting Providers (99451, 99446-9)

- Consult must be requested by another provider
- Can be for a new or exacerbated condition
- Cannot be reported more than 1 time per 7 days for the same patient
- Cumulative time spent reported, even if time occurs over multiple days
- Cannot be reported if a transfer of care or request for face-to-face visit occurs as a result of the consultation within the next 14 days
- Cannot be reported if the patient was seen by the consultant within the past 14 days
- Request and reason for consultation request must be documented in the patient's medical record
- Requires a minimum of 5 minutes

Requesting Providers (99452)

- eConsult must be reported by requesting provider (not for the transfer of a patient or request for face-to-face consult)
- Reported only when the patient is not on-site and with the provider at the time of consultation
- Cannot be reported more than 1 time per 14 days per patient
- Requires a minimum of 16 minutes. Includes time for referral prep and/or communicating with the consultant.
- Can be reported with prolonged services, non-direct

Appendix A
Revised Guideline Notes

Limited information provided by one clinician to another that does not contribute to collaboration (e.g., interpretation of an electroencephalogram, report on an x-ray or scan, or reporting the results of a diagnostic test) is not considered a consultation.

Appendix B
New Guideline Notes

GUIDELINE XXX BONE MARROW TRANSPLANT FOR SICKLE CELL DISEASE

Line 114

Allogeneic hematopoietic cell transplantation for sickle cell disease is included on this line only when:

1) Patient has a related human leukocyte antigen (HLA) matched donor; *or*
2) Patient has an unrelated or HLA mismatched related donor AND severe sickle cell disease (e.g. recurrent chest syndrome, recurrent vaso-occlusive crises, red blood cell alloimmunization on chronic transfusion therapy).

GUIDELINE NOTE XXX SURGERIES RELATED TO FEMALE GENITAL MUTILATION

Line 120

Female genital mutilation of children or adults is not included on any line on the Prioritized List, including returning a woman to her former status after delivery.

Repair of female genital mutilation (e.g. Type II or III) with defibulation or lysis of adhesions is included on this line when causing interference in function (i.e. urinary, menstrual, or potential future vaginal childbirth) or causing recurrent complications including chronic pain related to the mutilation. Clitoral reconstruction is not included on this line due to an unclear risk/benefit ratio.

Appendix C

New Statement of Intent

STATEMENT OF INTENT 6: TELEPHONIC SERVICES DURING AN OUTBREAK OR EPIDEMIC

During an outbreak or epidemic of an infectious disease, reducing administrative barriers (e.g. increasing reimbursement rates) for telephonic evaluation and management services (CPT 99441-99443) and assessment and management services (CPT 98966-98968) is appropriate to ensure access to care while avoiding and preventing unnecessary potential infectious exposure.

DRAFT

Section 2.0

Staff Report

Guidelines with Outside References Needing Monitoring for Updates

Several Prioritized List guidelines contain references to outside guidelines some of these are out of date and require updating. All of these references should be monitored yearly and updated as needed going forward. HERC staff proposes having this as a standing agenda item for the November meeting yearly (to match up with GAP review of NCCN references). Some guidelines will be updated sooner as part of issues that have been brought up to HERC staff. Below are listed the guidelines and HERC staff notations on when review is expected.

1) NCCN
    a. DIAGNOSTIC GUIDELINE D25, HEREDITARY CANCER GENETIC TESTING
        i. GAP 2020
    b. GUIDELINE NOTE 3, PROPHYLACTIC TREATMENT FOR PREVENTION OF BREAST CANCER IN HIGH-RISK WOMEN
        i. October 2020 agenda
2) ASCCP
    a. GUIDELINE NOTE 1, ROUTINE CERVICAL CANCER SCREENING
        i. August 2020 agenda
    b. GUIDELINE NOTE 66, CERVICAL DYSPLASIA
        i. August 2020 agenda
3) American College of Medical Genetics Standards and Guidelines for Clinical Genetics Laboratories
    a. DIAGNOSTIC GUIDELINE D1, NON-PRENATAL GENETIC TESTING GUIDELINE
        i. GAP 2020
4) Oregon Public Health Division "Standard Tobacco Cessation Coverage"
    a. GUIDELINE NOTE 4, TOBACCO DEPENDENCE, INCLUDING DURING PREGNANCY
        i. Reviewed and current as of July 2020
5) Lymphology Association of North America
    a. GUIDELINE NOTE 43, LYMPHEDEMA
        i. Reviewed and current as of July 2020
6) World Professional Association for Transgender Health (WPATH)
    a. GUIDELINE NOTE 127, GENDER DYSPHORIA
        i. Anticipate new guideline release in the next year
7) USPSTF
    a. GUIDELINE NOTE 197, COUNSELING FOR PREGNANT AND POSTPARTUM WOMEN
        i. Reviewed and current as of July 2020
8) Various
    a. Will need updating in October or November, 2020

GUIDELINE NOTE 106, PREVENTIVE SERVICES

Lines 3,622

Included on Line 3 are the following preventive services:

A) US Preventive Services Task Force (USPSTF) "A" and "B" Recommendations in effect and issued prior to January 1, 2019.
    1) http://www.uspreventiveservicestaskforce.org/Page/Name/uspstf-a-and-b-recommendations/

a) Treatment of falls prevention with exercise interventions is included on Line 292.

2) USPSTF "D" recommendations are not included on this line or any other line of the Prioritized List.

B) American Academy of Pediatrics (AAP) Bright Futures Guidelines:

1) http://brightfutures.aap.org. Periodicity schedule available at http://www.aap.org/en-us/professional-resources/practice-support/Periodicity/Periodicity Schedule_FINAL.pdf.

2) Screening for lead levels is defined as blood lead level testing and is indicated for Medicaid populations at 12 and 24 months. In addition, blood lead level screening of any child between ages 24 and 72 months with no record of a previous blood lead screening test is indicated.

C) Health Resources and Services Administration (HRSA) Women's Preventive Services-Required Health Plan Coverage Guidelines as updated by HRSA on December 20, 2016. Available at https://www.hrsa.gov/womens-guidelines-2016/index.html as of 11/5/2019.

D) Immunizations as recommended by the Advisory Committee on Immunization Practices (ACIP): http://www.cdc.gov/vaccines/schedules/hcp/index.html or approved for the Oregon Immunization Program: https://public.health.oregon.gov/PreventionWellness/VaccinesImmunization/ImmunizationProviderResources/Documents/DMAPvactable.pdf

MULTISECTOR INTERVENTION STATEMENT 1: TOBACCO PREVENTION AND CESSATION, INCLUDING DURING PREGNANCY

Benefit coverage for smoking cessation on Line 5 and in Guideline Note 4 TOBACCO DEPENDENCE, INCLUDING DURING PREGNANCY is intended to be offered with minimal barriers, in order to encourage utilization. To further prevent tobacco use and help people quit, additional evidence-based policy and programmatic interventions from a population perspective are available here:

- Oregon Public Health Division's Health Promotion and Chronic Disease Prevention Section: Evidence-Based Strategies for Reducing Tobacco Use A Guide for CCOs https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/TOBACCOPREVENTION/Documents/evidence-based_strategies_reduce_tob_use_guide_cco.pdf

Community Preventive Services Task Force (supported by the CDC) - What Works: Tobacco Use http://www.thecommunityguide.org/about/What-Works-Tobacco-factsheet-and-insert.pdf

Items Discussed with Leadership

1) Coverage of vitamin D testing for COVID patients due to evidence that adequate vitamin D levels might improve outcomes of respiratory infections. NICE has done a rapid review (June 29, 2020): “There is no evidence to support taking vitamin D supplements to specifically prevent or treat COVID-19.” Insufficient evidence to move to VbBS/HERC consideration.

Section 3.0

Consent Agenda-

Straightforward Items

Straightforward Updates to GN172 and GN173

Issue:
GN172 and GN173 have entries listing non-covered CPT and HCPCS codes, as well as a rationale for non-coverage and a date of last review. Multiple entries, however, do not have a rationale or date of last review. CCOs have requested that we try to complete these entries if at all possible, to aid in their reviews and responses to coverage requests. Staff have reviewed old minutes and materials and filled in about 2/3 of these missing entries. While doing this review, staff determined that a few entries needed to be updated or otherwise altered.

1) Photoscreening was reviewed by HERC staff and leadership prior to the May, 2019 HERC meeting and no changes were recommended
2) Certain codes had no date of last review or rationale; HERC staff has done further research and identified when the code was recommended for non coverage
    a. CPT 20696-20697 were reviewed as new codes in January 2009 and placed on the Excluded File
    b. CPT 20979 was discussed as a new code in 2000 and no evidence of effectiveness was found
    c. CPT 27080 was discussed in December 2000 and no evidence of effectiveness was found
    d. CPT 28890 was reviewed as a new code in December 2005 and placed on the Excluded list
    e. CPT 29866-29868 were reviewed in November 2007 and no evidence of effectiveness was found
    f. CPT 33140-33141 was discussed in February 2000 and added to the Excluded File
    g. CPT 33548 was discussed in December 2005 and found to be experimental
    h. CPT 41530 was discussed in December 2008 and found to be experimental
    i. CPT 50380 was discussed in November 2000 and added to the Excluded File
    j. CPT 50592 was discussed in December 2005 and no evidence of effectiveness was found
    k. CPT 62263 was discussed in February 2000 and placed on the Excluded File
    l. Discography was discussed in August 2007 and no evidence of effectiveness was found.
    m. CPT 83037 was reviewed in January 2006 and added to the Excluded File
    n. CPT 83951, 87905, 88740, and 88741 were reviewed in August 2008 and added to the Excluded file
    o. CPT 83631 was discussed in January 2006 and it was determined that this device would not change therapy
    p. CPT 83700-87004 were discussed in October 2006 and the decision to placed on the Excluded File was upheld
    q. CPT 83861 was reviewed as a new code in December 2010 and added to the Excluded File
    r. CPT 86356 was reviewed as a new code in December 2007 and added to the Excluded File
    s. CPT 91117 was reviewed as a new code in December 2010 and added to the Excluded File
    t. CPT 91120 was reviewed as a new code in December 2004 and added to the Excluded File
    u. CPT 92620-92621 were reviewed in December 2005 and added to the Excluded File
    v. CPT 92625 had an evidence review conducted in December 2005 and no evidence of effectiveness was found
    w. CPT 93571-93572 were reviewed in January 2008 and added to the Excluded File
    x. CPT 93890-93893 were reviewed in December 2004 and added to the Excluded File

y. CPT 95928-95929 had an evidence review conducted in December 2004 and found to be experimental
z. The placement of CPT 97035 on the Excluded file was reviewed in June 2011 and upheld
aa. The placement of CPT 97533 on the Excluded file was reviewed in August 2010 and upheld
bb. Esophageal balloon distension study was reviewed in December 2004 and found to have only 4% to diagnostic sensitivity
cc. Exchange transfusion was reviewed in November 2016 and added to the Services Recommended for Non Coverage file
dd. Psychoanalysis was reviewed in November 2017 and found to no longer be used in clinical practice

3) Colonoscopy with endoscopic ultrasound was discussed in January 2005 and found to be less effective than sigmoidoscopy with endoscopic ultrasound for follow up of rectal cancer
    a. Staff recommends moving from GN173 to GN172
4) Digital breast tomosynthesis was reviewed as part of a coverage guidance in 2017, and no change was made to the placement on GN173
5) Functional MRI was reviewed in May 2019 and expert testimony was received. No change was made in the placement on GN173
6) An evidence review was done for Lp-PLA2 assay (CPT 83698) in October 2013 and no evidence of effective was found

HERC staff recommendations:

1) Make modifications to GN172 and GN173 as shown below
    a. Housekeeping; no change in HERC intent
2) Remove CPT 45391-45392 (Colonoscopy, flexible; with endoscopic ultrasound examination) from line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS and add to line502 CONDITIONS FOR WHICH INTERVENTIONS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS
    a. Effective, but more costly than the standard flexible sigmoidoscopy with endoscopic ultrasound for evaluation of rectal masses or follow up of rectal cancers
3) Staff plan to present topics re-reviewed by staff and discussed with leadership with a decision to not bring to HERC as consent agenda items going forward. This is in the interest of transparency for stakeholders and for ease in future queries and topic review.
    a. Example: Photoscreening was re-reviewed. HERC staff and leadership determined that insufficient evidence was found to justify HERC discussion. GN172 was updated as to date of review.
    b. Note: some items are already being brought as discussion topics (eg topics HERC staff were directed to bring back to the HERC after an expected study was published; topics where stakeholders indicate they plan to attend the meeting and disagree with HERC staff findings)
4) Give staff direction on any Commission desire for regular re-review of items in GN172/173; if there is a desire for regular re-review, give staff input on priorities

GUIDELINE NOTE 172, INTERVENTIONS WITH MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS FOR CERTAIN CONDITIONS

Line 502

The following interventions are prioritized on Line 502 CONDITIONS FOR WHICH INTERVENTIONS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS:

Procedure Code	Intervention Description	Rationale	Last Review
45391-45392	Colonoscopy, flexible; with endoscopic ultrasound examination	More costly than equally effective tests	January 2005
99174, 99177	Photoscreening	More costly than equally effective methods of screening	~~November, 2015~~ May 2019

GUIDELINE NOTE 173, INTERVENTIONS THAT ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS

Line 662

The following Interventions are prioritized on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:

Procedure Code	Intervention Description	Rationale	Last Review
20696-20697	Application of multiplane (pins or wires in more than 1 plane), unilateral, external fixation with	Insufficient evidence of effectiveness	January 2009

Procedure Code	Intervention Description	Rationale	Last Review
	stereotactic computer-assisted adjustment (eg, spatial frame)		
20979	Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)	Insufficient evidence of effectiveness	February 2000
28890	Extracorporeal shock wave, high energy involving the plantar fascia	Insufficient evidence of effectiveness	December 2005
21685	Hyoid myotomy and suspension	Insufficient evidence of effectiveness	December 2003
27080	Coccygectomy, primary	Insufficient evidence of effectiveness	November 2000
29866-29867	Arthroscopy, knee, surgical; osteochondral autograft(s)/allograft(s) (eg, mosaicplasty)	Insufficient evidence of effectiveness	November 2007
29868	Arthroscopy, knee, surgical; meniscal transplantation	Insufficient evidence of effectiveness	November 2007
33140-33141	Transmyocardial laser revascularization, by thoracotomy	Insufficient evidence of effectiveness	February 2000
33548	Surgical ventricular restoration procedure, includes prosthetic patch, when performed (eg, ventricular remodeling, SVR, SAVER, Dor procedures)	Insufficient evidence of effectiveness	December 2005
41530	Submucosal ablation of the tongue base, radiofrequency	Insufficient evidence of effectiveness	December 2008
36455	Exchange transfusion, blood; other than newborn	Insufficient evidence of effectiveness	November 2016
~~45391-45392~~	~~Colonoscopy, flexible; with endoscopic ultrasound examination~~		
50380	Renal autotransplantation, reimplantation of kidney	Insufficient evidence of effectiveness	November 2000
50592	Radiofrequency ablation, 1 or more renal tumor(s)	Insufficient evidence of effectiveness	December 2005
62263	Percutaneous lysis of epidural adhesions using solution injection (eg, hypertonic saline, enzyme) or mechanical means	Insufficient evidence of effectiveness	February 2000
62290-62292 72285, 72295	Discography	Insufficient evidence of effectiveness	August, 2007
70554	Functional MRI	Insufficient evidence of effectiveness	May 2019
77061-77063	Digital breast tomosynthesis	No evidence of effectiveness	~~November, 2014~~ March 2017

Procedure Code	Intervention Description	Rationale	Last Review
			Coverage guidance
83037	Hemoglobin; glycosylated (A1C) by device cleared by FDA for home use	Insufficient evidence of effectiveness	January 2006
83631	Lactoferrin, fecal; quantitative	Insufficient evidence of effectiveness	January 2006
83698	Lipoprotein-associated phospholipase A2 (Lp-PLA2)	Insufficient evidence of effectiveness	October 2013
83700-87004	Lipoprotein, blood	Insufficient evidence of effectiveness	October 2006
83861	Tear osmolarity	Insufficient evidence of effectiveness	December 2010
83951	Oncoprotein; des-gamma-carboxy-prothrombin (DCP)	Insufficient evidence of effectiveness	August 2008
86356	Mononuclear cell antigen, quantitative (eg, flow cytometry	Insufficient evidence of effectiveness	December 2007
87905	Infectious agent enzymatic activity other than virus (eg, sialidase activity in vaginal fluid)	Insufficient evidence of effectiveness	August 2008
88740	Hemoglobin, quantitative, transcutaneous, per day; carboxyhemoglobin	Insufficient evidence of effectiveness	August 2008
88741	Hemoglobin, quantitative, transcutaneous, per day; methhemoglobin	Insufficient evidence of effectiveness	August 2008
90845	Psychoanalysis	No longer used in clinical practice	November 2017
91040	Esophageal balloon distension study	Evidence of ineffectiveness	December 2004
91117	Colon motility (manometric) study	Insufficient evidence of effectiveness	December 2010
91120	Rectal sensation, tone, and compliance test	Insufficient evidence of effectiveness	December 2004
92620-92621	Evaluation of central auditory function	Insufficient evidence of effectiveness	January 2005
92625	Assessment of tinnitus	Insufficient evidence of effectiveness	January 2005
93571-93572	Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement	Insufficient evidence of effectiveness	January 2008
93890-93893	Transcranial Doppler study of the intracranial arteries	Insufficient evidence of effectiveness	December 2004

95928-95929	Central motor evoked potential study	Insufficient evidence of effectiveness	December 2004
97035	Application of a modality to 1 or more areas; ultrasound	Insufficient evidence of effectiveness	June 2011
97533	Sensory integrative techniques to enhance sensory processing and promote adaptive responses to environmental demands	Insufficient evidence of effectiveness	August 2010

Consent Agenda Issues—August 2020

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
61618 61619 62100	Secondary repair of dura for cerebrospinal fluid leak, anterior, middle or posterior cranial fossa following surgery of the skull base; by free tissue graft (eg, pericranium, fascia, tensor fascia lata, adipose tissue, homologous or synthetic grafts) by local or regionalized vascularized pedicle flap or myocutaneous flap (including galea, temporalis, frontalis or occipitalis muscle) Craniotomy for repair of dural/cerebrospinal fluid leak, including surgery for rhinorrhea/otorrhea	285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	CPT 61618 and 61619 are currently on lines 125,196. 62100 is on lines 19, 125, 156, 187, 196, 342, 371, 424. The other repair CPT codes for CSF leaks are on line 285, as is the ICD10 code G96.0 (Cerebrospinal fluid leak).	Add 61618, 61619 and 62100 to line 285

Straightforward Guideline Note and Coding Specification Changes
August 2020

1) Delete GN178. This guideline was added in 2018 as a stop-gap measure to define "vital site" that appeared in multiple burn line titles. The burn lines were reorganized as part of the 2020 Biennial Review, and now all vital site type burn codes are included on funded lines.

~~**GUIDELINE NOTE 178, VITAL SITE DEFINITION FOR BURN LINES**~~

~~*Line 127*~~

~~A burn to a "vital site" is defined as a burn involving the face, eyes, ears, hands, feet, or perineum that may result in functional impairment~~

2) At the March, 2020 meeting, the CPT code for Essure and similar devices were taken off of the Prioritized List; however, there was no recommendation about where to place this code (CPT 58565 (Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants)). These devices have been voluntarily withdrawn from the market due to reports of harm. Therefore, HERC staff felt placement on GN173 was most appropriate.
    a. Add the following entry to GN173

GUIDELINE NOTE 173, INTERVENTIONS THAT ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS

Line 662

The following Interventions are prioritized on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:

Procedure Code	Intervention Description	Rationale	Last Review
58565	Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants	Risk outweighs benefits	August 2020

3) In August, 2018, the HERC reviewed placement of ICD-10 F88 (Other disorders of psychological development), which was then on the Undefined File. F88 was add to lines 292, 345, and 377 with the following coding specification: "Coding specification: F88 is included on these lines for developmental delay. When it is used to indicate sensory integration disorder or sensory processing disorder, it is included on Line 659." F88 was not added to line 659 (now line 661) in error. There is also no coding specification on line 661. A coding specification should be added to line 661 to match the coding specification on lines 292, 345, and 377.
    a. Add ICD-10 F88 (Other disorders of psychological development) to line 661 MISCELLANEOUS CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
    b. Add the following coding specification to line 661 MISCELLANEOUS CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
        i. "F88 is included on line 661 when on these lines it is used to indicate sensory integration disorder or sensory processing disorder. When F88 is used for developmental delay, it is included on lines 292, 345, and 377."

Guideline Note 44 Update

Question: Should transvaginal ultrasound be added to the dysfunctional uterine bleeding guideline as a modality for evaluation for uterine pathology?

Question source: Alison Little, CCO medical director

Issue: GN44 MENSTRUAL BLEEDING DISORDERS requires "No evidence of treatable intrauterine conditions or lesions by" and then lists 3 acceptable tests (sonohhysterography, hysteroscopy, or hysterosalpingography). ACOG guidelines recommend "sonohysterography, hysteroscopy, MRI or transvaginal ultrasonography" as methods to visualize the uterus in cases of abnormal uterine bleeding. Hystersalpingography is currently Excluded as its main use is in infertility work up. Endometrial ultrasound is allowed as a work up prior to endometrial ablation. Dr. Little is requesting that the HERC consider adding vaginal ultrasound as an acceptable imaging modality in GN44. MRI is a more expensive and less clinically utilized tool for visualization, but could also be considered for addition to the guideline if the subcommittee wants to more closely mirror the ACOG recommendations.

HERC staff recommendation:

1) Modify GN44 as shown below

GUIDELINE NOTE 44, MENSTRUAL BLEEDING DISORDERS

Line 422

Endometrial ablation or hysterectomy for abnormal uterine bleeding in Premenopausal women may be indicated when all of the following are documented (A-C):

A) Patient history of (1, 2, 3, 4, and 5):
   1) Excessive uterine bleeding evidence by (a, b and c):
      a) Profuse bleeding lasting more than 7 days or repetitive periods at less than 21-day intervals
      b) Anemia due to acute or chronic blood loss (hemoglobin less than 10 g/dL or hemoglobin less than 11 g/dL if use of iron is documented) for hysterectomy. No documented hemoglobin level is required for endometrial ablation procedures.
      c) Bleeding causes major impairment or interferes with quality of life
   2) Failure of hormonal treatment for a six-month trial period or contraindication to hormone use (oral contraceptive pills or patches, progesterone-containing IUDs, injectable hormone therapy, or similar)
   3) No current medication use that may cause bleeding, or contraindication to stopping those medications
   4) Endometrial sampling performed
   5) For hysterectomy, no evidence of treatable intrauterine conditions or lesions by (a, b or c):
      a) Sonohysterography
      b) Hysteroscopy
      ~~c) Hysterosalpingography~~
      c) Transvaginal ultrasound

      For endometrial ablation, a pre-operative ultrasound should be performed.
B) Negative preoperative pregnancy test result unless patient has been previously sterilized
C) Nonmalignant cervical cytology, if cervix is present

Box 1. Clinical Screening for an Underlying Disorder of Hemostasis in the Patient With Excessive Menstrual Bleeding ⇦

Initial screening for an underlying disorder of hemostasis in patients with excessive menstrual bleeding should be structured by medical history (positive screen comprises any of the following): *

Heavy menstrual bleeding since menarche

One of the following:

- Postpartum hemorrhage
- Surgery-related bleeding
- Bleeding associated with dental work

Two or more of the following symptoms:

- Bruising one to two times per month
- Epistaxis one to two times per month
- Frequent gum bleeding
- Family history of bleeding symptoms

*Patients with a positive screen should be considered for further evaluation, including consultation with a hematologist and testing of von Willebrand factor and ristocetin cofactor.

Reprinted from Kouides PA, Conard J, Peyvandi F, Lukes A, Kadir R. Hemostasis and menstruation: appropriate investigation for underlying disorders of hemostasis in women with excessive menstrual bleeding. Fertil Steril 2005;84(5):1345–51. [PubMed] [Full Text]

include petechiae, ecchymoses, skin pallor, or swollen joints, although absence of these signs does not exclude the possibility of an underlying bleeding condition (18–20). A pelvic examination also should be performed as part of the physical examination, and in adults, this should include speculum and bimanual examination. A speculum examination should be performed to assess for cervical or vaginal lesions, with appropriate tissue sampling when abnormalities are noted. A bimanual examination should be performed to assess the size and contour of the uterus.

Laboratory Testing

Laboratory assessment for AUB should include a pregnancy test, complete blood count (CBC); measurement of thyroid-stimulating hormone (TSH) levels; and cervical cancer screening. Testing for *Chlamydia trachomatis* should be considered, especially in patients at high risk of infection (see Box 2). Ovulatory status usually can be determined by the presence of cyclic menses.

A CBC will indicate whether the patient has anemia or thrombocytopenic bleeding. The onset of heavy menses at menarche is often the first sign of von Willebrand disease. In all adolescents with heavy menstrual bleeding and adult patients with a positive screening history for a bleeding disorder, laboratory testing is indicated. Initial tests should include a CBC with platelets, prothrombin time, and partial thromboplastin time (fibrinogen or thrombin time are optional); bleeding time is neither

Box 2. Diagnostic Evaluation of Abnormal Uterine Bleeding ⇦

Medical History

- Age of menarche and menopause
- Menstrual bleeding patterns
- Severity of bleeding (clots or flooding)
- Pain (severity and treatment)
- Medical conditions
- Surgical history
- Use of medications
- Symptoms and signs of possible hemostatic disorder

Physical Examination

- General physical
- Pelvic Examination
  - –External
  - –Speculum with Pap test, if needed*
  - –Bimanual

Laboratory Tests

- Pregnancy test (blood or urine)
- Complete blood count
- Targeted screening for bleeding disorders (when indicated)†
- Thyroid-stimulating hormone level
- *Chlamydia trachomatis*

Available Diagnostic or Imaging Tests (when indicated)

- Saline infusion sonohysterography
- Transvaginal ultrasonography
- Magnetic resonance imaging
- Hysteroscopy

Available Tissue Sampling Methods (when indicated)

- Office endometrial biopsy
- Hysteroscopy directed endometrial sampling (office or operating room)

*For the nonadolescent patient only.

†Including a coagulation panel for adolescents and adult patients with suspected bleeding disorders.

Straightforward Nasal Fracture Coding Change

Issue: In 2016, an error in ICD-10 placement for uncomplicated nasal fractures was corrected. ICD10 S02.2XXA (Fracture of nasal bones, initial encounter for closed fracture) was removed from line 233 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES and added to on line 578 DEVIATED NASAL SEPTUM, ACQUIRED DEFORMITY OF NOSE, OTHER DISEASES OF UPPER RESPIRATORY TRACT. However, two similar codes were not moved. S02.2XXD (Fracture of nasal bones, subsequent encounter for fracture with routine healing) and S02.2XXG (Fracture of nasal bones, subsequent encounter for fracture with delayed healing) are both on lines 233 and 578. Based on HERC intent, these codes should only be on line 578.

From 8/2016 meeting materials:

> Historically, closed nasal fracture repair has not been on a covered line on the Prioritized List. The ICD-9 code (802.0) was on the equivalent to line 578 DEVIATED NASAL SEPTUM, ACQUIRED DEFORMITY OF NOSE, OTHER DISEASES OF UPPER RESPIRATORY TRACT paired with several repair CPT codes. The ICD-9 code (802.1) for open nasal fracture has been on line 228 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL for many years. The ICD-10 code for closed nasal fracture (S02.2XXA) was GEM-mapped to lines 228 and 578, and subsequently line 228 was reviewed by the ICD-10 Maxillofacial surgery review group, which consisted of a single oral surgeon without expertise in nasal fractures. The code was not moved off of line 228 at that time, and no discussion of this change in coverage occurred at HERC. The closed nasal fracture ICD-10 code was also reviewed by the ENT ICD-10 review group, who only saw the lower line placement and did not recommend any change in this placement.

HERC staff recommendations:

1) Remove S02.2XXD (Fracture of nasal bones, subsequent encounter for fracture with routine healing) and S02.2XXG (Fracture of nasal bones, subsequent encounter for fracture with delayed healing) from line 233 FRACTURE OF FACE BONES; INJURY TO OPTIC AND OTHER CRANIAL NERVES

Update of Cervical Cancer Screening and Cervical Dysplasia Guidelines

Question: Should Guideline Notes 1 and 66 be updated?

Question source: Holly Jo Hodges, CCO medical director; HERC staff

Issues: GN1 and GN66 both refer to an ASCCP guideline from April 2013. This guideline has been updated as of April 2020. Both Prioritized List guidelines need to be updated.

HERC staff recommendations:

1) Modify GN1 as shown below

GUIDELINE NOTE 1, ROUTINE CERVICAL CANCER SCREENING

Line 3

Cervical cancer screening is covered on Line 3 for women:

Age group in years	Type of screening covered	Frequency
<21	None	Never
21-29	Cytology alone Mandatory HPV testing (87620-87621) is not covered for women age 21-29	Every 3 years
30-65	High-risk human papillomavirus (hrHPV) testing alone, co-testing (hrHPV and cytology) or cytology alone	Co-testing every 5 years hrHPV testing alone every 5 years Cytology alone every 3 years
>65	None Unless adequate screening* has not been achieved, or it is <20 years after regression or appropriate management of a high-grade precancerous lesion	Never
Women who have had a hysterectomy with removal of cervix for non cervical cancer related reasons (i.e. other than high grade precancerous lesion, CIN 2 or 3, or cervical cancer)	None	Never
Women who have abnormal testing	Per ASCCP** Guideline, until indicated to resume routine screening	Per ASCCP Guideline, until indicated to resume routine screening

* Adequate screening is defined as 3 consecutive negative cytology results or 2 consecutive negative HPV results within 10 years of the cessation of screening, with the most recent test occurring within 5 years.
** American Cancer Society, American Society for Colposcopy and Cervical Pathology, and American Society for Clinical Pathology guideline (~~Saslow 2012~~ Perkins 2020)

Women who have received a diagnosis of a high-grade precancerous cervical lesion or cervical cancer, women with in utero exposure to diethylstilbestrol, or women who are immunocompromised (such as those who are HIV positive) are intended to have screening more frequently than delineated in this guideline.

2) Modify GN66 as shown below

GUIDELINE NOTE 66, CERVICAL DYSPLASIA

Line 25

Work up and treatment of cervical dysplasia should follow the American Society for Cervical Colposcopy and Pathology guidelines as published in the Journal of Lower Genital Tract Disease, April 2020 ~~2013~~.

OPEN

2019 ASCCP Risk-Based Management Consensus Guidelines for Abnormal Cervical Cancer Screening Tests and Cancer Precursors

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A. EXECUTIVE SUMMARY

Updated US consensus guidelines for management of cervical screening abnormalities are needed to accommodate the 3 available cervical screening strategies: primary human papillomavirus (HPV) screening, cotesting with HPV testing and cervical cytology, and cervical cytology alone. New data indicate that a patient's risk of developing cervical precancer or cancer can be estimated using current screening test results and previous screening test and biopsy results, while considering personal factors such as age and immunosuppression. Routine screening applies only to asymptomatic individuals who do not require surveillance for prior abnormal screening results.

The 2012 consensus guidelines were the first to be based on the principle of equal management for equal risk, specifically, the risk of a patient developing cervical cancer, estimated by the surrogate end point of the 5-year risk of cervical intraepithelial neoplasia (CIN) grade 3 (CIN 3) or more severe diagnoses (CIN 3+), regardless of which test combinations yielded this risk level. Introduction of risk-based guidelines in 2012 was a conceptual breakthrough, but the recommendations retained a continued reliance on complicated algorithms and insufficiently incorporated screening history. With a more nuanced understanding of how previous results affect risk, and more variables to consider, the 2019 guidelines further align management recommendations with current understanding of HPV natural history and cervical carcinogenesis. More frequent surveillance, colposcopy, and treatment are recommended for patients at progressively higher risk, whereas those at lower risk can defer colposcopy, undergo follow-up at longer surveillance intervals, and, when at sufficiently low risk, return to routine screening. Clearly defined risk thresholds to guide management are designed to continue functioning appropriately when population-level prevalence of CIN 3+ decreases because of HPV vaccination and also as new screening and triage tests are introduced. The revised guidelines provide a framework for incorporating new data and technologies as ongoing incremental recommendation revisions, minimizing the time needed to implement changes that are beneficial to patient care.

B. INTRODUCTION

This is the fourth American Society of Colposcopy and Cervical Pathology (ASCCP)-sponsored consensus guidelines for management of cervical cancer screening abnormalities, after the original consensus conferences in 2001[1] and subsequent updates in 2006[2] and 2012.[3] An interim guidance publication providing management recommendations for primary HPV screening was released in 2015.[4] *This document updates and replaces all previous guidance.* The key difference between 2019 guidelines and previous versions is the change from primarily test results–based algorithms (*e.g.,* "Colposcopy is recommended for patients with HPV-positive atypical squamous cells of undetermined significance [ASC-US], low-grade squamous intraepithelial lesion [LSIL]," etc.) to primarily "risk-based" guidelines (*e.g.,* "Colposcopy is recommended for any combination of history and current test results yielding a 4.0% or greater probability of finding CIN 3+," etc.). See Box 1 for essential changes. Tables of risk estimates for possible combinations of current screening test results and screening history (including unknown history) have been generated from a prospective longitudinal cohort of more than 1.5 million patients followed for more than a decade at Kaiser Permanente Northern California (KPNC). All KPNC estimates of risk underlying guideline decisions are detailed in the accompanying article by Egemen *et al*.[5] The applicability of these risk estimates to other United States regions and populations has been confirmed in other data sets from screening programs and clinical trials.[6] Many patients, especially those with minor abnormalities, can be managed by identifying their risk level using Tables 1A to 5B in Egemen *et al*[5] and linking it to a recommended clinical action (return to routine screening, surveillance with repeat testing at 1- or 3-year

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Section 4.0

New Codes

Diagnosis C	Description	Similar code(s)	Proposed placement	Comments
A84.81	Powassan virus disease	A84.8 (Other tick-borne viral encephalitis) was on line 535 VIRAL, SELF-LIMITING ENCEPHALITIS, MYELITIS AND ENCEPHALOMYELITIS. Powassan virus disease is a rare tick borne encephalitis	535 VIRAL, SELF-LIMITING ENCEPHALITIS, MYELITIS AND ENCEPHALOMYELITIS	
A84.89	Other tick-borne viral encephalitis	See above	535 VIRAL, SELF-LIMITING ENCEPHALITIS, MYELITIS AND ENCEPHALOMYELITIS	
B60.00	Babesiosis, unspecified	B60.0 (Babesiosis) was on lines 108 SUBACUTE MENINGITIS (E.G., TUBERCULOSIS, CRYPTOCOCCOSIS) and 268 RICKETTSIAL AND OTHER ARTHROPOD-BORNE DISEASES	108 SUBACUTE MENINGITIS (E.G., TUBERCULOSIS, CRYPTOCOCCOSIS) 268 RICKETTSIAL AND OTHER ARTHROPOD-BORNE DISEASES	
B60.01	Babesiosis due to Babesia microti	See above	108, 268	
B60.02	Babesiosis due to Babesia duncani	See above	108, 268	
B60.03	Babesiosis due to Babesia divergens	See above	108, 268	
B60.09	Other babesiosis	See above	108, 268	
D57.03	Hb-SS disease with cerebral vascular involvement	See issues document	113 APLASTIC ANEMIAS; AGRANULOCYTOSIS; SICKLE CELL DISEASE Treatment: BONE MARROW TRANSPLANT 194 HEREDITARY ANEMIAS, HEMOGLOBINOPATHIES, AND DISORDERS OF THE SPLEEN	
D57.09	Hb-SS disease with crisis with other specified complication	See issues document	113,194	
D57.213	Sickle-cell/Hb-C disease with cerebral vascular involvement	Other D57.2 codes on line 194	194 HEREDITARY ANEMIAS, HEMOGLOBINOPATHIES, AND DISORDERS OF THE SPLEEN	

Diagnosis C	Description	Similar code(s)	Proposed placement	Comments
D57.218	Sickle-cell/Hb-C disease with crisis with other specified complication	Other D57.2 codes on line 194	194 HEREDITARY ANEMIAS, HEMOGLOBINOPATHIES, AND DISORDERS OF THE SPLEEN	
D57.413	Sickle-cell thalassemia, unspecified, with cerebral vascular involvement	Other D57.4 codes on line 194	194 HEREDITARY ANEMIAS, HEMOGLOBINOPATHIES, AND DISORDERS OF THE SPLEEN	
D57.418	Sickle-cell thalassemia, unspecified, with crisis with other specified complication	Other D57.4 codes on line 194	194 HEREDITARY ANEMIAS, HEMOGLOBINOPATHIES, AND DISORDERS OF THE SPLEEN	
D57.42	Sickle-cell-thalassemia beta zero without crisis	Other D57.4 codes on line 194	194 HEREDITARY ANEMIAS, HEMOGLOBINOPATHIES, AND DISORDERS OF THE SPLEEN	
D57.431	Sickle-cell thalassemia beta zero with acute chest syndrome	Other D57.4 codes on line 194	194 HEREDITARY ANEMIAS, HEMOGLOBINOPATHIES, AND DISORDERS OF THE SPLEEN	
D57.432	Sickle-cell thalassemia beta zero with splenic sequestration	Other D57.4 codes on line 194	194 HEREDITARY ANEMIAS, HEMOGLOBINOPATHIES, AND DISORDERS OF THE SPLEEN	
D57.433	Sickle-cell thalassemia beta zero with cerebral vascular involvement	Other D57.4 codes on line 194	194 HEREDITARY ANEMIAS, HEMOGLOBINOPATHIES, AND DISORDERS OF THE SPLEEN	
D57.438	Sickle-cell thalassemia beta zero with crisis with other specified complication	Other D57.4 codes on line 194	194 HEREDITARY ANEMIAS, HEMOGLOBINOPATHIES, AND DISORDERS OF THE SPLEEN	
D57.439	Sickle-cell thalassemia beta zero with crisis, unspecified	Other D57.4 codes on line 194	194 HEREDITARY ANEMIAS, HEMOGLOBINOPATHIES, AND DISORDERS OF THE SPLEEN	
D57.44	Sickle-cell thalassemia beta plus without crisis	Other D57.4 codes on line 194	194 HEREDITARY ANEMIAS, HEMOGLOBINOPATHIES, AND DISORDERS OF THE SPLEEN	
D57.451	Sickle-cell thalassemia beta plus with acute chest syndrome	Other D57.4 codes on line 194	194 HEREDITARY ANEMIAS, HEMOGLOBINOPATHIES, AND DISORDERS OF THE SPLEEN	

Diagnosis C	Description	Similar code(s)	Proposed placement	Comments
D57.452	Sickle-cell thalassemia beta plus with splenic sequestration	Other D57.4 codes on line 194	194 HEREDITARY ANEMIAS, HEMOGLOBINOPATHIES, AND DISORDERS OF THE SPLEEN	
D57.453	Sickle-cell thalassemia beta plus with cerebral vascular involvement	Other D57.4 codes on line 194	194 HEREDITARY ANEMIAS, HEMOGLOBINOPATHIES, AND DISORDERS OF THE SPLEEN	
D57.458	Sickle-cell thalassemia beta plus with crisis with other specified complication	Other D57.4 codes on line 194	194 HEREDITARY ANEMIAS, HEMOGLOBINOPATHIES, AND DISORDERS OF THE SPLEEN	
D57.459	Sickle-cell thalassemia beta plus with crisis, unspecified	Other D57.4 codes on line 194	194 HEREDITARY ANEMIAS, HEMOGLOBINOPATHIES, AND DISORDERS OF THE SPLEEN	
D57.813	Other sickle-cell disorders with cerebral vascular involvement	Other D57.8 codes on line 194	194 HEREDITARY ANEMIAS, HEMOGLOBINOPATHIES, AND DISORDERS OF THE SPLEEN	
D57.818	Other sickle-cell disorders with crisis with other specified complication	Other D57.8 codes on line 194	194 HEREDITARY ANEMIAS, HEMOGLOBINOPATHIES, AND DISORDERS OF THE SPLEEN	
D59.10	Autoimmune hemolytic anemia, unspecified	D59.1 (Other autoimmune hemolytic anemias) was on line 148	148 ACQUIRED HEMOLYTIC ANEMIAS	
D59.11	Warm autoimmune hemolytic anemia	See above	148 ACQUIRED HEMOLYTIC ANEMIAS	
D59.12	Cold autoimmune hemolytic anemia	See above	148 ACQUIRED HEMOLYTIC ANEMIAS	
D59.13	Mixed type autoimmune hemolytic anemia	See above	148 ACQUIRED HEMOLYTIC ANEMIAS	
D59.19	Other autoimmune hemolytic anemia	See above	148 ACQUIRED HEMOLYTIC ANEMIAS	
D72.10	Eosinophilia, unspecified	D72.1 (Eosinophilia) was on the DIAGNOSTIC WORKUP FILE (DWF)	DIAGNOSTIC WORKUP FILE (DWF)	
D72.110	Idiopathic hypereosinophilic syndrome [IHES]	See issues document	161 GRANULOCYTE DISORDERS	

Diagnosis (	Description	Similar code(s)	Proposed placement	Comments
D72.111	Lymphocytic Variant Hypereosinophilic Syndrome [LHES]	See issues document	161 GRANULOCYTE DISORDERS	
D72.118	Other hypereosinophilic syndrome	See issues document	161 GRANULOCYTE DISORDERS	
D72.119	Hypereosinophilic syndrome [HES], unspecified	See issues document	161 GRANULOCYTE DISORDERS	
D72.12	Drug rash with eosinophilia and systemic symptoms syndrome	See issues document	161 GRANULOCYTE DISORDERS	
D72.18	Eosinophilia in diseases classified elsewhere	See issues document	161 GRANULOCYTE DISORDERS	
D72.19	Other eosinophilia	See issues document	DIAGNOSTIC WORKUP FILE (DWF)	
D84.81	Immunodeficiency due to conditions classified elsewhere	D84.8 (Other specified immunodeficiencies) was on line 313 DISORDERS INVOLVING THE IMMUNE SYSTEM	313 DISORDERS INVOLVING THE IMMUNE SYSTEM	
D84.821	Immunodeficiency due to drugs	Other conditions "due to drugs" appear on the line for that condition, not complication lines	313 DISORDERS INVOLVING THE IMMUNE SYSTEM	
D84.822	Immunodeficiency due to external causes	See D84.81	313 DISORDERS INVOLVING THE IMMUNE SYSTEM	
D84.89	Other immunodeficiencies	See D84.81	313 DISORDERS INVOLVING THE IMMUNE SYSTEM	
D89.831	Cytokine release syndrome, grade 1	Similar D89 codes appear on line 313	313 DISORDERS INVOLVING THE IMMUNE SYSTEM	
D89.832	Cytokine release syndrome, grade 2	Similar D89 codes appear on line 313	313 DISORDERS INVOLVING THE IMMUNE SYSTEM	
D89.833	Cytokine release syndrome, grade 3	Similar D89 codes appear on line 313	313 DISORDERS INVOLVING THE IMMUNE SYSTEM	
D89.834	Cytokine release syndrome, grade 4	Similar D89 codes appear on line 313	313 DISORDERS INVOLVING THE IMMUNE SYSTEM	
D89.835	Cytokine release syndrome, grade 5	Similar D89 codes appear on line 313	313 DISORDERS INVOLVING THE IMMUNE SYSTEM	

Diagnosis (	Description	Similar code(s)	Proposed placement	Comments
D89.839	Cytokine release syndrome, grade unspecified	Similar D89 codes appear on line 313	313 DISORDERS INVOLVING THE IMMUNE SYSTEM	
E70.81	Aromatic L-amino acid decarboxylase deficiency	E70.8 (Other disorders of aromatic amino-acid metabolism) was on lines 71,177,241,292,345,377	71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES 177 DISORDERS OF AMINO-ACID TRANSPORT AND METABOLISM (NON PKU); HEREDITARY FRUCTOSE INTOLERANCE 241 ACUTE AND SUBACUTE NECROSIS OF LIVER; SPECIFIED INBORN ERRORS OF METABOLISM (E.G., MAPLE SYRUP URINE DISEASE, TYROSINEMIA) Treatment: LIVER TRANSPLANT 292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS 345 NEUROLOGICAL DYSFUNCTION IN COMMUNICATION CAUSED BY CHRONIC CONDITIONS 377 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	
E70.89	Other disorders of aromatic amino-acid metabolism	See above	71,177,241,292,345,300	

Diagnosis (	Description	Similar code(s)	Proposed placement	Comments
E74.810	Glucose transporter protein type 1 deficiency	E74.8 (Other specified disorders of carbohydrate metabolism) was on line 177. Treatment of glucose transporter protein type 1 deficiency is a ketogenic diet.	177 DISORDERS OF AMINO-ACID TRANSPORT AND METABOLISM (NON PKU); HEREDITARY FRUCTOSE INTOLERANCE	
E74.818	Other disorders of glucose transport	E74.8 (Other specified disorders of carbohydrate metabolism) was on line 177	177 DISORDERS OF AMINO-ACID TRANSPORT AND METABOLISM (NON PKU); HEREDITARY FRUCTOSE INTOLERANCE	
E74.819	Disorders of glucose transport, unspecified	E74.8 (Other specified disorders of carbohydrate metabolism) was on line 177	177 DISORDERS OF AMINO-ACID TRANSPORT AND METABOLISM (NON PKU); HEREDITARY FRUCTOSE INTOLERANCE	
E74.89	Other specified disorders of carbohydrate metabolism	E74.8 (Other specified disorders of carbohydrate metabolism) was on line 177	177 DISORDERS OF AMINO-ACID TRANSPORT AND METABOLISM (NON PKU); HEREDITARY FRUCTOSE INTOLERANCE	
F10.130	Alcohol abuse with withdrawal, uncomplicated	F10.230 (Alcohol dependence with withdrawal, uncomplicated) is on line 65	65 SUBSTANCE-INDUCED DELIRIUM; SUBSTANCE INTOXICATION AND WITHDRAWAL	
F10.131	Alcohol abuse with withdrawal delirium	See above	65 SUBSTANCE-INDUCED DELIRIUM; SUBSTANCE INTOXICATION AND WITHDRAWAL	
F10.132	Alcohol abuse with withdrawal with perceptual disturbance	See above	65 SUBSTANCE-INDUCED DELIRIUM; SUBSTANCE INTOXICATION AND WITHDRAWAL	
F10.139	Alcohol abuse with withdrawal, unspecified	See above	65 SUBSTANCE-INDUCED DELIRIUM; SUBSTANCE INTOXICATION AND WITHDRAWAL	
F10.930	Alcohol use, unspecified with withdrawal, uncomplicated	See above	65 SUBSTANCE-INDUCED DELIRIUM; SUBSTANCE INTOXICATION AND WITHDRAWAL	

Diagnosis C	Description	Similar code(s)	Proposed placement	Comments
F10.931	Alcohol use, unspecified with withdrawal delirium	See above	65 SUBSTANCE-INDUCED DELIRIUM; SUBSTANCE INTOXICATION AND WITHDRAWAL	
F10.932	Alcohol use, unspecified with withdrawal with perceptual disturbance	See above	65 SUBSTANCE-INDUCED DELIRIUM; SUBSTANCE INTOXICATION AND WITHDRAWAL	
F10.939	Alcohol use, unspecified with withdrawal, unspecified	See above	65 SUBSTANCE-INDUCED DELIRIUM; SUBSTANCE INTOXICATION AND WITHDRAWAL	
F11.13	Opioid abuse with withdrawal	F11.23 (Opioid dependence with withdrawal) is on line 65	65 SUBSTANCE-INDUCED DELIRIUM; SUBSTANCE INTOXICATION AND WITHDRAWAL	
F12.13	Cannabis abuse with withdrawal	F12.23 (Cannabis dependence with withdrawal) is on line 65	65 SUBSTANCE-INDUCED DELIRIUM; SUBSTANCE INTOXICATION AND WITHDRAWAL	
F13.130	Sedative, hypnotic or anxiolytic abuse with withdrawal, uncomplicated	F13.23 (Sedative, hypnotic or anxiolytic dependencedependence with withdrawal) is on line 65	65 SUBSTANCE-INDUCED DELIRIUM; SUBSTANCE INTOXICATION AND WITHDRAWAL	
F13.131	Sedative, hypnotic or anxiolytic abuse with withdrawal delirium	See above	65 SUBSTANCE-INDUCED DELIRIUM; SUBSTANCE INTOXICATION AND WITHDRAWAL	
F13.132	Sedative, hypnotic or anxiolytic abuse with withdrawal with perceptual disturbance	See above	65 SUBSTANCE-INDUCED DELIRIUM; SUBSTANCE INTOXICATION AND WITHDRAWAL	
F13.139	Sedative, hypnotic or anxiolytic abuse with withdrawal, unspecified	See above	65 SUBSTANCE-INDUCED DELIRIUM; SUBSTANCE INTOXICATION AND WITHDRAWAL	
F14.13	Cocaine abuse, unspecified with withdrawal	F14.23 (Cocaine dependence with withdrawal) is on line 65	65 SUBSTANCE-INDUCED DELIRIUM; SUBSTANCE INTOXICATION AND WITHDRAWAL	

Diagnosis (	Description	Similar code(s)	Proposed placement	Comments
F14.93	Cocaine use, unspecified with withdrawal	See above	65 SUBSTANCE-INDUCED DELIRIUM; SUBSTANCE INTOXICATION AND WITHDRAWAL	
F15.13	Other stimulant abuse with withdrawal	F15.23 (Other stimulant dependence with withdrawal) is on line 65	65 SUBSTANCE-INDUCED DELIRIUM; SUBSTANCE INTOXICATION AND WITHDRAWAL	
F19.130	Other psychoactive substance abuse with withdrawal, uncomplicated	F19.23 (Other psychoactive substance dependence with withdrawal) is on line 65	65 SUBSTANCE-INDUCED DELIRIUM; SUBSTANCE INTOXICATION AND WITHDRAWAL	
F19.131	Other psychoactive substance abuse with withdrawal delirium	See above	65 SUBSTANCE-INDUCED DELIRIUM; SUBSTANCE INTOXICATION AND WITHDRAWAL	
F19.132	Other psychoactive substance abuse with withdrawal with perceptual disturbance	See above	65 SUBSTANCE-INDUCED DELIRIUM; SUBSTANCE INTOXICATION AND WITHDRAWAL	
F19.139	Other psychoactive substance abuse with withdrawal, unspecified	See above	65 SUBSTANCE-INDUCED DELIRIUM; SUBSTANCE INTOXICATION AND WITHDRAWAL	

Diagnosis (	Description	Similar code(s)	Proposed placement	Comments
G11.10	Early-onset cerebellar ataxia, unspecified	G11.1 (Early-onset cerebellar ataxia) was on lines 71,292,345,377	71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES 292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS 345 NEUROLOGICAL DYSFUNCTION IN COMMUNICATION CAUSED BY CHRONIC CONDITIONS 377 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	
G11.11	Friedreich ataxia	See above	71,292,345,377	
G11.19	Other early-onset cerebellar ataxia	See above	71,292,345,377	

Diagnosis (	Description	Similar code(s)	Proposed placement	Comments
G40.42	Cyclin-Dependent Kinase-Like 5 Deficiency Disorder	Developmental encephalopathy caused by pathogenic variants in the gene CDKL5. This unique disorder includes early infantile onset refractory epilepsy, hypotonia, developmental intellectual and motor disabilities, and cortical visual impairment. Similar diagnoses are on lines 30,71,292,345,377	30 EPILEPSY AND FEBRILE CONVULSIONS 71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES 292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS 345 NEUROLOGICAL DYSFUNCTION IN COMMUNICATION CAUSED BY CHRONIC CONDITIONS 377 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	
G40.833	Dravet syndrome, intractable, with status epilepticus	Severe type of epilepsy characterized by prolonged seizures that begin in the first year of life	30 EPILEPSY AND FEBRILE CONVULSIONS	
G40.834	Dravet syndrome, intractable, without status epilepticus	See above	30 EPILEPSY AND FEBRILE CONVULSIONS	
G71.20	Congenital myopathy, unspecifed	G71.2 (Congenital myopathies) was on the dysfunction lines	71,292,345,377	
G71.21	Nemaline myopathy	See above	71,292,345,377	
G71.220	X-linked myotubular myopathy	See above	71,292,345,377	
G71.228	Other centronuclear myopathy	See above	71,292,345,377	
G71.29	Other congenital myopathy	See above	71,292,345,377	
G96.00	Cerebrospinal fluid leak, unspecified	G96.0 (Cerebrospinal fluid leak) was on line 285	285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	

Diagnosis C	Description	Similar code(s)	Proposed placement	Comments
G96.01	Cranial cerebrospinal fluid leak, spontaneous	See issues document	285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	
G96.02	Spinal cerebrospinal fluid leak, spontaneous	See issues document	285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	
G96.08	Other cranial cerebrospinal fluid leak	G96.0 (Cerebrospinal fluid leak) was on line 285	285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	
G96.09	Other spinal cerebrospinal fluid leak	G96.0 (Cerebrospinal fluid leak) was on line 285	285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	
G96.191	Perineural cyst	G96.19 (Other disorders of meninges, not elsewhere classified) was on line 333	333 BENIGN CEREBRAL CYSTS	
G96.198	Other disorders of meninges, not elsewhere classified	See above	333 BENIGN CEREBRAL CYSTS	
G96.810	Intracranial hypotension, unspecified	See issues document.	285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	
G96.811	Intracranial hypotension, spontaneous	See issues document.	285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	
G96.819	Other intracranial hypotension	See issues document.	285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	
G96.89	Other specified disorders of central nervous system		Undefined	

Diagnosis C	Description	Similar code(s)	Proposed placement	Comments
G97.83	Intracranial hypotension following lumbar cerebrospinal fluid shunting	Similar codes are on lines 71,285,292,345,377	71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT 292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS 345 NEUROLOGICAL DYSFUNCTION IN COMMUNICATION CAUSED BY CHRONIC CONDITIONS 377 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	
G97.84	Intracranial hypotension following other procedure	See above	71,285,292,345,377	
H18.501	Unspecified hereditary corneal dystrophies, right eye	H18.50 (Unspecified hereditary corneal dystrophies) was on line 310	310 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA	
H18.502	Unspecified hereditary corneal dystrophies, left eye	See above	310 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA	
H18.503	Unspecified hereditary corneal dystrophies, bilateral	See above	310 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA	
H18.509	Unspecified hereditary corneal dystrophies, unspecified eye	See above	310 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA	
H18.511	Endothelial corneal dystrophy, right eye	H18.51 (Endothelial corneal dystrophy) was on line 310	310 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA	

Diagnosis C	Description	Similar code(s)	Proposed placement	Comments
H18.512	Endothelial corneal dystrophy, left eye	See above	310 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA	
H18.513	Endothelial corneal dystrophy, bilateral	See above	310 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA	
H18.519	Endothelial corneal dystrophy, unspecified eye	See above	310 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA	
H18.521	Epithelial (juvenile) corneal dystrophy, right eye	H18.52 (Epithelial (juvenile) corneal dystrophy) was on line 310	310 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA	
H18.522	Epithelial (juvenile) corneal dystrophy, left eye	See above	310 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA	
H18.523	Epithelial (juvenile) corneal dystrophy, bilateral	See above	310 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA	
H18.529	Epithelial (juvenile) corneal dystrophy, unspecified eye	See above	310 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA	
H18.531	Granular corneal dystrophy, right eye	H18.53 (Granular corneal dystrophy) was on line 310	310 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA	
H18.532	Granular corneal dystrophy, left eye	See above	310 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA	
H18.533	Granular corneal dystrophy, bilateral	See above	310 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA	
H18.539	Granular corneal dystrophy, unspecified eye	See above	310 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA	
H18.541	Lattice corneal dystrophy, right eye	H18.54 (Lattice corneal dystrophy) was on line 310	310 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA	
H18.542	Lattice corneal dystrophy, left eye	See above	310 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA	
H18.543	Lattice corneal dystrophy, bilateral	See above	310 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA	
H18.549	Lattice corneal dystrophy, unspecified eye	See above	310 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA	
H18.551	Macular corneal dystrophy, right eye	H18.55 (Macular corneal dystrophy) was on line 310	310 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA	

Diagnosis C	Description	Similar code(s)	Proposed placement	Comments
H18.552	Macular corneal dystrophy, left eye	See above	310 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA	
H18.553	Macular corneal dystrophy, bilateral	See above	310 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA	
H18.559	Macular corneal dystrophy, unspecified eye	See above	310 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA	
H18.591	Other hereditary corneal dystrophies, right eye	H18.59 (Other hereditary corneal dystrophies) was on line 310	310 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA	
H18.592	Other hereditary corneal dystrophies, left eye	See above	310 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA	
H18.593	Other hereditary corneal dystrophies, bilateral	See above	310 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA	
H18.599	Other hereditary corneal dystrophies, unspecified eye	See above	310 CORNEAL OPACITY AND OTHER DISORDERS OF CORNEA	
H55.82	Deficient smooth pursuit eye movements	See issues document	DIAGNOSTIC WORKUP FILE (DWF)	
J82.81	Chronic eosinophilic pneumonia	J82 (Pulmonary eosinophilia, not elsewhere classified) is on line 283 CHRONIC OBSTRUCTIVE PULMONARY DISEASE; CHRONIC RESPIRATORY FAILURE	283 CHRONIC OBSTRUCTIVE PULMONARY DISEASE; CHRONIC RESPIRATORY FAILURE	
J82.82	Acute eosinophilic pneumonia	Other pneumonia diagnoses are on lines 204 PNEUMOCOCCAL PNEUMONIA, OTHER BACTERIAL PNEUMONIA, BRONCHOPNEUMONIA and 304 VIRAL PNEUMONIA	204 PNEUMOCOCCAL PNEUMONIA, OTHER BACTERIAL PNEUMONIA, BRONCHOPNEUMONIA	
J82.83	Eosinophilic asthma	Other asthma diagnoses are on line 9	9 ASTHMA	
J82.89	Other pulmonary eosinophilia, not elsewhere classified		283 CHRONIC OBSTRUCTIVE PULMONARY DISEASE; CHRONIC RESPIRATORY FAILURE	

Diagnosis C	Description	Similar code(s)	Proposed placement	Comments
J84.170	Interstitial lung disease with progressive fibrotic phenotype in diseases classified elsewhere	J84.1 (Pulmonary fibrosis, unspecified) is on line 219 PULMONARY FIBROSIS	219 PULMONARY FIBROSIS	
J84.178	Other interstitial pulmonary diseases with fibrosis in diseases classified elsewhere		219 PULMONARY FIBROSIS	
K20.80	Other esophagitis without bleeding	K20.8 (Other esophagitis) is on lines 380,513	380 ESOPHAGITIS; GERD 513 ESOPHAGITIS AND GERD; ESOPHAGEAL SPASM; ASYMPTOMATIC DIAPHRAGMATIC HERNIA	
K20.81	Other esophagitis with bleeding	If significant bleeding, can use K92.9 (Gastrointestinal hemorrhage, unspecified) which is online 56 ULCERS, GASTRITIS, DUODENITIS, AND GI HEMORRHAGE	380 ESOPHAGITIS; GERD 513 ESOPHAGITIS AND GERD; ESOPHAGEAL SPASM; ASYMPTOMATIC DIAPHRAGMATIC HERNIA	
K20.90	Esophagitis, unspecified without bleeding		380 ESOPHAGITIS; GERD 513 ESOPHAGITIS AND GERD; ESOPHAGEAL SPASM; ASYMPTOMATIC DIAPHRAGMATIC HERNIA	
K20.91	Esophagitis, unspecified with bleeding		380 ESOPHAGITIS; GERD 513 ESOPHAGITIS AND GERD; ESOPHAGEAL SPASM; ASYMPTOMATIC DIAPHRAGMATIC HERNIA	
K21.00	Gastro-esophageal reflux disease with esophagitis, without bleeding		380 ESOPHAGITIS; GERD 513 ESOPHAGITIS AND GERD; ESOPHAGEAL SPASM; ASYMPTOMATIC DIAPHRAGMATIC HERNIA	
K21.01	Gastro-esophageal reflux disease with esophagitis, with bleeding		380 ESOPHAGITIS; GERD 513 ESOPHAGITIS AND GERD; ESOPHAGEAL SPASM; ASYMPTOMATIC DIAPHRAGMATIC HERNIA	

Diagnosis (	Description	Similar code(s)	Proposed placement	Comments
K59.81	Ogilvie syndrome	see issues document	41 INTUSSCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION	
K59.89	Other specified functional intestinal disorders	K59.8 (Other specified functional intestinal disorders) was on line 528 DISORDERS OF FUNCTION OF STOMACH AND OTHER FUNCTIONAL DIGESTIVE DISORDERS	528 DISORDERS OF FUNCTION OF STOMACH AND OTHER FUNCTIONAL DIGESTIVE DISORDERS	
K74.00	Hepatic fibrosis, unspecified	See issues document	334 ALCOHOLIC FATTY LIVER OR ALCOHOLIC HEPATITIS, CIRRHOSIS OF LIVER	
K74.01	Hepatic fibrosis, early fibrosis	See issues document	334 ALCOHOLIC FATTY LIVER OR ALCOHOLIC HEPATITIS, CIRRHOSIS OF LIVER	
K74.02	Hepatic fibrosis, advanced fibrosis	See issues document	307 CIRRHOSIS OF LIVER OR BILIARY TRACT; BUDD-CHIARI SYNDROME; HEPATIC VEIN THROMBOSIS; INTRAHEPATIC VASCULAR MALFORMATIONS; CAROLI'S DISEASE 334 ALCOHOLIC FATTY LIVER OR ALCOHOLIC HEPATITIS, CIRRHOSIS OF LIVER	
M05.7A	Rheumatoid arthritis with rheumatoid factor of other specified site without organ or systems involvement	Rheumatoid arthritis diagnoses are on lines 46,356	46 RHEUMATOID ARTHRITIS AND OTHER INFLAMMATORY POLYARTHROPATHIES 356 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE	

Diagnosis (	Description	Similar code(s)	Proposed placement	Comments
M05.8A	Other rheumatoid arthritis with rheumatoid factor of other specified site	See above	46,356	
M06.0A	Rheumatoid arthritis without rheumatoid factor, other specified site	See above	46,356	
M06.8A	Other specified rheumatoid arthritis, other specified site	See above	46,356	
M08.0A	Unspecified juvenile rheumatoid arthritis, other specified site	See above	46,356	
M08.2A	Juvenile rheumatoid arthritis with systemic onset, other specified site	See above	46,356	
M08.4A	Pauciarticular juvenile rheumatoid arthritis, other specified site	See above	46,356	
M08.9A	Juvenile arthritis, unspecified, other specified site	See above	46,356	
M19.09	Primary osteoarthritis, other specified site	Osteoarthritis diagnoses are on lines 356,463	356 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE 463 OSTEOARTHRITIS AND ALLIED DISORDERS	
M19.19	Post-traumatic osteoarthritis, other specified site	See above	356,463	
M19.29	Secondary osteoarthritis, other specified site	See above	356,463	
M24.19	Other articular cartilage disorders, other specified site	M24.10 (Other articular cartilage disorders, unspecified site) is on line 659 MUSCULOSKELETAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY	659 MUSCULOSKELETAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY	

Diagnosis (	Description	Similar code(s)	Proposed placement	Comments
M24.29	Disorder of ligament, other specified site	Other disorder of ligament codes are on line 608	608 SPRAINS AND STRAINS OF ADJACENT MUSCLES AND JOINTS, MINOR	
M24.39	Pathological dislocation of other specified joint, not elsewhere classified	M24.4 (Recurrent dislocation, unspecified joint) is on line 659. Other joints (knee, elbow, etc.) are on covered lines	659 MUSCULOSKELETAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY	
M24.49	Recurrent dislocation, other specified joint		659 MUSCULOSKELETAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY	
M24.59	Contracture, other specified joint	Other contracture diagnoses are on line 292	292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS	
M24.69	Ankylosis, other specified joint	Other ankylosis diagnoses are on line 527	527 DEFORMITIES OF UPPER BODY AND ALL LIMBS	
M24.89	Other specific joint derangement of other specified joint, not elsewhere classified	Unspecified code	659 MUSCULOSKELETAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY	
M25.39	Other instability, other specified joint	Unspecified code	659 MUSCULOSKELETAL CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY	
M25.59	Pain in other specified joint	Other pain in joint codes are DWF	DIAGNOSTIC WORKUP FILE (DWF)	
M25.69	Stiffness of other specified joint, not elsewhere classified	Other stiffness in joint codes are DWF	DIAGNOSTIC WORKUP FILE (DWF)	
M26.641	Arthritis of right temporomandibular joint	TMJ disorders are on lines 549,643	549 TMJ DISORDER 643 TMJ DISORDERS	
M26.642	Arthritis of left temporomandibular joint	See above	549,643	

Diagnosis C	Description	Similar code(s)	Proposed placement	Comments
M26.643	Arthritis of bilateral temporomandibular joint	See above	549,643	
M26.649	Arthritis of unspecified temporomandibular joint	See above	549,643	
M26.651	Arthropathy of right temporomandibular joint	See above	549,643	
M26.652	Arthropathy of left temporomandibular joint	See above	549,643	
M26.653	Arthropathy of bilateral temporomandibular joint	See above	549,643	
M26.659	Arthropathy of unspecified temporomandibular joint	See above	549,643	
M80.0AXA	Age-related osteoporosis with current pathological fracture, other site, initial encounter for fracture	M80.00XA (Age-related osteoporosis with current pathological fracture, unspecified site, initial encounter for fracture) is on line 355. Osteoporotic fractures frequently occur in the spine	150 CERVICAL VERTEBRAL DISLOCATIONS/FRACTURES, OPEN OR CLOSED; OTHER VERTEBRAL DISLOCATIONS/FRACTURES, OPEN OR UNSTABLE; SPINAL CORD INJURIES WITH OR WITHOUT EVIDENCE OF VERTEBRAL INJURY 355 CLOSED FRACTURE OF EXTREMITIES (EXCEPT MINOR TOES) 478 CLOSED DISLOCATIONS/FRACTURES OF NON-CERVICAL VERTEBRAL COLUMN WITHOUT NEUROLOGIC INJURY OR STRUCTURAL INSTABILITY	
M80.0AXD	Age-related osteoporosis with current pathological fracture, other site, subsequent encounter for fracture with routine healing	See above	150,355,478	

Diagnosis (	Description	Similar code(s)	Proposed placement	Comments
M80.0AXG	Age-related osteoporosis with current pathological fracture, other site, subsequent encounter for fracture with delayed healing	See above	150,355,478	
M80.0AXK	Age-related osteoporosis with current pathological fracture, other site, subsequent encounter for fracture with nonunion	Fracture nonunion diagnoses are on line 442	442 MALUNION AND NONUNION OF FRACTURE	
M80.0AXP	Age-related osteoporosis with current pathological fracture, other site, subsequent encounter for fracture with malunion		442 MALUNION AND NONUNION OF FRACTURE	
M80.0AXS	Age-related osteoporosis with current pathological fracture, other site, sequela		150,355,478	
M80.8AXA	Other osteoporosis with current pathological fracture, other site, initial encounter for fracture		150,355,478	
M80.8AXD	Other osteoporosis with current pathological fracture, other site, subsequent encounter for fracture with routine healing		150,355,478	
M80.8AXG	Other osteoporosis with current pathological fracture, other site, subsequent encounter for fracture with delayed healing		150,355,478	
M80.8AXK	Other osteoporosis with current pathological fracture, other site, subsequent encounter for fracture with nonunion		442 MALUNION AND NONUNION OF FRACTURE	

Diagnosis (	Description	Similar code(s)	Proposed placement	Comments
M80.8AXP	Other osteoporosis with current pathological fracture, other site, subsequent encounter for fracture with malunion		442 MALUNION AND NONUNION OF FRACTURE	
M80.8AXS	Other osteoporosis with current pathological fracture, other site, sequela		150,355,478	
M92.501	Unspecified juvenile osteochondrosis, right leg	M92.50 (Juvenile osteochondrosis of tibia and fibula, unspecified leg) was on line 359	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	
M92.502	Unspecified juvenile osteochondrosis, left leg	See above	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	
M92.503	Unspecified juvenile osteochondrosis, bilateral leg	See above	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	
M92.509	Unspecified juvenile osteochondrosis, unspecified leg	See above	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	
M92.511	Juvenile osteochondrosis of proximal tibia, right leg	See above	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	
M92.512	Juvenile osteochondrosis of proximal tibia, left leg	See above	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	
M92.513	Juvenile osteochondrosis of proximal tibia, bilateral	See above	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	
M92.519	Juvenile osteochondrosis of proximal tibia, unspecified leg	See above	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	

Diagnosis C	Description	Similar code(s)	Proposed placement	Comments
M92.521	Juvenile osteochondrosis of tibia tubercle, right leg	See above	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	
M92.522	Juvenile osteochondrosis of tibia tubercle, left leg	See above	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	
M92.523	Juvenile osteochondrosis of tibia tubercle, bilateral	See above	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	
M92.529	Juvenile osteochondrosis of tibia tubercle, unspecified leg	See above	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	
M92.591	Other juvenile osteochondrosis of tibia and fibula, right leg	See above	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	
M92.592	Other juvenile osteochondrosis of tibia and fibula, left leg	See above	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	
M92.593	Other juvenile osteochondrosis of tibia and fibula, bilateral	See above	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	
M92.599	Other juvenile osteochondrosis of tibia and fibula, unspecified leg	See above	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	
N00.A	Acute nephritic syndrome with C3 glomerulonephritis	Acute nephritic syndrome is on line 126	126 ACUTE KIDNEY INJURY	
N01.A	Rapidly progressive nephritic syndrome with C3 glomerulonephritis	Rapidly progressive nephritic syndrome is on lines 99,126	99 END STAGE RENAL DISEASE 126 ACUTE KIDNEY INJURY	
N02.A	Recurrent and persistent hematuria with C3 glomerulonephritis	Recurrent and persistent hematuria diagnoses are on lines 99,339	99 END STAGE RENAL DISEASE 339 CHRONIC KIDNEY DISEASE	

Diagnosis (	Description	Similar code(s)	Proposed placement	Comments
N03.A	Chronic nephritic syndrome with C3 glomerulonephritis	Chronic nephritis cyndrome is on lines 99,339	99 END STAGE RENAL DISEASE 339 CHRONIC KIDNEY DISEASE	
N04.A	Nephrotic syndrome with C3 glomerulonephritis	Nephrotic syndrome is on lines 99.339	99 END STAGE RENAL DISEASE 339 CHRONIC KIDNEY DISEASE	
N05.A	Unspecified nephritic syndrome with C3 glomerulonephritis	Nephrotic syndrome is on lines 99.339	99 END STAGE RENAL DISEASE 339 CHRONIC KIDNEY DISEASE	
N06.A	Isolated proteinuria with C3 glomerulonephritis	Glomerulonephritis diagnoses are on lines 99.339	99 END STAGE RENAL DISEASE 339 CHRONIC KIDNEY DISEASE	
N07.A	Hereditary nephropathy, not elsewhere classified with C3 glomerulonephritis	Glomerulonephritis diagnoses are on lines 99.339	99 END STAGE RENAL DISEASE 339 CHRONIC KIDNEY DISEASE	
N18.30	Chronic kidney disease, stage 3 unspecified	Chronic kidney disease is on line 339	339 CHRONIC KIDNEY DISEASE	
N18.31	Chronic kidney disease, stage 3a	See above	339 CHRONIC KIDNEY DISEASE	
N18.32	Chronic kidney disease, stage 3b	See above	339 CHRONIC KIDNEY DISEASE	
N61.20	Granulomatous mastitis, unspecified breast	See issues document	205 SUPERFICIAL ABSCESSES AND CELLULITIS	
N61.21	Granulomatous mastitis, right breast	See issues document	205 SUPERFICIAL ABSCESSES AND CELLULITIS	
N61.22	Granulomatous mastitis, left breast	See issues document	205 SUPERFICIAL ABSCESSES AND CELLULITIS	
N61.23	Granulomatous mastitis, bilateral breast	See issues document	205 SUPERFICIAL ABSCESSES AND CELLULITIS	
O34.218	Maternal care for other type scar from previous cesarean delivery		1 PREGNANCY	
O34.22	Maternal care for cesarean scar defect (isthmocele)		1 PREGNANCY	
O99.891	Other specified diseases and conditions complicating pregnancy		1 PREGNANCY	
O99.892	Other specified diseases and conditions complicating childbirth		1 PREGNANCY	
O99.893	Other specified diseases and conditions complicating puerperium		1 PREGNANCY	

Diagnosis (	Description	Similar code(s)	Proposed placement	Comments
P91.821	Neonatal cerebral infarction, right side of brain	See issues document	23 INTRACRANIAL HEMORRHAGES; CEREBRAL CONVULSIONS, DEPRESSION, COMA, AND OTHER ABNORMAL CEREBRAL SIGNS OF THE NEWBORN	
P91.822	Neonatal cerebral infarction, left side of brain	See issues document	23 INTRACRANIAL HEMORRHAGES; CEREBRAL CONVULSIONS, DEPRESSION, COMA, AND OTHER ABNORMAL CEREBRAL SIGNS OF THE NEWBORN	
P91.823	Neonatal cerebral infarction, bilateral	See issues document	23 INTRACRANIAL HEMORRHAGES; CEREBRAL CONVULSIONS, DEPRESSION, COMA, AND OTHER ABNORMAL CEREBRAL SIGNS OF THE NEWBORN	
P91.829	Neonatal cerebral infarction, unspecified side	See issues document	23 INTRACRANIAL HEMORRHAGES; CEREBRAL CONVULSIONS, DEPRESSION, COMA, AND OTHER ABNORMAL CEREBRAL SIGNS OF THE NEWBORN	
R51.0	Headache with orthostatic component, not elsewhere classified	See issues document	540 TENSION HEADACHES	
R51.9	Headache, unspecified	See issues document	540 TENSION HEADACHES	
R74.01	Elevation of levels of liver transaminase levels	R74.0 (Nonspecific elevation of levels of transaminase and lactic acid dehydrogenase [LDH]) was on DWF	DIAGNOSTIC WORKUP FILE (DWF)	
R74.02	Elevation of levels of lactic acid dehydrogenase [LDH]	See above	DIAGNOSTIC WORKUP FILE (DWF)	
S20.213A	Contusion of bilateral front wall of thorax, initial encounter	Contusions are on line 634	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	

Diagnosis (	Description	Similar code(s)	Proposed placement	Comments
S20.213D	Contusion of bilateral front wall of thorax, subsequent encounter	See above	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.213S	Contusion of bilateral front wall of thorax, sequela	See above	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.214A	Contusion of middle front wall of thorax, initial encounter	See above	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.214D	Contusion of middle front wall of thorax, subsequent encounter	See above	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.214S	Contusion of middle front wall of thorax, sequela	See above	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.223A	Contusion of bilateral back wall of thorax, initial encounter	See above	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.223D	Contusion of bilateral back wall of thorax, subsequent encounter	See above	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.223S	Contusion of bilateral back wall of thorax, sequela	See above	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.224A	Contusion of middle back wall of thorax, initial encounter	See above	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.224D	Contusion of middle back wall of thorax, subsequent encounter	See above	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.224S	Contusion of middle back wall of thorax, sequela	See above	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.303A	Unspecified superficial injuries of bilateral front wall of thorax, initial encounter	Other unspecified superficial injuries are on line 634	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.303D	Unspecified superficial injuries of bilateral front wall of thorax, subsequent encounter	See above	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.303S	Unspecified superficial injuries of bilateral front wall of thorax, sequela	See above	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	

Diagnosis (	Description	Similar code(s)	Proposed placement	Comments
S20.304A	Unspecified superficial injuries of middle front wall of thorax, initial encounter	See above	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.304D	Unspecified superficial injuries of middle front wall of thorax, subsequent encounter	See above	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.304S	Unspecified superficial injuries of middle front wall of thorax, sequela	See above	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.313A	Abrasion of bilateral front wall of thorax, initial encounter	Other abrasion injuries are on line 634	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.313D	Abrasion of bilateral front wall of thorax, subsequent encounter	See above	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.313S	Abrasion of bilateral front wall of thorax, sequela	See above	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.314A	Abrasion of middle front wall of thorax, initial encounter	See above	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.314D	Abrasion of middle front wall of thorax, subsequent encounter	See above	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.314S	Abrasion of middle front wall of thorax, sequela	See above	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.323A	Blister (nonthermal) of bilateral front wall of thorax, initial encounter	Other blister injuries are on line 634	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.323D	Blister (nonthermal) of bilateral front wall of thorax, subsequent encounter	Other blister injuries are on line 634	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.323S	Blister (nonthermal) of bilateral front wall of thorax, sequela	Other blister injuries are on line 634	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.324A	Blister (nonthermal) of middle front wall of thorax, initial encounter	Other blister injuries are on line 634	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.324D	Blister (nonthermal) of middle front wall of thorax, subsequent encounter	Other blister injuries are on line 634	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	

Diagnosis (	Description	Similar code(s)	Proposed placement	Comments
S20.324S	Blister (nonthermal) of middle front wall of thorax, sequela	Other blister injuries are on line 634	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.343A	External constriction of bilateral front wall of thorax, initial encounter	External constriction diagnoses are on line 634	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.343D	External constriction of bilateral front wall of thorax, subsequent encounter	External constriction diagnoses are on line 634	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.343S	External constriction of bilateral front wall of thorax, sequela	External constriction diagnoses are on line 634	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.344A	External constriction of middle front wall of thorax, initial encounter	External constriction diagnoses are on line 634	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.344D	External constriction of middle front wall of thorax, subsequent encounter	External constriction diagnoses are on line 634	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.344S	External constriction of middle front wall of thorax, sequela	External constriction diagnoses are on line 634	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.353A	Superficial foreign body of bilateral front wall of thorax, initial encounter	Superficial foreign body diagnoses are on line 634	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.353D	Superficial foreign body of bilateral front wall of thorax, subsequent encounter	Superficial foreign body diagnoses are on line 634	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.353S	Superficial foreign body of bilateral front wall of thorax, sequela	Superficial foreign body diagnoses are on line 634	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.354A	Superficial foreign body of middle front wall of thorax, initial encounter	Superficial foreign body diagnoses are on line 634	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.354D	Superficial foreign body of middle front wall of thorax, subsequent encounter	Superficial foreign body diagnoses are on line 634	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.354S	Superficial foreign body of middle front wall of thorax, sequela	Superficial foreign body diagnoses are on line 634	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	

Diagnosis (	Description	Similar code(s)	Proposed placement	Comments
S20.363A	Insect bite (nonvenomous) of bilateral front wall of thorax, initial encounter	Insect bite diagnoses are on line 634	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.363D	Insect bite (nonvenomous) of bilateral front wall of thorax, subsequent encounter	Insect bite diagnoses are on line 634	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.363S	Insect bite (nonvenomous) of bilateral front wall of thorax, sequela	Insect bite diagnoses are on line 634	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.364A	Insect bite (nonvenomous) of middle front wall of thorax, initial encounter	Insect bite diagnoses are on line 634	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.364D	Insect bite (nonvenomous) of middle front wall of thorax, subsequent encounter	Insect bite diagnoses are on line 634	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.364S	Insect bite (nonvenomous) of middle front wall of thorax, sequela	Insect bite diagnoses are on line 634	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.373A	Other superficial bite of bilateral front wall of thorax, initial encounter	Insect bite diagnoses are on line 634	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.373D	Other superficial bite of bilateral front wall of thorax, subsequent encounter	Insect bite diagnoses are on line 634	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.373S	Other superficial bite of bilateral front wall of thorax, sequela	Insect bite diagnoses are on line 634	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.374A	Other superficial bite of middle front wall of thorax, initial encounter	Insect bite diagnoses are on line 634	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.374D	Other superficial bite of middle front wall of thorax, subsequent encounter	Insect bite diagnoses are on line 634	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	
S20.374S	Other superficial bite of middle front wall of thorax, sequela	Insect bite diagnoses are on line 634	634 SUPERFICIAL WOUNDS WITHOUT INFECTION AND CONTUSIONS	

Diagnosis (	Description	Similar code(s)	Proposed placement	Comments
T40.411A	Poisoning by fentanyl or fentanyl analogs, accidental (unintentional), initial encounter	T40.4X1A (Poisoning by other synthetic narcotics, accidental (unintentional), initial encounter) is on lines 71,102,292,345,377	71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES 102 POISONING BY INGESTION, INJECTION, AND NON-MEDICINAL AGENTS 292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS 345 NEUROLOGICAL DYSFUNCTION IN COMMUNICATION CAUSED BY CHRONIC CONDITIONS 377 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION	
T40.411D	Poisoning by fentanyl or fentanyl analogs, accidental (unintentional), subsequent encounter	See above	71,102,292,345,377	
T40.411S	Poisoning by fentanyl or fentanyl analogs, accidental (unintentional), sequela	See above	71,102,292,345,377	
T40.412A	Poisoning by fentanyl or fentanyl analogs, intentional self-harm, initial encounter	See above	71,102,292,345,377	
T40.412D	Poisoning by fentanyl or fentanyl analogs, intentional self-harm, subsequent encounter	See above	71,102,292,345,377	

Diagnosis (	Description	Similar code(s)	Proposed placement	Comments
T40.412S	Poisoning by fentanyl or fentanyl analogs, intentional self-harm, sequela	See above	71,102,292,345,377	
T40.413A	Poisoning by fentanyl or fentanyl analogs, assault, initial encounter	See above	71,102,292,345,377	
T40.413D	Poisoning by fentanyl or fentanyl analogs, assault, subsequent encounter	See above	71,102,292,345,377	
T40.413S	Poisoning by fentanyl or fentanyl analogs, assault, sequela	See above	71,102,292,345,377	
T40.414A	Poisoning by fentanyl or fentanyl analogs, undetermined, initial encounter	See above	71,102,292,345,377	
T40.414D	Poisoning by fentanyl or fentanyl analogs, undetermined, subsequent encounter	See above	71,102,292,345,377	
T40.414S	Poisoning by fentanyl or fentanyl analogs, undetermined, sequela	See above	71,102,292,345,377	
T40.415A	Adverse effect of fentanyl or fentanyl analogs, initial encounter	See above	71,102,292,345,377	
T40.415D	Adverse effect of fentanyl or fentanyl analogs, subsequent encounter	See above	71,102,292,345,377	
T40.415S	Adverse effect of fentanyl or fentanyl analogs, sequela	See above	71,102,292,345,377	
T40.416A	Underdosing of fentanyl or fentanyl analogs, initial encounter	Other underdosing diagnoses are DWF	DIAGNOSTIC WORKUP FILE (DWF)	
T40.416D	Underdosing of fentanyl or fentanyl analogs, subsequent encounter	See above	DIAGNOSTIC WORKUP FILE (DWF)	
T40.416S	Underdosing of fentanyl or fentanyl analogs, sequela	See above	DIAGNOSTIC WORKUP FILE (DWF)	
T40.421A	Poisoning by tramadol, accidental (unintentional), initial encounter		71,102,292,345,377	

Diagnosis (	Description	Similar code(s)	Proposed placement	Comments
T40.421D	Poisoning by tramadol, accidental (unintentional), subsequent encounter		71,102,292,345,377	
T40.421S	Poisoning by tramadol, accidental (unintentional), sequela		71,102,292,345,377	
T40.422A	Poisoning by tramadol, intentional self-harm, initial encounter	Intentional self harm included with all other poisoning codes. Suicide attempt could be coded separately for psychiatric lines	71,102,292,345,377	
T40.422D	Poisoning by tramadol, intentional self-harm, subsequent encounter		71,102,292,345,377	
T40.422S	Poisoning by tramadol, intentional self-harm, sequela		71,102,292,345,377	
T40.423A	Poisoning by tramadol, assault, initial encounter		71,102,292,345,377	
T40.423D	Poisoning by tramadol, assault, subsequent encounter		71,102,292,345,377	
T40.423S	Poisoning by tramadol, assault, sequela		71,102,292,345,377	
T40.424A	Poisoning by tramadol, undetermined, initial encounter		71,102,292,345,377	
T40.424D	Poisoning by tramadol, undetermined, subsequent encounter		71,102,292,345,377	
T40.424S	Poisoning by tramadol, undetermined, sequela		71,102,292,345,377	
T40.425A	Adverse effect of tramadol, initial encounter		71,102,292,345,377	
T40.425D	Adverse effect of tramadol, subsequent encounter		71,102,292,345,377	
T40.425S	Adverse effect of tramadol, sequela		71,102,292,345,377	
T40.426A	Underdosing of tramadol, initial encounter		DIAGNOSTIC WORKUP FILE (DWF)	

Diagnosis C	Description	Similar code(s)	Proposed placement	Comments
T40.426D	Underdosing of tramadol, subsequent encounter		DIAGNOSTIC WORKUP FILE (DWF)	
T40.426S	Underdosing of tramadol, sequela		DIAGNOSTIC WORKUP FILE (DWF)	
T40.491A	Poisoning by other synthetic narcotics, accidental (unintentional), initial encounter		71,102,292,345,377	
T40.491D	Poisoning by other synthetic narcotics, accidental (unintentional), subsequent encounter		71,102,292,345,377	
T40.491S	Poisoning by other synthetic narcotics, accidental (unintentional), sequela		71,102,292,345,377	
T40.492A	Poisoning by other synthetic narcotics, intentional self-harm, initial encounter		71,102,292,345,377	
T40.492D	Poisoning by other synthetic narcotics, intentional self-harm, subsequent encounter		71,102,292,345,377	
T40.492S	Poisoning by other synthetic narcotics, intentional self-harm, sequela		71,102,292,345,377	
T40.493A	Poisoning by other synthetic narcotics, assault, initial encounter		71,102,292,345,377	
T40.493D	Poisoning by other synthetic narcotics, assault, subsequent encounter		71,102,292,345,377	
T40.493S	Poisoning by other synthetic narcotics, assault, sequela		71,102,292,345,377	
T40.494A	Poisoning by other synthetic narcotics, undetermined, initial encounter		71,102,292,345,377	

Diagnosis (	Description	Similar code(s)	Proposed placement	Comments
T40.494D	Poisoning by other synthetic narcotics, undetermined, subsequent encounter		71,102,292,345,377	
T40.494S	Poisoning by other synthetic narcotics, undetermined, sequela		71,102,292,345,377	
T40.495A	Adverse effect of other synthetic narcotics, initial encounter		71,102,292,345,377	
T40.495D	Adverse effect of other synthetic narcotics, subsequent encounter		71,102,292,345,377	
T40.495S	Adverse effect of other synthetic narcotics, sequela		71,102,292,345,377	
T40.496A	Underdosing of other synthetic narcotics, initial encounter		DIAGNOSTIC WORKUP FILE (DWF)	
T40.496D	Underdosing of other synthetic narcotics, subsequent encounter		DIAGNOSTIC WORKUP FILE (DWF)	
T40.496S	Underdosing of other synthetic narcotics, sequela		DIAGNOSTIC WORKUP FILE (DWF)	
T86.8401	Corneal transplant rejection, right eye	T86.840 (Corneal transplant rejection) was on line 285	285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	
T86.8402	Corneal transplant rejection, left eye	See above	285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	
T86.8403	Corneal transplant rejection, bilateral	See above	285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	
T86.8409	Corneal transplant rejection, unspecified eye	See above	285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	
T86.8411	Corneal transplant failure, right eye	See above	285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	
T86.8412	Corneal transplant failure, left eye	See above	285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	
T86.8413	Corneal transplant failure, bilateral	See above	285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	
T86.8419	Corneal transplant failure, unspecified eye	See above	285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	

Diagnosis (	Description	Similar code(s)	Proposed placement	Comments
T86.8421	Corneal transplant infection, right eye	See above	285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	
T86.8422	Corneal transplant infection, left eye	See above	285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	
T86.8423	Corneal transplant infection, bilateral	See above	285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	
T86.8429	Corneal transplant infection, unspecified eye	See above	285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	
T86.8481	Other complications of corneal transplant, right eye	See above	285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	
T86.8482	Other complications of corneal transplant, left eye	See above	285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	
T86.8483	Other complications of corneal transplant, bilateral	See above	285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	
T86.8489	Other complications of corneal transplant, unspecified eye	See above	285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	
T86.8491	Unspecified complication of corneal transplant, right eye	See above	285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	
T86.8492	Unspecified complication of corneal transplant, left eye	See above	285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	
T86.8493	Unspecified complication of corneal transplant, bilateral	See above	285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	
T86.8499	Unspecified complication of corneal transplant, unspecified eye	See above	285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT	
U07.0	Vaping-related disorder	See issues document	4 SUBSTANCE USE DISORDER 5 TOBACCO DEPENDENCE	
U07.1	COVID-19	Previously placed on line 399 at May HERC meeting	399 INFLUENZA, NOVEL RESPIRATORY VIRUSES	
V00.031A	Pedestrian on foot injured in collision with rider of standing electric scooter, initial encounter		INFORMATIONAL DIAGNOSES	

Diagnosis (	Description	Similar code(s)	Proposed placement	Comments
V00.031D	Pedestrian on foot injured in collision with rider of standing electric scooter, subsequent encounter		INFORMATIONAL DIAGNOSES	
V00.031S	Pedestrian on foot injured in collision with rider of standing electric scooter, sequela		INFORMATIONAL DIAGNOSES	
V00.038A	Pedestrian on foot injured in collision with rider of other standing micro-mobility pedestrian conveyance, initial encounter		INFORMATIONAL DIAGNOSES	
V00.038D	Pedestrian on foot injured in collision with rider of other standing micro-mobility pedestrian conveyance, subsequent encounter		INFORMATIONAL DIAGNOSES	
V00.038S	Pedestrian on foot injured in collision with rider of other standing micro-mobility pedestrian conveyance, sequela		INFORMATIONAL DIAGNOSES	
V00.841A	Fall from standing electric scooter, initial encounter		INFORMATIONAL DIAGNOSES	
V00.841D	Fall from standing electric scooter, subsequent encounter		INFORMATIONAL DIAGNOSES	
V00.841S	Fall from standing electric scooter, sequela		INFORMATIONAL DIAGNOSES	
V00.842A	Pedestrian on standing electric scooter colliding with stationary object, initial encounter		INFORMATIONAL DIAGNOSES	
V00.842D	Pedestrian on standing electric scooter colliding with stationary object, subsequent encounter		INFORMATIONAL DIAGNOSES	

Diagnosis C	Description	Similar code(s)	Proposed placement	Comments
V00.842S	Pedestrian on standing electric scooter colliding with stationary object, sequela		INFORMATIONAL DIAGNOSES	
V00.848A	Other accident with standing micro-mobility pedestrian conveyance, initial encounter		INFORMATIONAL DIAGNOSES	
V00.848D	Other accident with standing micro-mobility pedestrian conveyance, subsequent encounter		INFORMATIONAL DIAGNOSES	
V00.848S	Other accident with standing micro-mobility pedestrian conveyance, sequela		INFORMATIONAL DIAGNOSES	
V01.031A	Pedestrian on standing electric scooter injured in collision with pedal cycle in nontraffic accident, initial encounter		INFORMATIONAL DIAGNOSES	
V01.031D	Pedestrian on standing electric scooter injured in collision with pedal cycle in nontraffic accident, subsequent encounter		INFORMATIONAL DIAGNOSES	
V01.031S	Pedestrian on standing electric scooter injured in collision with pedal cycle in nontraffic accident, sequela		INFORMATIONAL DIAGNOSES	
V01.038A	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with pedal cycle in nontraffic accident, initial encounter		INFORMATIONAL DIAGNOSES	

Diagnosis (	Description	Similar code(s)	Proposed placement	Comments
V01.038D	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with pedal cycle in nontraffic accident, subsequent encounter		INFORMATIONAL DIAGNOSES	
V01.038S	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with pedal cycle in nontraffic accident, sequela		INFORMATIONAL DIAGNOSES	
V01.131A	Pedestrian on standing electric scooter injured in collision with pedal cycle in traffic accident, initial encounter		INFORMATIONAL DIAGNOSES	
V01.131D	Pedestrian on standing electric scooter injured in collision with pedal cycle in traffic accident, subsequent encounter		INFORMATIONAL DIAGNOSES	
V01.131S	Pedestrian on standing electric scooter injured in collision with pedal cycle in traffic accident, sequela		INFORMATIONAL DIAGNOSES	
V01.138A	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with pedal cycle in traffic accident, initial encounter		INFORMATIONAL DIAGNOSES	
V01.138D	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with pedal cycle in traffic accident, subsequent encounter		INFORMATIONAL DIAGNOSES	

Diagnosis (	Description	Similar code(s)	Proposed placement	Comments
V01.138S	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with pedal cycle in traffic accident, sequela		INFORMATIONAL DIAGNOSES	
V01.931A	Pedestrian on standing electric scooter injured in collision with pedal cycle, unspecified whether traffic or nontraffic accident, initial encounter		INFORMATIONAL DIAGNOSES	
V01.931D	Pedestrian on standing electric scooter injured in collision with pedal cycle, unspecified whether traffic or nontraffic accident, subsequent encounter		INFORMATIONAL DIAGNOSES	
V01.931S	Pedestrian on standing electric scooter injured in collision with pedal cycle, unspecified whether traffic or nontraffic accident, sequela		INFORMATIONAL DIAGNOSES	
V01.938A	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with pedal cycle, unspecified whether traffic or nontraffic accident, initial encounter		INFORMATIONAL DIAGNOSES	
V01.938D	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with pedal cycle, unspecified whether traffic or nontraffic accident, subsequent encounter		INFORMATIONAL DIAGNOSES	

Diagnosis (	Description	Similar code(s)	Proposed placement	Comments
V01.938S	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with pedal cycle, unspecified whether traffic or nontraffic accident, sequela		INFORMATIONAL DIAGNOSES	
V02.031A	Pedestrian on standing electric scooter injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, initial encounter		INFORMATIONAL DIAGNOSES	
V02.031D	Pedestrian on standing electric scooter injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, subsequent encounter		INFORMATIONAL DIAGNOSES	
V02.031S	Pedestrian on standing electric scooter injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, sequela		INFORMATIONAL DIAGNOSES	
V02.038A	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, initial encounter		INFORMATIONAL DIAGNOSES	
V02.038D	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, subsequent encounter		INFORMATIONAL DIAGNOSES	

Diagnosis (	Description	Similar code(s)	Proposed placement	Comments
V02.038S	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with two- or three-wheeled motor vehicle in nontraffic accident, sequela		INFORMATIONAL DIAGNOSES	
V02.131A	Pedestrian on standing electric scooter injured in collision with two- or three-wheeled motor vehicle in traffic accident, initial encounter		INFORMATIONAL DIAGNOSES	
V02.131D	Pedestrian on standing electric scooter injured in collision with two- or three-wheeled motor vehicle in traffic accident, subsequent encounter		INFORMATIONAL DIAGNOSES	
V02.131S	Pedestrian on standing electric scooter injured in collision with two- or three-wheeled motor vehicle in traffic accident, sequela		INFORMATIONAL DIAGNOSES	
V02.138A	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with two- or three-wheeled motor vehicle in traffic accident, initial encounter		INFORMATIONAL DIAGNOSES	
V02.138D	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with two- or three-wheeled motor vehicle in traffic accident, subsequent encounter		INFORMATIONAL DIAGNOSES	

Diagnosis (	Description	Similar code(s)	Proposed placement	Comments
V02.138S	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with two- or three-wheeled motor vehicle in traffic accident, sequela		INFORMATIONAL DIAGNOSES	
V02.931A	Pedestrian on standing electric scooter injured in collision with two- or three wheeled motor vehicle, unspecified whether traffic or nontraffic accident, initial encounter		INFORMATIONAL DIAGNOSES	
V02.931D	Pedestrian on standing electric scooter injured in collision with two- or three wheeled motor vehicle, unspecified whether traffic or nontraffic accident, subsequent encounter		INFORMATIONAL DIAGNOSES	
V02.931S	Pedestrian on standing electric scooter injured in collision with two- or three wheeled motor vehicle, unspecified whether traffic or nontraffic accident, sequela		INFORMATIONAL DIAGNOSES	
V02.938A	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with two- or three wheeled motor vehicle, unspecified whether traffic or nontraffic accident, initial encounter		INFORMATIONAL DIAGNOSES	

Diagnosis (	Description	Similar code(s)	Proposed placement	Comments
V02.938D	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with two- or three wheeled motor vehicle, unspecified whether traffic or nontraffic accident, subsequent encounter		INFORMATIONAL DIAGNOSES	
V02.938S	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with two- or three wheeled motor vehicle, unspecified whether traffic or nontraffic accident, sequela		INFORMATIONAL DIAGNOSES	
V03.031A	Pedestrian on standing electric scooter injured in collision with car, pick-up or van in nontraffic accident, initial encounter		INFORMATIONAL DIAGNOSES	
V03.031D	Pedestrian on standing electric scooter injured in collision with car, pick-up or van in nontraffic accident, subsequent encounter		INFORMATIONAL DIAGNOSES	
V03.031S	Pedestrian on standing electric scooter injured in collision with car, pick-up or van in nontraffic accident, sequela		INFORMATIONAL DIAGNOSES	
V03.038A	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with car, pick-up or van in nontraffic accident, initial encounter		INFORMATIONAL DIAGNOSES	

Diagnosis (	Description	Similar code(s)	Proposed placement	Comments
V03.038D	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with car, pick-up or van in nontraffic accident, subsequent encounter		INFORMATIONAL DIAGNOSES	
V03.038S	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with car, pick-up or van in nontraffic accident, sequela		INFORMATIONAL DIAGNOSES	
V03.131A	Pedestrian on standing electric scooter injured in collision with car, pick-up or van in traffic accident, initial encounter		INFORMATIONAL DIAGNOSES	
V03.131D	Pedestrian on standing electric scooter injured in collision with car, pick-up or van in traffic accident, subsequent encounter		INFORMATIONAL DIAGNOSES	
V03.131S	Pedestrian on standing electric scooter injured in collision with car, pick-up or van in traffic accident, sequela		INFORMATIONAL DIAGNOSES	
V03.138A	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with car, pick-up or van in traffic accident, initial encounter		INFORMATIONAL DIAGNOSES	
V03.138D	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with car, pick-up or van in traffic accident, subsequent encounter		INFORMATIONAL DIAGNOSES	

Diagnosis (	Description	Similar code(s)	Proposed placement	Comments
V03.138S	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with car, pick-up or van in traffic accident, sequela		INFORMATIONAL DIAGNOSES	
V03.931A	Pedestrian on standing electric scooter injured in collision with car, pick-up or van, unspecified whether traffic or nontraffic accident, initial encounter		INFORMATIONAL DIAGNOSES	
V03.931D	Pedestrian on standing electric scooter injured in collision with car, pick-up or van, unspecified whether traffic or nontraffic accident, subsequent encounter		INFORMATIONAL DIAGNOSES	
V03.931S	Pedestrian on standing electric scooter injured in collision with car, pick-up or van, unspecified whether traffic or nontraffic accident, sequela		INFORMATIONAL DIAGNOSES	
V03.938A	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with car, pick-up or van, unspecified whether traffic or nontraffic accident, initial encounter		INFORMATIONAL DIAGNOSES	
V03.938D	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with car, pick-up or van, unspecified whether traffic or nontraffic accident, subsequent encounter		INFORMATIONAL DIAGNOSES	

Diagnosis (	Description	Similar code(s)	Proposed placement	Comments
V03.938S	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with car, pick-up or van, unspecified whether traffic or nontraffic accident, sequela		INFORMATIONAL DIAGNOSES	
V04.031A	Pedestrian on standing electric scooter injured in collision with heavy transport vehicle or bus in nontraffic accident, initial encounter		INFORMATIONAL DIAGNOSES	
V04.031D	Pedestrian on standing electric scooter injured in collision with heavy transport vehicle or bus in nontraffic accident, subsequent encounter		INFORMATIONAL DIAGNOSES	
V04.031S	Pedestrian on standing electric scooter injured in collision with heavy transport vehicle or bus in nontraffic accident, sequela		INFORMATIONAL DIAGNOSES	
V04.038A	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with heavy transport vehicle or bus in nontraffic accident, initial encounter		INFORMATIONAL DIAGNOSES	
V04.038D	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with heavy transport vehicle or bus in nontraffic accident, subsequent encounter		INFORMATIONAL DIAGNOSES	
V04.038S	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with heavy transport vehicle or bus in nontraffic accident, sequela		INFORMATIONAL DIAGNOSES	

Diagnosis C	Description	Similar code(s)	Proposed placement	Comments
V04.131A	Pedestrian on standing electric scooter injured in collision with heavy transport vehicle or bus in traffic accident, initial encounter		INFORMATIONAL DIAGNOSES	
V04.131D	Pedestrian on standing electric scooter injured in collision with heavy transport vehicle or bus in traffic accident, subsequent encounter		INFORMATIONAL DIAGNOSES	
V04.131S	Pedestrian on standing electric scooter injured in collision with heavy transport vehicle or bus in traffic accident, sequela		INFORMATIONAL DIAGNOSES	
V04.138A	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with heavy transport vehicle or bus in traffic accident, initial encounter		INFORMATIONAL DIAGNOSES	
V04.138D	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with heavy transport vehicle or bus in traffic accident, subsequent encounter		INFORMATIONAL DIAGNOSES	
V04.138S	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with heavy transport vehicle or bus in traffic accident, sequela		INFORMATIONAL DIAGNOSES	
V04.931A	Pedestrian on standing electric scooter injured in collision with heavy transport vehicle or bus, unspecified whether traffic or nontraffic accident, initial encounter		INFORMATIONAL DIAGNOSES	

Diagnosis (	Description	Similar code(s)	Proposed placement	Comments
V04.931D	Pedestrian on standing electric scooter injured in collision with heavy transport vehicle or bus, unspecified whether traffic or nontraffic accident, subsequent encounter		INFORMATIONAL DIAGNOSES	
V04.931S	Pedestrian on standing electric scooter injured in collision with heavy transport vehicle or bus, unspecified whether traffic or nontraffic accident, sequela		INFORMATIONAL DIAGNOSES	
V04.938A	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with heavy transport vehicle or bus, unspecified whether traffic or nontraffic accident, initial encounter		INFORMATIONAL DIAGNOSES	
V04.938D	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with heavy transport vehicle or bus, unspecified whether traffic or nontraffic accident, subsequent encounter		INFORMATIONAL DIAGNOSES	
V04.938S	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with heavy transport vehicle or bus, unspecified whether traffic or nontraffic accident, sequela		INFORMATIONAL DIAGNOSES	
V05.031A	Pedestrian on standing electric scooter injured in collision with railway train or railway vehicle in nontraffic accident, initial encounter		INFORMATIONAL DIAGNOSES	

Diagnosis (	Description	Similar code(s)	Proposed placement	Comments
V05.031D	Pedestrian on standing electric scooter injured in collision with railway train or railway vehicle in nontraffic accident, subsequent encounter		INFORMATIONAL DIAGNOSES	
V05.031S	Pedestrian on standing electric scooter injured in collision with railway train or railway vehicle in nontraffic accident, sequela		INFORMATIONAL DIAGNOSES	
V05.038A	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with railway train or railway vehicle in nontraffic accident, initial encounter		INFORMATIONAL DIAGNOSES	
V05.038D	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with railway train or railway vehicle in nontraffic accident, subsequent encounter		INFORMATIONAL DIAGNOSES	
V05.038S	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with railway train or railway vehicle in nontraffic accident, sequela		INFORMATIONAL DIAGNOSES	
V05.131A	Pedestrian on standing electric scooter injured in collision with railway train or railway vehicle in traffic accident, initial encounter		INFORMATIONAL DIAGNOSES	
V05.131D	Pedestrian on standing electric scooter injured in collision with railway train or railway vehicle in traffic accident, subsequent encounter		INFORMATIONAL DIAGNOSES	

Diagnosis (	Description	Similar code(s)	Proposed placement	Comments
V05.131S	Pedestrian on standing electric scooter injured in collision with railway train or railway vehicle in traffic accident, sequela		INFORMATIONAL DIAGNOSES	
V05.138A	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with railway train or railway vehicle in traffic accident, initial encounter		INFORMATIONAL DIAGNOSES	
V05.138D	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with railway train or railway vehicle in traffic accident, subsequent encounter		INFORMATIONAL DIAGNOSES	
V05.138S	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with railway train or railway vehicle in traffic accident, sequela		INFORMATIONAL DIAGNOSES	
V05.931A	Pedestrian on standing electric scooter injured in collision with railway train or railway vehicle, unspecified whether traffic or nontraffic accident, initial encounter		INFORMATIONAL DIAGNOSES	
V05.931D	Pedestrian on standing electric scooter injured in collision with railway train or railway vehicle, unspecified whether traffic or nontraffic accident, subsequent encounter		INFORMATIONAL DIAGNOSES	

Diagnosis (	Description	Similar code(s)	Proposed placement	Comments
V05.931S	Pedestrian on standing electric scooter injured in collision with railway train or railway vehicle, unspecified whether traffic or nontraffic accident, sequela		INFORMATIONAL DIAGNOSES	
V05.938A	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with railway train or railway vehicle, unspecified whether traffic or nontraffic accident, initial encounter		INFORMATIONAL DIAGNOSES	
V05.938D	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with railway train or railway vehicle, unspecified whether traffic or nontraffic accident, subsequent encounter		INFORMATIONAL DIAGNOSES	
V05.938S	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with railway train or railway vehicle, unspecified whether traffic or nontraffic accident, sequela		INFORMATIONAL DIAGNOSES	
V06.031A	Pedestrian on standing electric scooter injured in collision with other nonmotor vehicle in nontraffic accident, initial encounter		INFORMATIONAL DIAGNOSES	
V06.031D	Pedestrian on standing electric scooter injured in collision with other nonmotor vehicle in nontraffic accident, subsequent encounter		INFORMATIONAL DIAGNOSES	

Diagnosis (	Description	Similar code(s)	Proposed placement	Comments
V06.031S	Pedestrian on standing electric scooter injured in collision with other nonmotor vehicle in nontraffic accident, sequela		INFORMATIONAL DIAGNOSES	
V06.038A	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with other nonmotor vehicle in nontraffic accident, initial encounter		INFORMATIONAL DIAGNOSES	
V06.038D	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with other nonmotor vehicle in nontraffic accident, subsequent encounter		INFORMATIONAL DIAGNOSES	
V06.038S	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with other nonmotor vehicle in nontraffic accident, sequela		INFORMATIONAL DIAGNOSES	
V06.131A	Pedestrian on standing electric scooter injured in collision with other nonmotor vehicle in traffic accident, initial encounter		INFORMATIONAL DIAGNOSES	
V06.131D	Pedestrian on standing electric scooter injured in collision with other nonmotor vehicle in traffic accident, subsequent encounter		INFORMATIONAL DIAGNOSES	
V06.131S	Pedestrian on standing electric scooter injured in collision with other nonmotor vehicle in traffic accident, sequela		INFORMATIONAL DIAGNOSES	

Diagnosis (	Description	Similar code(s)	Proposed placement	Comments
V06.138A	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with other nonmotor vehicle in traffic accident, initial encounter		INFORMATIONAL DIAGNOSES	
V06.138D	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with other nonmotor vehicle in traffic accident, subsequent encounter		INFORMATIONAL DIAGNOSES	
V06.138S	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with other nonmotor vehicle in traffic accident, sequela		INFORMATIONAL DIAGNOSES	
V06.931A	Pedestrian on standing electric scooter injured in collision with other nonmotor vehicle, unspecified whether traffic or nontraffic accident, initial encounter		INFORMATIONAL DIAGNOSES	
V06.931D	Pedestrian on standing electric scooter injured in collision with other nonmotor vehicle, unspecified whether traffic or nontraffic accident, subsequent encounter		INFORMATIONAL DIAGNOSES	
V06.931S	Pedestrian on standing electric scooter injured in collision with other nonmotor vehicle, unspecified whether traffic or nontraffic accident, sequela		INFORMATIONAL DIAGNOSES	

Diagnosis (	Description	Similar code(s)	Proposed placement	Comments
V06.938A	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with other nonmotor vehicle, unspecified whether traffic or nontraffic accident, initial encounter		INFORMATIONAL DIAGNOSES	
V06.938D	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with other nonmotor vehicle, unspecified whether traffic or nontraffic accident, subsequent encounter		INFORMATIONAL DIAGNOSES	
V06.938S	Pedestrian on other standing micro-mobility pedestrian conveyance injured in collision with other nonmotor vehicle, unspecified whether traffic or nontraffic accident, sequela		INFORMATIONAL DIAGNOSES	
Y77.11	Contact lens associated with adverse incidents	Y77 codes are informational	INFORMATIONAL DIAGNOSES	
Y77.19	Other therapeutic (nonsurgical) and rehabilitative ophthalmic devices associated with adverse incidents	See above	INFORMATIONAL DIAGNOSES	
Z03.821	Encounter for observation for suspected ingested foreign body ruled out	"Ruled out" diagnoses are typically DWF	DIAGNOSTIC WORKUP FILE (DWF)	
Z03.822	Encounter for observation for suspected aspirated (inhaled) foreign body ruled out	See above	DIAGNOSTIC WORKUP FILE (DWF)	
Z03.823	Encounter for observation for suspected inserted (injected) foreign body ruled out	See above	DIAGNOSTIC WORKUP FILE (DWF)	

2021 ICD-10 Codes Requiring Discussion

1) **D57 series** (various sickle cell diagnoses)
    a. Sickle cell disease was added to the bone marrow transplant line recently. During the discussion of BMT for sickle cell disease, the hematology experts did not recommend BMT for any variation of sickle cell disease (sickle/thalassemia, etc.) other than Hb-SS disease
    b. D57.00 (Hb-SS disease with crisis, unspecified) was on lines 113,194
    c. HERC staff recommendation:
        i. Add only D57.03 (Hb-SS disease with cerebral vascular involvement) and D57.09 (Hb-SS disease with crisis with other specified complication) to line 113 APLASTIC ANEMIAS; AGRANULOCYTOSIS; SICKLE CELL DISEASE Treatment: BONE MARROW TRANSPLANT
        ii. Add all new codes in the D57 series to 194 HEREDITARY ANEMIAS, HEMOGLOBINOPATHIES, AND DISORDERS OF THE SPLEEN

2) **D72.1** series (eosinophilia diagnoses)
    a. D72.10 (Eosinophilia, unspecified)
        i. D72.1 (Eosinophilia) was on DIAGNOSTIC WORKUP FILE (DWF)
    b. D72.110 (Idiopathic hypereosinophilic syndrome [IHES])
        i. IHES is a condition characterized by peripheral blood eosinophilia with manifestations of organ system involvement or dysfunction directly related to eosinophilia in the absence of parasitic, allergic, or other secondary causes of eosinophilia. Various organs can be affected. Treatment may involve prednisone and, in one common subtype, includes imatinib. Eosinphils are a type of granulocyte; other granulocyte disorders are on line 161 GRANULOCYTE DISORDERS
    c. D72.111 (Lymphocytic Variant Hypereosinophilic Syndrome [LHES])
        i. Variant of IHES in which patients are more likely to develop angioedema and occasionally develop T-cell lymphoma
    d. D72.118 (Other hypereosinophilic syndrome) and D72.119 (Hypereosinophilic syndrome [HES], unspecified)
        i. Appears to be similar to D72.110 and D72.111
    e. D72.12 (Drug rash with eosinophilia and systemic symptoms syndrome)
        i. Other drug rashes are on line 568 DERMATITIS DUE TO SUBSTANCES TAKEN INTERNALLY; however, these diagnoses do not include systemic symptoms
    f. D72.18 (Eosinophilia in diseases classified elsewhere)
    g. D72.19 (Other eosinophilia)
    h. HERC staff recommendation
        i. Place D72.10 and D72.19 on the DIAGNOSTIC WORKUP FILE (DWF)
        ii. Place other D72.11x codes on line 161 GRANULOCYTE DISORDERS

3) **G96.01** (Cranial cerebrospinal fluid leak, spontaneous) and **G96.02** (Spinal cerebrospinal fluid leak, spontaneous) and **G96.81x** (Intracranial hypotension)

a. G96.0 (Cerebrospinal fluid leak) was on line 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
b. CPT 63707 (Repair of dural/cerebrospinal fluid leak, not requiring laminectomy) and similar codes are on lines 33 SPINA BIFIDA,285,424 (complications lines)
c. G96.8 (Other specified disorders of central nervous system) was on the Undefined list. G96.81x code for intracranial hypotension, which is generally caused by a CSF leak. Treatment is the same as for a CSF leak
d. Despite being spontaneous and not a procedure complication, the most straightforward way to pair the new diagnoses with the procedure codes necessary to treat them would be to add to line 285
e. HERC staff recommendation
    i. Place G96.01, G96.02, and G96.81x on line 285 COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
    ii. Additional placement for consideration: Should G96.81x (Intracranial hypotension) also be added to the dysfunction lines? Similar codes appear on line 285 and the dysfunction lines

4) **H55.82** (Deficient smooth pursuit eye movements)
    a. Smooth pursuit eye movements allow the eyes to closely follow a moving object. Other H55.8 diagnoses are on line 654 SENSORY ORGAN CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY. Lack of smooth pursuit can occur in conditions such as autism, schizophrenia, alcohol intoxication, and preterm birth
    b. Similar diagnoses (H55.81 Saccadic eye movements; H55.89 Other irregular eye movements) appear on line 654 SENSORY ORGAN CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY. These conditions do not appear to be symptoms of multiple diseases requiring work up
    c. HERC staff recommendation
        i. Place H55.82 on DIAGNOSTIC WORKUP FILE (DWF)

5) **K59.81** (Ogilvie syndrome)
    a. K59.8 (Other specified functional intestinal disorders) was on line 528 DISORDERS OF FUNCTION OF STOMACH AND OTHER FUNCTIONAL DIGESTIVE DISORDERS. Ogilvie syndrome is acute megacolon due to other illness. K59.39 (Other megacolon) is on line 41 INTUSSCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION
    b. HERC staff recommendation
        i. Place K59.81 on line 41 INTUSSCEPTION, VOLVULUS, INTESTINAL OBSTRUCTION, HAZARDOUS FOREIGN BODY IN GI TRACT WITH RISK OF PERFORATION OR OBSTRUCTION

6) **K74.0X** (hepatic fibrosis)
    a. K74.0 (Hepatic fibrosis) is on lines 307 CIRRHOSIS OF LIVER OR BILIARY TRACT; BUDD-CHIARI SYNDROME; HEPATIC VEIN THROMBOSIS; INTRAHEPATIC VASCULAR

MALFORMATIONS; CAROLI'S DISEASE Treatment: LIVER TRANSPLANT, LIVER-KIDNEY TRANSPLANT and 334 ALCOHOLIC FATTY LIVER OR ALCOHOLIC HEPATITIS, CIRRHOSIS OF LIVER

b. Line 307 is a liver transplant line which would only be needed for advanced fibrosis
c. HERC staff recommendation:
    i. Add K74.0X series to line 334 ALCOHOLIC FATTY LIVER OR ALCOHOLIC HEPATITIS, CIRRHOSIS OF LIVER
    ii. Add K74.02 (Hepatic fibrosis, advanced fibrosis) to line 307 CIRRHOSIS OF LIVER OR BILIARY TRACT; BUDD-CHIARI SYNDROME; HEPATIC VEIN THROMBOSIS; INTRAHEPATIC VASCULAR MALFORMATIONS; CAROLI'S DISEASE Treatment: LIVER TRANSPLANT, LIVER-KIDNEY TRANSPLANT as well

7) **N61.2x** (Granulomatous mastitis)
    a. Granulomatous mastitis is a rare benign inflammatory breast disease. Therapy includes antibiotics and corticosteroids, followed by continuous steroid therapy and surgery in patients with persisting symptoms. N61.0 (Mastitis without abscess) is on line 205
    b. HERC staff recommendation
        i. Add N61.2x series to line 205 SUPERFICIAL ABSCESSES AND CELLULITIS

8) **P91.82x** (Neonatal cerebral infarction)
    a. Similar diagnoses such as P91.0 (Neonatal cerebral ischemia) are on line 23 INTRACRANIAL HEMORRHAGES; CEREBRAL CONVULSIONS, DEPRESSION, COMA, AND OTHER ABNORMAL CEREBRAL SIGNS OF THE NEWBORN
    b. Other stroke type diagnoses are on the dysfunction lines as well as a specific line
    c. HERC staff recommendation
        i. Add P91.82x series to line 23 INTRACRANIAL HEMORRHAGES; CEREBRAL CONVULSIONS, DEPRESSION, COMA, AND OTHER ABNORMAL CEREBRAL SIGNS OF THE NEWBORN
        ii. Consider adding P91.82x series to the dysfunction lines
            1. 71 NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES
               292 NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS
               345 NEUROLOGICAL DYSFUNCTION IN COMMUNICATION CAUSED BY CHRONIC CONDITIONS
               377 DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION

9) **R51.0** (Headache with orthostatic component, not elsewhere classified) and **R51.9** (Headache, unspecified)
    a. These codes replace ICD-10 R51 (Headache) which is on line 540 TENSION HEADACHES and has been for years

b. Diagnostic guideline D5 outlines when neuroimaging is covered for headache, which was adopted based on a coverage guidance in 2013
c. HERC staff recommendation:
    i. Place R51.0 and R51.9 on the Diagnostic Workup File
    ii. Alternative placement: line 540 TENSION HEADACHES

DIAGNOSTIC GUIDELINE D5, NEUROIMAGING FOR HEADACHE

Neuroimaging is not covered in patients with a defined tension or migraine type of headache, or a variation of their usual headache (e.g. more severe, longer in duration, or not responding to drugs).

Neuroimaging is covered for headache when a red flag* is present.
*The following represent red flag conditions for underlying abnormality with headache:

A) New onset or change in headache in patients who are aged over 50
B) Thunderclap headache: rapid time to peak headache intensity (seconds to 5 minutes)
C) Focal neurological symptoms (e.g. limb weakness, lack of coordination, numbness or tingling)
D) Non-focal neurological symptoms (e.g altered mental status, dizziness)
E) Abnormal neurological examination
F) Headache that changes with posture
G) Headache wakening the patient up (Nota bene migraine is the most frequent cause of morning headache)
H) Headache precipitated by physical exertion or valsalva maneuver (e.g. coughing, laughing, straining)
I) Patients with risk factors for cerebral venous sinus thrombosis
J) Jaw claudication
K) Nuchal rigidity
L) New onset headache in a patient with a history of human immunodeficiency virus (HIV) infection
M) New onset headache in a patient with a history of cancer
N) Cluster headache, paroxysmal hemicrania, short-lasting unilateral neuralgiform headache attacks with conjunctival injection and tearing (SUNCT), or short-lasting unilateral neuralgiform headache attacks with cranial autonomic features (SUNA).

The development of this guideline note was informed by a HERC coverage guidance. See https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx.

10) **U07.0** (Vaping-related disorder)
    a. Vaping may be tobacco or marijuana
    b. HERC staff recommendation:
        i. Add U07.0 to lines 4 SUBSTANCE USE DISORDER and 5 TOBACCO DEPENDENCE

Section 5.0

Biennial Review

Polydactyly of the Foot, Flat Foot, and Tarsal Coalition
2022 Biennial Review

Question: Should the line with polydactyly of the foot, tarsal coalition, and/or flat foot be moved to a higher priority position or should a new line be created with a higher priority for more severe forms of these conditions?

Question source: Justin Roth, MD orthopedic surgery

Issue: Polydactyly of toes is a condition in which a child is born with extra toes. These may be rudimentary and easily removed in the office or may be complex and require surgical removal. Polydactyly of toes can result in difficulty wearing shoes. Uncorrected polydactyly may also result in some degree of difficulty with walking. This topic was last reviewed in 2010, and no change was made to the prioritization at that time.

Flat foot is a condition in which the arches on the inside of someone's foot have less curve to them or are flat, so that the entire sole of the foot rests on the ground when the person is standing. Flat feet generally do not require treatment or may require orthotics. This topic was discussed during the ICD10 Podiatry review. Adult acquired flatfoot was discussed in October 2016 and no additional coverage was added. Congenital rigid flatfoot is referred to as calcaneovalgus (ICD-10 Q66.40) and is covered on line 356 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS.

Tarsal coalition is an abnormal connection that develops between two bones in the back of the foot (the tarsal bones). This abnormal connection, which can be composed of bone, cartilage or fibrous tissue, may lead to limited motion and pain in one or both feet. Treatments include physical therapy, orthotics, or surgery.

Dr. Justin Roth contacted the HERC to request reconsideration of the lack of coverage for these conditions. He feels that to prevent disability, surgery for correction of complex polydactyly or polydactyly that does not allow a child to wear shoes should be covered. Similarly, rigid flat feet in children should have treatments covered. Lastly, he requests coverage of surgical repair of tarsal coalition to prevent the development of flat feet.

Current Prioritized List status

ICD10 Code	Code Description	Current Placement
M21.4	Flat foot [pes planus] (acquired)	578 CAVUS DEFORMITY OF FOOT; FLAT FOOT; POLYDACTYLY AND SYNDACTYLY OF TOES
Q66.89	Other specified congenital deformities of feet [used for tarsal coalition]	542 DEFORMITIES OF FOOT
Q69.9	Polydactyly, unspecified [used for toe polydactyly]	578

Other foot deformity diagnoses and polydactyly of fingers are on line 359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS.

Of note, repair of macrodactyly (multiple extra toes) is included on line 359 and 578.

Evidence

Polydactyly of toes

Little was found on review of the literature. It appears to be standard surgical procedure to remove extra toes, with the goal to prevent pain, improve ability to wear shoes, and to improve use of the foot. The literature identified examined timing of surgery, and genetic syndromes that should be investigated in children with complex polydactyly.

Flatfoot

An update of the 2016 evidence review did not identify any additional high quality systematic reviews. Of note, Rome 2012 (Cochrane review of treatment of flatfoot in children) found the evidence too limited to draw any conclusions.

Tarsal coalition

Only case reports and one small case series identified. One review was found which also cited small case series showing benefit of surgical treatment on return to sports or reported limitation of function.

HERC staff summary:

Polydactyly of toes is generally only of concern when it affects a child's ability to wear shoes. Flatfoot was previously reviewed in 2016 and no evidence to support coverage was found; an updated literature review found no additional evidence. Congenital rigid flatfoot (calcaneovalgus) is on a covered line. Tarsal coalition similarly has little evidence to determine treatment benefit.

HERC staff recommendations:

1) Add ICD10 Q69.9 (Polydactyly, unspecified) to line 359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS and keep on line 578 CAVUS DEFORMITY OF FOOT; FLAT FOOT; POLYDACTYLY AND SYNDACTYLY OF TOES
2) Add the following treatment codes to line 359
    a. CPT 28344 Reconstruction, toe(s); polydactyly
    b. CPT 28345 Reconstruction, toe(s); syndactyly, with or without skin graft(s), each web
3) Note: CPT 28340-28342 (Reconstruction, toe, macrodactyly) are already on line 359
4) Add the guideline below to lines 359 and 578

GUIDELINE NOTE XXX POLYDACTYLY OF TOES

Lines 359,578

Polydactyly of toes is only included on line 359 when a child cannot be fitted into a shoe after age 1. Otherwise, polydactyly of toes is included on line 578.

2020 Review of Back and Spine Conditions
Surgical Guideline

Question: Should GN37 regarding surgical interventions for conditions of the back and spine be modified?

Question source: HERC

Issue: HERC staff presented recent Washington HTA guidance on surgical intervention for lumbar spine at the May, 2020 HERC/VBBS joint meeting. Based on member feedback from that meeting, HERC staff have drafted changes to the current surgical guideline to:

1) Modify the indications for surgery
2) Specify lack of coverage for diagnostic spinal injections
    a. See separate review document
3) Do not merge this guideline with the guideline on artificial disks
    a. See separate review document
    b. HERC staff found the merged guideline too complicated and difficult to use

Current Prioritized List guideline

GUIDELINE NOTE 37, SURGICAL INTERVENTIONS FOR CONDITIONS OF THE BACK AND SPINE OTHER THAN SCOLIOSIS

Lines 346,529

Spine surgery is included on Line 346 only in the following circumstances:

A) Decompressive surgery is included on Line 346 to treat debilitating symptoms due to central or foraminal spinal stenosis, and only when the patient meets the following criteria:
    1) Has MRI evidence of moderate or severe central or foraminal spinal stenosis AND
    2) Has neurogenic claudication OR
    3) Has objective neurologic impairment consistent with the MRI findings. Neurologic impairment is defined as objective evidence of one or more of the following:
        a) Markedly abnormal reflexes
        b) Segmental muscle weakness
        c) Segmental sensory loss
        d) EMG or NCV evidence of nerve root impingement
        e) Cauda equina syndrome
        f) Neurogenic bowel or bladder
        g) Long tract abnormalities

    Foraminal or central spinal stenosis causing only radiating pain (e.g. radiculopathic pain) is included only on Line 529.

B) Spinal fusion procedures are included on Line 346 for patients with MRI evidence of moderate or severe central spinal stenosis only when one of the following conditions are met:
    1) spinal stenosis in the cervical spine (with or without spondylolisthesis) which results in objective neurologic impairment as defined above OR
    2) spinal stenosis in the thoracic or lumbar spine caused by spondylolisthesis resulting in signs and symptoms of neurogenic claudication and which correlate with xray flexion/extension films showing at least a 5 mm translation OR
    3) pre-existing or expected post-surgical spinal instability (e.g. degenerative scoliosis >10 deg, >50% of facet joints per level expected to be resected)

For all other indications, spine surgery is included on Line 529.

The following interventions are not included on these lines due to lack of evidence of effectiveness for the treatment of conditions on these lines, including cervical, thoracic, lumbar, and sacral conditions:

- local injections (including ozone therapy injections)
- botulinum toxin injection
- intradiscal electrothermal therapy
- therapeutic medial branch block
- coblation nucleoplasty
- percutaneous intradiscal radiofrequency thermocoagulation
- percutaneous laser disc decompression
- radiofrequency denervation
- corticosteroid injections for cervical pain

Corticosteroid injections for low back pain with or without radiculopathy are only included on Line 529.

The development of this guideline note was informed by HERC coverage guidances on Percutaneous Interventions for Low Back Pain, Percutaneous Interventions for Cervical Spine Pain, Low Back Pain: Corticosteroid Injections and Low Back Pain: Minimally Invasive and Non-Cordicosteroid Percutaneous Interventions. See https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx.

Summary of Washington HTA 2018 review of surgery for lumbar radiculopathy

1) **Conclusions:** Most findings are based on a body of RCT evidence graded as low to very low certainty. Compared with nonsurgical interventions, surgery reduces pain and improves function more up to 26 weeks follow-up, but this difference does not persist at 1 year or longer. Minimally-invasive surgery, microdiscectomy, and discectomy are generally comparable with respect to efficacy and surgical morbidity; findings are mixed for reoperations. Surgery may be cost-effective when compared with nonsurgical interventions, depending on a decision maker's willingness to pay threshold, but the evidence is inconclusive about the cost-effectiveness of minimally-invasive surgery.

HTCC coverage determination:

- Surgery for lumbar radiculopathy or sciatica is a **covered benefit with conditions**.
- **Limitations of coverage:**

Open discectomy or microdiscectomy with or without endoscopy (lumbar laminectomy, laminotomy, discectomy, foraminotomy) are covered with the following conditions:
For adult patients with lumbar radiculopathy with subjective and objective neurologic findings that are corroborated with an advanced imaging test (i.e., Computed Tomography (CT) scan, Magnetic Resonance Imaging (MRI) or myelogram), AND
There is a failure to improve with a minimum of six weeks of non-surgical care, unless progressive motor weakness is present

Feedback from CCO medical directors:

The CCOs were unanimous in their support for the current guideline. They find no issues with administration of the guideline and feel that it is very useful. Specifically, there was strong disagreement with removing neurogenic claudication from the guideline.

2020 Review of Back and Spine Conditions
Surgical Guideline

HERC staff recommendation:

1) Minimal modifications to GN 37 as shown below
    a. Based on CCO feedback, the current guideline is working well.
    b. Includes suggested wording from the diagnostic injection for spine surgery review

GUIDELINE NOTE 37, SURGICAL INTERVENTIONS FOR CONDITIONS OF THE BACK AND SPINE OTHER THAN SCOLIOSIS

Lines 346,529

Spine surgery is included on Line 346 only in the following circumstances:

A) Decompressive surgery is included on Line 346 to treat debilitating symptoms due to central or foraminal spinal stenosis, and only when the patient meets the following criteria:
    1) Has MRI evidence of moderate or severe central or foraminal spinal stenosis AND
    2) Has neurogenic claudication OR
    1) Has objective neurologic impairment consistent with the MRI findings. Neurologic impairment is defined as objective evidence of one or more of the following:
        a) Markedly abnormal reflexes
        b) Segmental muscle weakness
        c) Segmental sensory loss
        d) EMG or NCV evidence of nerve root impingement
        e) Cauda equina syndrome
        f) Neurogenic bowel or bladder
        g) Long tract abnormalities

    Foraminal or central spinal stenosis causing only radiating pain (e.g. radiculopathic pain) is included only on Line 529.

B) Spinal fusion procedures are included on Line 346 for patients with MRI evidence of moderate or severe central spinal stenosis only when one of the following conditions are met:
    1) spinal stenosis in the cervical spine (with or without spondylolisthesis) which results in objective neurologic impairment as defined above OR
    2) spinal stenosis in the thoracic or lumbar spine caused by spondylolisthesis resulting in signs and symptoms of neurogenic claudication and which correlate with x-ray flexion/extension films showing at least a 5 mm translation OR
    3) pre-existing or expected post-surgical spinal instability (e.g. degenerative scoliosis >10 deg, >50% of facet joints per level expected to be resected)

For all other indications, spine surgery is included on Line 529.

The following interventions are not included on these lines due to lack of evidence of effectiveness for the treatment of conditions on these lines, including cervical, thoracic, lumbar, and sacral conditions:

- local injections (including ozone therapy injections)
- botulinum toxin injection
- intradiscal electrothermal therapy
- therapeutic medial branch block
- coblation nucleoplasty
- percutaneous intradiscal radiofrequency thermocoagulation
- percutaneous laser disc decompression

- radiofrequency denervation
- corticosteroid injections for cervical pain

Corticosteroid injections for low back pain with or without radiculopathy are only included on Line 529. Diagnostic anesthetic injections for selective nerve root blocks are included on line 529 for lumbar or sacral symptoms.

The development of this guideline note was informed by HERC coverage guidances on Percutaneous Interventions for Low Back Pain, Percutaneous Interventions for Cervical Spine Pain, Low Back Pain: Corticosteroid Injections and Low Back Pain: Minimally Invasive and Non-Cordicosteroid Percutaneous Interventions. See https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx.

Washington State Health Care Authority

Health Technology Clinical Committee
Findings and Decision

Topic: Surgery for lumbar radiculopathy/ sciatica
Meeting date: May 18, 2018
Final adoption: **July 13, 2018**

Meeting materials are available on the HTA website.

Number and coverage topic:

20180518A - Surgery for lumbar radiculopathy/ sciatica

HTCC coverage determination:

Surgery for lumbar radiculopathy or sciatica is a **covered benefit with conditions**.

HTCC reimbursement determination:

Limitations of coverage:

Open discectomy or microdiscectomy with or without endoscopy (lumbar laminectomy, laminotomy, discectomy, foraminotomy) are covered with the following conditions:

- For adult patients with lumbar radiculopathy with subjective and objective neurologic findings that are corroborated with an advanced imaging test (i.e., Computed Tomography (CT) scan, Magnetic Resonance Imaging (MRI) or myelogram), AND
- There is a failure to improve with a minimum of six weeks of non-surgical care, unless progressive motor weakness is present

Non-covered indicators:

Minimally invasive procedures that do not include laminectomy, laminotomy, or foraminotomy including but not limited to energy ablation techniques, Automated Percutaneous Lumbar Discectomy (APLD), percutaneous laser, nucleoplasty, etc. are not covered.

Agency contact information:

Agency	Phone Number
Labor and Industries	1-800-547-8367
Public Employees Health Plan	1-800-200-1004
Washington State Medicaid	1-800-562-3022

HTCC coverage vote and formal action:

Committee decision

Based on the deliberations of key health outcomes the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and state agency utilization information. The committee also determined that current evidence is sufficient to make a determination on this topic.

The committee concluded that the current evidence on surgery for lumbar radiculopathy/ sciatica should be considered and voted on by separate procedure type: open procedures, microdisectomy procedures and procedures that do not include laminectomy, laminotomy or foraminotomy. The committee discussed and voted separately on the evidence for use of these procedures by type. The committee considered the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Based on these findings, the committee voted to cover with conditions open discectomy and microdiscectomy, with or without endoscopy. This includes lumbar laminectomy, laminotomy, discectomy, foraminotomy. Separately, the committee voted to not cover minimally invasive procedures that do not include laminectomy, laminotomy, or foraminotomy including, but not limited to, energy ablation techniques, Automated Percutaneous Lumbar Discectomy (APLD), percutaneous laser, and nucleoplasty.

	Not covered	Covered under certain conditions	Covered unconditionally
Open procedures	1	8	0
Microdiscectomy surgical procedures	1	8	0
Minimally invasive procedures	8	1	0

Discussion

The committee reviewed and discussed the available studies of surgical treatment for lumbar radiculopathy. Details of study design, inclusion criteria and other factors affecting study quality were discussed and considered. A majority of committee members found the evidence sufficient to determine that select open and micro-procedures for lumbar radiculopathy were equivalent for safety and equivalent for effectiveness compared to alternatives, and less than sufficient or unproven for cost-effectiveness. For minimally invasive techniques that do not include laminectomy, laminotomy or foraminotomy a majority found the evidence to be unproven for efficacy, safety and cost-effectiveness. Based on the information reviewed and considered the committee identified conditions for coverage. A majority of the committee voted to cover with conditions surgery for lumbar radiculopathy/ sciatica.

Limitations

Open discectomy and microdiscectomy with or without endoscopy (lumbar laminectomy, laminotomy, discectomy, foraminotomy) are covered with conditions:

- Adult patients with lumbar radiculopathy with subjective and objective neurologic findings that are corroborated with an advanced imaging test (CT scan, MRI or myelogram), AND

- Failure to improve with minimum of six weeks of non-surgical care unless progressive motor weakness is present.

Not covered - Minimally invasive procedures that do not include laminectomy, laminotomy, or foraminotomy including, but not limited to, energy ablation techniques, APLD, percutaneous laser, nucleoplasty, etc.

Action

The committee checked for availability of a Medicare national coverage decision (NCD). Medicare does not have an NCD for open standard or microsurgical decompressive procedures.

The committee discussed clinical guidelines identified for surgery for lumbar radiculopathy/ sciatica from the following organizations:

- Low back pain and sciatica in over 16s: assessment and management-Invasive treatments; National Institute for Health and Care Excellence (NICE) 2016.
- Clinical Guidelines for Diagnosis and Treatment of Lumbar Disc Herniation with Radiculopathy; North American Spine Society (2012).
- Interventional Therapies, Surgery, and Interdisciplinary Rehabilitation for Low Back Pain; American Society of Interventional Pain Physicians (2013).
- Low back disorders. In occupational medicine practice guidelines: evaluation and management of common health problems and functional recovery in workers; American College of Occupational and Environmental Medicine (2016).
- Percutaneous transforaminal endoscopic lumbar discectomy for sciatica: Interventional procedures guidance (2016).
- Percutaneous interlaminar endoscopic lumbar discectomy for sciatica: Interventional procedures guidance (2016).
- Percutaneous coblation of the intervertebral disc for low back pain and sciatica: Interventional procedures guidance (2016).
- Percutaneous electrothermal treatment of the intervertebral disc annulus for low back pain and sciatica: Interventional procedures guidance (2016).
- Percutaneous intradiscal radiofrequency treatment of the intervertebral disc nucleus for low back pain: Interventional procedures guidance (2016).
- Epiduroscopic lumbar discectomy through the sacral hiatus for sciatica: Interventional procedures guidance (2016).
- Percutaneous intradiscal laser ablation in the lumbar spine: Interventional guidance (2010).
- Automated percutaneous mechanical lumbar discectomy: Interventional procedures guidance (2005).
- Endoscopic laser foraminoplasty: Interventional procedures guidance (2003).

The committee's determinations are consistent with these guidelines.

The committee chair directed HTA staff to prepare a findings and decision document on surgery for lumbar radiculopathy/ sciatica for public comment; followed by consideration for final approval at the next public meeting.

Health Technology Clinical Committee Authority:

Washington State's legislature believes it is important to use a science-based, clinician-centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority (HCA), through its Health Technology Assessment (HTA) program, to engage in an evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and that takes public input at all stages.

Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC), composed of eleven independent health care professionals, reviews all the information and renders a decision at an open public meeting. The Washington State HTCC determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases its decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Administrator.

Health Technology Clinical Committee
Findings and Decision

Topic: **Lumbar Fusion for Degenerative Disc Disease**
Meeting Date: November 20, 2015
Final Adoption: January 15, 2016

Meeting materials and transcript are available on the HTA website:
www.hca.wa.gov/hta/meetingmaterials/Forms/ExtMeetingMaterials.aspx

Number and Coverage Topic:

20151120A – Lumbar Fusion for Degenerative Disc Disease

HTCC Coverage Determination:

Lumbar fusion for degenerative disc disease uncomplicated by comorbidities is **not a covered benefit.**

The population addressed in this decision includes individuals > 17 years of age with chronic (3 or more months) lumbar pain and uncomplicated degenerative disc disease; excluded conditions include radiculopathy, spondylolisthesis (> Grade 1) or severe spinal stenosis, as well as acute trauma or systemic disease affecting the lumbar spine (e.g., malignancy).

HTCC Reimbursement Determination:

Limitations of Coverage: N/A

Non-Covered Indicators: N/A

Agency Contact Information:

Agency	Phone Number
Labor and Industries	1-800-547-8367
Public Employees Health Plan	1-800-200-1004
Washington State Medicaid	1-800-562-3022

HTCC Coverage Vote and Formal Action

Committee Decision

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and state agency utilization information. The committee concluded that the current evidence on lumbar fusion is sufficient to make a determination and that there is new evidence available since the original, 2007 determination on this topic. The committee discussed and voted on the evidence of lumbar fusion for degenerative disc disease compared to non-invasive alternative treatments including intensive and minimal options. The committee considered the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable. Based on these findings, the committee voted to not cover lumbar fusion for patients >17 years of age with chronic (≥ 3 months) lumbar pain and uncomplicated degenerative disc disease.

	Not Covered	Covered Under Certain Conditions	Covered Unconditionally
Lumbar Fusion for DDD	10	1	0

Discussion

The committee discussed the meaning of "uncomplicated degenerative disc disease" for this review and noted, for the record, that the population addressed in this decision includes individuals > 17 years of age with chronic (3 or more months) lumbar pain and uncomplicated degenerative disc disease; excluded conditions include radiculopathy, spondylolisthesis (> Grade 1) or severe spinal stenosis, as well as acute trauma or systemic disease affecting the lumbar spine (e.g., malignancy).

Limitations

N/A

Action

The committee checked for availability of a Medicare national coverage decision (NCD). There is no NCD for lumbar fusion for degenerative disc disease.

The committee discussed clinical guidelines identified for Lumbar Fusion including guidelines from the following organizations:

American Association of Neurological Surgeons (AANS) (2014)
American Pain Society (APS) (2009)
Dr. Robert Bree Collaborative (2014)
International Society for the Advancement of Spine Surgery (ISASS) (2015)
National Institute for Health Care and Excellence (NICE) (2009)
North American Spine Society (2014)
Washington State Department of Labor and Industries (2009)

The chair noted differences between the committee determination and some of the guidelines. The following reasons for the differences were cited by the committee: availability of information not

considered in some guidelines; committee consideration of the long-term follow-up data in studies; concerns with potential adverse effects from surgery; and concerns about cost-effectiveness of surgery versus non-invasive alternatives. The committee determination agreed with some of the guidelines.

The committee chair directed HTA staff to prepare a findings and decision document on lumbar fusion for degenerative disc disease reflective of the majority vote for final approval at the next public meeting.

Health Technology Clinical Committee Authority:

Washington State's legislature believes it is important to use a science-based, clinician-centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority (HCA), through its Health Technology Assessment (HTA) program, to engage in an evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and that takes public input at all stages.

Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State HTCC determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases its decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Administrator.

Two Level Cervical Artificial Discs

Question: Should 2 level cervical artificial disc replacement be included on the Prioritized List?

Question source: Dave Pass, MD, medical director at Providence

Issue: Disc degeneration can lead to neck or low back pain. One treatment option is to replace the damaged disc with an artificial disc. This surgery is done as an alternative to spinal fusion. Currently, GN 101, ARTIFICIAL DISC REPLACEMENT limits artificial discs to one level for both the lumbar and cervical spine. There is a growing body of evidence that two level disc replacement is effective, particularly for the cervical spine.

GN101 was based on a HERC coverage guidance regarding artificial disc replacement. During the rescan of topics in 2016, not enough new evidence was found to justify a full review of that coverage guidance by HTAS. When this rescan was discussed at HTAS in December 2016, the group found that "there is emerging evidence about performing two-level cervical disc replacement, but many of the authors believe evidence to be insufficient at this point; on balance he would say the coverage guidance is up-to-date. In the future, there may be a need to update it regarding two-level cervical disc replacement."

From Dr. Pass:

> The FDA now approved 2 level Artificial Disc Replacements (though some insurers do not cover them yet). So the wording of the GN can now be confusing! Is it the intent to cover all that is FDA approved, or to cover only for single level Artificial Cervical Disc Replacement?
>
> …I have become convinced by the literature that 2 level Cervical ADR is Ok, possibly even desirable. I have also had several discussions with Out of area physicians who tell me that the overall cost (total hospital cost) at least in their areas are very close to doing a standard ACDF as the cost of the cage, graft, and other hardware is pretty close to the cost of the ADR.

Current guideline note:

GUIDELINE NOTE 101, ARTIFICIAL DISC REPLACEMENT

Lines 346,529

Artificial disc replacement (CPT 22856-22865) is included on these lines as an alternative to fusion only when all of the following criteria are met:

Lumbar artificial disc replacement

A) Patients must first complete a structured, intensive, multi-disciplinary program for management of pain, if covered by the agency;
B) Patients must be 60 years or under;
C) Patients must meet FDA approved indications for use and not have any contraindications. FDA approval is device specific but includes:
   - Failure of at least six months of conservative treatment
   - Skeletally mature patient
   - Replacement of a single disc for degenerative disc disease at one level confirmed by patient history and imaging

Cervical artificial disc replacement

D) Patients must meet FDA approved indications for use and not have any contraindications. FDA approval is device specific but includes:
   - Skeletally mature patient
   - Reconstruction of a single disc following single level discectomy for intractable symptomatic cervical disc disease (radiculopathy or myelopathy) confirmed by patient findings and imaging.

The development of this guideline note was informed by a HERC coverage guidance. See http://www.oregon.gov/oha/herc/Pages/blog-artificial-disc-replace.aspx

From the CEBP rescan for HTAS:
Most of the newly identified summary evidence shows that cervical disc replacement is either equivalent to or superior to anterior cervical discectomy with fusion. Additionally, disc replacement may be associated with fewer adverse effects and a reduced need for reoperation. Emerging evidence suggests that two-level disc replacement may have similar outcomes to one-level disc replacement, but others judge the evidence insufficient at this point. There were few new studies of lumbar disc replacement, but those that were identified support its use as an alternative to lumbar fusion in patients who have failed conservative management.

Evidence

Note: an updated literature search August 2020 did not find additional literature

1) **Washington HTA 2016**, Artificial Disc Replacement-Rereview
   https://www.hca.wa.gov/assets/program/adr-rr-final-report-20161219.pdf
   a. Lumbar artificial disc replacement (L-ADR)
      i. N=5 RCTs (in 11 publications), 5 non-randomized comparative studies, and 3 economic evaluations were included
      ii. 1 level L-ADR
         1. Efficacy at 24 months: Low quality evidence suggests that 1-level L-ADR is comparable with single level anterior lumbar interbody fusion or circumferential fusion up to in terms of overall clinical success, ODI success and pain improvement and insufficient evidence with regard to neurological success
         2. Efficacy at 60 months: Low quality evidence suggests that 1-level L-ADR is comparable with single level anterior lumbar interbody fusion or circumferential fusion up to in terms of overall clinical success, ODI success, neurological success and pain improvement at 60 months.
         3. Safety:
            a. There is low quality evidence that single-level L-ADR results in a similar proportion of secondary surgery at the index level, device-related adverse events (excluding secondary surgery at the index level) and experience of any adverse event, based on data from the two FDA IDE trials. (Low quality evidence)
            b. There is low quality evidence that L-ADR results in a similar proportion of major complications (0 to 1%) compared with lumbar fusion (0 to 1%); Sample sizes may have precluded detection of such events and their frequency may be underestimated.
      iii. 2 level L-ADR
         1. Efficacy at 24 months: Low quality evidence suggests that 2-level L-ADR is comparable with fusion up to 24 months in terms of overall clinical success, ODI scores neurological success and improvement in VAS pain scores. Evidence is from one FDA, non-inferiority IDE trial.
         2. Safety: Low quality evidence suggests that 2-level L-ADR was associated with fewer additional surgeries at the index level compared with fusion (2.4% vs. 8.3%) at 24 months. Major surgery-related complications were less common with L- ADR (0.7%) than with fusion (4.9%) (low quality evidence). Device-related events were similar between groups (2.4% for L-ADR vs. 1.4% for fusion) (low quality evidence).
         3. Cost effectiveness: no evidence found
      iv. 1 or 2 level L-ADR vs multidisciplinary rehabilitation:
         1. Efficacy: Low quality evidence suggests that L-ADR is better than multidisciplinary rehabilitation with regard to clinical success, (defined ODI improvement of ≥15-points) and improvement in VAS pain scores at 24 months. Evidence is from one trial
         2. Cost-effectiveness: One moderate to high quality cost-effectiveness analysis suggests that L-ADR may to be a cost effective alternative to

rehabilitation given a willingness to pay greater than $49,132 based on utilities derived from the EQ-5D. The same was not true with SF-6D was used.

b. Cervical Artificial Disc Replacement (C-ADR)
    i. N=19 RCTs (in 49 publications), nine non-randomized comparative studies, and 6 economic evaluations were included
    ii. 1 level C-ADR (vs fusion)
        a. Effectiveness: At 24-60 months: Moderate quality evidence suggests that 1-level C-ADR is superior to ACDF in terms of overall success, NDI success, and neurological success. However, there was low quality evidence that the groups were comparable in terms of arm and neck pain success.
        b. Safety: Single-level C-ADR is superior to ACDF in terms of the incidence of secondary surgery at the index level (moderate quality evidence), serious/major adverse events (low quality evidence), and device-related adverse events (moderate quality evidence).
        c. Cost-effectiveness Overall, results from four cost utility analyses (CUAs) found that both C-ADR and ACDF were cost effective options based on a WTP threshold of $50,000. However, C-ADR was more effective and less costly than ACDF for 1-level disc procedures
    iii. 2 level C-ADR (vs fusion)
        a. Effectiveness at 24-60 months: Moderate quality evidence suggests that 2-level C-ADR is superior to ACDF in terms of overall success and NDI success; while low quality evidence suggests that C-ADR is as good as or better than ACDF in terms of arm and neck pain scores. However, the groups are comparable in terms of neurological success (low quality evidence). (Arm and neck pain success were not reported.)
        b. Safety: Low quality evidence suggests that 2-level C-ADR is superior to ACDF in terms of the incidence of secondary surgery at the index level, serious/major adverse events, and device-related adverse events.
        c. Cost-effectiveness: Two high-quality CUAs (QHES scores of both were 100/100) based on a single RCT suggest that, based on a willingness to pay threshold of $50,000/QALY, C-ADR was highly cost-effective at 24 and 60 months when compared to ACDF for 2-level degenerative disc disease with radiculopathy or myelopathy that had not responded to six weeks of conservative care.

2) **Jiang 2016**, systematic review and meta-analysis of multiple level vs single level C-ADR for cervical spondylosis
    a. N=10 studies (1402 patients). 3 RCTs, 5 prospective studies,and 3 retrospective studies.
    b. No significant differences between single-level and multiple-level groups were found in terms of the prevalence of heterotopic ossification and reoperation rate, Neck Disability Index score, Visual Analog Scale score, and success rate using the Odom grading system.
    c. Conclusions: On the basis of this meta-analysis, clinical outcomes of multiple-level CDR are similar to those of single-level CDR for cervical spondylosis, which suggests the multiple-level CDR is as effective and safe as the single-level CDR.

3) **Kuang 2016**, systematic review and meta-analysis of 2 level cervical disc arthroplasty vs fusion for cervical spondylopathy
    a. N=6 studies (646 patients)
    b. There were no significant differences in neck disability index (MD, -1.53; 95% CI -3.80 to 0.73), VAS neck pain (MD, -0.19; 95% CI -0.71 to 0.33), and VAS arm pain (MD, -0.23; 95% CI -0.61 to 0.16) between 2-level CDA and 2-level ACDF cases. ROM at C2–C7 (MD, 15.82; 95% CI, 10.66–20.99), functional segment unit ROM (MD, 8.58; 95% CI, 7.93–9.23), and ROM at the operated level (MD, 9.54; 95% CI, 7.73–11.35) were greater, but the incidence of radiologic changes at adjacent levels (OR, 0.29; 95% CI, 0.13–0.67) were lower, in 2-level CDA cases. In 2-level CDA cases, the operating time was longer (MD, 57.41; 95% CI, 24.67–90.14), but surgery-related complications rates (OR, 0.47; 95% CI, 0.30–0.74) was lower.
    c. Conclusions: CDA may be a safe and effective alternative to ACDF for the treatment of 2-level cervical degenerative disease.
    a. Level of Evidence: Level II.
4) **Zhao 2015**, meta-analysis of multi-level vs single level cervical disc arthroplasty for cervical disc disease
    a. N=8 studies, four were prospective cohorts and the other four were retrospective.
    b. There was no significant difference in neck disability index scores, neck visual analog scale (VAS), arm VAS, morbidity of reoperation, heterotopic ossification, and parameters of living quality when comparing multi-level CDA with single-level CDA at 1 and 2 years follow-up postoperatively (p[0.05).
    c. Conclusions The meta-analysis revealed that the outcomes and functional recovery of patients performed with multi-level CDA are equivalent to those with single-level CDA, which suggests the multi-level CDA is as effective and safe as single-level invention for the treatment of cervical spondylosis. Nonetheless, more well-designed studies with large groups of patients are needed to provide further evidence for the benefit and reliability of multilevel CDA in the treatment of cervical disc diseases.

Other policies:

1) Private insurers vary on coverage with some covering only single level cervical disc replacement and others covering 1 or 2 level replacement

HERC staff summary:
Based on new meta-analyses and high-quality systematic reviews, there appears to be moderate evidence that two-level cervical artificial disc replacement is as effective or more effective than fusion surgery and appears to be safer and more cost-effective.

HERC staff recommendation:

1) Option 1: Request EGBS update the coverage guidance.

2) Option 2: No change.

3) Option 3: Modify GN101 as shown below to allow 2 level cervical artificial disc replacement and retire coverage guidance

GUIDELINE NOTE 101, ARTIFICIAL DISC REPLACEMENT

Lines 346,529

Artificial disc replacement (CPT 22856-22865) is included on ~~these lines~~ line 346 as an alternative to fusion only when all of the following criteria are met:

Lumbar artificial disc replacement

A) Patients must first complete a structured, intensive, multi-disciplinary program for management of pain, if covered by the agency;
B) Patients must be 60 years or under;
C) Patients must meet FDA approved indications for use and not have any contraindications. FDA approval is device specific but includes:
   - Failure of at least six months of conservative treatment
   - Skeletally mature patient
   - Replacement of a single disc for degenerative disc disease at one level confirmed by patient history and imaging

Cervical artificial disc replacement

A) Patients must meet FDA approved indications for use and not have any contraindications. FDA approval is device specific but includes:
   - Skeletally mature patient
   - Reconstruction of a single or 2 level disc following single or 2 level discectomy for intractable symptomatic cervical disc disease (radiculopathy or myelopathy) confirmed by patient findings and imaging.

Otherwise, artificial disc replacement is included on line 529.

The development of this guideline note was informed by a HERC coverage guidance. See http://www.oregon.gov/oha/herc/Pages/blog-artificial-disc-replace.aspx

Artificial Disc Replacement – 2016 Rescanning Summary

Subcommittee

Health Technology Assessment Subcommittee (HERC Approved August 2012, Reaffirmed November 2014)

Coverage Recommendation (Box Language)

Artificial disc replacement is recommended for coverage only when all of the following criteria are met:

Lumbar artificial disc replacement

1) Patients must first complete a structured, intensive, multi-disciplinary program for management of pain, if covered by the agency;
2) Patients must be 60 years or under;
3) Patients must meet FDA approved indications for use and not have any contra-indications. FDA approval is device specific but includes:

- Failure of at least six months of conservative treatment
- Skeletally mature patient
- Replacement of a single disc for degenerative disc disease at one level confirmed by patient history and imaging

Cervical artificial disc replacement

1) Patients must meet FDA approved indications for use and not have any contra-indications. FDA approval is device specific but includes:

- Skeletally mature patient
- Reconstruction of a single disc following single level discectomy for intractable symptomatic cervical disc disease (radiculopathy or myelopathy) confirmed by patient findings and imaging.

Scope Statement

Population description	Adults with uncomplicated chronic cervical or lumbar back pain
Intervention(s)	Artificial disc replacement *Intervention exclusions: None*
Comparator(s)	Other interventions for neck and back pain, no treatment

Outcome(s) (up to five)	Critical: Long-term function, utilization of other surgical procedures (e.g., spinal fusion) Important: Short-term function, harms (including development of adjacent segment disease), utilization of non-surgical interventions (e.g. opioids) *Considered but not selected for GRADE Table: Short-term pain, long-term pain*
Key questions	1. What is the comparative effectiveness of artificial disc replacement for the treatment of chronic cervical or lumbar back pain? 2. Does the comparative effectiveness of artificial disc replacement vary by: a. Age b. Etiology of chronic cervical or lumbar back pain c. Duration of back pain d. Location or severity of degenerative changes e. Type of artificial disc f. Previous back surgery g. Number of levels treated h. Presence of radiculopathy, radicular symptoms or myelopathy i. Response to previous treatments 3. What are the harms of artificial disc replacement?

Newly Identified Evidence

	Suggests need to update CG?
Alvin & Mroz (2014)	No
Alvin et al. (2014)	No
Ament, Yang, Nunley, Stone, & Kim (2014)	No
Aragones, Hevia, & Barrios (2015)	No
Bakar, Lubelski, Abdullah, & Mroz (2014)	No
Blue Cross Blue Shield Association (2014)	No
Boselie, Willems, van Mameren, de Bie, & van Santbrink (2016)	No
Canadian Agency for Drugs and Technologies in Health (2014)	No
Colorado Division of Workers' Compensation (2014a)	No
Colorado Division of Workers' Compensation (2014b)	No
Ding et al. (2016)	No
Gao et al. (2015)	No

Hiratzka et al. (2015)	No
Hu, Lv, Ren, & Johansen (2016)	No
Jia et al. (2014)	No
Jiang et al. (2016)	No
Kang, Shi, Gu, Yang, & Gao (2015)	No
Kuang, Chen, Wang, Li, & Lu (2016)	No
Lewis, Attiah, Malhotra, Burnett, & Stein (2014)	No
Li et al., 2015; Luo, Gong, Huang, Yu, & Zou (2015)	No
Luo, Huang, et al. (2015)	No
Manchikanti & Hirsch (2015)	No
McAnany et al. (2014)	No
Molinari, Pagarigan, Dettori, Molinari, & Dehaven (2016)	No
Muheremu, Niu, Wu, Muhanmode, & Tian (2015)	No
National Institute for Health and Care Excellence (2014)	No
National Institute for Health and Care Excellence (2016)	No
Nie, Chen, Wang, & Zeng (2015)	No
Noshchenko et al. (2015)	No
Rao & Cao (2014)	No
Rao et al. (2015)	No
Ren, Song, Xue, & Yang (2014)	No
Shriver et al. (2016)	No
Thavaneswaran & Vandepeer (2014)	No
Veruva, Steinbeck, Toth, Alexander, & Kurtz (2014)	No
Wu et al., (2015)	No
Xie, Liu, Ding, Li, & Ma (2016)	No
Yao, Liang, Xia, & Jia (2016)	No
Zhang et al. (2015)	No
Zhao et al. (2015)	No
Zhong, Li, et al. (2016)	No
Zhong, Zhu, Zhuang, Wu, & Chen (2016)	No
Zhong, Zhu, Zhuang, Wu, & Chen (2016)	No
Zhou, Qu, Dong, Kang, & Zhao (2015)	No
Zhu, Tian, et al. (2016)	No
Zhu, Zhang, Liu, Wu, & Zhu (2016)	No
Zou et al. (2016)	No

Discussion

Most of the newly identified summary evidence shows that cervical disc replacement is either equivalent to or superior to anterior cervical discectomy with fusion. Additionally, disc replacement may be associated with fewer adverse effects and a reduced need for reoperation. Emerging evidence suggests that two-level disc replacement may have similar outcomes to one-level disc replacement, but

others judge the evidence insufficient at this point. There were few new studies of lumbar disc replacement, but those that were identified support its use as an alternative to lumbar fusion in patients who have failed conservative management.

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Comparisons of Safety and Clinical Outcomes Between Multiple-level and Single-level Cervical Disk Replacement for Cervical Spondylosis

A Systematic Review and Meta-analysis

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Study Design: This is a systematic review and meta-analysis.

Objective: The aim of this study was to evaluate the efficacy and safety of multiple-level cervical disk replacement (CDR) over single-level CDR for the treatment of cervical spondylosis.

Summary of Background Data: Some authors advocate for the multiple-level CDR instead of anterior decompression and fusion in cervical multiple-level spondylosis. However, whether the efficacy and safety of multi-level CDR are as favorable as that of single-level CDR remains controversial.

Methods: MEDLINE, EMBASE, and Cochrane library databases were searched up to November 2015 for controlled studies that compared the clinical outcomes of single-level and multiple-level CDR for the treatment of cervical spondylosis. The following outcomes were extracted and analyzed: prevalence of heterotopic ossification and reoperation, preoperative and postoperative Neck Disability Index scores, preoperative and postoperative Visual Analog Scale scores, and success rate using the Odom grading system.

Results: Ten studies involving 1402 patients were included: including 3 randomized controlled trials, 5 prospective studies, and 3 retrospective studies. No significant differences between single-level and multiple-level groups were found in terms of the prevalence of heterotopic ossification and reoperation rate, Neck Disability Index score, Visual Analog Scale score, and success rate using the Odom grading system.

Conclusions: On the basis of this meta-analysis, clinical outcomes of multiple-level CDR are similar to those of single-level CDR for cervical spondylosis, which suggests the multiple-level CDR is as effective and safe as the single-level CDR. Nonetheless, more well-designed studies are needed for further evaluation.

Key Words: cervical disk replacement, multiple-level, single-level, systematic review, meta-analysis

(*Clin Spine Surg* 2016;29:419–426)

For decades, anterior cervical discectomy and fusion (ACDF) has been the standard treatment for cervical spondylosis and has elicited excellent clinical results.[1–3] However, ACDF eliminates segmental motion at the treatment level, and increases segmental motion of adjacent levels, which is believed to be associated with adjacent segment disease (ASD).[4–6]

In recent years, cervical disk replacement (CDR) has emerged as an alternative treatment to ACDF.[7–10] Compared with single-level ACDF, single-level CDR has the superiorities of greater segmental motion preservation,[11–13] fewer secondary operation rate,[12,13] and less ASD onset.[14]

Confronted with cervical multiple-level spondylosis, some authors advocate for the multiple-level CDR instead of anterior decompression and fusion.[15,16] Multiple-level CDR is being more and more widely used. But the efficacy and safety of multiple-level CDR remain uncertain. A meta-analysis about the comparison between multiple-level CDR and multiple-level ACDF can evaluate the efficacy and safety of multiple-level CDR effectively. However, there are not enough studies comparing multiple-level CDR and ACDF after our thorough research. We believe the comparison between multiple-level CDR and single-level CDR can help to assess the efficacy and safety of multi-level CDR to a large extent. Whether the efficacy and safety of multi-level CDR are as favorable as that of single-level CDR remains controversial. Some studies have demonstrated the clinical outcome of multiple-level CDR was similar to that of single-level CDR,[17] whereas some other studies have demonstrated differences, including the prevalence of heterotopic ossification (HO), Visual Analog Scale (VAS) scores for pain,

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Cervical Disk Arthroplasty Versus Anterior Cervical Decompression and Fusion for the Treatment of 2-Level Cervical Spondylopathy

A Systematic Review and Meta-analysis

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Study Design: Systematic review and meta-analysis.

Objective: To assess the safety and efficacy of cervical disk arthroplasty (CDA) compared with anterior cervical decompression and fusion (ACDF) for the treatment of 2-level cervical spondylopathy.

Summary of Background Data: CDA has emerged as a potential alternative to ACDF in patients with cervical disk degeneration. But there are no published systematic reviews and meta-analyses comparing CDA with ACDF for the treatment of 2-level cervical spondylopathy.

Methods: The Pubmed, Embase, Web of science, Scopus, and Cochrane library databases were searched comparing CDA to ACDF in patients with 2-level cervical spondylopathy. Outcome measures were neck disability index, visual analog scale (VAS) of arm and neck pain, range of movement (ROM) at C2–C7, functional segment unit ROM, ROM at the operated level, and incidence of radiologic changes at adjacent levels approximately 2 years after surgery, as well as operating time and incidence of surgery-related complications. Mean difference (MD), odds ratios (OR), and their corresponding 95% confidence intervals (95% CIs) were calculated.

Results: Six studies involving 646 patients were included. There were no significant differences in neck disability index (MD, −1.53; 95% CI −3.80 to 0.73), VAS neck pain (MD, −0.19; 95% CI −0.71 to 0.33), and VAS arm pain (MD, −0.23; 95% CI −0.61 to 0.16) between 2-level CDA and 2-level ACDF cases. ROM at C2–C7 (MD, 15.82; 95% CI, 10.66–20.99), functional segment unit ROM (MD, 8.58; 95% CI, 7.93–9.23), and ROM at the operated level (MD, 9.54; 95% CI, 7.73–11.35) were greater, but the incidence of radiologic changes at adjacent levels (OR, 0.29; 95% CI, 0.13–0.67) were lower, in 2-level CDA cases. In 2-level CDA cases, the operating time was longer (MD, 57.41; 95% CI, 24.67–90.14), but surgery-related complications rates (OR, 0.47; 95% CI, 0.30–0.74) was lower.

Conclusions: CDA may be a safe and effective alternative to ACDF for the treatment of 2-level cervical degenerative disease.

Level of Evidence: Level II.

Key Words: cervical disk arthroplasty, anterior cervical decompression and fusion, cervical disk disease, meta-analysis

(*Clin Spine Surg* 2016;29:372–382)

Cervical spondylopathy refers to the process of age-related degeneration of the spinal joints and disks in the neck. Multilevel disease is seen in the majority of patients, with C5/6 being the most commonly affected level.[1] The slow process of degeneration eventually causes disk bulging, hypertrophy of the facet joints, and formation of osteophytes, which can pinch the spinal nerves or compress the spinal cord. Hence, cervical spondylopathy is a common cause of neurological dysfunction. The symptoms of cervical spondylopathy can be neck stiffness and pain, motor dysfunction, decrease of hand dexterity, and instability of gait and balance.

Multiple cervical spondylopathy can be treated by an anterior or posterior surgical approach. Both approaches can effectively relieve symptoms, but both have advantages and disadvantages.[2] Anterior cervical decompression and fusion (ACDF) has been widely performed as the gold standard anterior surgical procedure for over 50 years.[3] Postoperatively, ACDF provides clinical stability of the cervical spine. However, ACDF alters the normal biomechanical traits of the cervical spine, decreases mobility at the fused segments, and increases motion at the adjacent level, especially in patients with multilevel cervical spondylopathy.[4,5] This may accelerate adjacent segment degeneration (ASD) and result in the need for further surgery in the near future.[6,7]

Recently, cervical disk arthroplasty (CDA) has emerged as a potential alternative to ACDF in patients with cervical disk degeneration. CDA has been accepted by an increasing number of surgeons as it can restore intervertebral height and spinal alignment, preserve the

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ORIGINAL ARTICLE

Multi-level cervical disc arthroplasty (CDA) versus single-level CDA for the treatment of cervical disc diseases: a meta-analysis

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Abstract
Purpose Cervical disc arthroplasty (CDA) was developed to treat cervical degenerated disc diseases with the advantages of preserving the kinematics of the functional spinal unit. However, the safety and reliability of multi-level CDA are still controverted when comparing to the single-level CDA. It has shown unclear benefits in terms of clinical results, functional recovery, heterotopic ossification, and the need for secondary surgical procedures. The purpose of this study is to estimate the effectiveness of multi-level cervical arthroplasty over single-level CDA for the treatment of cervical spondylosis and disc diseases.
Methods To compare the studies of multi-level CDA versus single-level CDA in patients with cervical spondylosis that reported at least one of the following outcomes: functionality, neck pain, arm pain, quality of life, reoperation and incidence of heterotopic ossification, electronic databases (Medline, Embase, Pubmed, Cochrane library, and Cochrane Central Register of Controlled Trials) were searched. No language restrictions were used. Two authors independently assessed the methodological quality of included studies and extracted the relevant data.
Results Out of Eight cohorts that were included in the study, four were prospective cohorts and the other four were retrospective. The results of the meta-analysis indicated that there was no significant difference in neck disability index scores, neck visual analog scale (VAS), arm VAS, morbidity of reoperation, heterotopic ossification, and parameters of living quality when comparing multi-level CDA with single-level CDA at 1 and 2 years follow-up postoperatively ($p > 0.05$).
Conclusions The meta-analysis revealed that the outcomes and functional recovery of patients performed with multi-level CDA are equivalent to those with single-level CDA, which suggests the multi-level CDA is as effective and safe as single-level invention for the treatment of cervical spondylosis. Nonetheless, more well-designed studies with large groups of patients are needed to provide further evidence for the benefit and reliability of multi-level CDA in the treatment of cervical disc diseases.

Keywords Cervical disc arthroplasty · Multi-level · Single-level · Cervical disc diseases · Meta-analysis

Introduction

Cervical spondylosis and disc diseases are the most common cause of radiculopathy and myelopathy resulting in significant disability [1]. For decades, anterior cervical discectomy with fusion (ACDF) has been regarded as the "gold standard" of surgical intervention in treating cervical disc diseases, achieving neural decompression, segmental stabilization, and excellent clinical outcomes [2–4]. However, in recent years, cervical disc arthroplasty (CDA) has become an emerging option, which is designed to preserve segmental motion and theoretically prevent adjacent segment disease (ASD) [5, 6]. CDA has been increasingly regarded as an acceptable surgical intervention to treat cervical disc diseases.

H. Zhao and L. Cheng contributed equally to this study.

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Diagnostic Spinal Injections for Spine Surgery

Question: Should the Prioritized List be clarified with regard to noncoverage of diagnostic spinal injections for spine surgery?

Question source: Medical Directors from CCOs

Issue:
CCOs have received requests from orthopedic surgeons for epidural injections with steroid and local anesthetic as a diagnostic procedure to try to ascertain the likelihood of a foraminotomy surgery improving a patient's symptoms and believe that these diagnostic injections are a valuable diagnostic tool.

CCO medical directors have asked us to explicitly denote the intent of HERC coverage.

Epidural steroid injections have recently been reviewed in detail in a Coverage Guidance addressing epidural steroid injections for low back pain.
https://www.oregon.gov/oha/HPA/DSI-HERC/EvidenceBasedReports/Coverage%20Guidance%20-%20Low%20back%20pain-Corticosteroid%20Injections.pdf

HERC Coverage Guidance:

> Epidural corticosteroid injections are not recommended for coverage for the treatment of low back pain with radiculopathy *(weak recommendation).*
>
> Epidural corticosteroid injections are not recommended for coverage for the treatment of low back pain without radiculopathy (e.g., spinal stenosis, non-radicular pain) *(strong recommendation).*
>
> Corticosteroid injections (including facet joint, medial branch, and sacroiliac joint) are not recommended for coverage for the treatment of low back pain *(strong recommendation).*

No specific statement has been made about diagnostic anesthetic injections or selective nerve root blocks, although the codes are in the unfunded region.

Clinical background
From Beynon, 2019
UK guidelines recommend surgery for patients with radicular pain when non-surgical treatments have not improved symptoms and radiological findings are consistent with physical examination. However, surgery does not always resolve radicular pain and 5%–36% of patients suffer from recurrent back and leg pain within 2 years postsurgery. The main cause of unsuccessful back surgery is inaccurate diagnosis. Improved diagnosis could help identify patients most likely to benefit from surgery and minimise the cost and risks associated with unsuccessful back surgery.

Current Prioritized List Status

Code	Code Description	Current List Placement
64479	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); cervical or thoracic, single level	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
64480	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional level (List separately in addition to code for primary procedure)	662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
64483	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); lumbar or sacral, single level	529 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS
64484	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional level (List separately in addition to code for primary procedure)	529 CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS
0228T	Injections(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, cervical or thoracic; single level	Temporary code
0229T	each additional level (List separately in addition to code for primary procedure)	Temporary code
0230T	Injections(s), anesthetic agent and/or steroid, transforaminal epidural, with ultrasound guidance, lumbar or sacral; single level	Temporary code
0231T	each additional level (List separately in addition to code for primary procedure)	Temporary code
77003	Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (epidural or subarachnoid) (List separately in addition to code for primary procedure)	Ancillary Procedures File
77012	Computed tomography guidance for needle placement (eg, biopsy, aspiration, injection, localization device), radiological supervision and interpretation	Ancillary Procedures File

Line:	**402**
Condition:	CONDITIONS OF THE BACK AND SPINE (See Guideline Notes 6,56,60,64,65,92,160,166)
Treatment:	RISK ASSESSMENT, PHYSICAL MODALITIES, COGNITIVE BEHAVIORAL THERAPY, MEDICAL THERAPY
ICD-10:	F45.42,G83.4,G95.0,M24.08,M25.78,M40.00-M40.15,M40.202-M40.57,M42.00-M42.09, M42.11-M42.9,M43.00-M43.4,M43.5X2-M43.5X9,M43.8X1-M43.9,M45.0-M45.9,M46.1, M46.40-M46.99,M47.10-M47.28,M47.811-M47.9,M48.00-M48.05,M48.061-M48.38, M48.8X1-M48.9,M49.80-M49.89,M50.00-M50.01,M50.020-M50.93,M51.04-M51.9, M53.2X1-M53.9,M54.10-M54.9,M62.830,M96.1-M96.4,M99.00-M99.09,M99.20-M99.79, M99.81-M99.84,Q06.0-Q06.3,Q06.8-Q06.9,Q68.0,Q76.0-Q76.2,Q76.411-Q76.49,S13.0XXA-S13.0XXD,S13.4XXA-S13.4XXD,S13.8XXA-S13.8XXD,S13.9XXA-S13.9XXD,S16.1XXA-S16.1XXD,S23.0XXA-S23.0XXD,S23.100A-S23.100D,S23.101A-S23.101D,S23.110A-S23.110D,S23.111A-S23.111D,S23.120A-S23.120D,S23.121A-S23.121D,S23.122A-S23.122D, S23.123A-S23.123D,S23.130A-S23.130D,S23.131A-S23.131D,S23.132A-S23.132D, S23.133A-S23.133D,S23.140A-S23.140D,S23.141A-S23.141D,S23.142A-S23.142D, S23.143A-S23.143D,S23.150A-S23.150D,S23.151A-S23.151D,S23.152A-S23.152D, S23.153A-S23.153D,S23.160A-S23.160D,S23.161A-S23.161D,S23.162A-S23.162D, S23.163A-S23.163D,S23.170A-S23.170D,S23.171A-S23.171D,S23.3XXA-S23.3XXD, S23.8XXA-S23.8XXD,S23.9XXA-S23.9XXD,S33.0XXA-S33.0XXD,S33.100A-S33.100D, S33.101A-S33.101D,S33.110A-S33.110D,S33.111A-S33.111D,S33.120A-S33.120D, S33.121A-S33.121D,S33.130A-S33.130D,S33.131A-S33.131D,S33.140A-S33.140D, S33.141A-S33.141D,S33.5XXA-S33.5XXD,S33.8XXA-S33.8XXD,S33.9XXA-S33.9XXD, S34.3XXA-S34.3XXD,S39.092A-S39.092D,S39.82XA-S39.82XD,S39.92XA-S39.92XD
CPT:	90785,90832-90840,90853,93792,93793,96150-96155,97110-97124,97140,97150,97161-97168,97530,97535,97810-98942,98966-98969,99051,99060,99070,99078,99201-99215, 99281-99285,99304-99337,99340-99404,99408-99449,99451,99452,99487-99491,99495, 99496,99605-99607
HCPCS:	G0068,G0071,G0157-G0160,G0248-G0250,G0396,G0397,G0425-G0427,G0463-G0467, G0469,G0470,G0490,G0511,G2010-G2012,S9451

Line:	**529**
Condition:	CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS (See Guideline Notes 37,60,64,65,100,101,161)
Treatment:	SURGICAL THERAPY
ICD-10:	G95.0,M40.00-M40.15,M40.202-M40.57,M42.00-M42.9,M43.00-M43.28,M43.8X1-M43.8X9,M45.0-M45.9,M46.1,M46.40-M46.99,M47.20-M47.28,M47.811-M47.9,M48.00-M48.05,M48.061-M48.19,M48.30-M48.38,M48.8X1-M48.9,M49.80-M49.89,M50.10-M50.11,M50.120-M50.93,M51.14-M51.9,M53.80-M53.9,M54.10-M54.18,M96.1-M96.4,M99.20-M99.79,Q06.0-Q06.3,Q06.8-Q06.9,Q76.0-Q76.2,Q76.411-Q76.49,S13.0XXA-S13.0XXD,S23.0XXA-S23.0XXD,S23.100A-S23.100D,S23.110A-S23.110D,S23.120A-S23.120D,S23.122A-S23.122D,S23.130A-S23.130D,S23.132A-S23.132D,S23.140A-S23.140D,S23.142A-S23.142D,S23.150A-S23.150D,S23.152A-S23.152D,S23.160A-S23.160D,S23.162A-S23.162D,S23.170A-S23.170D,S33.0XXA-S33.0XXD,S33.100A-S33.100D,S33.110A-S33.110D,S33.120A-S33.120D,S33.130A-S33.130D,S33.140A-S33.140D,S34.3XXA-S34.3XXD
CPT:	20610,20660-20665,20930,20931,20936-20938,21720,21725,22206-22226,22532-22865,27035,27096,27279,29000-29046,29710,29720,62322,62323,63001-63091,63170,63173-63200,63270-63273,63295-63610,63650,63655,63685,64483,64484,64493-64495,93792,93793,96150-96155,97110-97124,97140,97150,97161-97168,97530,97535,98966-98969,99051,99060,99070,99078,99184,99201-99239,99281-99285,99291-99404,99408-99449,99451,99452,99468-99480,99487,99489,99491,99495,99496,99605-99607
HCPCS:	C1767,C1778,C1816,C1820,C1822,C1823,C1897,G0068,G0071,G0157-G0160,G0248-G0250,G0260,G0396,G0397,G0406-G0408,G0425-G0427,G0463-G0467,G0508-G0511,G2010-G2012,S2350,S2351

GUIDELINE NOTE 37, SURGICAL INTERVENTIONS FOR CONDITIONS OF THE BACK AND SPINE OTHER THAN SCOLIOSIS

Lines 346,529

Spine surgery is included on Line 346 only in the following circumstances:

A) Decompressive surgery is included on Line 346 to treat debilitating symptoms due to central or foraminal spinal stenosis, and only when the patient meets the following criteria:
   1) Has MRI evidence of moderate or severe central or foraminal spinal stenosis AND
   2) Has neurogenic claudication OR
   3) Has objective neurologic impairment consistent with the MRI findings. Neurologic impairment is defined as objective evidence of one or more of the following:
      a) Markedly abnormal reflexes
      b) Segmental muscle weakness
      c) Segmental sensory loss
      d) EMG or NCV evidence of nerve root impingement
      e) Cauda equina syndrome
      f) Neurogenic bowel or bladder
      g) Long tract abnormalities

   Foraminal or central spinal stenosis causing only radiating pain (e.g. radiculopathic pain) is included only on Line 527.

B) Spinal fusion procedures are included on Line 346 for patients with MRI evidence of moderate or severe central spinal stenosis only when one of the following conditions are met:
   1) spinal stenosis in the cervical spine (with or without spondylolisthesis) which results in objective neurologic impairment as defined above OR
   2) spinal stenosis in the thoracic or lumbar spine caused by spondylolisthesis resulting in signs and symptoms of neurogenic claudication and which correlate with xray flexion/extension films showing at least a 5 mm translation OR
   3) pre-existing or expected post-surgical spinal instability (e.g. degenerative scoliosis >10 deg, >50% of facet joints per level expected to be resected)

For all other indications, spine surgery is included on Line 529.

The following interventions are not included on these lines due to lack of evidence of effectiveness for the treatment of conditions on these lines, including cervical, thoracic, lumbar, and sacral conditions:

- local injections (including ozone therapy injections)
- botulinum toxin injection
- intradiscal electrothermal therapy
- therapeutic medial branch block
- coblation nucleoplasty
- percutaneous intradiscal radiofrequency thermocoagulation
- percutaneous laser disc decompression
- radiofrequency denervation
- corticosteroid injections for cervical pain

Corticosteroid injections for low back pain with or without radiculopathy are only included on Line 529.

The development of this guideline note was informed by HERC coverage guidances on Percutaneous Interventions for Low Back Pain, Percutaneous Interventions for Cervical Spine Pain, Low Back Pain: Corticosteroid Injections and Low Back Pain: Minimally Invasive and Non-Cordicosteroid Percutaneous Interventions. See https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx.

GUIDELINE NOTE 173, INTERVENTIONS THAT ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS

Line 662

The following Interventions are prioritized on Line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:

64479-64480	Transforaminal epidural steroid injections, cervical and thoracic spine	Insufficient evidence of benefit	March, 2015 Coverage guidance

Evidence summary

Beynon, 2019

- Systematic review of diagnostic nerve root blocks for lumbar radiculopathy
- 6 studies, 341 patients
- Selective nerve root blocks administered under imaging guidance; patients with low back pain and leg symptoms
- All studies with high risk of bias and with substantial heterogeneity
- Sensitivity (range 57%–100%) and specificity (10%–86%) estimates. Four studies were diagnostic cohort studies that used either intraoperative findings during surgery (pooled sensitivity: 93.5% [95% CI 84.0 to 97.6]; specificity: 50.0% [16.8 to 83.2]) or 'outcome following surgery' as the reference standard (pooled sensitivity: 90.9% [83.1 to 95.3]; specificity 22.0% [7.4 to 49.9]).
    - Given low specificity, many patients without nerve root disease have a false positive
- Complication rate 0-6%. No major complications reported.
- Due to small number of studies, unable to explore subgroups
- Author conclusions: We found limited evidence which was of low methodological quality indicating that the diagnostic accuracy of SNRB is uncertain and that specificity in particular may be low. SNRB is a safe test with a low risk of clinically significant complications, but it remains unclear whether the additional diagnostic information it provides justifies the cost of the test.

No systematic reviews of cervical or thoracic diagnostic spinal injections were found.

Other payers

AIM, 2019

http://www.aimspecialtyhealth.com/PDF/Guidelines/2019/Jan01/AIM_Guidelines_MSK_Interventional-Pain-Management.pdf

Diagnostic Selective Nerve Root Block (DSNRB), also known as diagnostic transforaminal injection, is defined as the injection of anesthetic only, for the purpose of determining the need for surgical intervention.

DSNRB may be indicated in the evaluation and diagnostic work-up of radicular pain following consultation with a spine surgeon in any of the following scenarios:

• To confirm nerve root compression or spinal stenosis (central or foraminal) noted on an advanced imaging study (MRI or CT) and that is consistent with, and appears to be contributing to, the patient's symptoms.

• To determine or confirm the (or most) symptomatic level (i.e., site of compression) in the presence of multi-level involvement for which the primary symptomatic level is unclear.

• When radiculopathy is highly suspected but cannot be confirmed with advanced imaging studies.

Procedural Requirements and Restrictions:

• Injections must be performed under fluoroscopy or CT guidance.

• A maximum of three (3) injection sessions (including diagnostic transforaminal injections) may be performed in each spinal region (cervical or lumbosacral) in a six (6)-month period.

• No more than two (2) transforaminal injections may be performed at a single setting (e.g., single level bilaterally or two levels unilaterally). Injecting one level bilaterally would be considered two injections. Injecting two levels, each unilaterally, would also be considered two injections.

• For caudal or cervical/lumbar interlaminar injections, only one injection per session may be performed and NOT in conjunction with a transforaminal injection. A session is defined as all ESIs or spinal procedures performed on a single day.

• After three injections in the same region, the total cumulative dose of steroid must be documented and may not exceed 240 mg of methylprednisolone or triamcinolone or 36 mg of betamethasone or 45 mg of dexamethasone.

Contraindications and Risks

The following conditions should prompt further evaluation prior to considering ESI:

• New onset of low back pain or neck pain in the setting of established malignancy, or where there is a suspicion of malignancy based on the clinical presentation

• New onset of low back pain or neck pain in persons with risk factors for spinal infection

• Comorbid conditions associated with increased risk of bleeding due to coagulopathy or treatment with anticoagulants

• Back pain in the setting of trauma

Additional contraindications include the following conditions:

• Cauda equina syndrome

• Conus medullaris syndrome

• Epidural hematoma

- Subarachnoid hemorrhage
- Epidural mass
- Spinal cord ischemia
- Spinal fracture which occurred less than 6 weeks prior to injection
- Demyelinating disease or other CNS processes which predispose to transverse myelitis
- Systemic infection
- Local infection at the injection site
- Uncontrolled diabetes

Exclusions
Indications other than those addressed in this guideline are considered not medically necessary, including but not limited to the following:

- Thoracic level ESI performed for thoracic pathology
- Moderate to severe myelopathy on clinical exam
- Myelopathy associated with intramedullary cord signal change on T1 or T2 weighted MRI
- Isolated axial neck pain or low back pain

Aetna, 2018
http://www.aetna.com/cpb/medical/data/700_799/0722.html

1. Aetna considers diagnostic selective nerve root block (SNRB), also known as selective transforaminal epidural injection with imaging guidance (fluoroscopy or CT), medically necessary for identifying the etiology of pain in persons with symptoms suggestive of chronic radiculopathy, where the diagnosis remains uncertain after standard evaluation (neurological examination, radiological and neurodiagnostic studies):
    1. To establish the diagnosis of radiculopathy, when pain appears to be due to classic mono-radiculopathy but radiological or neurodiagnostic studies fail to provide a structural explanation; *or*
    2. To establish the diagnosis of radiculopathy in a person with classic mono-radicular pain, in whom radiological studies demonstrate an abnormality related to an adjacent nerve root only; *or*
    3. For those cases in which the clinical picture is suggestive but not typical for both nerve root and distal nerve or joint disease.

    Aetna considers diagnostic SNRBs experimental and investigational for all other indications because its effectiveness other than the ones listed above has not been established.

HERC Staff Summary

The evidence for the utility of diagnostic anesthetic injections are quite limited, with high risk of bias and high heterogeneity. The benefit therefore is unclear and coverage of these procedures would add cost. The guideline note for spine surgery already requires objective neurologic impairment consistent with MRI findings, and not for pain alone, therefore, further lessening any utility of these injections.

Recommendations:

1. **Maintain noncoverage for diagnostic spinal injections.** The codes for epidural anesthetic agents/steroids are currently located on line 529 (64483-64484, lumbar and sacral) or on line 662 (64479-64480, cervical or thoracic)

2. **Modify Guideline Note 37 as follows for clarity:**

GUIDELINE NOTE 37, SURGICAL INTERVENTIONS FOR CONDITIONS OF THE BACK AND SPINE OTHER THAN SCOLIOSIS

Lines 346,59

Spine surgery is included on Line 346 only in the following circumstances:

C) Decompressive surgery is included on Line 346 to treat debilitating symptoms due to central or foraminal spinal stenosis, and only when the patient meets the following criteria:
   1) Has MRI evidence of moderate or severe central or foraminal spinal stenosis AND
   2) Has neurogenic claudication OR
   3) Has objective neurologic impairment consistent with the MRI findings. Neurologic impairment is defined as objective evidence of one or more of the following:
      a) Markedly abnormal reflexes
      b) Segmental muscle weakness
      c) Segmental sensory loss
      d) EMG or NCV evidence of nerve root impingement
      e) Cauda equina syndrome
      f) Neurogenic bowel or bladder
      g) Long tract abnormalities

   Foraminal or central spinal stenosis causing only radiating pain (e.g. radiculopathic pain) is included only on Line 527.

D) Spinal fusion procedures are included on Line 346 for patients with MRI evidence of moderate or severe central spinal stenosis only when one of the following conditions are met:
   1) spinal stenosis in the cervical spine (with or without spondylolisthesis) which results in objective neurologic impairment as defined above OR

2) spinal stenosis in the thoracic or lumbar spine caused by spondylolisthesis resulting in signs and symptoms of neurogenic claudication and which correlate with xray flexion/extension films showing at least a 5 mm translation OR
3) pre-existing or expected post-surgical spinal instability (e.g. degenerative scoliosis >10 deg, >50% of facet joints per level expected to be resected)

For all other indications, spine surgery is included on Line 527.

The following interventions are not included on these lines due to lack of evidence of effectiveness for the treatment of conditions on these lines, including cervical, thoracic, lumbar, and sacral conditions:

- local injections (including ozone therapy injections)
- botulinum toxin injection
- intradiscal electrothermal therapy
- therapeutic medial branch block
- coblation nucleoplasty
- percutaneous intradiscal radiofrequency thermocoagulation
- percutaneous laser disc decompression
- radiofrequency denervation
- corticosteroid injections for cervical pain

Corticosteroid injections for low back pain with or without radiculopathy are only included on Line 529. Diagnostic anesthetic injections for selective nerve root blocks are included on line 529 for lumbar or sacral symptoms.

The development of this guideline note was informed by HERC coverage guidances on Percutaneous Interventions for Low Back Pain, Percutaneous Interventions for Cervical Spine Pain, Low Back Pain: Corticosteroid Injections and Low Back Pain: Minimally Invasive and Non-Cordicosteroid Percutaneous Interventions. See https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx.

3. Modify Guideline Note 173 as follows:

GUIDELINE NOTE 173, INTERVENTIONS THAT ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS

Line 662

The following Interventions are prioritized on Line 660 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:

64479-64480	Transforaminal epidural steroid injections, or diagnostic anesthetic injections, cervical and thoracic spine	Insufficient evidence of benefit	March, 2015 Coverage guidance; August 2020 HERC

BMJ Open

The utility of diagnostic selective nerve root blocks in the management of patients with lumbar radiculopathy: a systematic review

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ABSTRACT

Objective Lumbar radiculopathy (LR) often manifests as pain in the lower back radiating into one leg (sciatica). Unsuccessful back surgery is associated with significant healthcare costs and risks to patients. This review aims to examine the diagnostic accuracy of selective nerve root blocks (SNRBs) to identify patients most likely to benefit from lumbar decompression surgery.

Design Systematic review of diagnostic test accuracy studies.

Eligibility criteria Primary research articles using a patient population with low back pain and symptoms in the leg, SNRB administered under radiological guidance as index test, and any reported reference standard for the diagnosis of LR.

Information sources MEDLINE (Ovid), MEDLINE In-Process & Other Non-Indexed Citations, EMBASE, Science Citation Index, Biosis, LILACS, Dissertation abstracts and National Technical Information Service from inception to 2018.

Methods Risk of bias and applicability was assessed using the QUADAS-2 tool. We performed random-effects logistic regression to meta-analyse studies grouped by reference standard.

Results 6 studies (341 patients) were included in this review. All studies were judged at high risk of bias. There was substantial heterogeneity across studies in sensitivity (range 57%–100%) and specificity (10%–86%) estimates. Four studies were diagnostic cohort studies that used either intraoperative findings during surgery (pooled sensitivity: 93.5% [95% CI 84.0 to 97.6]; specificity: 50.0% [16.8 to 83.2]) or 'outcome following surgery' as the reference standard (pooled sensitivity: 90.9% [83.1 to 95.3]; specificity 22.0% [7.4 to 49.9]). Two studies had a within-patient case-control study design, but results were not pooled because different types of control injections were used.

Conclusions We found limited evidence which was of low methodological quality indicating that the diagnostic accuracy of SNRB is uncertain and that specificity in particular may be low. SNRB is a safe test with a low risk of clinically significant complications, but it remains unclear whether the additional diagnostic information it provides justifies the cost of the test.

Strengths and limitations of this study

- Comprehensive synthesis of the current evidence on diagnostic accuracy of selective nerve root block (SNRB) in lumbar radiculopathy.
- Extensive literature searches were conducted using several databases without restrictions on publication date, language or study type, in an attempt to locate all relevant studies.
- We used rigorous eligibility criteria, which excluded studies with mixed cervical and lumbar spine pathology and studies where there was insufficient data to construct estimates of sensitivity and specificity.
- Only a small number of primary diagnostic accuracy studies could be included in our review and all had methodological limitations.
- Due to the small number of studies, we were unable to explore the value of SNRB in potentially important patient subgroups, such as those with suspected multilevel radiculopathy.

INTRODUCTION

In Western Europe, low back pain is the leading cause of disability and represents a high economic burden,[1] in particular due to production losses and cost of informal care.[1] In a subgroup of patients, low back pain is accompanied by pain radiating to a lower extremity in a radicular distribution (sciatic pain). Leg pain is one of the symptoms of lumbar radiculopathy (LR) but other symptoms, such as numbness, tingling, weakness, can also develop. LR can be the result of compressive or inflammatory disorders of the spinal nerve roots or a combination of these. Randomised trial evidence on the effectiveness of lumbar decompressive surgery in patients with radiculopathy and intervertebral disc herniation suggests that early surgery leads to faster pain relief, but longer-term effectiveness is less clear.[2–7] Current UK guidelines recommend spinal decompression

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surgery for patients with radicular pain when non-surgical treatments have not improved symptoms and radiological findings are consistent with physical examination.[8] However, surgery does not always resolve radicular pain and 5%–36% of patients suffer from recurrent back and leg pain within 2 years postsurgery.[9] The main cause of unsuccessful back surgery is inaccurate diagnosis.[10] Improved diagnosis could help identify patients most likely to benefit from surgery and minimise the cost and risks associated with unsuccessful back surgery.

A timely and accurate diagnosis of the cause of low back pain and radicular pain is important, since it is occasionally an early symptom of serious systemic disease,[11] and an inaccurate diagnosis can lead to a cascade of costly, invasive and ineffective therapy. In most patients, the diagnosis of radiculopathy, caused by nerve root compression, is made by correlation of symptoms, clinical signs and imaging findings. However, neither clinical findings nor radiological imaging have perfect diagnostic accuracy.[12] When clinical and imaging findings are equivocal or discordant, uncertainty remains about the source of the symptoms and whether nerve root decompression will relieve symptoms. Additional diagnostic tests could help clinicians and patients to choose between surgical and conservative care or guide surgery in patients with suspected multilevel radiculopathy.

Diagnostic selective nerve root blocks (SNRBs) inject local anaesthetic or other substances around spinal nerves under imaging guidance. Both provocative responses (replicating symptoms during needle placement) and analgesic responses (significant reduction of symptoms) to SNRB may be diagnostically useful in confirming or ruling out a given nerve root as the source of clinical symptoms. Some clinical guidelines and consensus statements have endorsed the use of SNRB to identify the source of pain in patients with multilevel pathology and in the preoperative evaluation of patients with a negative or inconclusive imaging study.[13 14] Over the last decade, several systematic reviews have investigated SNRB as diagnostic tool, covering the literature up to 2012.[15–18] However, evidence was scarce and of low quality and the diagnostic accuracy and reliability of SNRB remained unclear. We updated our previous systematic review to determine the diagnostic performance of SNRB in addition to clinical and imaging findings for identifying patients with LR who are good candidates for lumbar decompression surgery.[15] A secondary aim was to summarise evidence on the incidence of procedure-related complications.

MATERIALS AND METHODS

Literature search

We updated the search from our previous review, searching all databases to March 2018. Our previous search aimed to identify published and unpublished studies by searching MEDLINE (Ovid), MEDLINE In-Process & Other Non-Indexed Citations, EMBASE, Science Citation Index, Biosis and LILACS (Latin American and Caribbean literature database), Dissertation abstracts and National Technical Information Servicefrom inception to March 2018. Our search strategy combined terms for SNRB with terms for sciatica or radiculopathy (see online supplementary search strategy).[15] We did not use a methodological search filter to identify diagnostic accuracy studies as such filters result in the omission of relevant studies.[19–21] No language restrictions were applied. Attempts were made to identify further studies by examining the reference lists of all included articles.

Study selection

Studies were eligible for the diagnostic accuracy review if they included patients with low back pain and leg pain who underwent SNRB under imaging guidance. The studies needed to report sufficient data to construct a table detailing diagnostic accuracy (ie, numbers of true negative, true positive, false positive and false negative results) of the index test (SNRB) compared with any reported 'reference standard'. When we were unable to extract sufficient details from otherwise eligible studies we contacted study authors.

In diagnostic accuracy studies, the reference standard is typically a definitive test used to determine the true diagnosis, but no such definitive test exists for radicular pain due to nerve root compression. Therefore, most diagnostic studies used either intraoperative findings or postsurgical follow-up as the reference standard to judge the diagnostic accuracy of SNRB. An alternative approach is to determine the sensitivity of SNRB using a 'case' injection at a symptomatic nerve root level where nerve root compression is confirmed by imaging. Specificity is evaluated by a 'control' injection at an asymptomatic site (eg, adjacent nerve root) where imaging demonstrates no nerve root compression. Hence, in this approach, concordant clinical and imaging findings are used as the reference standard.

Two reviewers independently screened titles and abstracts for relevance and full papers for eligibility. Any disagreements were resolved by consensus or referred to the review team.

Data extraction and quality (bias and applicability) assessment

Data extraction was performed by one reviewer and checked by a second: disagreements were resolved by consensus or discussion among coauthors. We extracted data on: study design, inclusion and exclusion criteria, included patients, SNRB details and reference standard details. 'Per patient' data were extracted: if these were unavailable we extracted 'per injection' data.

Studies included in the diagnostic review were assessed for methodological quality using the QUADAS-2 measure of bias and applicability.[16] Bias occurs if the results of a study are distorted by flaws or limitations in its design or conduct (eg, knowledge of the index test result when interpreting the reference standard). Applicability may be reduced if patient characteristics, or the use or

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interpretation of the index test in the study differ from those likely to prevail in clinical practice. Reviewers rate concerns regarding applicability and risk of bias as low, high or unclear. At least two reviewers assessed quality using QUADAS-2 and any disagreements were resolved by consensus.[22]

Studies were judged to be of high applicability if: (1) they recruited patients with low back pain and suspected radiculopathy (sciatica) with non-congruent imaging and clinical findings, who might benefit from lumbar decompression surgery; (2) the SNRB included injection of anaesthetic, sometimes in conjunction with a steroid, close to the lumbar nerve root most often under guidance by fluoroscopy or other imaging; (3) the test aimed to identify patients with radiculopathy (sciatica) that was amenable to surgery and (4) the reference standard was outcome of surgery. We did not carry out formal quality assessment of studies reporting on adverse events.

Data synthesis and analysis

We performed all analyses in Stata V.15.1.[23] We calculated sensitivity and specificity of SNRB from each study and plotted these in receiver-operating characteristic space. We performed random-effects logistic regression to meta-analyse studies grouped by reference standard,[24] using an updated version of the *metandi* package.[25] Data from studies on adverse events were combined in a narrative summary. We reported our findings according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysesfor diagnostic test accuracy studies.[26]

Patient and public involvement

Patients and members of the public were not involved in this review.

RESULTS

The original searches identified 12 883 titles and abstracts and an additional 5267 were identified in the update search in 2018. Overall, 61 titles and abstracts were considered potentially relevant and full papers were retrieved and screened. Our original review included five studies. We identified one additional relevant study through our updated searches. A total of six studies (total 341 patients, sample size range 15–100) were therefore included in the review of diagnostic accuracy (figure 1). Where reported, the mean age of patients was in the mid-forties, the majority were male, and most had had symptoms for at least 3 months. One study excluded patients with a previous history of lumbar surgery,[27] in contrast a substantial minority of patients (up to 48%) had had previous surgery in two of the other studies. Details of the patients included, and the injections delivered in each study are given in table 1 (online supplementary table 1).

Four diagnostic cohort studies (one prospective and three retrospective) recruited patients with suspected LR in whom some doubt remained due to equivocal or discordant clinical and radiological findings. Schutz *et al* and Dooley *et al* used intraoperative findings during surgery as the reference standard (table 2).[28 29] In addition, Dooley *et al* used outcome following surgery as a second reference standard.[29] Williams and Germon and Sasso *et al* used outcome following surgery at 3 and 12 months,[30 31] respectively, as the reference standard.

Two studies had a within-patient case-control study design. In the Yeom *et al* study, control injections were given at adjacent asymptomatic nerve roots,[27] whereas in the North *et al* study, other anatomic sites in the lumbar spine were injected (sciatic nerve, facet joint and subcutaneous).[32] All cases were confirmed by concordant clinical and radiological or surgical findings prior to the use of SNRB.

Quality of included studies

All studies were judged at high risk of bias (table 3). All studies had high risk of bias for the reference standard because postsurgical outcomes were not considered[27 32] or selectively measured[28–31] (eg, surgery was predominantly

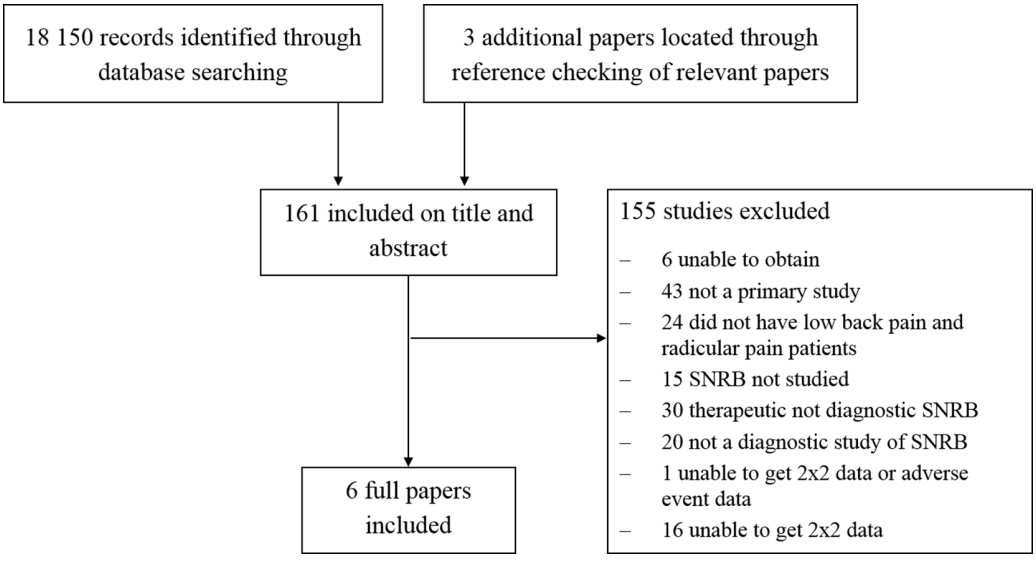

Figure 1 Flowchart of diagnostic study selection process. SNRB, selective nerve root block.

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Table 1 Details of included studies

Author (year) country	N analysed/N recruited	Description of included patients	Details of previous surgery	Needle level	Anaesthetic details	Guided method	Needle provocation	Number of control injections	Time to pain measurement
Within-patient case–control studies									
Yeom *et al*[27] (2008) NR	47/83	Established single-level radiculopathy. Concordant imaging and clinical findings	No history of lumbar surgeries	L3, L4, L5, S1	1 mL of 2% lidocaine	Fluoroscopy	No	1 or 2	30 min
North *et al*[32] (1996) USA	33/33	Established sciatica with or without low back pain. History of nerve root compression or imaging findings of ongoing nerve root compression	48% history of root compression corrected surgically	L5, S1	3 mL of 0.5% bupivacaine	Fluoroscopy	Yes	3	Every 15 min for 3 hours
Prospective diagnostic cohort studies									
Schutz *et al*[28] (1973) Canada	15/23	Current sciatica symptoms	Unclear if patients included in analysis had previous surgeries	NR	1 mL of procaine (concentration NR)	Guided but method NR	Yes	1 or 2	Immediate
Retrospective diagnostic cohort studies									
Sasso *et al*[31] (2005) USA	83/83	Cervical or lumbar radiculopathy. Discordant imaging and clinical findings	Unclear how many previous lumbar surgeries	NR	0.5–0.7 mL of 2% lidocaine	Fluoroscopy	Yes	NR	Immediate
Dooley *et al*[29] (1988) Canada	62/73	Radicular pain and previous nerve root infiltration	32≥1 previous surgery, 3 had 4surgeries	L3, L4, L5, S1	1 mL of 1% mepivacaine or lidocaine	Fluoroscopy	Yes	NR	Immediate
Williams *et al*[30] (2015) UK	96/100	Presumed radicular leg pain. Discordant clinical and imaging findings	NR	L1, L3, L4, L5, S1	2 mL of 1% lidocaine and 0.5–1 mL of Iopamidol	Fluoroscopy	Yes	NR	Immediate

DRGB, dorsal root ganglion block; NR, not reported; SNRB, selective nerve root block.

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Table 2 Diagnostic accuracy results

Author (year)	Threshold	Reference standard	TP	FN	Sensitivity % (95% CI)	TN	FP	Specificity % (95% CI)	PLR (95% CI)	NLR (95% CI)
Within-patient case-control studies*										
Yeom *et al*[27] (2008)	70% pain relief—several other thresholds also evaluated	Concordant symptoms and imaging evidence of compression (case injections) or no symptoms or imaging evidence of compression (control injections)	27	20	57 (43 to 70)	50	8	86 (75 to 93)	4.1 (2.1 to 8.3)	0.5 (0.4 to 0.7)
North *et al*[32] (1996)	50% reduction in baseline pain following block	Concordant symptoms and imaging evidence of compression (case injections) or no symptoms or imaging evidence of compression (control injections)	30	3	91 (76 to 97)	8	25	24 (12 to 41)	1.2 (1.0 to 1.5)	0.4 (0.1 to 1.3)
Diagnostic cohort studies										
Schutz *et al*[28] (1973)	100% pain relief. Full trunk flexion and straight leg raising possible	Intraoperative findings	12	0	100 (76 to 100)	1	2	33 (6 to 79)	1.5 (0.7 to 3.3)	0.0
Sasso *et al*[31] (2005)	Visual Analogue Scale score 0–1 and immediate relief of >95% pain	Outcome 12 months following surgery	71	3	96 (89 to 99)	5	4	56 (27 to 81)	2.2 (1.0 to 4.5)	0.1 (0.0 to 0.3)
Dooley *et al*[29] (1988)	Pain relief	Intraoperative surgical confirmation of root pathology	46	4	92 (81 to 98)	2	1	67 (9 to 99)	2.8 (0.6 to 13.7)	0.1 (0.0 to 0.4)
		Outcome following surgery (follow-up range 24–36 months)	28	4	88 (71 to 96)	2	19	10 (1 to 30)	1.0 (0.8 to 1.2)	1.2 (0.3 to 6.5)
Williams *et al*[30] (2015)	Pain relief	Outcome 3 months following surgery (resolution of symptoms)	41	7	85 (72 to 94)	2	10	17 (3 to 48)	1.0 (0.8 to 1.4)	0.9 (0.2 to 3.7)

*Please note that the unit used in the within-patient case–control studies is number of injections and some patients had two control injections at adjacent levels in addition to the affected nerve; in all other studies it is number of patients.
FN, false negative; FP, false positive; NLR, negative likelihood ratio; PLR, positive likelihood ratio; TN, true negative; TP, true positive.

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Table 3 QUADAS-2 results

Author (year)	Risk of bias				Applicability concerns		
	Patient selection	Index test	Reference standard	Flow and timing	Patient selection	Index test	Reference standard
Within-patient case-control studies							
Yeom *et al*[27] (2008)	☹	☹	☹	☹	☹	☺	☹
North *et al*[32] (1996)	☹	☺	☹	☺	☹	☺	☹
Diagnostic cohort studies							
Sasso *et al*[31] (2005)	☺	☺	☹	☹	☺	☺	☺
Schutz *et al*[28] (1973)	?	☺	☹	☹	?	☺	☹
Dooley *et al*[29] (1988)	☺	☺	☹	☹	☺	☺	☺
Williams *et al*[30] (2015)	☺	?	☹	☹	☺	☺	☺

☹, low risk/concern; ☺, high risk/concern; ?, unclear risk/concern.

performed in patients with positive SNRB findings). The four cohort studies were at high risk of bias for flow and timing because patients were selected to undergo surgery based on the SNRB result, with patients testing positive more likely to receive surgery. It is likely that the patients with negative SNRB results who, despite this, were selected for surgery were a biased subset of those testing negative as these are likely to have been the patients in whom the clinicians suspected a false negative result. The two within-patient case-control studies were at high risk of bias and poor applicability for patient selection because they recruited patients with unequivocal and concordant imaging and clinical findings rather than patients where diagnostic uncertainty remained. Three cohort studies were judged as low concerns regarding applicability on all domains.[29–31] There were high concerns regarding the applicability of the fourth cohort study as the reference standard consisted of intraoperative findings alone.[28]

Summary of test accuracy results

The diagnostic cohort studies reported data at the patient level, but only data at the injection level were available for the within-patient case-control studies. The threshold used to determine a positive SNRB test varied between studies (table 2). We decided not to pool the results of studies that used different reference standards.

There was substantial heterogeneity in estimates of sensitivity and specificity across studies; sensitivity ranged from 57% to 100% and specificity from 10% to 86% (table 2, figure 2). Sensitivity exceeded 85% in all studies except Yeom *et al* (57%).[27] Specificity was lower than 75% in all studies except Yeom *et al* (86%).[27] Interpretation of specificity is particularly hampered by verification bias in the cohort studies. Because surgeons were not blinded to the SNRB results, very few patients with negative test findings had surgery. Williams and Germon, Sasso *et al*, Schutz *et al* and Dooley *et al* contributed a total of just 10 true negative cases.[28–31] The higher specificity reported by Yeom *et al* could be a manifestation of patient selection bias as 'control' injections were performed at a level of the spine where the patients had no symptoms or imaging findings suggestive of pathology.[27] Positive likelihood ratios were generally low (<5), meaning that a positive SNRB result did not greatly increase the posttest probability that the nerve root was the source of the low back and radicular pain.

Due to the patient selection bias inherent in within-patient case-control designs, we decided that it would be inappropriate statistically to combine their results with those of the diagnostic cohort studies, and because of differences in the type of control injection we did not pool the results of the two studies. Based on the two

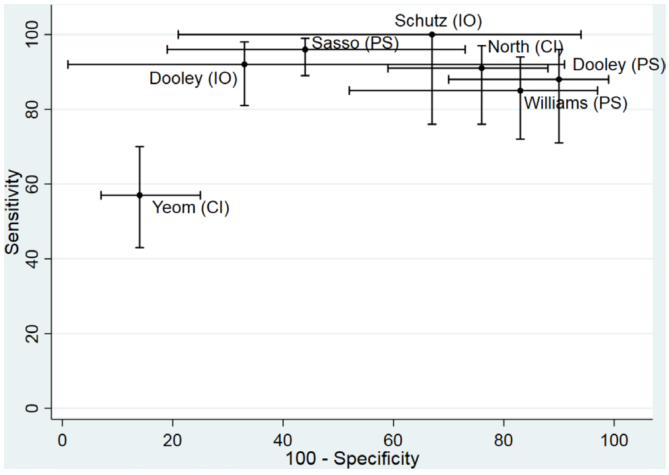

Figure 2 ROC plot displaying diagnostic accuracy results of included studies. CI, control injection reference standard; IO, intraoperative reference standard; PS, postsurgical reference standard; ROC, receiver-operating characteristic.

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cohort studies that used an intraoperative reference standard the pooled sensitivity was 93.5% (95% CI 84.0% to 97.6%) and specificity was 50.0% (16.8% to 83.2%). For the three studies that used postsurgery as the reference standard, the summary sensitivity was 90.9% (83.1% to 95.3%) and summary specificity was 22.0% (7.4% to 49.9%). Low specificity implies that a high proportion of patients without nerve root compromise have a positive SNRB result.

Adverse events review

Eight studies assessed complications and/or adverse events (online supplementary table 2).[28 30 33–38] Two were diagnostic cohorts,[28 30] one was a randomised controlled trial[34] and five were case series.[33 35–38] Only one reported the complications of SNRBs in the lumbar spine as the primary outcome.[33] Five studies reported that there were no complications. Tajima *et al* reported aggravated pain in the lower extremity for 1–2 days following selective radiculography and block in 4 (3.8%) patients.[38] The largest study reported that minor and transient complications were encountered in 98 of the 1777 total patient visits (during which 2217 injections were delivered to 1203 patients), giving an overall per patient visit complication rate of 5.5%.[33] Complications occurred in 134 of the 2217 total injections (6% complication rate per injection). There were no major or permanent complications resulting from SNRB in this large case series.

DISCUSSION

Despite the long-standing use of SNRB to help in the selection of patients who might benefit from surgery and in guiding the surgical approach, few studies have estimated its diagnostic accuracy. Our systematic review identified six studies, all at high risk of bias. Many were at risk of verification bias, because patients with positive SNRB were more likely to undergo surgery than those testing negative. There was substantial variation in estimates of sensitivity and specificity across studies. Based on the three cohort studies that used postsurgery outcomes as the reference standard, the summary sensitivity was 90.9% (83.1% to 95.3%) and summary specificity was 22.0% (7.4% to 49.9%). SNRB is a safe test with a low risk of clinically significant complications, but it remains unclear whether the additional diagnostic information it provides, improves patient outcomes or justifies the cost of the test.

Extensive literature searches were conducted in an attempt to locate all relevant studies. These included electronic searches in a wide variety of databases, scanning the references of included studies and previous systematic reviews. Diagnostic accuracy studies are difficult to identify from electronic databases as there are no specific indexing terms. Therefore, very sensitive searches were carried out to ensure that relevant studies were not missed. It is unlikely that any relevant published studies have been missed, although it is possible that some unpublished studies were not identified. The small number of primary diagnostic accuracy studies included in our review, all had methodological limitations. Due to the small number of studies, we were unable to explore the value of SNRB in potentially important patient subgroups, such as those with suspected multilevel radiculopathy.

Four previous systematic reviews of the diagnostic utility of SNRB in patients whose pain was of spinal origin have been reported.[15–18] The two earlier reviews had positive interpretations of the data and concluded that there was moderate evidence for SNRB in the 'pre-operative evaluation of patients with negative or inconclusive imaging studies, but with clinical findings of nerve root irritation'.[16 18] More recent reviews, however, concluded that there was limited evidence for the accuracy of SNRB as a diagnostic tool.[15 17] Our update review shows similar results. We found limited evidence which was of low methodological quality indicating that the diagnostic accuracy of SNRB is uncertain and that specificity in particular may be low. The differences in interpretation between our review and those conducted previously may be partly due to the smaller number of primary studies included in our review. We used rigorous eligibility criteria, which excluded studies with mixed cervical and lumbar spine pathology and studies where there was insufficient data to construct estimates of sensitivity and specificity.

For centres that currently rely on SNRB for diagnostic information to help decide whether, or at which level, to perform lumbar decompressive surgery, it is vital that better evidence is generated. Moreover, according to Hospital Episodes Statistics (HES), which contains records of all admissions, appointments and attendances for patients at NHS hospitals in England, 58 399 injections of therapeutic substance around spinal nerve root took place from 1 April 2016 to 31 March 2017.[8] Due to the granularity of HES data, it is not possible to tell how many of these injections were diagnostic lumbar SNRB. Nevertheless, the number is substantial, and it is therefore apparent that the community of spinal surgeons has a responsibility to generate robust evidence for the use of diagnostic SNRBs. A methodologically ideal diagnostic accuracy study is unlikely to be clinically acceptable as it would require all patients, including those with negative SNRB findings, to undergo surgery. Furthermore, while diagnostic accuracy studies can explore whether SNRB accurately predicts surgical outcomes, they cannot answer the more fundamental question of whether SNRB improves surgical decisions and patient outcomes. Much better evidence would be provided by a trial randomising patients who are being considered for surgery but have discordant or equivocal clinical and imaging findings of nerve root compression to receive a diagnostic SNRB or to have management based on clinical and imaging findings alone. Given the lack of high quality evidence on the diagnostic accuracy of SNRB, we believe that such a trial would be ethically acceptable and would help patients, clinicians and healthcare payers decide whether SNRB

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can improve patient outcomes by targeting surgery at those most likely to benefit.

Finally, it should be mentioned that this systematic review did not consider the use of SNRBs as a therapeutic option for patients with radicular pain due to a prolapsed lumbar intervertebral disc. The most recent National Institute for Heath and Care Excellence (NICE) guidance concluded that the evidence for both image guided and non-image guided injections for patients with acute and severe sciatica was mostly low or moderate.[8] However, the guidance recommends that an injection of local anaesthetic and steroid should be considered in acute, severe sciatica where patients would otherwise be offered surgery. The NErve Root Block VErsus Surgery (NERVES) randomised trial, which enrolled patients in 12 NHS hospitals, aimed to compare surgical microdiscectomy versus SNRB in patients with sciatica of at least 6 weeks' duration secondary to a prolapsed intervertebral disc. The results of this trial, which is currently in follow-up, will elucidate the role of SNRB as a therapeutic but not diagnostic option. Hence, it is important that consideration is given to a trial of diagnostic SNRB as outlined above.

CONCLUSIONS

There is no high-quality evidence on the diagnostic accuracy of SNRB in patients with radiculopathy and discordant or equivocal imaging findings. The evidence that is available suggests that the specificity of SNRB is low. As there is no adequate reference standard for determining the diagnostic accuracy of SNRB, future research should focus on randomised controlled trials to evaluate whether SNRB improves the process of care or patient outcomes.

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Contributors RB conducted the reviews of diagnostic accuracy and adverse events, conducted analyses and completed the first draft of the manuscript. MMCE updated the review, including abstract and full text screening, data extraction, risk of bias assessment, analysis and updated the draft of the manuscript. AS updated the review, including abstract and full text screening and checking of data extraction and risk of bias assessment. RJL contributed to the conception and design of the study, provided clinical expertise in neurosurgery, helped with acquisition of data for the service evaluation of SNRB and critically revised the manuscript. AGK provided clinical expertise in neurosurgery and critically revised the manuscript. JNH was involved in the inception of study and critical appraisal of literature, particularly from a radiological perspective. PW contributed to the conception and design of the study, supervised conduct of reviews of diagnostic accuracy and adverse events and critically revised the manuscript. WH was principal investigator on the project, contributed to the conception and design of the study, supervised conduct of reviews of diagnostic accuracy and adverse events and critically revised the manuscript. All authors approved the manuscript for publication.

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General issues

No.	Question/Issue	Origin/Source	Packet Location	Decision/ Action Needed	Evidence source
1	Medical back guideline	AHRQ report		Issues below, delete out of date table	AHRQ report
2	Surgical back guideline	WA HTA		Any changes needed in general guideline	WA HTA report
3	Back opioid guideline	Advocates		Any changes needed in guideline	AHRQ report, multiple studies submitted by advocates

Specific questions

No.	Question/Issue	Origin/Source	Packet Location	Decision/ Action Needed	Evidence source
1	Low level laser therapy	AHRQ report Primary Health CCO Manufacturer		Decide on adding coverage or clarifying lack of coverage	AHRQ report, WA HTA report, Cochrane review, 2 SRs
2	Artificial disks	Providence		1) Decide on adding coverage for 2 levels 2) minor guideline edits	WA HTA report, 3 SRs
3	Diagnostic spinal injections	CCO medical directors		1) Determine continuation of lack of coverage 2) Minor edits to 2 guidelines	1 SR, other payer policies
4	Massage therapy	CCO medical directors		What limits, if any, should be placed on massage therapy	Payer policies
5	Exercise therapy	VBBS/HERC members		What type of exercise is most beneficial?	AHRQ report

Low Level Laser Therapy

Question: Where should low level laser therapy (LLLT) be included on the Prioritized List?

Question source: Primary Health CCO

Issue: Low level laser therapy (LLLT) is the application of low-level (low-power) lasers or light-emitting diodes (LEDs) to the surface of the body. LLLT is used for a variety of applications, including low back pain, rheumatoid arthritis, neck pain, various tendinopathies, and other chronic pain conditions.

Variations of LLLT have gone by a variety of alternate names including low-power laser therapy (LPLT), soft laser therapy, low-intensity laser therapy, low-energy laser therapy, cold laser therapy, bio-stimulation laser therapy, photobiomodulation, photo-biotherapy, therapeutic laser, and monochromatic infrared light energy (MIRE) therapy. When LLLT is administered to acupuncture points, the procedure may be called laser acupuncture. When applied to the head, LLLT may be known as transcranial photobiomodulation, transcranial near-infrared laser therapy (NILT), or transcranial low level light therapy.

Primary Health has been seeing claims for LLLT, generally billed as an office visit (i.e. CPT 99214), but where the entire purpose of the office visit appears to be for the LLLT therapy. An all payer claims search found that the majority of claims submitted with HCPCS S8948 were for musculoskeletal back pain or similar diagnoses.

Current Prioritized List status:
HCPCS S8948 (Application of a modality (requiring constant provider attendance) to one or more areas; low-level laser; each 15 minutes): never reviewed

CPT 97039 (Unlisted modality (specify type and time if constant attendance)): never reviewed
CPT 97139 (Unlisted therapeutic procedure (specify)): never reviewed
CPT 99199 (Unlisted special service, procedure or report): never reviewed

Evidence

1) **AHRQ 2020,** Systematic review of treatments for chronic pain
    a. *Low back pain*
        i. One trial (Basford 1999, fair quality) found low-level laser therapy associated with a small improvement compared with sham laser for short-term function (difference −8.2 on the 0 to 100 ODI, 95% CI −13.6 to −2.8) and a moderate improvement for short-term pain (difference −16.0 on a 0 to 100 scale, 95% CI −28.3 to −3.7) (SOE: low).
        ii. One trial (Djavid 2007, fair quality) found no differences between low-level laser therapy versus exercise therapy in intermediate-term function or pain (SOE: low).
        iii. One trial of low-level laser therapy reported no adverse events (SOE: low).
    b. *Chronic neck pain*
        i. Low-level laser therapy was associated with a moderate improvement in short-term function (2 trials, pooled difference −13.60, 95% CI −26.30 to −6.30, I2=0%, 0-100 scale) and pain (3 trials, pooled difference −1.89 on a 0-10 scale, 95% CI

−3.34 to −0.06, I2=61%) compared with sham (SOE: moderate for function and pain).

2) **Washington State Bureau of Labor and Industry 2018,** health technology assessment of low level laser therapy for musculoskeletal disorders
    a. There are numerous RCTs conducted and published since last the review in 2004 on LLLT for various indications related to musculoskeletal conditions. Overall, the quality of the evidence for LLLT was low or very low.
    b. Safety data are sparse, especially the long-term data. Some adverse events associated with LLT or sham laser include mild pain, discomfort and tingling sensation during LLLT treatment. LLLT appears to be safe.
    c. The results on efficacy are highly inconsistent. There seems to be a small, statistically significant difference between LLLT and placebo for some indications in the short term, but the clinical meaningfulness is uncertain. Long term data are lacking.
    d. Laser wavelength, energy density, treatment duration, numbers of sessions and site of application are highly variable. Substantial uncertainty remains regarding the treatment benefit in comparison with other treatment modalities, long-term benefits, safety, and patient selection criteria.
3) **Brosseau 2010**; Cochrane review of low level laser therapy for rheumatoid arthritis
    a. N=5 placebo controlled trials (222 patients with 130 randomized to laser therapy) to the hand
    b. Relative to a separate control group, LLLT reduced pain by 1.10 points (95% CI: 1.82, 0.39) on visual analogue scale relative to placebo, reduced morning stiffness duration by 27.5 minutes (95%CI: 2.9 to 52 minutes) and increased tip to palm flexibility by 1.3 cm (95% CI: 0.8 to 1.7).
    c. Other outcomes such as functional assessment, range of motion and local swelling did not differ between groups. There were no significant differences between subgroups based on LLLT dosage, wavelength, site of application or treatment length.
    d. **Authors' conclusions** LLLT could be considered for short-term treatment for relief of pain and morning stiffness for RA patients, particularly since it has few side-effects. Despite some positive findings, this meta-analysis lacked data on how LLLT effectiveness is affected by four important factors: wavelength, treatment duration of LLLT, dosage and site of application over nerves instead of joints.
4) **Kadhim-Saleh 2013**, systematic review and meta-analysis of low level laser therapy for neck pain
    a. N=8 RCTs (443 patients)
        i. Five trials included patients with cervical myofascial pain syndrome (CMPS), and three trials included different patient populations.
    b. A meta-analysis of five CMPS trials revealed a mean improvement of VAS score of 10.54 with LLLT (95 % CI 0.37–20.71; Heterogeneity I2 = 65 %, P = 0.02).
    c. This systematic review provides inconclusive evidence because of significant between-study heterogeneity and potential risk of bias. The benefit seen in the use of LLLT, although statistically significant, does not constitute the threshold of minimally important clinical difference.
5) **Bjordal 2008**, systematic review of low level laser therapy for tennis elbow
    a. N=13 RCTs (730 patients)
    b. The weighted mean difference (WMD) for pain relief was 10.2 mm [95% CI: 3.0 to 17.5] and the RR for global improvement was 1.36 [1.16 to 1.60]. Trials which targeted acupuncture points reported negative results, as did trials with wavelengths 820, 830

and 1064 nm. In a subgroup of five trials with 904 nm lasers and one trial with 632 nm wavelength where the lateral elbow tendon insertions were directly irradiated, WMD for pain relief was 17.2 mm [95% CI: 8.5 to 25.9] and 14.0 mm [95% CI: 7.4 to 20.6] respectively, while RR for global pain improvement was only reported for 904 nm at 1.53 [95% CI: 1.28 to 1.83]. Secondary outcome measures of pain free grip strength, pain pressure threshold, sick leave and follow-up data from 3 to 8 weeks after the end of treatment, showed consistently significant results in favor of the same LLLT subgroup ($p < 0.02$).

c. No serious side-effects were reported.
d. **Conclusion:** LLLT administered with optimal doses of 904 nm and possibly 632 nm wavelengths directly to the lateral elbow tendon insertions, seem to offer short-term pain relief and less disability in LET, both alone and in conjunction with an exercise regimen. This finding contradicts the conclusions of previous reviews which failed to assess treatment procedures, wavelengths and optimal doses.

Other payer policies:
Aetna, Cigna and Wellmark BCBS all consider low level laser therapy to be experimental for all indications (as of March 2020).

Low Level Laser Therapy

HERC staff summary

Low level laser therapy as low to very low evidence of efficacy, and most studies do not show clinically significant benefit. No other payer is currently reimbursing for low level laser therapy.

Two of the HERC's high level evidence sources have reviewed low level laser therapy. Washington HTA found the quality of evidence to be low to very low for LLLT and the results of efficacy highly inconsistent, with lack of long-term data. However, AHRQ has determined that there is a small short term effect on function and a moderate short term effect on function for low back pain (low SOE) based on a single study and a moderate short term effect on pain and function for neck pain (moderate SOE) based on 3 studies.

Given the conflicting findings of two high quality evidence sources and the HERC staff review which also concludes that the evidence for efficacy of LLLT is lacking, HERC staff are not currently recommending inclusion of LLLT on the Prioritized List.

HERC staff recommendations:

1) Add HCPCS S8948 (Application of a modality (requiring constant provider attendance) to one or more areas; low-level laser; each 15 minutes) to line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
2) Add the following entry to GN173

GUIDELINE NOTE 173, INTERVENTIONS THAT ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS

Line 662

The following Interventions are prioritized on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:

Procedure Code	Intervention Description	Rationale	Last Review
S8948	Low level laser therapy and all similar therapies	Insufficient evidence of effectiveness	August 2020

January 18, 2018

Technology Assessment Update - Low Level Laser Therapy for Musculoskeletal Disorders

Low level laser therapy (LLLT) is a noninvasive treatment that involves the application of light from a low-intensity laser at a specific wavelength. L&I reviewed the technology for various musculoskeletal (MSK) conditions in 2004 and made a non-coverage decision.

The efficacy and the mechanism(s) of action of LLLT have not been established, although there have been many trials on LLLT conducted and published since the last review. In addition, there is no standardized protocol (e.g., dose, number of treatments, duration of treatment) for performing LLLT in treating MSK conditions. The purpose of this document is to review the new evidence and assess the effectiveness and harm of LLLT for treating MSK conditions. We focused on randomized controlled trials (RCTs) by reviewing relevant systematic reviews and meta-analyses. Six systematic reviews were found and reviewed.

A. Evidence reviewed

We searched Cochrane Database of Systematic Reviews and found three relevant systematic reviews on LLLT for MSK disorders. One of them (Brosseau et al. 2007) was withdrawn due to incompleteness in evidence collection and errors in data extraction. We reviewed the other two (Rankin et al. 2017; Yousefi-Nooraie et al. 2008) in detail.

We searched Hayes' database and assessed three systematic reviews on LLLT for MSK disorders, including carpal tunnel syndrome (Hayes, Inc. 2016, updated 2017), joint pain (Hayes, Inc. 2008, update 2012) and soft tissue pain (Hayes, Inc. 2008, updated 2012).

A recent systematic review on LLLT for pain in patients with MSK disorders (Clijsen et al. 2017) found in PubMed was also reviewed.

B. Quality assessment of the systematic reviews

The quality (Good, Fair or Poor) of the systematic reviews was assessed using the quality assessment tool developed by the NIH National Heart, Lung and Blood Institute. All the systematic reviews assessed have either good or fair quality.

C. Summary of the evidence

1. LLLT on pain in patients with MSK disorders or soft tissue pain

1.1. (Clijsen et al. 2017) – Good quality

The meta-analysis includes 18 RCTs comparing the effect of LLLT on pain in patients with different MSK disorders. From the 21 head-to-head comparisons, 17 favored LLLT while four comparisons (extracted from three studies) reported no beneficial effects of LLLT on pain. The overall weighted raw mean difference (*D*) in pain between LLLT and the control groups was -0.85 [95% CI: -1.22 to -0.48] (P<0.001). Heterogeneity of the studies was high (I^2= 85.6%) and statistically significant (Cochran's *Q*=139.2; df=20; P<0.001).

The authors concluded that "LLLT appears to be an effective treatment modality to achieve pain relief in adult patients with MSK disorders". Though this is a meta-analysis of good quality, there are several limitations with the results. 1). the heterogeneity of the studies included was quite high (I^2 = 85.6%); 2). The overall weighted raw mean difference in pain was difficult to interpret, because it was derived from 18 studies with 7 different comparators for 13 different pain conditions; 3). The overall weighted raw mean difference was small and may not be meaningful clinically.

1.2. (Hayes, Inc. 2008, Updated in 2012) – Fair quality

Evidence evaluated in this report covers the years 2005 to February 2008, and was updated in 2012. The previous version of this report covered literature published between 1980 and July 2005. Only randomized placebo-controlled trials and meta-analyses of randomized placebo-controlled trials were considered for inclusion. Eighteen trials of LLLT for different indications were selected for detailed analysis, including: Achilles tendinopathy (2 trials); ankle sprain (1 trial); carpal tunnel syndrome (3 trials); lateral epicondylitis (5 trials); low back pain (2 trials); and neck and/or shoulder girdle pain (5 trials).

Authors' conclusion: the available RCTs of LLLT reported a mix of negative (no effect) and positive results for a variety of soft tissue pain conditions, which can be summarized by indication as follows: (1) Achilles tendinopathy, very positive in younger, athletic patients but otherwise negative; (2) ankle sprain, negative; (3) carpal tunnel syndrome, conflicting but on balance negative; (4) lateral epicondylitis, conflicting but best study strongly positive; (5) low back pain, small positive effect according to sparse evidence; and (6) neck/shoulder girdle pain, on balance positive with an apparent correspondence between positive results and number of spots treated. The trials addressing each indication had several limitations. Possible combinations of treatment parameters far exceed those tested in the trials that were selected, and data relevant to specific combinations of dose, wavelength, and spot number/size were sparse. LLLT appears to be safe, but no long-term assessment has been made. The authors concluded that low-quality, inconsistent evidence showing potentially improved outcomes for treatment of pain and

disability due to Achilles tendinopathy, lateral epicondylitis, low back pain, and myofascial pain syndrome or similar symptomatology in the neck and shoulder girdle region, but substantial uncertainty remains regarding the extent of treatment benefit in comparison with other treatment modalities, long-term health benefits, safety, and patient selection criteria. There is limited evidence of no benefit or no benefit beyond end of treatment for treatment of pain and disability due to ankle sprain or carpal tunnel syndrome.

We believe there are several limitations with the conclusions. 1). the quality of RCTs included was not assessed explicitly in the systematic review. The authors seemed to assume the quality of these studies was equally good because they were RCTs; 2). Some conclusions were made based on very limited number of studies. For example, there were two studies reviewed for Achilles tendinopathy, one showed positive results and the other had negative results; 3). No meta-analysis done on multiple studies for specific indications; 4). Short term follow-up for most of the studies; 5). The effect size was small if any, and it is uncertain about clinical significance.

2. LLLT on carpal tunnel syndrome

2.1. (Rankin et al. 2017) – Good quality

The authors identified 22 trials randomizing 1153 participants that were eligible for inclusion; nine trials (525 participants, 256 randomized to LLLT) compared LLLT with placebo, two (150 participants, 75 randomized to LLLT) compared LLLT with ultrasound, one compared LLLT with placebo and LLLT with ultrasound, two compared LLLT with steroid injection, and one trial each compared LLLT with other non-surgical interventions: fascialmanipulation, application of a pulsedmagnetic field, transcutaneous electrical nerve stimulation (TENS), steroid injection, tendon gliding exercises, and applying a wrist splint combined with non-steroidal anti-inflammatory drugs. Three studies compared LLLT as part of multiple interventions. Risk of bias varied across the studies, but was high or unclear in most assessed domains in most studies. Most studies were small, with few events, and effect estimates were generally imprecise and inconsistent; the combination of these factors led the authors to categorize the quality of evidence for most outcomes as very low or low.

The authors concluded that evidence is of very low quality and they found no data to support any clinical effect of LLLT in treating CTS. Only VAS pain and finger-pinch strength met previously published MCIDs but these are likely to be overestimates of effect given the small studies and significant risk of bias. There is low or very low-quality evidence to suggest that LLLT is less effective than ultrasound in the management of CTS based on short-term, clinically significant improvements in pain and finger-pinch strength. There is insufficient evidence to support LLLT being better or worse than any other type of non-surgical treatment in the management of CTS. Any further research of LLLT should be definitive, blinded, and of high quality.

2.2. (Hayes, Inc. 2017) – Fair quality

A total of 11 RCTs met predefined inclusion criteria and answered 1 or more relevant questions. Of the eligible RCTs, 6 evaluated LLLT compared with sham laser for the treatment of mild to moderate carpal tunnel syndrome (CTS) in adults. Six RCTs also evaluated LLLT compared with an active control, including ultrasound, splinting, or steroid injections either alone or in combination with another conservative treatment. All studies evaluated LLLT for the treatment of mild to moderate CTS in adults.

Results were conflicting regarding the efficacy and comparative effectiveness of LLLT compared with sham laser, ultrasound, or splinting for the treatment of mild to moderate CTS. For all outcomes, there were unexplained inconsistencies across studies when comparing LLLT with sham laser. In 3 RCTs comparing LLLT with ultrasound, inconsistencies in comparative effectiveness exist. In general, patients treated with LLLT reported improved clinical symptoms and nerve conduction compared with baseline, as did patients in control groups. Evaluations of safety were limited and were only reported in 2 RCTs. Long term follow-up was not evaluated in any study. The authors concluded that there was low-quality and inconsistent evidence showing potentially improved outcomes among patients with mild to moderate CTS receiving LLLT either alone or in combination with other conservative treatments. Substantial uncertainty remains regarding the extent of treatment benefit in comparison with other treatment modalities, long-term health benefits, safety, and patient selection criteria. The evidence for LLLT for treatment of severe CTS in adults was lacking.

3. LLLT on non-specific lower back pain

3.1. (Yousefi-Nooraie et al. 2008) – Good quality

Seven heterogeneous English language RCTs with reasonable quality were included. Three small studies (168 people) separately showed statistically significant but clinically unimportant pain relief for LLLT versus sham therapy for sub-acute and chronic low-back pain at short-term and intermediate-term follow-up (up to six months). One study (56 people) showed that LLLT was more effective than sham at reducing disability in the short term. Three studies (102 people) reported that LLLT plus exercise were not better than exercise, with or without sham in the short-term in reducing pain or disability. Two studies (90 people) reported that LLLT was not more effective than exercise, with or without sham in reducing pain or disability in the short term. Two small trials (151 people) independently found that the relapse rate in the LLLT group was significantly lower than in the control group at the six-month follow-up.

No side effects were reported.

The authors concluded that based on the heterogeneity of the populations, interventions and comparison groups, there are insufficient data to draw firm conclusions on the clinical effect of LLLT for low-back pain. There is a need for further methodologically rigorous RCTs to evaluate the effects of LLLT compared to other treatments, different lengths of treatment, wavelengths and dosages.

4. LLLT on joint pain

4.1. (Hayes, Inc. 2008, update 2012) - Fair quality

This updated report covers literature published in the years 2005 to February 2008 (the previous version of this report covered literature published between 1980 and July 2005) including eight studies: six original blinded, placebo-controlled, randomized trials and two meta-analyses of such trials. Four of the original trials and one meta-analysis applied LLLT to knee osteoarthritis. Another original trial applied LLLT to hand osteoarthritis. One meta-analysis of trials of LLLT for rheumatoid arthritis was selected. A single trial of LLLT for patellar chondromalacia was selected. Pain assessment for all indications was typically made according to a visual analog scale (VAS). Numerous tools were used for assessment of function or disability.

The authors concluded that evidence derived from several placebo-controlled, randomized trials suggests that LLLT administered above a certain dosage level can accelerate improvement in patients with osteoarthritis of the knee by bringing immediate relief of pain and disability but that the effect is temporary. Evidence from a single placebo-controlled, randomized trial demonstrated no effect from LLLT on pain or disability in patients with osteoarthritis of the hand. Evidence from a single placebo-controlled, randomized trial indicated modest, temporary pain relief from rheumatoid arthritis of the hand and foot. A single, very small trial failed to demonstrate clinically significant improvement of pain and disability associated with chondromalacia. The trials addressing each indication had a number of methodological limitations, including variation in treatment parameters, small sample size, and lack of comparison with other treatment modalities. The authors further concluded that low-quality, inconsistent evidence showing potentially improved outcomes for treatment of pain and disability due to knee osteoarthritis, but substantial uncertainty remains regarding the extent of treatment benefit in comparison with other treatment modalities, long-term health benefits, safety, and patient selection criteria; there is either limited evidence of no benefit or no evidence of LLLT for treatment of pain and disability due to hand osteoarthritis, osteoarthritis in joints other than the knee or hand, rheumatoid arthritis in the hand and foot; and chondromalacia patellae, respectively; there is no evidence for patient-administered LLLT pertaining to the efficacy and safety of LLLT used outside of healthcare settings.

D. CMS and selected private payer coverage policies on LLLT

Table 1. Other Payer's Policy on LLLT

Payer	Policy	Note
CMS	The use of infrared and/or near-infrared light and/or heat, including monochromatic infrared energy, **is non-covered** for the treatment, including the symptoms such as pain arising from these conditions, of diabetic and/or non-diabetic peripheral sensory neuropathy, wounds and/or ulcers of the skin and/or subcutaneous tissues	National Coverage Decision (NCD) for Infrared Therapy Devices (270.6). Effective date: 10/24/2006.
Blue Cross	Investigational	2017 Federal employee program
NICE	No policy or guideline was found on LLLT	
Aetna	Experimental and investigational	2017-2018
Cigna	Experimental, investigational or unproven	2017-2018
Humana	Not covered	2018
Regence	Investigational	2017

E. Conclusions

1. There are numerous RCTs conducted and published since last review in 2004 on LLLT for various indications related to MSK conditions. Overall, the quality of the evidence for LLLT was low or very low.
2. Safety data are sparse, especially the long term data. Some adverse events associated with LLT or sham laser reported include mild pain, discomfort and tingling sensation during LLLT treatment. No reported treatment-related mortality was noticed. LLLT appears to be safe.
3. The results on efficacy are highly inconsistent. There seems to be a small statistically significant difference between LLLT and placebo for some indications in short term, but the clinical meaningfulness is uncertain. Long term data are lacking.
4. Laser wavelength, energy density, treatment duration, numbers of sessions and site of application are highly variable. Substantial uncertainty remains regarding the treatment benefit in comparison with other treatment modalities, long-term benefits, safety, and patient selection criteria.
5. None of the major payers covers LLLT for MSK disorders.

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Low level laser therapy (Classes I, II and III) for treating rheumatoid arthritis (Review)

Brosseau L, Welch V, Wells GA, de Bie R, Gam A, Harman K, Morin M, Shea B, Tugwell P



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[Intervention Review]

Low level laser therapy (Classes I, II and III) for treating rheumatoid arthritis

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ABSTRACT

Background

Rheumatoid arthritis (RA) affects a large proportion of the population. Low Level Laser Therapy (LLLT) was introduced as an alternative non-invasive treatment for RA about ten years ago. LLLT is a light source that generates extremely pure light, of a single wavelength. The effect is not thermal, but rather related to photochemical reactions in the cells. The effectiveness of LLLT for rheumatoid arthritis is still controversial. This review is an update of the original review published in October 1998.

Objectives

To assess the effectiveness of LLLT in the treatment of RA.

Search methods

We initially searched MEDLINE, EMBASE (from 1998), the registries of the Cochrane Musculoskeletal Group and the field of Rehabilitation and Related Therapies as well as the Cochrane Central Register of Controlled Trials (CENTRAL) up to June 2001. This search has now been updated to include articles published up to June 2005.

Selection criteria

Following an a priori protocol, only randomized controlled trials of LLLT for the treatment of patients with a clinical diagnosis of RA were eligible. Abstracts were excluded unless further data could be obtained from the authors.

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Data collection and analysis

Two reviewers independently selected trials for inclusion, then extracted data and assessed quality using predetermined forms. Heterogeneity was tested using chi-squared. A fixed effects model was used throughout for continuous variables, except where heterogeneity existed, in which case, a random effects model was used. Results were analyzed as weighted mean differences (WMD) with 95% confidence intervals (CI), where the difference between the treated and control groups was weighted by the inverse of the variance. Dichotomous outcomes were analyzed with relative risks.

Main results

A total of 222 patients were included in the five placebo-controlled trials, with 130 randomized to laser therapy. Relative to a separate control group, LLLT reduced pain by 1.10 points (95% CI: 1.82, 0.39) on visual analogue scale relative to placebo, reduced morning stiffness duration by 27.5 minutes (95%CI: 2.9 to 52 minutes) and increased tip to palm flexibility by 1.3 cm (95% CI: 0.8 to 1.7). Other outcomes such as functional assessment, range of motion and local swelling did not differ between groups. There were no significant differences between subgroups based on LLLT dosage, wavelength, site of application or treatment length. For RA, relative to a control group using the opposite hand, there was no difference observed between the control and treatment hand for morning stiffness duration, and also no significant improvement in pain relief RR 13.00 (95% CI: 0.79 to 214.06). However, only one study was included as using the contralateral limb as control. .

Authors' conclusions

LLLT could be considered for short-term treatment for relief of pain and morning stiffness for RA patients, particularly since it has few side-effects. Clinicians and researchers should consistently report the characteristics of the LLLT device and the application techniques used. New trials on LLLT should make use of standardized, validated outcomes. Despite some positive findings, this meta-analysis lacked data on how LLLT effectiveness is affected by four important factors: wavelength, treatment duration of LLLT, dosage and site of application over nerves instead of joints. There is clearly a need to investigate the effects of these factors on LLLT effectiveness for RA in randomized controlled clinical trials.

PLAIN LANGUAGE SUMMARY

Low level laser therapy for rheumatoid arthritis

Does low level laser therapy work for treating rheumatoid arthritis?

Six studies of medium quality were reviewed and provide the best evidence we have today. Collectively, these studies tested over 220 people with rheumatoid arthritis. The studies compared how well people did while receiving either laser therapy or a 'placebo' (fake) laser therapy. Laser therapy was given mostly on the hands and generally for two to three times a week for four weeks. There were also many different wavelengths and dosages given.

What is rheumatoid arthritis and low level laser therapy?

Rheumatoid arthritis (RA) is a disease in which the body's immune system attacks its own healthy tissues. The attack happens mostly in the joints of the hands and feet and causes redness, pain, swelling and heat around the joints. Drug and non-drug treatments are used to relieve pain and/or swelling. Low level laser therapy, is a non-drug treatment used to decrease swelling and pain. Without producing heat, the laser emits very pure light that causes light and chemical reactions in cells where it is targeted.

What did the studies show?

Studies showed that laser therapy decreased pain and morning stiffness more than 'placebo' laser therapy. Laser therapy also increased hand flexibility more than placebo therapy.

Pain decreased by 1.10 points on a scale of 1-10. The length of time for morning stiffness decreased by 28 minutes.

Studies also showed that laser therapy worked just as well as 'placebo' laser therapy to improve range of motion, function, swelling and grip strength.

Only two of the studies measured the effect of laser therapy three months after the end of treatment. The results from these studies indicated that laser therapy worked just as well as 'placebo' therapy after three months times.

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ORIGINAL ARTICLE

Is low-level laser therapy in relieving neck pain effective? Systematic review and meta-analysis

Amjed Kadhim-Saleh · Harinad Maganti · Michelle Ghert · Sheila Singh · Forough Farrokhyar

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Abstract The aim of this study is to determine the efficacy of low-level laser therapy (LLLT) in reducing acute and chronic neck pain as measured by the visual analog scale (VAS). A systematic search of nine electronic databases was conducted to identify original articles. For study selection, two reviewers independently assessed titles, abstracts, and full text for eligibility. Methodological quality was assessed using the Detsky scale. Data were analyzed using random-effects model in the presence of heterogeneity and fixed-effect model in its absence. Heterogeneity was assessed using Cochran's Q statistic and quantifying I^2. Risk ratios (RR) with 95 % confidence intervals (CI) were reported. Eight randomized controlled trials involving 443 patients met the strict inclusion criteria. Inter-rater reliability for study selection was 92.8 % (95 % CIs 80.9–100 %) and for methodological quality assessment was 83.9 % (95 % CIs 19.4–96.8 %). Five trials included patients with cervical myofascial pain syndrome (CMPS), and three trials included different patient populations. A meta-analysis of five CMPS trials revealed a mean improvement of VAS score of 10.54 with LLLT (95 % CI 0.37–20.71; Heterogeneity $I^2 = 65$ %, $P = 0.02$). This systematic review provides inconclusive evidence because of significant between-study heterogeneity and potential risk of bias. The benefit seen in the use of LLLT, although statistically significant, does not constitute the threshold of minimally important clinical difference.

Keywords Neck pain · Laser therapy, low-level · Myofascial pain syndrome · Meta-analysis

Abbreviations

CI	Confidence interval
CID	Clinical important difference
CMPS	Cervical myofascial pain syndrome
ICC	Intraclass correlation coefficient
LLLT	Low-level laser therapy
RCT	Randomized controlled trial
RR	Risk ratio
VAS	Visual analog scale

Background

Neck pain is one of the most common pain complaints encountered by primary care providers. There is great variation in the overall prevalence of neck pain between studies, ranging from 0.4 to 86.8 % in the general population, with a mean prevalence of 23.1 % [1]. Several mechanisms can lead to neck pain, including trauma, repetitive and forceful occupational movements, as well as pathological factors, such as inflammatory and neurological conditions [2]. The consequences of neck pain range from minor discomfort to debilitating pain that interferes with daily living activities, work conditions, and sleep [3, 4].

A number of treatment options are available for patients with neck pain, including pharmacological, surgical, behavioral, and alternative therapies [3]. Low-level laser

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A systematic review with procedural assessments and meta-analysis of Low Level Laser Therapy in lateral elbow tendinopathy (tennis elbow)

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Abstract

Background: Recent reviews have indicated that low level level laser therapy (LLLT) is ineffective in lateral elbow tendinopathy (LET) without assessing validity of treatment procedures and doses or the influence of prior steroid injections.

Methods: Systematic review with meta-analysis, with primary outcome measures of pain relief and/or global improvement and subgroup analyses of methodological quality, wavelengths and treatment procedures.

Results: 18 randomised placebo-controlled trials (RCTs) were identified with 13 RCTs (730 patients) meeting the criteria for meta-analysis. 12 RCTs satisfied half or more of the methodological criteria. Publication bias was detected by Egger's graphical test, which showed a negative direction of bias. Ten of the trials included patients with poor prognosis caused by failed steroid injections or other treatment failures, or long symptom duration or severe baseline pain. The weighted mean difference (WMD) for pain relief was 10.2 mm [95% CI: 3.0 to 17.5] and the RR for global improvement was 1.36 [1.16 to 1.60]. Trials which targeted acupuncture points reported negative results, as did trials with wavelengths 820, 830 and 1064 nm. In a subgroup of five trials with 904 nm lasers and one trial with 632 nm wavelength where the lateral elbow tendon insertions were directly irradiated, WMD for pain relief was 17.2 mm [95% CI: 8.5 to 25.9] and 14.0 mm [95% CI: 7.4 to 20.6] respectively, while RR for global pain improvement was only reported for 904 nm at 1.53 [95% CI: 1.28 to 1.83]. LLLT doses in this subgroup ranged between 0.5 and 7.2 Joules. Secondary outcome measures of painfree grip strength, pain pressure threshold, sick leave and follow-up data from 3 to 8 weeks after the end of treatment, showed consistently

significant results in favour of the same LLLT subgroup ($p < 0.02$). No serious side-effects were reported.

Conclusion: LLLT administered with optimal doses of 904 nm and possibly 632 nm wavelengths directly to the lateral elbow tendon insertions, seem to offer short-term pain relief and less disability in LET, both alone and in conjunction with an exercise regimen. This finding contradicts the conclusions of previous reviews which failed to assess treatment procedures, wavelengths and optimal doses.

Background

Lateral elbow tendinopathy (LET) or "tennis elbow" is a common disorder with a prevalence of at least 1.7% [1], and occuring most often between the third and sixth decades of life. Physical strain may play a part in the development of LET, as the dominant arm is significantly more often affected than the non-dominant arm. The condition is largely self-limiting, and symptoms seem to resolve between 6 and 24 months in most patients [2].

A number of interventions have been suggested for LET. Steroid injections, non-steroidal anti-inflammatory drugs or a regimen of physiotherapy with various modalities, seem to be the most commonly applied treatments [3]. However, treatment effect sizes seem to be rather small, and recommendations have varied over the years. In several systematic reviews over the last decade [4,5], glucocorticoid steroid injections have been deemed effective, at least in the short-term. But in later well-designed trials evidence is found that intermediate and long-term effects of steroid injections groups yield consistently and significantly poorer outcomes than placebo injection groups, and physiotherapy or wait-and-see groups [6,7]. Nevertheless, steroid injections have been considered as the most thoroughly investigated intervention, with 13 randomized controlled trials comparing steroid injections to either placebo/local anaesthetic or another type of intervention [5]. Non-steroidal anti-inflammatory drugs (NSAIDs) have been found to achieve smaller short-term effect sizes than steroid injections [8], and topical application seems to be the best medication administration route [8] For oral administration of NSAIDs for LET, evidence is inconclusive from two heterogeneous trials only [9]. The positive short-term results of anti-inflammatory therapies in LET appear to partly contradict the recent paradigm in tendinopathy research, where LET is thought to be mainly a degenerative disorder with minimal inflammation [10,11].

Exercise therapy and stretching exercises have been used either alone or in conjunction with manipulation techniques or physical interventions. Although the sparse evidence makes it difficult to assess the separate effect of active exercises or stretching [12], four studies have found that either exercises alone [13], or in conjunction with a physiotherapy package, are more effective than placebo ultrasound therapy or wait-and-see controls. Also exercise therapy, particularly eccentric exercises, have been found effective in the intermediate term in tendinopathies of the Achilles, patellar or shoulder tendons [14-17]. There is some evidence suggesting that joint manipulation or mobilisation techniques either of the wrist, elbow or cervical spine may contribute to short-term effects in LET [18-20].

Among the physical interventions, ultrasound therapy has been considered to offer a small benefit over placebo from two small trials [12], but a well-designed and more recent trial did not find significant effects of ultrasound therapy in LET [21]. Reviewers have arrived at different conclusions for the effect of acupuncture [22,23]. In reviews of physical interventions for LET, conclusions may vary between reviews because of differences in the treatment procedures. A good example of this is the negative conclusion of the LET review for extracorporeal shockwave therapy (ESWT) by Buchbinder et al. [24], where a later review with in-depth assessments of treatment intervention protocols [25], found that a subgroup of trials with proper treatment procedures and adequate timing of outcomes gave a positive result.

Low level laser therapy (LLLT) has been available for nearly three decades, and scattered positive results have been countered by numerous negative trial results. Several systematic reviews have found no significant effects from LLLT, in musculoskeletal disorders in general [26], and in LET in particular [12,23,27]. In this perspective it may seem futile to perform yet another systematic review in this area. But none of these reviews evaluated the results separately for the different LLLT treatment procedures, laser wavelengths or doses involved. Neither did they implement evidence of the newly discovered biomodulatory mechanisms which are involved when LLLT is applied. During the last 5–6 years the annual number of published LLLT reports in Medline has increased from 25 to around 200. We recently made a review of this literature, and concluded that LLLT has an anti-inflammatory effect in 21 out of 24 controlled laboratory trials, and a biostimulatory effect on collagen production in 31 out of 36 trials [28]. Both of these effects were dose-dependent

Massage Therapy

Question: What restrictions, if any, should be placed on massage therapy on the Prioritized List?

Question source: CCO Medical Directors

Issue: Massage therapy can be provided by a massage therapist, or by professionals such as physical therapists and chiropractors. Additionally, HSD rules allow massage therapy to be billed by MD, NP, PA, podiatrist, naturopath and occupational therapists. By HSD rules, a massage therapist cannot be enrolled as a Medicaid provider and therefore cannot bill fee-for-service for massage directly, but can be employed by a clinic and supervised by one of the approved types of providers, and the clinic can be paid for the service. CCOs can contract with massage therapists, and these therapists can be enrolled with Medicaid for that purpose only. The CCOs are requesting clarification on what provider types can bill for massage therapy. A state plan amendment would be required in order for Licensed Massage Therapists to be separately enrolled in Medicaid. HERC seldom makes determinations on which types of providers can provide what service as this is determined by licensing rules and other factors unrelated to evidence of effectiveness.

Currently, there are no restrictions in Guideline Note 6 REHABILITATIVE AND HABILITATIVE THERAPIES regarding how often massage can be billed. The current CPT code is billed in 15 min increments, and can be billed more than 1 time per day. The CCOs have a question about whether there should be a minimum time for massage in which this code can be used (i.e. 8 min, or 15 min). There are also questions about billing with combined codes.

Additionally, massage therapy appears on many lines, which have not been recently reviewed for appropriateness. Of note, massage therapy is billed as part of a general PT treatment for a variety of conditions. Currently, massage is listed as an evidence-based intervention that is encouraged when available for treatment of conditions of the back and spine.

Current Prioritized List status:
CPT 97124 (Therapeutic procedure, 1 or more areas, each 15 minutes; massage, including effleurage, petrissage and/or tapotement (stroking, compression, percussion))—on 60+ lines (generally all lines with other PT procedure codes).

Line	Line Description
31	SEVERE BIRTH TRAUMA FOR BABY; INTRAVENTRICULAR HEMORRHAGE
46	RHEUMATOID ARTHRITIS AND OTHER INFLAMMATORY POLYARTHROPATHIES
57	SEVERE BURNS
68	ACUTE BACTERIAL MENINGITIS
71	NEUROLOGICAL DYSFUNCTION IN BREATHING, EATING, SWALLOWING, BOWEL, OR BLADDER CONTROL CAUSED BY CHRONIC CONDITIONS; ATTENTION TO OSTOMIES
80	FRACTURE OF HIP
90	GUILLAIN-BARRE SYNDROME
91	SEVERE/MODERATE HEAD INJURY: HEMATOMA/EDEMA WITH PERSISTENT SYMPTOMS
127	MODERATE BURNS
131	CRUSH INJURIES OTHER THAN DIGITS; COMPARTMENT SYNDROME
132	OPEN FRACTURE/DISLOCATION OF EXTREMITIES
136	TRAUMATIC AMPUTATION OF LEG(S) (COMPLETE)(PARTIAL) WITH AND WITHOUT COMPLICATION
150	CERVICAL VERTEBRAL DISLOCATIONS/FRACTURES, OPEN OR CLOSED; OTHER VERTEBRAL DISLOCATIONS/FRACTURES, OPEN OR UNSTABLE; SPINAL CORD INJURIES WITH OR WITHOUT EVIDENCE OF VERTEBRAL INJURY
153	PYOGENIC ARTHRITIS
160	TRAUMATIC AMPUTATION OF ARM(S), HAND(S), THUMB(S), AND FINGER(S) (COMPLETE)(PARTIAL) WITH AND WITHOUT COMPLICATION
178	INTRACEREBRAL HEMORRHAGE
183	FRACTURE OF PELVIS, OPEN AND CLOSED
184	ACUTE OSTEOMYELITIS
196	SUBARACHNOID AND INTRACEREBRAL HEMORRHAGE/HEMATOMA; CEREBRAL ANEURYSM; COMPRESSION OF BRAIN
200	CANCER OF BONES
254	CHRONIC OSTEOMYELITIS
256	DEFORMITIES OF HEAD
272	TRAUMATIC AMPUTATION OF FOOT/FEET
285	COMPLICATIONS OF A PROCEDURE ALWAYS REQUIRING TREATMENT
292	NEUROLOGICAL DYSFUNCTION IN POSTURE AND MOVEMENT CAUSED BY CHRONIC CONDITIONS
301	GOUT
309	CONGENITAL DISLOCATION OF HIP; COXA VARA AND VALGA
317	STROKE
341	RHEUMATIC FEVER
345	NEUROLOGICAL DYSFUNCTION IN COMMUNICATION CAUSED BY CHRONIC CONDITIONS
346	CONDITIONS OF THE BACK AND SPINE WITH URGENT SURGICAL INDICATIONS
348	MILD/MODERATE BIRTH TRAUMA FOR BABY

355	CLOSED FRACTURE OF EXTREMITIES (EXCEPT MINOR TOES)
356	RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDRITIS DISSECANS, AND ASEPTIC NECROSIS OF BONE
359	DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS
361	SCOLIOSIS
376	DISRUPTIONS OF THE LIGAMENTS AND TENDONS OF THE ARMS AND LEGS, EXCLUDING THE KNEE, RESULTING IN SIGNIFICANT INJURY/IMPAIRMENT
377	DYSFUNCTION RESULTING IN LOSS OF ABILITY TO MAXIMIZE LEVEL OF INDEPENDENCE IN SELF-DIRECTED CARE CAUSED BY CHRONIC CONDITIONS THAT CAUSE NEUROLOGICAL DYSFUNCTION
401	BENIGN CONDITIONS OF BONE AND JOINTS AT HIGH RISK FOR COMPLICATIONS
402	CONDITIONS OF THE BACK AND SPINE
408	EPIDERMOLYSIS BULLOSA
416	PERIPHERAL NERVE ENTRAPMENT; PALMAR FASCIAL FIBROMATOSIS
418	DISORDERS OF SHOULDER, INCLUDING SPRAINS/STRAINS GRADE 4 THROUGH 6
423	LYMPHEDEMA
424	COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT
431	INTERNAL DERANGEMENT OF KNEE AND LIGAMENTOUS DISRUPTIONS OF THE KNEE, RESULTING IN SIGNIFICANT INJURY/IMPAIRMENT
442	MALUNION AND NONUNION OF FRACTURE
463	OSTEOARTHRITIS AND ALLIED DISORDERS
467	BRACHIAL PLEXUS LESIONS
478	CLOSED DISLOCATIONS/FRACTURES OF NON-CERVICAL VERTEBRAL COLUMN WITHOUT NEUROLOGIC INJURY OR STRUCTURAL INSTABILITY
486	PERIPHERAL ENTHESOPATHIES
509	PERIPHERAL NERVE DISORDERS
529	CONDITIONS OF THE BACK AND SPINE WITHOUT URGENT SURGICAL INDICATIONS
555	CHONDROMALACIA
558	BENIGN NEOPLASM OF BONE AND ARTICULAR CARTILAGE INCLUDING OSTEOID OSTEOMAS; BENIGN NEOPLASM OF CONNECTIVE AND OTHER SOFT TISSUE
571	OTHER COMPLICATIONS OF A PROCEDURE
589	SYNOVITIS AND TENOSYNOVITIS
608	SPRAINS AND STRAINS OF ADJACENT MUSCLES AND JOINTS, MINOR

Evidence

1) **AHRQ 2020**
    a. The included studies on massage for low back pain had the following visit numbers
        i. 24 sessions (Ajimsha 2014)
        ii. 10 sessions (Cherkin 2001, Cherkin 2011, Quinn 2008)
        iii. 9 sessions (Movahedi 2017)
        iv. 6 sessions (Little 2008, Poole 2007)
        v. 4 sessions (Arquisuelas 2017)
        vi. All but one study were one session per week
        vii. No relationship seen in number of sessions and reported effectiveness
    b. The included studies on massage for neck pain had the following visit numbers
        i. 22 sessions (Rudolfsson 2014)
        ii. 10 sessions (Sherman 2009)
        iii. 6 sessions (Pach 2018)
        iv. All but one study were one session per week
        v. No relationship seen in number of sessions and reported effectiveness

Other payer policies

1) CMS 2010 does not cover any services by licensed massage therapies. CMS covers CPT 97124 if provided by chiropractors or occupational therapists in certain circumstances
2) Private insurers (Aetna, Cigna, Regence) offer massage (using CPT 97124) as a benefit in some plans, generally as a "complementary and alternative medicine" expanded benefit

HERC staff recommendation:

1) Modify GN6 as shown below
    a. Discuss "session" vs other wording to allow other modalities (eg PT manipulation) to occur at same visit

GUIDELINE NOTE 6, REHABILITATIVE AND HABILITATIVE THERAPIES

Lines 31,46,57,68,71,72,74,81,91,92,131,132,136,150,153,160,178,183,184,196,197,201, 202,208,255,257,272,285,287,292,300,301,309,317,341,345,348,355,356,359,376,377,400, 401,407,415,417,421,422,430,441,453,461,464,465,476,484,495,507,553,556,569,586,605

The quantitative limits in this guideline note do not apply to mental health or substance abuse conditions.

A total of 30 visits per year of rehabilitative therapy and a total of 30 visits per year of habilitative therapy (physical, occupational and speech therapy) are included on these lines when medically appropriate. Additional visits, not to exceed 30 visits per year of rehabilitative therapy and 30 visits per year of habilitative therapy, may be authorized in cases of a new acute injury, surgery, or other significant change in functional status. Children under age 21 may have additional visits authorized beyond these limits if medically appropriate. Massage therapy (CPT 97124) is included in these service limits. When billing CPT 97124, there must be a minimum of 8 minutes of massage provided. Massage is limited to no more than one session per week.

Physical, occupational and speech therapy are only included on these lines when the following criteria are met:

A) therapy is provided by a licensed physical therapist, occupational therapist, speech language pathologist, physician, or other practitioner licensed to provide the therapy,
B) there is objective, measurable documentation of clinically significant progress toward the therapy plan of care goals and objectives,
C) the therapy plan of care requires the skills of a medical provider, and
D) the client and/or caregiver cannot be taught to carry out the therapy regimen independently.

No limits apply while in a skilled nursing facility for the primary purpose of rehabilitation, an inpatient hospital or an inpatient rehabilitation unit.

Spinal cord injuries, traumatic brain injuries, or cerebral vascular accidents are not subject to the visit limitations during the first year after an acute injury.

2020 Review of Back and Spine Conditions
Medical Guideline

Question: Should GN56 regarding surgical interventions for conditions of the back and spine be modified?

Question source: HERC staff

Issue: HERC staff presented the 2020 AHRQ report on non-pharmacologic intervention for conditions of the back and neck at the May 2020 HERC/VBBS joint meeting. Based on member feedback from that meeting, HERC staff have drafted changes to the current medical guideline to take into account the following:

1) Consider adding low level laser therapy
    a. See separate evidence review
2) Add limitations to the number of visits for massage therapy
    a. See separate evidence review
3) Clarify, if possible based on AHRQ included studies, what type of exercise therapy is most beneficial
4) Identify, if possible based on AHRQ report, what services have been studied in rural areas
    a. Only exercise therapy identified specifically as studied in rural areas

Current Prioritized list guideline

GUIDELINE NOTE 56, NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE

Lines 361,402

Patients seeking care for back pain should be assessed for potentially serious conditions ("red flag" symptoms requiring immediate diagnostic testing), as defined in Diagnostic Guideline D4. Patients lacking red flag symptoms should be assessed using a validated assessment tool (e.g. STarT Back Assessment Tool) in order to determine their risk level for poor functional prognosis based on psychosocial indicators.

For patients who are determined to be low risk on the assessment tool, the following services are included on these lines:

- Office evaluation and education,
- Up to four total visits, consisting of the following treatments: OMT/CMT, acupuncture, and PT/OT. Massage, if available, may be provided as part of these four total visits.
- First line medications: NSAIDs, acetaminophen, and/or muscle relaxers. Opioids may be considered as a second line treatment, subject to the limitations on coverage of opioids in Guideline Note 60 OPIOIDS FOR CONDITIONS OF THE BACK AND SPINE. See evidence table.

For patients who are determined to be medium- or high risk on the validated assessment tool, as well as patients undergoing opioid tapers as in Guideline Note 60 OPIOIDS FOR CONDITIONS OF THE BACK AND SPINE, the following treatments are included on these lines:

- Office evaluation, consultation and education

- Cognitive behavioral therapy. The necessity for cognitive behavioral therapy should be re-evaluated every 90 days and coverage will only be continued if there is documented evidence of decreasing depression or anxiety symptomatology, improved ability to work/function, increased self-efficacy, or other clinically significant, objective improvement.
- Prescription and over-the-counter medications; opioid medications subject to the limitations on coverage of opioids in Guideline Note 60 OPIOIDS FOR CONDITIONS OF THE BACK AND SPINE. See evidence table.
- The following evidence-based therapies, when available, may be provided: yoga, massage, supervised exercise therapy, intensive interdisciplinary rehabilitation. HCPCS S9451 is only included on Line 402 for the provision of yoga or supervised exercise therapy.
- A total of 30 visits per year of any combination of the following evidence-based therapies when available and medically appropriate. These therapies are only included on these lines if provided by a provider licensed to provide the therapy and when there is documentation of measurable clinically significant progress toward the therapy plan of care goals and objectives using evidence based objective tools (e.g. Oswestry, Neck Disability Index, SF-MPQ, and MSPQ).
    1) Rehabilitative therapy (physical and/or occupational therapy), if provided according to Guideline Note 6 REHABILITATIVE AND HABILITATIVE THERAPIES. Rehabilitation services provided under this guideline also count towards visit totals in Guideline Note 6. CPT 97124 is included in this category.
    2) Chiropractic or osteopathic manipulation
    3) Acupuncture

Mechanical traction (CPT 97012) is not included on these lines, due to evidence of lack of effectiveness for treatment of back and neck conditions.

The development of this guideline note was informed by HERC coverage guidances on Low Back Pain Non-Pharmacologic, Non-Invasive Intervention, Low Back Pain, Pharmacological and Herbal Therapies. See https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx.

Evidence Table of Effective Treatments for the Management of Low Back Pain

Intervention Category*	Intervention	Acute < 4 Weeks	Subacute & Chronic > 4 Weeks
Self-care	Advice to remain active	●	●
	Books, handout	●	●
	Application of superficial heat	●	
Nonpharmacologic therapy	Spinal manipulation	●	●
	Exercise therapy		●
	Massage		●
	Acupuncture		●
	Yoga		●
	Cognitive-behavioral therapy		●
	Progressive relaxation		●
Pharmacologic therapy (Carefully consider risks/harms)	Acetaminophen	●	●
	NSAIDs	●(▲)	●(▲)
	Skeletal muscle relaxants	●	
	Antidepressants (TCA)		●
	*Benzodiazepines***	●(▲)	●(▲)
	*Tramadol, opioids***	●(▲)	●(▲)
Interdisciplinary therapy	Intensive interdisciplinary rehabilitation		●

- Interventions supported by grade B evidence (at least fair-quality evidence of moderate benefit, or small benefit but no significant harms, costs, or burdens). No intervention was supported by grade "A" evidence (good-quality evidence of substantial benefit).

▲ *Carries greater risk of harms than other agents in table.*

NSAIDs = nonsteroidal anti-inflammatory drugs; TCA = tricyclic antidepressants.

*These are general categories only. Individual care plans need to be developed on a case by case basis. For more detailed information please see: http://www.annals.org/content/147/7/478.full.pdf

**Associated with significant risks related to potential for abuse, addiction and tolerance. This evidence evaluates effectiveness of these agents with relatively short term use studies. Chronic use of these agents may result in significant harms.

Selected evidence reviews

Exercise therapy for low back pain

1) **AHRQ 2020**
    a) N=11 trials
        i) N=3 trials of neuromuscular re-education exercise (motor control exercises)
        ii) N=4 trials of Pilates or modified Pilates
        iii) N=3 trials of combined exercise techniques (exercises, stretching, relaxation, muscle function and ergonomic advice)
        iv) N=1 trial of strength training
    b) The duration of exercise therapy ranged from 6 to 12 weeks and the number of exercise sessions ranged from 6 to 24.
    c) No particular subgroup appeared to be superior for short, intermediate, or long term outcomes

HERC staff recommendation:

3) Modify GN as shown below
    a) Remove out of date table previously recommended for removal by HERC but not implemented
    b) Do not add low level laser therapy (see separate review)
    c) Clarify that massage using CPT 97124 is included in the 30-visit limit for other therapies such as PT/OT
    d) Add Pilates as an intervention that can be provided "if available" based on AHRQ review

GUIDELINE NOTE 56, NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE

Lines 361,402

Patients seeking care for back pain should be assessed for potentially serious conditions ("red flag" symptoms requiring immediate diagnostic testing), as defined in Diagnostic Guideline D4. Patients lacking red flag symptoms should be assessed using a validated assessment tool (e.g. STarT Back Assessment Tool) in order to determine their risk level for poor functional prognosis based on psychosocial indicators.

For patients who are determined to be low risk on the assessment tool, the following services are included on these lines:

- Office evaluation and education,
- Up to four total visits, consisting of the following treatments: OMT/CMT, acupuncture, and PT/OT. Massage, if available, may be provided as part of these four total visits.
- First line medications: NSAIDs, acetaminophen, and/or muscle relaxers. Opioids may be considered as a second line treatment, subject to the limitations on coverage of opioids in Guideline Note 60 OPIOIDS FOR CONDITIONS OF THE BACK AND SPINE. ~~See evidence table.~~

For patients who are determined to be medium- or high risk on the validated assessment tool, as well as patients undergoing opioid tapers as in Guideline Note 60 OPIOIDS FOR CONDITIONS OF THE BACK AND SPINE, the following treatments are included on these lines:

- Office evaluation, consultation and education
- Cognitive behavioral therapy. The necessity for cognitive behavioral therapy should be re-evaluated every 90 days and coverage will only be continued if there is documented evidence of decreasing depression or anxiety symptomatology, improved ability to work/function, increased self-efficacy, or other clinically significant, objective improvement.
- Prescription and over-the-counter medications; opioid medications subject to the limitations on coverage of opioids in Guideline Note 60 OPIOIDS FOR CONDITIONS OF THE BACK AND SPINE. ~~See evidence table.~~
- The following evidence-based therapies, when available, may be provided: yoga, massage (when not billed under CPT 97124 and limited to one session per week),

Pilates, supervised exercise therapy, intensive interdisciplinary rehabilitation. HCPCS S9451 is only included on Line 402 for the provision of yoga or supervised exercise therapy.

- A total of 30 visits per year of any combination of the following evidence-based therapies when available and medically appropriate. These therapies are only included on these lines if provided by a provider licensed to provide the therapy and when there is documentation of measurable clinically significant progress toward the therapy plan of care goals and objectives using evidence based objective tools (e.g. Oswestry, Neck Disability Index, SF-MPQ, and MSPQ).
    4) Rehabilitative therapy (physical and/or occupational therapy), if provided according to Guideline Note 6 REHABILITATIVE AND HABILITATIVE THERAPIES. Rehabilitation services provided under this guideline also count towards visit totals in Guideline Note 6. Massage billed under CPT 97124 is included in this category and is subject to the restrictions on massage in Guideline Note 6.
    5) Chiropractic or osteopathic manipulation
    6) Acupuncture

Mechanical traction (CPT 97012) is not included on these lines, due to evidence of lack of effectiveness for treatment of back and neck conditions.

The development of this guideline note was informed by HERC coverage guidances on Low Back Pain Non-Pharmacologic, Non-Invasive Intervention, Low Back Pain, Pharmacological and Herbal Therapies. See https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx.

~~**Evidence Table of Effective Treatments for the Management of Low Back Pain [delete entire table below]**~~

Intervention Category*	Intervention	Acute < 4 Weeks	Subacute & Chronic > 4 Weeks
Self-care	Advice to remain active	●	●
	Books, handout	●	●
	Application of superficial heat	●	
Nonpharmacologic therapy	Spinal manipulation	●	●
	Exercise therapy		●
	Massage		●
	Acupuncture		●
	Yoga		●
	Cognitive-behavioral therapy		●
	Progressive relaxation		●
Pharmacologic therapy (Carefully consider risks/harms)	Acetaminophen	●	●
	NSAIDs	●(▲)	●(▲)
	Skeletal muscle relaxants	●	
	Antidepressants (TCA)		●
	*Benzodiazepines***	●(▲)	●(▲)
	*Tramadol, opioids***	●(▲)	●(▲)
Interdisciplinary therapy	Intensive interdisciplinary rehabilitation		●

- Interventions supported by grade B evidence (at least fair-quality evidence of moderate benefit, or small benefit but no significant harms, costs, or burdens). No intervention was supported by grade "A" evidence (good-quality evidence of substantial benefit).

▲ *Carries greater risk of harms than other agents in table.*

NSAIDs = nonsteroidal anti-inflammatory drugs; TCA = tricyclic antidepressants.

*These are general categories only. Individual care plans need to be developed on a case by case basis. For more detailed information please see: http://www.annals.org/content/147/7/478.full.pdf

**Associated with significant risks related to potential for abuse, addiction and tolerance. This evidence evaluates effectiveness of these agents with relatively short term use studies. Chronic use of these agents may result in significant harms.



Comparative Effectiveness Review
Number 227

Noninvasive Nonpharmacological Treatment for Chronic Pain: A Systematic Review Update



AHRQ
Agency for Healthcare
Research and Quality

Comparative Effectiveness Review

Number 227

Noninvasive Nonpharmacological Treatment for Chronic Pain: A Systematic Review Update

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Noninvasive Nonpharmacological Treatment for Chronic Pain: A Systematic Review Update

Structured Abstract

Objectives. We updated the evidence from our 2018 report assessing persistent improvement in outcomes following completion of therapy for noninvasive nonpharmacological treatment for selected chronic pain conditions.

Data sources. Electronic databases (Ovid MEDLINE®, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews) through November 2017 (for prior report) and from September 2017 through September 2019 (for this update report), reference lists, ClinicalTrials.gov, and our previous report.

Review methods. Using predefined criteria, we selected randomized controlled trials (RCTs) of noninvasive nonpharmacological treatments for five common chronic pain conditions (chronic low back pain; chronic neck pain; osteoarthritis of the knee, hip, or hand; fibromyalgia; and tension headache) that reported results for a at least 1 month postintervention. We analyzed effects and assessed strength of evidence (SOE) at short term (1 to <6 months following treatment completion), intermediate term (≥6 to <12 months), and long term (≥12 months).

Results. We included 233 RCTs (31 new to this update). Many were small (N<70), and evidence beyond 12 months after treatment completion was sparse. The most common comparison was with usual care. Evidence on harms was limited, with no evidence suggesting increased risk for serious treatment-related harms for any intervention. Effect sizes were generally small for function and pain.

Chronic low back pain: Psychological therapies were associated with small improvements compared with usual care or an attention control for both function and pain at short-term, intermediate-term, and long-term followup (SOE: moderate). Function improved over short and/or intermediate term for exercise, low-level laser therapy, spinal manipulation, massage, yoga, acupuncture, and multidisciplinary rehabilitation (SOE moderate at short term for exercise, massage, and yoga; low for all others). Improvements in pain at short term were seen for massage, mindfulness-based stress reduction, acupuncture, and multidisciplinary rehabilitation (SOE: moderate), and exercise, low-level laser therapy, and yoga (SOE: low). At intermediate term, spinal manipulation, yoga, multidisciplinary rehabilitation (SOE: moderate) and exercise and mindfulness-based stress reduction (SOE: low) were associated with improved pain. Compared with exercise, multidisciplinary rehabilitation improved both function and pain at short and intermediate terms (small effects, SOE: moderate.)

Chronic neck pain: In the short term, low-level laser therapy (SOE: moderate) and massage (SOE: low) improved function and pain. Exercise in general improved function long term, and combination exercise improved function and pain both short and long term compared with usual care (SOE: low). Acupuncture improved function short and intermediate term, but there was no pain improvement compared with sham acupuncture (SOE: low). Compared with acetaminophen, Pilates improved both function and pain (SOE: low).

Osteoarthritis pain: Exercise resulted in small improvements in function and pain at short-term (SOE: moderate) and long-term (SOE: low), and moderate improvement at intermediate-term (SOE: low) followup for knee osteoarthritis versus nonactive comparators. Small improvements in function and pain with exercise were seen for hip osteoarthritis short term (SOE: low). Functional improvement persisted into intermediate term, but pain improvement did not (SOE: low).

Fibromyalgia: Functional improvements were seen with exercise, mind-body practices, multidisciplinary rehabilitation (SOE: low) and acupuncture (SOE: moderate) short term compared with usual care, attention control, or sham treatment. At intermediate term, there was functional improvement with exercise and acupuncture (SOE: moderate), cognitive-behavioral therapy (CBT), mindfulness-based stress reduction, myofascial release, and multidisciplinary rehabilitation (SOE: low). Long term, functional improvements persisted for multidisciplinary rehabilitation without improvement in pain (SOE: low). Compared with exercise, tai chi conferred improvement in function short and intermediate term (SOE: low). Pain was improved with exercise (short and intermediate term, SOE moderate), and for CBT (short term), mindfulness practices, and multidisciplinary rehabilitation (intermediate term) (SOE low).

Chronic tension headache: Evidence was sparse and the majority of trials were of poor quality. Spinal manipulation resulted in moderate improvement in pain short term.

Conclusions. Trials identified subsequent to the earlier report largely support previous findings—namely that exercise, multidisciplinary rehabilitation, acupuncture, CBT, mindfulness practices, massage, and mind-body practices most consistently improve function and/or pain beyond the course of therapy for specific chronic pain conditions. Additional research, including comparisons with pharmacological and other active controls, on effects beyond the immediate post-treatment period is needed, particularly for conditions other than low back pain.

2020 Review of Back and Spine Conditions
Opioid Guideline

Question: Should GN60 regarding opioid therapy for conditions of the back and spine be modified?

Question source: HERC staff

Issue: HERC staff presented the 2020 AHRQ report on opioid therapy for chronic pain at the May, 2020 HERC/VBBS joint meeting.

2020 AHRQ report conclusions:

- **Conclusions.** At short-term follow-up, for patients with chronic pain, opioids are associated with small beneficial effects versus placebo but are associated with increased risk of short-term harms and do not appear to be superior to nonopioid therapy. Evidence on intermediate-term and long-term benefits remains very limited, and additional evidence confirms an association between opioids and increased risk of serious harms that appears to be dose-dependent.

At the May, 2020 meeting, advocates submitted multiple piece of evidence for the HERC to consider. This additional evidence is summarized below.

Additionally, at the May meeting, a HERC Commissioner suggested it would be helpful to have a summary/timeline of the opioid coverage issues that HERC has been involved in.

Summary of HERC coverage for opioids for back and neck conditions

1) A Powerpoint presentation describing HERC back pain history summarizes the overall back pain coverage changes up through 2018. Most importantly for this discussion:
    a. Prior to 2016, uncomplicated back pain (i.e. without nerve damage) was technically not covered, but in practice most opioid prescriptions were covered as they were not subject to prior authorization.
    b. Beginning in July, 2016, coverage changes for opioids took effect gradually, as HERC's guideline note 60 was implemented by the Oregon Health Plan and CCOs.
        i. other conservative back pain treatments were newly covered
        ii. restrictions on new opioid prescriptions took effect
        iii. restrictions on long term opioid therapy took effect, including a requirement for a taper plan for continued coverage.
    c. Other restrictions to opioid coverage, including restrictions on high-dose opioid prescribing were implemented during this period, unrelated to the HERC decision.
2) Chronic Pain Task Force assembled in 2016, meeting from September 2017 to December 2018. While the recommendations to add coverage for conservative therapy for additional chronic pain conditions (including fibromyalgia and generalized chronic pain conditions) was not adopted by the Commission, the opioid guideline for back pain (Guideline Note 60) was revised in light of extensive public comment received by the task force as well as by the HERC. The new revisions, implemented in October 2019, do not allow OHP or CCOs to require taper plans as a condition for continued coverage of long-term opioid therapy, but rather encourage them where clinically appropriate, and encourage individualized care during the implementation of a taper plan.

Evidence Summary of the five studies from the May 21, 2020 VBBS/HERC public testimony

2020 Review of Back and Spine Conditions
Opioid Guideline

Oliva et al, 2020

- Objective: associations b/w stopping opioid treatment, length of treatment, and mortality
- Observational study, VA population (N=1,394,102), 2012-2014, med rec review
- Pop demographics: 60 yrs, 8%F, 61% urban residence, half had ≥3 diagnosis. 10% had alcohol use disorder.
- Stopping treatment was associated with increased risk of death from overdose/suicide regardless of length of treatment, with risk increasing the longer the treatment was (P<0.001)
- Other factors associated with risk of death: prescriptions for long-acting (0.08) or short-acting (0.06) opioids compared with tramadol; log maximum MME (0.03); number of medical diagnoses (0.01); having MH diagnosis (0.04)
- Hazard ratios for patients who stopped treatment were 1.67 (<30 days), 2.8 (31-90d), 6.77 (>400d)
- Death rates (suicide/overdose) increased immediately after stopping treatment, with incidence decreasing ~3months-12months
- Authors note that "The associations observed cannot be assumed to be causal; the context in which opioid prescriptions were started and stopped might contribute to risk and was not investigated."

Glanz et al, 2019

- Objective: association between opioid dose variability and opioid overdose
- Nested case-control within integrated health plan (N=14,898), 2006-2018, each overdose case matched up to 20 controls (228 cases matched to 3547 controls)
- Demographics: 56.3 years, 60% female, MH dx in 73% (95% of cases); short-acting opioid treatment 81%, drug/alcohol use 32% (70% in cases)
- Mean duration of opioid treatment was 36.7mo (case) vs. 33 months (control)
- Mean opioid doses for cases 110.6MME versus 73 MME control
- High-dose variability associated with increased risk of overdose compared with low-dose variability (OR: 3.32)
- Interaction between dose and dose variability was not statistically significant, meaning dose variability throughout all levels of dose poses overdose risk.
- Authors' conclusions: "This study suggests that dose variability is a risk factor for opioid overdose independent of dose alone, whereas sustained therapy discontinuation may be protective of overdose. Additional studies are needed to better understand the pathways by which patients undergoing long-term opioid therapy can safely discontinue opioid therapy. Until such pathways can be elucidated, policymakers and physicians should consider the risks that may be associated with dose variability when designing and implementing new policies to reduce opioid prescribing."

Mark & Parish, 2019

- Objective: relationship between time to opioid discontinuation and risk of opioid-related hospitalization/ER utilization among high dose opioid users
- Administrative claims review, Vermont Medicaid population w high-dose (>120MME for >90d) opioid treatment, N=494, 2013-2017
- 86% discontinued within 21 days (rapid tapering); median length of time to discontinuation was 1 day, indicating that half of patients had no dose reduction before discontinuing
- Among those that discontinued, 49% had an adverse opioid-related health care event

- For each week after discontinuation, 7% reduction in probability of adverse event (<0.01)
- 60% of patients had SUD, with <1% receiving SUD treatment
- Faster rates of tapering were associated with greater probability of adverse events
- Authors' conclusions: "Faster rates of opioid tapering were associated with a greater probability of adverse events and many patients discontinued opioids suddenly, with no dose reduction. Additional clinical guidance, research, and interventions are needed to ensure that patients' opioid prescriptions are discontinued safely."

Perez et al, 2019

- Objective: association between termination of care and tapering among chronic opioid risk of termination of care among chronic opioid users experiencing tapers compared to chronic opioid users continuing their usual dosages
- Retrospective cohort study of patients within large, urban health system, 2008-2012, N=1,624
- Demographics: mean 52 years, 54% female, median 90 MME, Back pain (63%), extremity pain (63%), MH diagnosis (47%), non-opioid drug use (20%)
- Among 1624 chronic opioid users, 207 (15%) had taper and 78 (4.8%) experienced termination of care (either patient- or provider-initiated)
- Taper was associated with greater than 4x odds of termination of care
- Author's conclusions: Opioid taper is associated with subsequent termination of care. These findings invite caution and demonstrate the need to fully understand the risks and benefits of opioid tapers.

James et al, 2019

- Objective: association between mortality, opioid use, and primary care utilization among patients discontinued from chronic opioid treatment (COT)
- Retrospective cohort registry of Seattle primary care clinic, N=572, 2010-2015
- Demographics: mean 55yrs; 46% female; 36% black; 86% public insurance; 25% patients had 120-359MME; 11% prescribed >360MME/day. 68% had short-acting opioids compared to 30% long-acting, 28% methadone.
- COT was discontinued in 344 (60%) patients during study period, with 77% of those being provider-initiated
- Between 2010-15, 119 registry patients died (21%), with 21 (3.7%) of definite overdose
- COT discontinuation associated with HR 1.35 for mortality (not sig, 0.122); HR 2.94 for overdose death (0.049)
- Among patients discontinued from opioid registry, 54& visited clinic ≥2 during remainder of study period
- Authors' conclusions: In conclusion, we found that primary care patients on COT had a high mortality risk and that discontinuation of COT was not associated with a reduced risk of death and in fact was associated with an increased risk of death from overdose. While more research is needed to evaluate the generalizability of these findings, and to understand how to better protect patients on COT from harm, caution when discontinuing COT is appropriate. Improved clinical strategies, including assessment and treatment of opioid use disorder and multimodal pain management, may be needed for patients being considered for opioid discontinuation.

Current guideline note:

2020 Review of Back and Spine Conditions
Opioid Guideline

GUIDELINE NOTE 60, OPIOIDS FOR CONDITIONS OF THE BACK AND SPINE

Lines 346,361,402,529

Opioid medications are only included on these lines under the following criteria:

For acute injury, acute flare of chronic pain, or after surgery:

1) During the first 6 weeks opioid treatment is included on these lines ONLY:
   a) When each prescription is limited to 7 days of treatment, AND
   b) For short acting opioids only, AND
   c) When one or more alternative first line pharmacologic therapies such as NSAIDs, acetaminophen, and muscle relaxers have been tried and found not effective or are contraindicated, AND
   d) When prescribed with a plan to keep active (home or prescribed exercise regime) and with consideration of additional therapies such as spinal manipulation, physical therapy, yoga, or acupuncture, AND
   e) There is documented verification that the patient is not high risk for opioid misuse or abuse.
2) Treatment with opioids after 6 weeks, up to 90 days after the initial injury/flare/surgery is included on these lines ONLY:
   a) With documented evidence of improvement of function of at least thirty percent as compared to baseline based on a validated tools (e.g. Oswestry, Neck Disability Index, SF-MPQ, and MSPQ).
   b) When prescribed in conjunction with therapies such as spinal manipulation, physical therapy, yoga, or acupuncture.
   c) With verification that the patient is not high risk for opioid misuse or abuse. Such verification may involve
      i) Documented verification from the state's prescription monitoring program database that the controlled substance history is consistent with the prescribing record
      ii) Use of a validated screening instrument to verify the absence of a current substance use disorder (excluding nicotine) or a history of prior opioid misuse or abuse
      iii) Administration of a baseline urine drug test to verify the absence of illicit drugs and non-prescribed opioids.
   d) Each prescription must be limited to 7 days of treatment and for short acting opioids only

3) Long-term opioid treatment (>90 days) after the initial injury/flare/surgery is not included on these lines except for the taper process described below.

<u>Transitional coverage for patients on long-term opioid therapy:</u>

For patients receiving long-term opioid therapy (>90 days) for conditions of the back and spine, continued coverage of opioid medications requires an individual treatment plan which includes a taper plan when clinically indicated. Opioid tapering should be done on an individualized basis with a shared goal set by the patient and provider based on the patient's overall status. Taper plans should include nonpharmacological treatment strategies for managing the patient's pain. During the taper, behavioral health conditions need to be regularly assessed and appropriately managed. In some situations (e.g., in the setting of active substance use disorder, history of opioid overdose, aberrant behavior), more rapid tapering or transition to medication assisted treatment may be appropriate and should be directed by the prescribing provider. If a patient has developed an opioid use disorder, treatment is included on Line 4 SUBSTANCE USE DISORDER.

2020 Review of Back and Spine Conditions
Opioid Guideline

HERC staff summary

The 2020 AHRQ report found that opioid therapy resulted in small benefits for pain but increased risk of short-term harms. There is very limited evidence for the effectiveness of opioids for intermediate or long-term treatment.

The submitted evidence from advocates shows that abrupt discontinuation of opioids results in higher risk of overdose and other harms. However, there are many reasons patients may have their opioids abruptly discontinued, such as use of illicit substances, that would also increase risk of overdose. Patients with long term opioid therapy had a higher risk of overdose or death with reduction or discontinuation of opioid therapy even when not abruptly discontinued.

HERC staff recommendation:

1) No changes are recommended to GN60. Taper plans are not required for coverage on long-term opioid therapy. Language encouraging an individualized taper plan is already included, and supportive care for chronic pain and other associated conditions a patient may be experiencing is encouraged during a taper.

Section 6.0

August 14 2020 List COVID-related changes

SARS-CoV-2 Testing Diagnostic Guideline

Question: Should a new diagnostic guideline regarding SARS-CoV-2 testing be added to the Prioritized List?

Question source: HERC staff; HSD; OHA public health

Issue: Currently, PCR testing for diagnosis of SARS-CoV-2 (the virus that causes COVID-19 illness) is covered as a Diagnostic Procedure. Antibody testing is also covered as a Diagnostic Procedure. Currently, there is no guideline limiting the use of either type of testing.

The Oregon Health Authority has guidance on when PCR or antigen testing should be conducted for detection of acute infection with SARS-CoV-2: https://sharedsystems.dhsoha.state.or.us/DHSForms/Served/le2267.pdf. Generally, testing is indicated for any person with symptoms of SARS-CoV-2. OHA only recommends testing of asymptomatic persons as part of contact investigations or persons in certain high risk or underserved groups.

Per the Oregon Health Authority, antibody testing is not recommended for diagnosis or exclusion of COVID-19. Molecular testing (e.g., PCR) is necessary to diagnose or confirm COVID-19**.** It takes up to 14 days after symptom onset for antibodies to SARS-CoV-2 to be detectable on serologic assays, yet in most people, the illness and contagious period are likely over by 14 days after symptom onset. Serology has limited utility in care of patients who may have COVID-19 but is useful for epidemiologic studies. It remains unknown whether antibodies confer full or partial immunity to COVID-19 or for how long immunity may last.

OHA recommends only using tests that have FDA Emergency Use Authorization (EUA). Note that EUA is an expedited vetting process that involves a much lower level of FDA review than FDA approval.

Current Prioritized List status

CPT code	Code descriptions	Current Placement
86328	Immunoassay for infectious agent antibody(ies), qualitative or semiquantitative, single step method (eg, reagent strip); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])	Diagnostic Procedure File
86769	Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])	Diagnostic Procedure File

Evidence

1) **Deeks 2020**, Cochrane rapid review on antibody tests for SARS-CoV-2
    a. N=57 studies
        i. 54 cohort studies (15,976 total samples, 8526 COVID positive samples)
        ii. 25 commercial tests and numerous in-house assays
        iii. Most studies (n = 44) only included people hospitalised due to suspected or confirmed COVID-19 infection.
        iv. There were no studies exclusively in asymptomatic participants.

v. Pooled results for IgG, IgM, IgA, total antibodies and IgG/IgM all showed low sensitivity during the first week since onset of symptoms (all less than 30.1%), rising in the second week and reaching their highest values in the third week. The combination of IgG/IgM had a sensitivity of 30.1% (95% CI 21.4 to 40.7) for 1 to 7 days, 72.2% (95% CI 63.5 to 79.5) for 8 to 14 days, 91.4% (95% CI 87.0 to 94.4) for 15 to 21 days.
vi. Estimates of accuracy beyond three weeks are based on smaller sample sizes and fewer studies. For 21 to 35 days, pooled sensitivities for IgG/IgM were 96.0% (95% CI 90.6 to 98.3). There are insufficient studies to estimate sensitivity of tests beyond 35 days post-symptom onset.
vii. Assuming a prevalence of 50%, a value considered possible in healthcare workers who have suffered respiratory symptoms, we would anticipate that 43 (28 to 65) would be missed and 7 (3 to 14) would be falsely positive in 1000 people undergoing IgG/IgM testing at days 15 to 21 post-symptom onset.
viii. At a prevalence of 20%, a likely value in surveys in high-risk settings, 17 (11 to 26) would be missed per 1000 people tested and 10 (5 to 22) would be falsely positive.
ix. At a lower prevalence of 5%, a likely value in national surveys, 4 (3 to 7) would be missed per 1000 tested, and 12 (6 to 27) would be falsely positive.
x. **Authors' conclusions:** The sensitivity of antibody tests is too low in the first week since symptom onset to have a primary role for the diagnosis of COVID-19, but they may still have a role complementing other testing in individuals presenting later, when RT-PCR tests are negative, or are not done. Antibody tests are likely to have a useful role for detecting previous SARS-CoV-2 infection if used 15 or more days a.er the onset of symptoms. However, the duration of antibody rises is currently unknown, and we found very little data beyond 35 days post-symptom onset. We are therefore uncertain about the utility of these tests for seroprevalence surveys for public health management purposes. Concerns about high risk of bias and applicability make it likely that the accuracy of tests when used in clinical care will be lower than reported in the included studies. Sensitivity has mainly been evaluated in hospitalised patients, so it is unclear whether the tests are able to detect lower antibody levels likely seen with milder and asymptomatic COVID-19 disease. This is a fast-moving field and we plan ongoing updates of this living systematic review.

HERC staff recommendation:

1) Adopt a new Diagnostic Guideline as shown below

DIAGNOSTIC GUIDELINE D27, SARS-COV-2 (COVID-19) TESTING

Testing for SARS-CoV-2 (COVID-19) virus RNA or viral antigen is a covered diagnostic service.

Antibody testing for SARS-CoV-2 (COVID-19; CPT 86328 or 86769) is covered as diagnostic only when such testing meets the following criteria:

A) Testing is done using tests that have FDA Emergency Use Authorization (EUA) or FDA approval; AND
B) Testing is used as part of the diagnostic work up of multisystem inflammatory syndrome in children (MIS-C) for hospitalized persons under the age of 21.

Cochrane Library

Cochrane Database of Systematic Reviews

Antibody tests for identification of current and past infection with SARS-CoV-2 (Review)

Deeks JJ, Dinnes J, Takwoingi Y, Davenport C, Spijker R, Taylor-Phillips S, Adriano A, Beese S, Dretzke J, Ferrante di Ruffano L, Harris IM, Price MJ, Dittrich S, Emperador D, Hooft L, Leeflang MMG, Van den Bruel A, Cochrane COVID-19 Diagnostic Test Accuracy Group

Deeks JJ, Dinnes J, Takwoingi Y, Davenport C, Spijker R, Taylor-Phillips S, Adriano A, Beese S, Dretzke J, Ferrante di Ruffano L, Harris IM, Price MJ, Dittrich S, Emperador D, Hooft L, Leeflang MMG, Van den Bruel A.
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[Diagnostic Test Accuracy Review]

Antibody tests for identification of current and past infection with SARS-CoV-2

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ABSTRACT

Background

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus and resulting COVID-19 pandemic present important diagnostic challenges. Several diagnostic strategies are available to identify current infection, rule out infection, identify people in need of care escalation, or to test for past infection and immune response. Serology tests to detect the presence of antibodies to SARS-CoV-2 aim to identify previous SARS-CoV-2 infection, and may help to confirm the presence of current infection.

Objectives

To assess the diagnostic accuracy of antibody tests to determine if a person presenting in the community or in primary or secondary care has SARS-CoV-2 infection, or has previously had SARS-CoV-2 infection, and the accuracy of antibody tests for use in seroprevalence surveys.

Search methods

We undertook electronic searches in the Cochrane COVID-19 Study Register and the COVID-19 Living Evidence Database from the University of Bern, which is updated daily with published articles from PubMed and Embase and with preprints from medRxiv and bioRxiv. In addition, we checked repositories of COVID-19 publications. We did not apply any language restrictions. We conducted searches for this review iteration up to 27 April 2020.

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Selection criteria

We included test accuracy studies of any design that evaluated antibody tests (including enzyme-linked immunosorbent assays, chemiluminescence immunoassays, and lateral flow assays) in people suspected of current or previous SARS-CoV-2 infection, or where tests were used to screen for infection. We also included studies of people either known to have, or not to have SARS-CoV-2 infection. We included all reference standards to define the presence or absence of SARS-CoV-2 (including reverse transcription polymerase chain reaction tests (RT-PCR) and clinical diagnostic criteria).

Data collection and analysis

We assessed possible bias and applicability of the studies using the QUADAS-2 tool. We extracted 2x2 contingency table data and present sensitivity and specificity for each antibody (or combination of antibodies) using paired forest plots. We pooled data using random-effects logistic regression where appropriate, stratifying by time since post-symptom onset. We tabulated available data by test manufacturer. We have presented uncertainty in estimates of sensitivity and specificity using 95% confidence intervals (CIs).

Main results

We included 57 publications reporting on a total of 54 study cohorts with 15,976 samples, of which 8526 were from cases of SARS-CoV-2 infection. Studies were conducted in Asia (n = 38), Europe (n = 15), and the USA and China (n = 1). We identified data from 25 commercial tests and numerous in-house assays, a small fraction of the 279 antibody assays listed by the Foundation for Innovative Diagnostics. More than half (n = 28) of the studies included were only available as preprints.

We had concerns about risk of bias and applicability. Common issues were use of multi-group designs (n = 29), inclusion of only COVID-19 cases (n = 19), lack of blinding of the index test (n = 49) and reference standard (n = 29), differential verification (n = 22), and the lack of clarity about participant numbers, characteristics and study exclusions (n = 47). Most studies (n = 44) only included people hospitalised due to suspected or confirmed COVID-19 infection. There were no studies exclusively in asymptomatic participants. Two-thirds of the studies (n = 33) defined COVID-19 cases based on RT-PCR results alone, ignoring the potential for false-negative RT-PCR results. We observed evidence of selective publication of study findings through omission of the identity of tests (n = 5).

We observed substantial heterogeneity in sensitivities of IgA, IgM and IgG antibodies, or combinations thereof, for results aggregated across different time periods post-symptom onset (range 0% to 100% for all target antibodies). We thus based the main results of the review on the 38 studies that stratified results by time since symptom onset. The numbers of individuals contributing data within each study each week are small and are usually not based on tracking the same groups of patients over time.

Pooled results for IgG, IgM, IgA, total antibodies and IgG/IgM all showed low sensitivity during the first week since onset of symptoms (all less than 30.1%), rising in the second week and reaching their highest values in the third week. The combination of IgG/IgM had a sensitivity of 30.1% (95% CI 21.4 to 40.7) for 1 to 7 days, 72.2% (95% CI 63.5 to 79.5) for 8 to 14 days, 91.4% (95% CI 87.0 to 94.4) for 15 to 21 days. Estimates of accuracy beyond three weeks are based on smaller sample sizes and fewer studies. For 21 to 35 days, pooled sensitivities for IgG/IgM were 96.0% (95% CI 90.6 to 98.3). There are insufficient studies to estimate sensitivity of tests beyond 35 days post-symptom onset. Summary specificities (provided in 35 studies) exceeded 98% for all target antibodies with confidence intervals no more than 2 percentage points wide. False-positive results were more common where COVID-19 had been suspected and ruled out, but numbers were small and the difference was within the range expected by chance.

Assuming a prevalence of 50%, a value considered possible in healthcare workers who have suffered respiratory symptoms, we would anticipate that 43 (28 to 65) would be missed and 7 (3 to 14) would be falsely positive in 1000 people undergoing IgG/IgM testing at days 15 to 21 post-symptom onset. At a prevalence of 20%, a likely value in surveys in high-risk settings, 17 (11 to 26) would be missed per 1000 people tested and 10 (5 to 22) would be falsely positive. At a lower prevalence of 5%, a likely value in national surveys, 4 (3 to 7) would be missed per 1000 tested, and 12 (6 to 27) would be falsely positive.

Analyses showed small differences in sensitivity between assay type, but methodological concerns and sparse data prevent comparisons between test brands.

Authors' conclusions

The sensitivity of antibody tests is too low in the first week since symptom onset to have a primary role for the diagnosis of COVID-19, but they may still have a role complementing other testing in individuals presenting later, when RT-PCR tests are negative, or are not done. Antibody tests are likely to have a useful role for detecting previous SARS-CoV-2 infection if used 15 or more days after the onset of symptoms. However, the duration of antibody rises is currently unknown, and we found very little data beyond 35 days post-symptom onset. We are therefore uncertain about the utility of these tests for seroprevalence surveys for public health management purposes. Concerns about high risk of bias and applicability make it likely that the accuracy of tests when used in clinical care will be lower than reported in the included studies. Sensitivity has mainly been evaluated in hospitalised patients, so it is unclear whether the tests are able to detect lower antibody levels likely seen with milder and asymptomatic COVID-19 disease.

The design, execution and reporting of studies of the accuracy of COVID-19 tests requires considerable improvement. Studies must report data on sensitivity disaggregated by time since onset of symptoms. COVID-19-positive cases who are RT-PCR-negative should be included as well as those confirmed RT-PCR, in accordance with the World Health Organization (WHO) and China National Health Commission of the

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June 30, 2020

Significant recent changes are highlighted in blue text

COVID-19 testing guidance for health care providers

Oregon Health Authority (OHA) recommends COVID-19 viral testing for all people with new symptoms consistent with COVID-19, regardless of severity. A list of symptoms is available from the CDC here. OHA recommends that all people with symptoms consistent with COVID-19 call their health care provider before their visit to discuss their illness and testing availability.

OHA recommends using only tests that have U.S. Food and Drug Administration (FDA) approval or Emergency Use Authorization (EUA). The up-to-date list is available here.

Criteria for testing at OSPHL are described in a separate document, available at healthoregon.org/coronavirushcp.

Viral testing at clinical and private laboratories

1. **General guidance**:
    a. Providers do not need to notify the local public health authority (LPHA) or OHA when evaluating patients with respiratory illness or ordering COVID-19 testing.
    b. Because COVID-19 and influenza (which is treatable) can present in similar fashion, influenza testing should be considered in addition to COVID-19 testing.
    c. Employers are responsible for making testing available to their health care workers who should be tested according to the recommendations below.
    d. If a patient does not have a clinical need to be sent to an emergency department or a hospital, do not send them there.
    e. Specimens should be collected under appropriate infection prevention precautions. For information on recommended infection prevention measures for patients with suspected or confirmed COVID-19, see OHA's Provisional Guidance: Clinical Care and Healthcare Infection Prevention and Control for COVID-19.
    f. Note that nasopharyngeal (NP) swabs, oropharyngeal (OP) swabs, nasal swabs, and nasopharyngeal washes are not considered aerosol-generating procedures.
    g. COVID-19 disproportionately affects Black/African American, Latinx, American Indian/Alaska Native, Asian, Asian American and Pacific Islander communities. OHA requires health care providers to collect accurate race, ethnicity, language, and disability (REAL-D) data on all patients, including those being tested for COVID-19. Please ensure that these data have been collected in a patient's health record prior to ordering COVID-19 testing.

2. **OHA recommends that any person with symptoms consistent with COVID-19 be tested for COVID-19**.

   If resources are limited, the following groups should be prioritized. Severity of symptoms, testing availability and health care system capacity should also be considered.

   a. Healthcare workers and first responders (EMS, public safety workers)
   b. Residents, staff, children, and others in congregate settings (e.g., residential care facilities, group homes, schools, agricultural workplaces, food processing plants, jails or prisons, shelters)
   c. Workers who provide direct care or services in multiple group facilities or who provide in-home services (e.g., hospice care workers, physical or occupational therapists, in-home personal care workers)
   d. Essential front-line service workers who have regular contact with large numbers of people (e.g., those working in grocery, pharmacy, transit, delivery, and other critical infrastructure services)
   e. People 65 years of age or older
   f. People with underlying medical conditions, including, but not limited to hypertension, diabetes, cardiovascular disease, lung disease, obesity, and immunocompromising conditions
   g. People who identify as Black, African American, Latinx, American Indian/Alaska Native, Asian, Asian American or Pacific Islander
   h. People who identify as having a disability
   i. People whose first language is not English
   j. Pregnant women
   k. People whose condition requires hospitalization
   l. People who, within 14 days of their symptom, onset had close contact with a confirmed or presumptive COVID-19 case

3. OHA recommends that testing of people **without symptoms consistent with COVID-19** be limited to the following groups:

   a. Close contacts of confirmed or presumptive COVID-19 cases
   b. People exposed to COVID-19 in a congregate setting (e.g., residential care facilities, group homes, schools, agricultural workplaces, food processing plants, jails or prisons, shelters)
   c. Migrant/seasonal agricultural workers upon arrival in Oregon
   d. People who identify as Black, African-American, Latino, Latina, Latinx, American Indian/Alaska Native, Asian, Asian-American or Pacific Islander
   e. People who identify as having a disability
   f. People whose first language is not English

Patients and providers should be aware that COVID-19 testing for asymptomatic individuals may not be covered by insurance (e.g., when there is no known contact or high risk exposure to COVID-19).

Interpretation of test results

Tests for COVID-19 have significant limitations. Testing is most useful in patients with COVID-19 symptoms. Testing of people without symptoms is most useful in COVID-19 case, cluster and outbreak investigations. Antibody testing is not recommended (see next section).

Messaging to patients with symptoms of COVID-19		
	Viral test	**Antibody test**
Positive	You have COVID-19. Protect your community by isolating according to public health recommendations.	Approximately half of test results may be falsely positive.* Even if you do have antibodies, it's not yet known whether they provide protection against reinfection.
Negative	Tests are falsely negative in about 30% of patients with symptoms. Assume that you have COVID-19 and protect your community by isolating until you feel better.	Your symptoms may be caused by an illness that is not COVID-19. Results may also be falsely negative even if you have or had COVID-19. Antibody tests may not become positive for weeks following infection.

Messaging to patients without symptoms of COVID-19		
	Viral test	**Antibody test**
Positive	You have COVID-19. You may or may not develop symptoms. Protect your community by isolating according to public health recommendations.	Approximately half of test results may be falsely positive.* Even if you do have antibodies, it's not yet known whether they provide protection against reinfection.
Negative	You may have COVID-19. Tests may be falsely negative, and a negative result provides no indication that you are protected from infection.	Results may be falsely negative even if you have or had COVID-19. Antibody tests may not become positive for weeks following infection.

* False positive rate depends on the specificity of the test used and the prevalence of COVID-19 in the community.

Antibody testing at clinical and private laboratories

Serology-based tests for COVID-19 are increasingly available. Serology tests assess for the presence of antibodies to the SARS-CoV-2 virus in blood.

Antibody testing is **not** recommended for diagnosis or exclusion of COVID-19. Viral testing

(e.g., PCR) is necessary to confirm COVID-19. It may take up to 14 days for antibodies to SARS-CoV-2 to be detectable by serology assays.

Serology has limited utility in the care of patients who may have COVID-19, but it may be useful for epidemiologic studies. OHA has begun a series of SARS-CoV-2 seroprevalence studies to determine the prevalence of antibodies in Oregon.

Providers who order antibody testing should understand the limitations of the tests and explain these limitations to patients:

- Antibody tests cannot reliably diagnose or rule out active COVID-19.
- If antibody prevalence in the population is very low, or the specificity of the test is not very high (e.g., >99%), a positive serology test may be more likely to be a false positive than a true positive.
- FDA has published a comparison of selected antibody test performance, including estimates of positive predictive value—i.e., the likelihood that a positive test represents a true positive.

Whether antibodies confer or indicate any degree of immunity to COVID-19 remains unknown. Patients should not change their behavior based on antibody test results.

For individuals with disabilities or individuals who speak a language other than English, OHA can provide documents in alternate formats such as other languages, large print, braille or a format you prefer. Contact Mavel Morales at 1-844-882-7889, 711 TTY or OHA.ADAModifications@dhsoha.state.or.us.

Telehealth Guideline

Issue: Revisions to telehealth guideline and publication of new Interim Modification.

Discussion:

As the COVID-19 pandemic continues, telehealth is taking on an increasing role in clinical care in Oregon and across the nation. The guideline was revised with input from leadership since originally published, and the Health Systems Division has issued new rules and guidance on an ongoing basis. The current guideline note is tied to the Governor's emergency declaration. Since the situation seems likely to continue for some time, staff recommends a HERC decision to revise the list with a guideline note not tied to the public health emergency, which can be revised in the future.

Current guideline Note A5 and COVID-related list changes made at or since publication of 3/13/2020 list:

ANCILLARY GUIDELINE A5, TELEHEALTH, TELECONSULTATIONS AND ONLINE/TELEPHONIC SERVICES

As referred to in this guideline note, the COVID-19 emergency is defined as per Oregon Governor Kate Brown's executive order 20-03 and any subsequent executive order extending or reinstating a state of emergency related to COVID-19. Italicized portions of this guideline note apply only during the COVID-19 emergency.

Telehealth (Synchronous visits including audio and video. Audio-only telephone services can be provided using these codes only during the COVID-19 emergency and if providing the service via synchronous audio and video is not available or feasible)

Telehealth services described in this section are defined as synchronous services with both audio and video capability, when billed with the same codes that would be billed for in-person services, and when mode of delivery is indicated by the use of specific modifiers and/or place of service codes specified by the plan. The patient may be in the community or in a health care setting. The provider may be in any location in which appropriate privacy can be ensured. The clinical value of the telehealth service delivered must reasonably approximate the clinical value of services delivered in-person.

During the COVID-19 emergency, telephone (audio-only) visits are an acceptable replacement for the equivalent service provided by synchronous audio and video, if synchronous audio and video capabilities are not available or feasible.

Certain requirements for encryption will not be enforced by federal authorities (or required by OHP) during the COVID-19 emergency. This means services such as Facetime, Skype or Google Hangouts can be used for service delivery. HIPAA-compliant platforms are preferred when available. See https://www.hhs.gov/hipaa/for-

professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html for details.

When a COVID-19 emergency declaration is not in effect, codes eligible for telehealth delivery include 90785, 90791, 90792, 90832-90834, 90836, 90837-90840, 90846, 90847, 90951, 90952, 90954, 90955, 90957, 90958, 90960, 90961, 90963, 90964-90970, 96116, 96156-96171, 96160, 96161, 97802-97804, 99201-99205, 99211-99215, 99231-99233, 99307-99310, 99354-99357, 99406-99407, 99495-99498, G0108-G0109, G0270, G0296, G0396, G0397, G0406-G0408, G0420, G0421, G0425-G0427, G0438-G0439, G0442-G0447, G0459, G0506, G0508, G0509, G0513, G0514, G2086-G2088. During a COVID-19 emergency, additional codes are covered when otherwise appropriate according to this guideline note and other applicable coverage criteria.

The originating site code Q3014 can be billed only when the patient is present in an appropriate health care setting and receiving services from a provider in another location.

Telehealth visits are covered for inpatient and outpatient services for new or established patients.

Telehealth consultations are covered for emergency and inpatient services.

Billing for telehealth services requires the same level of documentation, medical necessity, and coverage determinations as in-person visits.

Patient to Clinician Services billed using specified codes indicating telephone or online service delivery

Telephonic and online services, including services related to diagnostic workup (CPT 98966-98968, 99441-99443, 99421-99423, 98970-98972, G2010, G2012, G2061-G2063) between a patient and clinician must:

A) Be provided only for established patients *(This requirement does not apply during a COVID-19 emergency)*
B) Be documented as follows:
    1) using model SOAP charting, or as described in program's OAR;
    2) include patient history, provider assessment, treatment plan and follow-up instructions;
    3) support the assessment and plan;
    4) be retained in the patient's medical record and be retrievable.
C) Include medical decision making or service delivery (e.g. behavioral health intervention/psychotherapy, other forms of therapy).
D) Include permanent storage (online or hard copy) of the encounter.
E) Meet applicable HIPAA standards for privacy.

F) Include patient-clinician agreement of informed consent, discussed with and agreed to by the patient and documented in the medical record. (During the COVID-19 emergency, verbal consent is sufficient.)
G) Not include any of the following:
    1) Services which are part of care plan oversight or anticoagulation management (CPT codes 99339-99340, 99374-99380 or 99363-99364).
    2) Services related to a service performed and billed by the physician or qualified health professional within the previous seven days, regardless of whether it is the result of patient-initiated or physician-requested follow-up.
    3) Services which result in the patient being seen within 24 hours or the next available appointment.
    4) Services which relate to or take place within the postoperative period of a procedure provided by the physician. (Such a service is considered part of the procedure and is not be billed separately.)

Examples of reimbursable telephone or online services include but are not limited to:
A) Extended counseling when person-to-person contact would involve an unwise delay or exposure to COVID-19.
B) Treatment of relapses that require significant investment of provider time and judgment.
C) Counseling and education for patients with complex chronic conditions.

Examples of non-reimbursable telephone/online consultations include but are not limited to:
A) Prescription renewal.
B) Scheduling a test.
C) Reporting normal test results.
D) Requesting a referral.
E) Follow up of medical procedure to confirm stable condition, without indication of complication or new condition.
F) Brief discussion to confirm stability of chronic problem and continuity of present management.

Clinician-to-Clinician Consultations (telephonic and online or using electronic health record)

Coverage of interprofessional consultations delivered online, through electronic health records or by telephone is included as follows:

Consulting Providers (CPT 99451, 99446-99449)
- For new or established patients
- Consult must be requested by another provider.
- Can be for a new or an exacerbated condition.
- Cannot be reported more than 1 time per 7 days for the same patient.

- Must report cumulative time spent, even if time occurs over multiple days.
- Cannot be reported if a transfer of care or request for face-to-face visit occurs as a result of the consultation within the following 14 days.
- Cannot be reported if the patient was seen by the consultant within the past 14 days.
- The request and reason for consultation is documented in the patient's medical record.
- Requires a minimum of 5 minutes of medical consultation, discussion and/or review

Requesting Providers (CPT 99452)

- Consult must be reported by requesting provider (not for the transfer of a patient or request for face-to-face consult)
- Reported only when the patient is not on-site with the requesting provider at the time of consultation
- Cannot be reported more than 1 time per 14 days per patient.
- Requires a minimum of 16 minutes. Includes time for referral prep and/or communicating with the consultant.
- Can be reported with prolonged services., non-direct

Limited information provided by one clinician to another that does not contribute to collaboration (e.g., interpretation of an electroencephalogram, report on an x-ray or scan, or reporting the results of a diagnostic test) is not considered a consultation.

Staff recommendations for new 8/14/2020 Prioritized List:

1) Revise Guideline Note A5 as shown below.
    a. Removing language tied to the Governor's emergency declaration
    b. Clearer delineation of the different sections, and what coverage criteria are related to each type of service.
    c. Removing two exclusion criteria related to the telephone/online codes (after review, these criteria may limit important care):
        i. Follow up of medical procedure to confirm stable condition, without indication of complication or new condition.
        ii. Brief discussion to confirm stability of chronic problem and continuity of present management.
    d. Modify the records retention requirements to refer to administrative rules.
    e. Correct the wording around SOAP model charting and clarify that the service must support the assessment and **treatment** plan (the word treatment was previously omitted).
2) Publish a new interim modification 8/14/2020 containing these changes, as well as the diagnostic guideline on COVID-19 testing and the coding changes made to the 3/13/2020 prioritized list.

ANCILLARY GUIDELINE A5, TELEHEALTH, TELECONSULTATIONS AND ONLINE/TELEPHONIC SERVICES

Telehealth services include a variety of health services provided by synchronous or asynchronous electronic communications, including secure electronic health portal, audio, or audio and video as well as remote monitoring devices.

Criteria for coverage

The clinical value of the telehealth service delivered must reasonably approximate the clinical value of the equivalent services delivered in-person.

Coverage of telehealth services requires the same level of documentation, medical necessity, and coverage determinations as in-person visits. Specifically, covered telehealth services must meet all of the following criteria.

A) Documentation must include all of the following:
   1) use SOAP model charting, or as described in program's OAR;
   2) include patient history, provider assessment, treatment plan and follow-up instructions;
   3) support the assessment and treatment plan;
   4) retain encounter in the patient's medical record and be retrievable for the duration required by administrative rules.

B) Include medical decision making or service delivery (e.g. behavioral health intervention/psychotherapy, other forms of therapy).

C) Include permanent storage (online or hard copy) of the encounter for the duration required by administrative rules.

D) Meet applicable HIPAA standards for privacy and security, except for regulations for which federal authorities are exercising enforcement discretion. (Certain requirements for encryption will not be enforced by federal authorities (or required by OHP) during the COVID-19 emergency.) This means services such as Facetime, Skype or Google Hangouts can be used for service delivery. See https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html for details.) HIPAA compliant platforms should be used whenever possible.

E) Include patient-clinician agreement of informed consent, discussed with and agreed to by the patient and documented in the medical record.

Examples of reimbursable telephone or online services include but are not limited to:

A) Extended counseling when person-to-person contact would involve an unwise delay or exposure to infectious disease.

B) Treatment of relapses that require significant investment of provider time and judgment.

C) Counseling and education for patients with complex chronic conditions.

Examples of non-reimbursable telehealth services include but are not limited to:

A) Prescription renewal.
B) Scheduling a test.
C) Reporting normal test results.
D) Requesting a referral.
E) Services which are part of care plan oversight or anticoagulation management (CPT codes 99339-99340, 99374-99380 or 99363-99364).
F) Services which relate to or take place within the postoperative period of a procedure provided by the physician are not separately covered. (Such a service is considered part of the procedure and is not be billed separately.)

Telehealth services billed using in-person codes

Telehealth services described in this section are synchronous services, generally provided with both audio and video capability and billed with the same procedure codes that would be billed for in-person services, with mode of delivery indicated by the use of specific modifiers and/or place of service codes specified by the plan. Telephone visits are an acceptable replacement for the equivalent service provided by synchronous audio and video, if synchronous audio and video capabilities are not available or feasible.

The patient may be in the community or in a health care setting. The provider may be in any location in which appropriate privacy can be ensured. If language services are provided, the interpreter may be in any location in which appropriate privacy can be ensured.

Codes eligible for telehealth delivery billed in this manner include 90785, 90791, 90792, 90832-90834, 90836, 90837-90840, 90846, 90847, 90951, 90952, 90954, 90955, 90957, 90958, 90960, 90961, 90963, 90964-90970, 96116, 96156-96171, 96160, 96161, 97802-97804, 99201-99205, 99211-99215, 99231-99233, 99307-99310, 99354-99357, 99406-99407, 99495-99498, G0108-G0109, G0270, G0296, G0396, G0397, G0406-G0408, G0420, G0421, G0425-G0427, G0438-G0439, G0442-G0447, G0459, G0506, G0508, G0509, G0513, G0514, G2086-G2088. Additional codes are covered when otherwise appropriate according to this guideline note and other applicable coverage criteria.

The originating site code Q3014 is covered only when the patient is present in an appropriate health care setting and receiving services from a provider in another location.

Telehealth services are covered for inpatient, outpatient and emergency services for new or established patients.

Clinician to Patient Services billed using specified codes indicating telephone or online service delivery

Telephonic and online services, including services related to diagnostic workup (CPT 98966-98968, 99441-99443, 99421-99423, 98970-98972, G2010, G2012, G2061-G2063) are covered for services for new and established patients.

Covered telephone and online services billed using these codes do not include either of the following:

A) Services related to a service performed and billed by the physician or qualified health professional within the previous seven days, regardless of whether it is the result of patient-initiated or physician-requested follow-up.
B) Services which result in the patient being seen within 24 hours or the next available appointment.

Clinician-to-Clinician Consultations (telephonic, online or using electronic health record)

Coverage of interprofessional consultations delivered online, through electronic health records or by telephone is included as follows:

Consulting Providers (CPT 99451, 99446-99449)

A) For new or established patients.
B) Consult must be requested by another provider.
C) Can be for a new or an exacerbated condition.
D) Cannot be reported more than 1 time per 7 days for the same patient.
E) Must report cumulative time spent, even if time occurs over multiple days.
F) Cannot be reported if a transfer of care or request for face-to-face visit occurs as a result of the consultation within the following 14 days.
G) Cannot be reported if the patient was seen by the consultant within the past 14 days.
H) The request and reason for consultation is documented in the patient's medical record.
I) Requires a minimum of 5 minutes of medical consultation, discussion and/or review.

Requesting Providers (CPT 99452)

A) Consult must be reported by requesting provider. (not for the transfer of a patient or request for face-to-face consult)
B) Reported only when the patient is not on-site with the requesting provider at the time of consultation.
C) Cannot be reported more than 1 time per 14 days per patient.

D) Requires a minimum of 16 minutes. Includes time for referral prep and/or communicating with the consultant.
E) Can be reported with prolonged services, non-direct.

Limited information provided by one clinician to another that does not constitute collaboration (e.g., interpretation of an electroencephalogram, report on an x-ray or scan, or reporting the results of a diagnostic test) is not considered a consultation.



Telehealth

Community partner and member experience findings

March-July 2020

Telehealth and teleservices Acknowledgement

- Telehealth has expanded access to essential health for many Oregonians who *can* access it
- Limits transmission risk of COVID-19 during stay at home orders
- Telehealth is allowing many Oregonians to access care when they need it in a way that works for them all while saving money on transportation and taking less time off work
- Supporting parents who don't have childcare to call their doctor from the convenience of their home
- Many Oregonians are benefiting from teleservices (SNAP, OHP, WIC) without risk of COVID exposure.

OHA CPOP partnerships March 2020-current

To build a strong, healthy Oregon, OHA CPOP is addressing the social determinants of health from a cross-sector approach thru partnerships.

OHA CPOP partnerships and strategies March 2020-current

Public Health and Office of Equity and Inclusion	• COVID-19 regional listening sessions online. Over 800 partners (including faith leaders) have registered for these sessions.
Oregon Employment Department	• Partnership with OED will ensure Oregonians are connected to employment resources thru community partner outreach
Oregon Department of Education	• Partnership with OED to ensure parents have access to employment benefits
Hunger free Oregon	• Partner with Hunger free Oregon to ensure Oregonians have access to food benefits through community partner work
Suicide Prevention Intervention and Postvention (S-PIP) workgroup	• Partners will reduce suicide risk factors by offering resources e.g. rent assistance connections, childcare resources, food, help with utilities

Who do OHA community partners serve?

- Oregonians enrolled in the Oregon Health Plan, Marketplace, underinsured and uninsured
- Homeless
- Tribal members
- Essential workers
- BIPOC
- Asian community
- Immigrant communities
- LGBTQ
- Justice Involved
- Vulnerable populations

Calling it out



Due to the digital divide, some Oregonians are struggling with getting health care and social services in a way that works for them

Systemic issues have created barriers for people who want to achieve their full health potential

Barriers and concerns from community partners

- No history or understanding of internet, phone and computer use
- In some cases, it's culturally inappropriate to engage with providers by phone or online
- For mental health, some people want in-person appointments. Most mental health providers are not meeting with patients in person right now
- Clients have privacy concerns with HIPPA Waiver for telehealth during emergency
- Some people don't believe in the seriousness of COVID because it has not impacted them or anyone they know, making it difficult to "buy into" telehealth
- Barriers for adults and children with ADHD, mental illness (visual or auditory hallucinations)
- People experiencing suicidal ideation (body language cues)

Barriers and concerns from community partners

- Some teens lack the privacy they need to talk with providers by phone or online
- Victims of domestic violence may also lack privacy at home and may need in-person appointments
- Homeless population doesn't have access to charging stations, tend to lose phones due to constant mobility, or they're often victims of theft. In Portland there is a lot of trauma and violence around protests and riots-making it difficult to concentrate and hear providers over the phone
- Telehealth appointments are challenging when an interpreter is needed
- Some providers are asking children to be interpreters and at times children are put in a position where they must use school borrowed technology and teach parents how to navigate phones or computers
- Not all CCOs have search functions online for clients to sort and filter and find providers who are offering in person appointments when needed

Testimonials from community partners

Based on CCO 2.0 focus groups and engagement. OHP clients want choice.

Tele-services: there are too many steps for some of our clients to get what they need. Fill out this form, upload that form, call this provider with your phone that has limited minutes and follow these steps. All the tele-steps make it overwhelming. Some of our clients feel defeated and run into set back after set back.

Testimonials from community partners

- *My job is to sign people up for OHP or and complete certain assessments, but right now I find myself doing things I'm not qualified to do. Some people can't complete a simple assessment on the phone (something that is required to speak with their mental health provider). I'm finding myself trying to de-escalate people's anger, stress or suicidal thoughts.*

- *I'm giving people hope that one day they will get to see their mental health provider in person again. People are holding onto that hope, but I'm not sure when they will get to see their provider face to face or how much longer clients can hang in there.*

Testimonials from community partners

At least 2/3 of my 50 cases or possibly higher report high anxiety and inability to sleep, increased stress, anxiety, depression and the host of other mental health issues related to inability to afford daily living expenses.

Another issue with immigrant families is the lack of cultural and linguistically appropriate mental health services. Some services are being treated through interpreters. This is a very ineffective way to treat mental health in this immigrant population.

Testimonials from clients and loved ones

- *One challenge I have with video is that the video is close to the health care provider. Seeing facial expressions zoomed in is out of context for professional interaction. It is confusing to only see the providers face and not see the rest of them. This is a burden for the patient trying to understand the provider's verbal messages and body language*. **-National Mental Illness Alliance Family to Family support group parent**

- *I need to establish care with a new mental health provider. I'm concerned because my CCO can't find me a mental health provider who will see me in person and I suffer from suicidal ideation, severe depression, ADHD. Phone and video appointments will not work for me. The delays in getting the care that works for me are concerning.* **–OHP Client with family advocate**

Testimonials from clients and loved ones

- *My doctor is insisting I upload my medical leave paperwork on an online portal, but I don't own a computer, libraries are closed, the employment office is closed, and I don't know how to upload documents. My provider is asking I get help from family/friends, I live alone, and we are supposed to be physical distancing. I get anxious about losing my job because everyone is so scared to get sick and insisting, I learn to use a computer.*

  –OHP client

- *My nephew has schitzoaffective disorder he is supposed to be seeing his mental health provider. He finds the telehealth appointments are not engaging and is not keeping them.*

  –-National Mental Illness Alliance Family to Family support group

Telehealth solutions

- Consider patient centered care by offering Oregonians a menu of health care delivery options while minimizing risk to COVID exposure
- Many CCOs offer sorting functions to find providers by language. Could CCOs also offer sorting options online to find providers who are offering both telehealth and in-person appointments?
- Ask CCOs to survey their members (in various languages) and get more data on telehealth- with the understanding that the hardest to reach communities may not respond.
- Ensure providers are paid the same for phone and video appointments to ease pressure for people who don't have access to data or a computer.
- Create work group of OHP members, community partners, telecommunications leaders to advise on telehealth and technology needs during COVID recovery period and after
- Offer guidelines for patients, medical providers and behavioral health providers to minimize risk of exposure during in-person appointments
    - COVID 19 guidance posters in clinic and in outdoor clinics e.g. masks, hygiene, cover your cough
    - Leverage summer months and offer outdoor clinics for people who can't utilize telehealth.

Telehealth and teleservices

- To build a strong, healthy Oregon, OHA CPOP is addressing the social determinants of health from a cross-sector approach. We can do this together.

- Continue sending us your creative ideas, barriers and let’s ensure all people and communities can achieve optimum physical, mental, and social well-being through partnerships, prevention, and access to quality, affordable health care.

Important links on the topic of barriers

- Requiring-video-calls-for-telemedicine-may-contribute-to-health-care-inequality
- COVID exposes the digital divide
- Disconnected-covid-19-the-digital-divide
- Telehealth has expanded access remains a problem

Thank you!

COVID-19 Changes for August 14, 2020 Prioritized List

Several changes were made to the Prioritized List effective March 13, 2020 due to the COVID-19 emergency. These changes were approved in consultation with HERC leadership. These were presented to VBBS and HERC at their joint meeting in May 2020. The document is to affirm these changes prior to publishing the August 14, 2020 Prioritized List which will contain several additional COVID-19 related changes (see separate issues).

In addition, on June 25th, 2020, the AMA released a new CPT code effective immediately for COVID-19 viral antigen testing. This is different from the PCR tests for detecting COVID-19. The antigen tests use ELISA or similar technology to detect a portion of the virus. HERC staff worked with the OHA senior health advisors on coverage of antigen testing—the recommendation was coverage particularly in resource poor settings. The test sensitivity is lower than for PCR, but the tests require less training/skill to run. HERC staff worked with HSD staff to add the antigen testing code (CPT 87426) on the Diagnostic Procedures file.

HERC staff recommendations:

1) Affirm the renaming of line 399
    a. 399 INFLUENZA, NOVEL RESPIRATORY VIRUSES
2) Affirm moving ICD10 J12.81 and B97.29 from line 304 VIRAL PNEUMONIA to line 399 INFLUENZA, NOVEL RESPIRATORY VIRUSES and the placement of the new code U07.1 on line 399

ICD-10-CM code	Code descriptions	Current Placement
J12.81	Pneumonia due to SARS-associated coronavirus	399 INFLUENZA, NOVEL RESPIRATORY VIRUSES
B97.29	Other coronavirus as the cause of diseases classified elsewhere	399 INFLUENZA, NOVEL RESPIRATORY VIRUSES
U07.1	COVID-19	399 INFLUENZA, NOVEL RESPIRATORY VIRUSES

3) Affirm the recommendations to HSD on the placement of the following new procedure codes

CPT code	Code descriptions	Current Placement	Notes
86328	Immunoassay for infectious agent antibody(ies), qualitative or semiquantitative, single step method (eg, reagent strip); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])	New code—May have limited clinical utility	Advise HSD to place on Diagnostic Procedure File
86769	Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])	New code—May have limited clinical utility	Advise HSD to place on Diagnostic Procedure File

COVID-19 Changes for August 14, 2020 Prioritized List

CPT code	Code descriptions	Current Placement	Notes
87426	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; severe acute respiratory syndrome coronavirus (eg, SARS-CoV, SARS-CoV-2 [COVID-19])	New code	Advise HSD to place on Diagnostic Procedure File
87635	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique	New code	Advise HSD to place on Diagnostic Procedure File
U0001	2019 Novel Coronavirus Real Time RT-PCR Diagnostic Test Panel (CDC test)	New code	Advise HSD to place on DIAGNOSTIC PROCEDURES
U0002	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19) using any technique, multiple types or subtypes (includes all targets).	New code	Advise HSD to place on DIAGNOSTIC PROCEDURES
U0003	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique, making use of high throughput technologies as described by CMS-2020-01-R	New code	Advise HSD to place on DIAGNOSTIC PROCEDURES
U0004	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCov (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC, making use of high throughput technologies as described by CMS-2020-01-R	New code	Advise HSD to place on DIAGNOSTIC PROCEDURES

4) Affirm the addition of Statement of Intent 6

STATEMENT OF INTENT 6: TELEPHONIC SERVICES DURING AN OUTBREAK OR EPIDEMIC
During an outbreak or epidemic of an infectious disease, reducing administrative barriers (e.g. increasing reimbursement rates) for telephonic evaluation and management services (CPT 99441-99443) and assessment and management services (CPT 98966-98968) is appropriate to ensure access to care while avoiding and preventing unnecessary potential infectious exposure.

Section 7.0

New Discussion Items

FIT-DNA Screening for Colorectal Cancer

Question: Should FIT-DNA testing be included on the Prioritized List for colorectal cancer screening?

Question source: Cologuard

Issue: FIT-DNA testing is a procedure in which stool is tested for fecal hemoglobin and 10 DNA cancer markers. It is a screening test for colorectal cancer. Currently, the Prioritized List includes colonoscopy, flexible sigmoidoscopy, and FIT (fecal hemoglobin) testing as screening options for colorectal cancer. Cologuard, which manufactures one type of FIT-DNA testing, is requesting a re-review of coverage for this modality. Currently, only Cologuard has an FDA approved test for fecal hemoglobin and DNA.

FIT-DNA testing (CPT 81528 Oncology (colorectal) screening, quantitative real-time target and signal amplification of 10 DNA markers (KRAS mutations, promoter methylation of NDRG4 and BMP3) and fecal hemoglobin, utilizing stool, algorithm reported as a positive or negative result) was reviewed as a new CPT code in November, 2015. At that time, this test was not recommended for routine screening by NCCN. CPT 81528 was placed on line 502 CONDITIONS FOR WHICH INTERVENTIONS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS.

Subsequently, colorectal cancer screening went through the coverage guidance process in 2017. The final conclusion of the coverage guidance was "Multitarget stool DNA testing for colorectal cancer screening (also known as Cologuard®, mt-sDNA, or FIT-DNA) is not recommended for coverage *(weak recommendation)*."

From the coverage guidance review

> Evidence is insufficient to establish any population screening benefit utilizing multi-target stool DNA testing (FIT-DNA). Sensitivity for detection of advanced colon adenomas is quite limited. Specificity for colorectal cancer is relatively low, which is likely to increase the need for additional work-up, with related cost and anxiety. No harms are evident with this testing modality, other than the risk of underdiagnosis of precancerous adenomas. Preferences weigh in favor of mt-sDNA as a noninvasive and safe testing strategy, but insufficient evidence of population benefit and the limited adenoma detection rate do not provide justification for the additional expenditures required for mt-sDNA coverage.

Current Prioritized List status

CPT 81528 (Oncology (colorectal) screening, quantitative real-time target and signal amplification of 10 DNA markers (KRAS mutations, promoter methylation of NDRG4 and BMP3) and fecal hemoglobin, utilizing stool, algorithm reported as a positive or negative result) is on line 502 CONDITIONS FOR WHICH INTERVENTIONS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS

FIT testing, flexible sigmoidoscopy and screening colonoscopy are on line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS

GUIDELINE NOTE 172, INTERVENTIONS WITH MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS FOR CERTAIN CONDITIONS

Line 502

The following interventions are prioritized on Line 502 CONDITIONS FOR WHICH INTERVENTIONS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS:

Procedure Code	Intervention Description	Rationale	Last Review
74263, 81528, 81327	Screening CT Colonography, FIT-DNA (Cologuard), mSEPT9, Chromoscopy	Insufficient evidence for use in population screening	September, 2017

Evidence

1) **Lin 2016**, USPSTF Systematic review of screening for colon cancer
    a. Only one stool test using stool DNA testing, the mtsDNA assay Cologuard® (Exact Sciences; Madison, WI), is available for clinical use. One fair-quality study (n=9,989) evaluated the mtsDNA assay compared to a commercial FIT and to colonoscopy, finding statistically significant improved performance for detection of CRC and advanced adenoma compared to OC FIT-CHEK. The increased sensitivity for CRC (92.3% [95% CI, 84.0 to 97.0]) and for advanced adenoma (42.4% [95% CI, 38.9 to 45.9]) compared to FIT is accompanied by reduced specificity (84.4% [95% CI, 83.6 to 85.1]) for CRC and 86.6% [95% CI, 85.9 to 87.2] for adenoma)
        i. Expected to result in a higher false positive rate than FIT testing
2) **Eckmann 2020**, cohort study of MT-sDNA screening
    a. Of 16,469 MT-sDNA tests completed, testing returned positive in 2,326 (14.1%) patients.
    b. Of the 1,558 patients who underwent diagnostic colonoscopy, any colorectal neoplasm was found in 1,046 (PPV=67%)
    c. Sessile serrated polyps of any size were found in 432 patients (PPV 28%, 95% CI [26, 31])
    d. Conclusion: MT-sDNA has a high PPV for any colorectal neoplasm. Adherence to diagnostic colonoscopy after positive MT-sDNA testing is high.
    e. Notes from CEBP staff:
        i. The PPV for any colorectal neoplasia was 67% and for advanced neoplasia was 28%
        ii. Other diagnostic operating characteristics can not be derived from this study
3) **Bosch 2019**, comparison study of MT-sDNA screening and FIT testing
    a. N = 1,047 patients
        i. Colonoscopy used as definitive test
        ii. All patients had both types of stool testing completed
    b. The MT-sDNA test was more sensitive than FIT alone in detecting advanced precancerous lesions (46% (55/119) vs 27% (32/119), respectively, P < 0.001). Specificities among individuals with nonadvanced or negative findings (controls) were 89% (791/888) and 93% (828/888) for MT-sDNA and FIT testing, respectively. A positive MT-sDNA test was associated with multiple lesions (P= 0.005), larger lesions (P=0.03), and lesions with tubulovillous architecture (P=0.04).
    c. The sensitivity of the MT-sDNA test or FIT in detecting individuals with high-risk advances adenomas (n = 19) from individuals with low-risk advanced adenomas (n = 52) was not significantly different.
    d. The specificity of single-application FIT was higher than the MTsDNA test among individuals without advanced colorectal neoplasia (93.2% vs 89.1%, respectively, P = 0.0003), but equal with the MT-sDNA test for individuals with negative findings only, e.g., no colorectal lesion of any type (94.7% vs 94.1%, respectively, P = 0.7).
    e. In conclusion, the MT-sDNA test combining DNA methylation and mutation markers with hemoglobin has a significantly increased sensitivity for advanced precancerous lesions than FIT alone at equal specificity, indicating
    f. Notes from the CEBP staff:
        i. Estimates of sensitivity and specificity of Cologuard and FIT for advanced adenoma are very similar to those reported in Imperiale, 2014 which was the basis of the prior coverage decision
        ii. Note that the cutoff for a positive FIT assay was 100 in the Imperiale study, and is reported here at 3 different cutoffs (50, 75, 100)

iii. While it's hard to make anything of the operating characteristics for detecting colorectal cancer given the small number of cases in this study, the sensitivity of FIT was better here compared with the Imperiale study and I would note that Cologuard would have missed 1 of the 7 CRC cases (which would have been detected by FIT50, but not at higher FIT cutoffs)

Expert recommendations

1) **USPSTF 2016**
    a. Recommended stool DNA testing as one option for colorectal cancer screening

FIT-DNA	Every 1 or 3 y	Test characteristic studies: Specificity is lower than for FIT, resulting in more false-positive results, more diagnostic colonoscopies, and more associated adverse events per screening test Improved sensitivity compared with FIT per single screening test	There is insufficient evidence about appropriate longitudinal follow-up of abnormal findings after a negative diagnostic colonoscopy; may potentially lead to overly intensive surveillance due to provider and patient concerns over the genetic component of the test

2) **NCCN 2020;** guideline for colorectal cancer screening
    a. FIT-DNA testing is listed as one option in their testing algorithm for average risk individuals ≥ age 50
        i. 3 year interval for testing (if negative)
        ii. One clinical effectiveness model found similar detection of colorectal cancer for FIT-DNA every 1 year compared to colonoscopy every 10 years; every 3 years showed a lower detection rate compared to colonoscopy

3) **US Multi-Society Task Force on Colorectal Cancer (MSTF) (American College of Gastroenterology [ACG], American Gastroenterological Association [AGA], and American Society for Gastrointestinal Endoscopy [ASGE]) 2019**
    a. Colonoscopy every 10 years or annual fecal immunochemical test (FIT) are the preferred (first-tier) methods of screening (strong recommendation; moderate-quality evidence).
    b. Computed tomography (CT) colonography every 5 years, FIT–fecal DNA test every 3 years (strong recommendation; low-quality evidence), and flexible sigmoidoscopy every 5 to 10 years (strong recommendation; high-quality evidence) are appropriate screening tests but are second tier because of disadvantages vs tier 1methods.
4) **ACP 2019**
    a. Clinicians should select the colorectal cancer screening test with the patient on the basis of a discussion of benefits, harms, costs, availability, frequency, and patient preferences. Suggested screening tests and intervals are fecal immunochemical testing or high-sensitivity guaiac-based fecal occult blood testing every 2 years, colonoscopy every 10 years, or flexible sigmoidoscopy every 10 years plus fecal immunochemical testing every 2 years.
    b. FIT Plus sDNA
        i. No RCT data were available to determine the clinical benefits, including effects on CRC incidence or CRC-related and all-cause mortality.
        ii. Concern for harms with lower specificity—more colonoscopies, more aggressive follow up if negative colonoscopy

Costs:
FIT: $12.37
FIT-DNA: list price of mt-sDNA (US $649)
Colonoscopy: $227.95 (plus other costs, such as prep, facility fees, and monitored sedation)

HERC staff summary:
MT-sDNA testing has advantages included a higher sensitivity that FIT testing and a lower screening frequency (3 yrs vs 1 yr for FIT); however, it has disadvantages included lower specificity that FIT testing which could result in more colonoscopies and has considerably higher cost than FIT testing. Newer cohort studies continue to find lower specificity of MT-sDNA compared to FIT. Expert groups are divided in their recommendations, with USPSTF and NCCN including MT-sDNA in their screening algorithms, but the gastroenterology and internal medicine societies not recommending MT-sDNA as first line screening modalities. MT-sDNA testing is significantly more expensive than FIT testing. The main change since MT-sDNA was last reviewed by HERC was the change of NCCN including this test in its algorithm as a screening option.

HERC staff recommendation:
1) Make no change in the current lack of coverage for MT-sDNA (see below)
    a. FIT, flexible sigmoidoscopy, and colonoscopy are all covered screening modalities on the Prioritized List
    b. MT-sDNA has lower cost effectiveness vs FIT

GUIDELINE NOTE 172, INTERVENTIONS WITH MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS FOR CERTAIN CONDITIONS

Line 502

The following interventions are prioritized on Line 502 CONDITIONS FOR WHICH INTERVENTIONS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS:

Procedure Code	Intervention Description	Rationale	Last Review
74263, 81528, 81327	Screening CT Colonography, FIT-DNA (Cologuard), mSEPT9, Chromoscopy	Insufficient evidence for use in population screening	September, 2017 August 2020 (Cologuard)

Evidence Synthesis

Number 135

Screening for Colorectal Cancer: A Systematic Review for the U.S. Preventive Services Task Force

Prepared for:
Agency for Healthcare Research and Quality
U.S. Department of Health and Human Services
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AHRQ Publication No. 14-05203-EF-1
June 2016

Structured Abstract

Objective: We conducted this systematic review to support the U.S. Preventive Services Task Force in updating its recommendation on screening for colorectal cancer (CRC). Our review addresses three questions: 1) What is the effectiveness of screening programs in reducing incidence of and mortality from CRC? 2) What are the test performance characteristics of the different screening tests for detecting CRC, advanced adenomas, and/or adenomatous polyps based on size? and 3) What are the adverse effects of the different screening tests, and do adverse effects vary by important subpopulations?

Data Sources: We updated our prior systematic review and searched MEDLINE, PubMed, and the Cochrane Central Register of Controlled Trials to locate relevant studies for all key questions, from the end of our prior review through December 31, 2014.

Study Selection: We reviewed 8,492 abstracts and 696 articles against the specified inclusion criteria. We carried an additional 33 studies forward from our prior review. Eligible studies included English-language studies conducted in asymptomatic screening populations age 40 years and older at average risk or unselected for risk factors.

Data Analysis: We conducted dual independent critical appraisal of all included studies and extracted all important study details and outcomes from fair- or good-quality studies. We synthesized results by key question and type of screening test. We primarily used qualitative synthesis. We used random-effects meta-analyses when appropriate. We also summarized the overall strength of evidence for each key question.

Results: *Key question 1.* We included 25 unique fair- to good-quality studies that assessed the effectiveness or comparative effectiveness of screening tests as a single application or in a screening program on CRC incidence and mortality. Based on four randomized, controlled trials (RCTs) (n=458,002), flexible sigmoidoscopy (FS) consistently decreased CRC-specific mortality compared to no screening at 11 to 12 years of followup (incidence rate ratio, 0.73 [95% CI, 0.66 to 0.82]). Based on five RCTs (n=404,396), biennial screening with the guaiac-based fecal occult blood test (Hemoccult II) compared to no screening resulted in reduction of CRC-specific mortality at 11 to 30 years of followup, ranging from 9 to 22 percentage points after two to nine rounds of screening. One prospective cohort (n=88,902) found that the CRC-specific mortality rate was lower at 24 years in persons who self-reported screening with colonoscopy (adjusted hazard ratio, 0.32 [95% CI, 0.24 to 0.45]) compared to those who had never had screening endoscopy.

Key question 2. We included 33 unique studies evaluating the one-time diagnostic accuracy of various screening tests compared to an adequate reference standard. Only four fair- to good-quality studies (n=4,821) reported the diagnostic accuracy of colonoscopy generalizable to community practice. Based on three studies comparing colonoscopy to CTC or CTC-enhanced colonoscopy (n=2,290), the per-person sensitivity for adenomas 10 mm or larger ranged from 89.1 percent (95% CI, 77.8 to 95.7) to 94.7 percent (95% CI, 74.0 to 99.9), and the per-person sensitivity for adenomas 6 mm or larger ranged from 74.6 percent (95% CI, 62.9 to 84.2) to 92.8 percent (95% CI, 88.1 to 96.0).

COLON

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Multitarget Stool DNA Screening in Clinical Practice: High Positive Predictive Value for Colorectal Neoplasia Regardless of Exposure to Previous Colonoscopy

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OBJECTIVES: **Multitarget stool DNA (MT-sDNA) testing has grown as a noninvasive screening modality for colorectal cancer (CRC), but real-world clinical data are limited in the post-FDA approval setting. The effect of previous colonoscopy on MT-sDNA performance is not known. We aimed to evaluate findings of colorectal neoplasia (CRN) at diagnostic colonoscopy in patients with positive MT-sDNA testing, stratified by patient exposure to previous colonoscopy.**

METHODS: **We identified consecutive patients completing MT-sDNA testing over a 39-month period and reviewed the records of those with positive tests for neoplastic findings at diagnostic colonoscopy. MT-sDNA test positivity rate, adherence to diagnostic colonoscopy, and the positive predictive value (PPV) of MT-sDNA for any CRN and neoplastic subtypes were calculated.**

RESULTS: **Of 16,469 MT-sDNA tests completed, testing returned positive in 2,326 (14.1%) patients. After exclusion of patients at increased risk for CRC, 1,801 patients remained, 1,558 (87%) of whom underwent diagnostic colonoscopy; 918 of 1,558 (59%) of these patients had undergone previous colonoscopy, whereas 640 (41%) had not. Any CRN was found in 1,046 of 1,558 patients (PPV = 67%). More neoplastic lesions were found in patients without previous colonoscopy (73%); however, the rates remained high among those who had undergone previous colonoscopy (63%, $P < 0.0001$). The large majority (79%) of patients had right-sided neoplasia.**

DISCUSSION: **MT-sDNA has a high PPV for any CRN regardless of exposure to previous colonoscopy. Right-sided CRN was found at colonoscopy in most patients with positive MT-sDNA testing, representing a potential advantage over other currently available screening modalities for CRC.**

SUPPLEMENTARY MATERIAL accompanies this paper at http://links.lww.com/AJG/B401, http://links.lww.com/AJG/B402, http://links.lww.com/AJG/B403

Am J Gastroenterol 2020;115:608–615. https://doi.org/10.14309/ajg.0000000000000546

INTRODUCTION

Colorectal cancer (CRC) is the second leading cause of cancer-related death in the United States (US) (1). Based on Surveillance, Epidemiology, and End Results (SEER) Program estimates, in 2019 alone, there will be over 145,000 new CRC diagnoses, with approximately 51,000 deaths attributed to CRC (2). Recent national trends demonstrate an overall decline in CRC mortality rates (2). This appears to be due in large part to the introduction of successful screening programs which have led to increased detection of precancerous colorectal neoplasia (CRN) and early stage CRC (3–5). However, approximately 1 in 3 screen-eligible adults has not participated in CRC screening, leaving over 23 million US adults without these benefits (6,7).

Colonoscopy, the most widely used screening modality in the United States, has been shown in observational studies to reduce mortality from CRC (6,8,9) but has important limitations. First, protective effects are reduced in the right colon compared with the left, believed to be largely because of missed lesions proximal

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Multitarget Stool DNA Test Performance in an Average-Risk Colorectal Cancer Screening Population

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INTRODUCTION: **We set out to evaluate the performance of a multitarget stool DNA (MT-sDNA) in an average-risk colonoscopy-controlled colorectal cancer (CRC) screening population. MT-sDNA stool test results were evaluated against fecal immunochemical test (FIT) results for the detection of different lesions, including molecularly defined high-risk adenomas and several other tumor characteristics.**

METHODS: **Whole stool samples (n = 1,047) were prospectively collected and subjected to an MT-sDNA test, which tests for *KRAS* mutations, *NDRG4* and *BMP3* promoter methylation, and hemoglobin. Results for detecting CRC (n = 7), advanced precancerous lesions (advanced adenoma [AA] and advanced serrated polyps; n = 119), and non-AAs (n = 191) were compared with those of FIT alone (thresholds of 50, 75, and 100 hemoglobin/mL). AAs with high risk of progression were defined by the presence of specific DNA copy number events as measured by low-pass whole genome sequencing.**

RESULTS: **The MT-sDNA test was more sensitive than FIT alone in detecting advanced precancerous lesions (46% (55/119) vs 27% (32/119), respectively, $P < 0.001$). Specificities among individuals with nonadvanced or negative findings (controls) were 89% (791/888) and 93% (828/888) for MT-sDNA and FIT testing, respectively. A positive MT-sDNA test was associated with multiple lesions ($P = 0.005$), larger lesions ($P = 0.03$), and lesions with tubulovillous architecture ($P = 0.04$). The sensitivity of the MT-sDNA test or FIT in detecting individuals with high-risk AAs (n = 19) from individuals with low-risk AAs (n = 52) was not significantly different.**

DISCUSSION: **In an average-risk screening population, the MT-sDNA test has an increased sensitivity for detecting advanced precancerous lesions compared with FIT alone. AAs with a high risk of progression were not detected with significantly higher sensitivity by MT-sDNA or FIT.**

SUPPLEMENTARY MATERIAL accompanies this paper at http://links.lww.com/AJG/B323, http://links.lww.com/AJG/B324

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INTRODUCTION

Colorectal cancer (CRC) is the third most common cancer and is one of the leading causes of cancer-related mortality (1). Although CRC incidence is increasing, a decrease in mortality has been observed due to the implementation of CRC screening and improved therapies (2,3). CRC screening not only leads to a reduction in morbidity and mortality but also to a lower CRC incidence when neoplastic lesions can be detected and removed at a premalignant stage (2). Therefore, CRC screening is considered cost-effective or even cost-saving (4).

Currently, colonoscopy is used for opportunistic screening programs in the United States, whereas in Europe, fecal immunochemical test (FIT) is the first choice for CRC screening in invitation-based screening programs. Both are considered cost-effective. Yet, FIT has suboptimal sensitivity for CRC (average 79%) and advanced adenomas (AAs; average 31%), precursor lesions with an increased risk of progression (5,6).

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US Preventive Services Task Force | RECOMMENDATION STATEMENT

Screening for Colorectal Cancer
US Preventive Services Task Force Recommendation Statement

US Preventive Services Task Force

IMPORTANCE Colorectal cancer is the second leading cause of cancer death in the United States. In 2016, an estimated 134 000 persons will be diagnosed with the disease, and about 49 000 will die from it. Colorectal cancer is most frequently diagnosed among adults aged 65 to 74 years; the median age at death from colorectal cancer is 73 years.

OBJECTIVE To update the 2008 US Preventive Services Task Force (USPSTF) recommendation on screening for colorectal cancer.

EVIDENCE REVIEW The USPSTF reviewed the evidence on the effectiveness of screening with colonoscopy, flexible sigmoidoscopy, computed tomography colonography, the guaiac-based fecal occult blood test, the fecal immunochemical test, the multitargeted stool DNA test, and the methylated *SEPT9* DNA test in reducing the incidence of and mortality from colorectal cancer or all-cause mortality; the harms of these screening tests; and the test performance characteristics of these tests for detecting adenomatous polyps, advanced adenomas based on size, or both, as well as colorectal cancer. The USPSTF also commissioned a comparative modeling study to provide information on optimal starting and stopping ages and screening intervals across the different available screening methods.

FINDINGS The USPSTF concludes with high certainty that screening for colorectal cancer in average-risk, asymptomatic adults aged 50 to 75 years is of substantial net benefit. Multiple screening strategies are available to choose from, with different levels of evidence to support their effectiveness, as well as unique advantages and limitations, although there are no empirical data to demonstrate that any of the reviewed strategies provide a greater net benefit. Screening for colorectal cancer is a substantially underused preventive health strategy in the United States.

CONCLUSIONS AND RECOMMENDATIONS The USPSTF recommends screening for colorectal cancer starting at age 50 years and continuing until age 75 years (A recommendation). The decision to screen for colorectal cancer in adults aged 76 to 85 years should be an individual one, taking into account the patient's overall health and prior screening history (C recommendation).

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Published online June 15, 2016. Last corrected on June 6, 2017.

Viewpoint page 2519 and **Editorial** page 2529

Author Audio Interview at jama.com

Related articles pages 2576 and 2595 and **JAMA Patient Page** pages 2635 and 2636

CME Quiz at jamanetworkcme.com

Related articles at jamaoncology.com jamainternalmedicine.com

Author/Group Information: The USPSTF members are listed at the end of this article.

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The US Preventive Services Task Force (USPSTF) makes recommendations about the effectiveness of specific preventive care services for patients without obvious related signs or symptoms.

It bases its recommendations on the evidence of both the benefits and harms of the service and an assessment of the balance. The USPSTF does not consider the costs of providing a service in this assessment.

The USPSTF recognizes that clinical decisions involve more considerations than evidence alone. Clinicians should understand the evidence but individualize decision making to the specific patient or situation. Similarly, the USPSTF notes that policy and coverage decisions involve considerations in addition to the evidence of clinical benefits and harms.

Summary of Recommendations and Evidence

The USPSTF recommends screening for colorectal cancer starting at age 50 years and continuing until age 75 years (A recommendation) (**Figure 1**).

The risks and benefits of different screening methods vary. See the Clinical Considerations section later in this article and the **Table** for details about screening strategies.

The decision to screen for colorectal cancer in adults aged 76 to 85 years should be an individual one, taking into account the patient's overall health and prior screening history (C recommendation).

- Adults in this age group who have never been screened for colorectal cancer are more likely to benefit.

JAMA Clinical Guidelines Synopsis

Colorectal Cancer Screening

Nina Gupta, MD; Sonia S. Kupfer, MD; Andrew M. Davis, MD, MPH

GUIDELINE TITLE Colorectal Cancer Screening: Recommendations for Physicians and Patients From the US Multi-Society Task Force on Colorectal Cancer

DEVELOPER US Multi-Society Task Force on Colorectal Cancer (MSTF) (American College of Gastroenterology [ACG], American Gastroenterological Association [AGA], and American Society for Gastrointestinal Endoscopy [ASGE])

RELEASE DATE June 9, 2017

PRIOR VERSION May 2008

TARGET POPULATION Adult patients being considered for colorectal cancer (CRC) screening

MAJOR RECOMMENDATIONS

- Screening should begin at age 50 years in average-risk persons (those without a high-risk family history) (strong recommendation; moderate-quality evidence), except in African American persons, in whom limited evidence supports screening starting at age 45 years (weak recommendation; very low-quality evidence).
- Persons with a family history of CRC or a documented advanced adenoma in a first-degree relative younger than 60 years or 2 first-degree relatives at any age are at higher risk and should undergo colonoscopy every 5 years, starting 10 years before the age at diagnosis of the youngest affected relative or at age 40 years, whichever is earlier (weak recommendation; low-quality evidence). (An advanced adenoma is ≥1 cm or with high-grade dysplasia or villous elements.) Persons with a single first-degree relative diagnosed at age 60 years or older should be screened starting at age 40 years (weak recommendation; very low-quality evidence).
- Colonoscopy every 10 years or annual fecal immunochemical test (FIT) are the preferred (first-tier) methods of screening (strong recommendation; moderate-quality evidence).
- Computed tomography (CT) colonography every 5 years, FIT–fecal DNA test every 3 years (strong recommendation; low-quality evidence), and flexible sigmoidoscopy every 5 to 10 years (strong recommendation; high-quality evidence) are appropriate screening tests but are second tier because of disadvantages vs tier 1 methods.
- Discontinuation of screening may be considered when a person with prior negative screenings reaches age 75 years or has less than 10 years of life expectancy (weak recommendation; low-quality evidence).

Summary of the Clinical Problem

Colorectal cancer is the fourth most diagnosed cancer and the second leading cause of cancer death in the United States. The majority of CRC is thought to arise from precancerous lesions called adenomas through the adenoma-carcinoma pathway.[1] Screening for and removing colon adenomas in asymptomatic individuals can reduce CRC incidence and mortality. Therefore, routine CRC screening is recommended for the general population.

Characteristics of the Guideline Source

This guideline[2] was developed by the MSTF, which consists of expert gastroenterologists representing the 3 major US gastroenterology societies: the ACG, the AGA, and the ASGE. The guideline was reviewed and approved by all 3 societies, and authors were required to disclose potential conflicts of interest.

Evidence Base

The MSTF performed a systematic review of articles related to CRC screening, supplemented by additional relevant articles found via manual review. The quality of evidence and strength of each recommendation were assessed using the GRADE system (**Table**).

Although randomized trial data are lacking, numerous cohort and case-control studies have shown an association between colonoscopy and decreased CRC incidence and mortality[3,4] leading to the recommendation for colonoscopy as first-tier CRC screening. The recommended 10-year interval is based on studies of the natural history of adenoma progression. Annual FIT is also supported as first-tier screening and is particularly suited to programmatic screening because of its noninvasive nature, low cost, and high sensitivity for CRC.[5,6]

The combination of FIT with an assay for DNA markers of CRC exfoliated into the stool at 3-year intervals is recommended by the MSTF as a second-tier screening method based on a study of 9989 average-risk patients who underwent colonoscopy as well as FIT and FIT–fecal DNA testing.[7] Compared with FIT testing alone, FIT–fecal DNA had a higher sensitivity for CRC (92% vs 74%) but lower specificity (87% vs 96%). The FIT–fecal DNA test is significantly more expensive than basic FIT alone and the MSTF concludes that annual FIT ($30 per year) is more cost-effective than FIT–fecal DNA every 3 years ($650).

Computed tomography colonography every 5 years is a second-tier screening recommendation. Sensitivity is high (82%-92%) for adenomas of 1 cm or larger[8] but has significantly lower sensitivity for

Table. Guideline Rating

Standard	Rating
Establishing transparency	Good
Management of conflict of interest in the guideline development group	Fair
Guideline development group composition	Poor
Clinical practice guideline-systematic review intersection	Good
Establishing evidence foundations and rating strength for each of the guideline recommendations	Fair
Articulation of recommendations	Good
External review	Fair
Updating	Fair
Implementation issues	Fair

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smaller adenomas and flat or serrated lesions. Flexible sigmoidoscopy every 5 to 10 years is also second tier based on randomized trials showing a 50% reduction in distal CRC incidence and a 25% reduction in overall CRC mortality.[2] However, its limited protection against right-sided CRC has limited widespread use in the United States.

The MSTF recommends starting CRC screening at age 50 years in most average-risk patients and suggests cessation of routine screening at age 75 years in patients with previous negative screening results. This decision should be individualized, taking into account patient preference; for instance, screening an active 80-year-old patient with no prior screening or avoiding screening in a 70-year-old patient with limited life expectancy. The task force now recommends that screening begin at age 45 years in African American patients. Although outcomes evidence is lacking, this recommendation is supported by the higher CRC incidence, increased prevalence of right-sided lesions, and lower mean onset age of CRC in African American individuals.[9]

Diagnosis of CRC in a first-degree relative before vs at or after age 60 years is used for risk stratification based on population-wide studies of CRC in patients with a positive family history.[10] Those with a first-degree relative diagnosed at or after age 60 years should start screening at age 40 years by any mode, without modifying screening frequency. Surveillance in conditions such as inflammatory bowel disease and genetic conditions such as Lynch syndrome are discussed elsewhere.

Benefits and Harms

A major advantage of colonoscopy over other screening methods is that diagnosis and treatment (polypectomy of precancerous lesions) can be performed in the same session. However, disadvantages include the need for bowel preparation, procedural risks (bleeding, perforation, aspiration), operator-dependent variability in adenoma detection, and expense.

FIT and FIT–fecal DNA testing do not require prep or carry procedural risk, can be less expensive, and are particularly appropriate for patients with multiple morbidities who are at high risk of complications from sedation and invasive testing. However, if stool-based screening is positive, subsequent colonoscopy is required, with attendant risks and costs. Computed tomography colonography also is noninvasive, although unlike FIT and FIT–fecal DNA testing, bowel preparation is generally still needed. Disadvantages of CT colonography include radiation exposure and incidental extracolonic findings.

Discussion

The guideline is similar to previously published versions from the MSTF but, importantly, differs in recommending 3 tiers of screening and in making weak recommendations for CRC screening in all African American individuals at age 45 years and a more detailed approach to screening for those with a positive family history.

The MSTF recommendations in this guideline are consistent with the US Preventive Services Task Force's (USPSTF's) 2016 grade A recommendation for CRC screening in average-risk individuals aged 50 to 75 years. However, the MSTF (and the USPSTF) recommendations differ from the American Cancer Society's 2018 CRC screening guideline update, which conditionally recommended CRC screening in all average-risk persons at age 45 years based on microsimulation modeling studies. All 3 guidelines acknowledge that screening decisions beyond age 75 years should be individualized.

Areas in Need of Future Study or Ongoing Research

A randomized trial of colonoscopy vs FIT in reducing mortality due to CRC in a US veteran population is ongoing (NCT01239082). Current screening guidelines are centered on detection of conventional adenomas because these lesions are thought to be precursors of about 70% of CRC.[2] Other precancerous polyps such as serrated adenomas account for up to 30% of CRC. These lesions are often flat and inconspicuous with few surface blood vessels and are harder to detect by any method. Further research is needed regarding the natural history of these lesions as well as optimal techniques for detection and management.

The increasing incidence of CRC in persons younger than 50 years warrants additional attention, along with improved population health approaches to unscreened persons in general.

Related guidelines and other resources

Colorectal cancer screening for average-risk adults: 2018 guideline update from the American Cancer Society

Screening for colorectal cancer: US Preventive Services Task Force recommendation statement (2016)

ARTICLE INFORMATION

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Conflict of Interest Disclosures: Dr Kupfer reported conduct of current research using Myriad Genetics data. No other disclosures were reported.

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Annals of Internal Medicine

CLINICAL GUIDELINE

Screening for Colorectal Cancer in Asymptomatic Average-Risk Adults: A Guidance Statement From the American College of Physicians

Amir Qaseem, MD, PhD, MHA; Carolyn J. Crandall, MD, MS; Reem A. Mustafa, MD, MPH, PhD; Lauri A. Hicks, DO; and Timothy J. Wilt, MD, MPH*; for the Clinical Guidelines Committee of the American College of Physicians*

Description: The purpose of this guidance statement is to guide clinicians on colorectal cancer screening in average-risk adults.

Methods: This guidance statement is derived from a critical appraisal of guidelines on screening for colorectal cancer in average-risk adults and the evidence presented in these guidelines. National guidelines published in English between 1 June 2014 and 28 May 2018 in the National Guideline Clearinghouse or Guidelines International Network library were included. The authors also included 3 guidelines commonly used in clinical practice. Web sites were searched for guideline updates in December 2018. The AGREE II (Appraisal of Guidelines for Research and Evaluation II) instrument was used to evaluate the quality of guidelines.

Target Audience and Patient Population: The target audience is all clinicians, and the target patient population is adults at average risk for colorectal cancer.

Guidance Statement 1: *Clinicians should screen for colorectal cancer in average-risk adults between the ages of 50 and 75 years.*

Guidance Statement 2: *Clinicians should select the colorectal cancer screening test with the patient on the basis of a discussion of benefits, harms, costs, availability, frequency, and patient preferences. Suggested screening tests and intervals are fecal immunochemical testing or high-sensitivity guaiac-based fecal occult blood testing every 2 years, colonoscopy every 10 years, or flexible sigmoidoscopy every 10 years plus fecal immunochemical testing every 2 years.*

Guidance Statement 3: *Clinicians should discontinue screening for colorectal cancer in average-risk adults older than 75 years or in adults with a life expectancy of 10 years or less.*

Ann Intern Med. 2019;171:643-654. doi:10.7326/M19-0642 **Annals.org**
For author affiliations, see end of text.

Colorectal cancer (CRC) is the second leading cause of cancer-related death in men and women in the United States. The goal of screening is to reduce overall and cancer-specific morbidity and mortality using strategies that have acceptable harms, burden, and costs. The typical pathogenesis of CRC is an adenomatous polyp that slowly increases in size and leads to dysplasia and cancer. Most CRC arises from colonic adenomas. However, 20% to 30% of CRC cases arise through pathways other than the adenoma–carcinoma sequence. Progression from adenoma to invasive cancer varies from 5 years or less to more than 20 years (1). The 10-year cumulative risk for progression to carcinoma is about 10%; some adenomas stabilize and others regress. Progression risk is related to number, size, and histology of adenomatous polyps (1).

Guidelines disagree on the age to start and stop screening, screening interval, and recommended screening method. Strategies differ in the quality of evidence regarding clinical effectiveness, harms, patient burden, recommended frequency of administration, and test accuracy. All strategies require adherence to the complete regimen of screening, follow-up testing, and treatment because benefits are accrued from identification and removal of precancerous lesions and localized cancer.

Purpose and Target Population

The goal of this American College of Physicians (ACP) guidance statement is to guide clinicians on age to start and stop CRC screening, frequency of screening, and optimal screening test in asymptomatic, average-risk adults, based on a critical review of existing guidelines and their evidence reviews. This guidance statement does not address surveillance in patients with previously detected adenomatous polyps or diagnosis in persons with signs or symptoms compatible with CRC. Evaluated screening tests include both stool-based tests (guaiac-based fecal occult blood test

See also:

Editorial comment 671
Summary for Patients I-22

Web-Only
Supplement

* This paper, authored by Amir Qaseem, MD, PhD, MHA; Carolyn J. Crandall, MD, MS; Reem A. Mustafa, MD, MPH, PhD; Lauri A. Hicks, DO; and Timothy J. Wilt, MD, MPH, was developed for the Clinical Guidelines Committee of the American College of Physicians. Individuals who served on the Clinical Guidelines Committee from initiation of the project until its approval were Timothy J. Wilt, MD, MPH† (*Chair*); Mary Ann Forciea, MD† (*Immediate Past Chair*); Carolyn J. Crandall, MD, MS†; Nick Fitterman, MD†; Lauri A. Hicks, DO†; Carrie A. Horwitch, MD, MPH†; Devan Kansagara, MD, MCR†; Jennifer S. Lin, MD, MCR‡; Michael Maroto, JD, MBA†§; Robert M. McLean, MD†; Reem A. Mustafa, MD, MPH, PhD†; Jairo Roa, MD†; Janice Tufte†§; and Sandeep Vijan, MD, MS‡. Approved by the ACP Board of Regents on 8 April 2019.

† Author (participated in discussion and voting).

‡ Nonauthor contributor (participated in discussion but excluded from voting).

§ Nonclinician public representative.

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This article has been corrected. The specific correction appears on the last page of this document. The original version (PDF) is available at www.annals.org.

Nerve Allografts

Question: Should nerve allografts be moved to a covered line on the Prioritized List?

Question source: Holly Jo Hodges, CCO medical director

Issue: Nerve allografts were reviewed in November 2017 as new CPT codes. At that time, an evidence search found only small case series. The review conclusion was "HERC staff summary: Nerve allografts appear to be an experimental therapy. Standard nerve autografts are covered for nerve injuries on the Prioritized List. NICE is currently reviewing decellular nerve allografts; this topic should be revisited when the NICE review is completed, and the results of the RANGER trial are published." The NICE review and the RANGER trial have both now been completed and published.

Nerve allografts involve the transplantation of a cadaver donor nerve (or nerve segment) into a recipient for the repair and closure of a nerve gap resulting from a peripheral nerve injury. Nerve allograft transplantation from cadavers offers an alternative without the morbidities associated with nerve autografts, but these grafts are rapidly rejected unless appropriate immunosuppression is achieved. There is a newer technology where the nerve allograft is processed to remove cellular components, and then acts as a substrate for the host to rebuild the nerve pathway. Such decellular nerve allografts do not require immunosuppression. Alternative therapies include nerve autograft (transplantation of nerve from elsewhere in the patient's own body), and synthetic nerve conduits for nerve regrowth.

Current Prioritized List status:
CPT **64912** Nerve repair; with nerve allograft, each nerve, first strand
CPT **64913** each additional strand

ICD10 S64.40X (Injury of digital nerve of unspecified finger) is on lines 207 DEEP OPEN WOUND, WITH OR WITHOUT TENDON OR NERVE INVOLVEMENT Treatment MEDICAL THERAPY, 509 PERIPHERAL NERVE DISORDERS and 536 PERIPHERAL NERVE DISORDERS Treatment SURGICAL TREATMENT

GUIDELINE NOTE 173, TREATMENTS THAT HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS; UNPROVEN TREATMENTS

The following treatments are prioritized on Line 660, CONDITIONS FOR WHICH CERTAIN TREATMENTS HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS; UNPROVEN TREATMENTS for the conditions listed here:

CPT/HCPCS code	INTERVENTION	Rationale	Date of last Review
64912-64913	Nerve repair; with nerve allograft	Unproven treatment	November, 2017

Nerve Allografts

Evidence

1) **Safa 2019**, RANGER trial
    a. Industry sponsored study
    b. Registry cohort study
    c. Outcome: "meaningful recovery, defined as ≥S3/M3"
    d. N=385 patients with 624 nerve repairs
        i. Subset of 1,041 patients (1,630 repairs) with sufficient assessments to determine the outcome of the repair
        ii. 86 sensory, 77 mixed, and 12 motor nerve repairs.
        iii. Nerve repairs occurred in the upper extremity, lower extremity, and head/neck regions of the body.
    e. 82% meaningful recovery (MR) was achieved across sensory, mixed, and motor nerve repairs up to gaps of 70 mm.
        i. 81% sensory meaningful recovery
        ii. 66% motor meaningful recovery
    f. Digital sensory repairs
        i. N=356, 84% had meaningful sensory recovery compared to 44-75% for conduit repair and 70-90% for autograph repair
        ii. Shorter graft lengths had significantly better recovery rates compared to lower graft lengths
    g. Adverse events
        a. There were 43 AEs reported in 39 subjects resulting in a 3.7% incidence rate by subjects. Twenty-three of these where considered serious events. The most common reported AE was neuroma at the repair site with 1.2% incidence rate followed by infection at the repair site at 0.9%. None of the AEs were determined to be related to the product but instead to the circumstances surrounding the original injury.
    b. Conclusions: These findings provide clinical evidence to support the continued use of PNA up to 70 mm in sensory, mixed and motor nerve repair throughout the body and across a broad patient population.
2) **NICE 2017**, processed nerve allografts
    a. Coverage decision:
        i. Current evidence on the safety and efficacy of processed nerve allografts to repair peripheral nerve discontinuities is adequate to support the use of this procedure for digital nerves
        ii. The evidence on the safety of processed nerve allografts to repair peripheral nerve discontinuities in other sites raises no major safety concerns. However, current evidence on its efficacy in these sites is limited in quantity. Therefore, for indications other than digital nerve repair, this procedure should only be used with special arrangements for clinical governance, consent and audit or research
    b. Evidence
        a. Digital nerve repair
            i. RCT of 23 patients with digital nerve repair comparing process nerve allograft vs bovine graft. The ability to discern the difference between 1 and 2 static pressure points) was statistically significantly better in the PNA group (n=5) than the $p<0.05$) at 12-month follow-up. In the same study, thermal sensation was totally different between the treatment (PNA group:

from 7% [1/14] to 100% [6/6] and bovine graft group: from 33% [3/9] to 100% [7/7]). bovine graft group (n=7; 5±1 mm versus 8±5 mm, p<0.05). In the same study, moving 2-point discrimination assessment (m2PD) was not statistically significantly different between the PNA group and the bovine graft group (5±1 mm versus 7±5 mm, p>0.05) at 12-month follow-up.

ii. Non-randomised comparative study of 153 patients needing digital nerve repair comparing PNA repair (n=72) with tension-free suture nerve repair (n=81), s2PD scores (excellent plus good, defined as the ability to distinguish between 2 static pressure points at a maximum distance of 15 mm) were not statistically significantly different between the PNA group (67% [48/72]) and the tension-free suture group (64% [52/81]) at 6-month follow-up (p=0.749).

iii. In a case series of 17 patients with digital nerve injuries treated by PNA grafting, s2PD was excellent or good in 78% (14/18) of digits repaired, at a mean follow-up of 15 months.

iv. In the RCT of 23 patients, Semmes–Weinstein monofilament test (testing of pressure threshold using a monofilament; range: 2.833=normal sensation to 6.650=residual sensation) was statistically significantly better in the PNA group than the treated bovine graft group (3.6±0.7 versus 4.4±1.4, improved from baseline at 12-month follow-up and not statistically significantly

b. Upper and lower extremity nerve allograft

i. Case series of 64 patients: meaningful recovery in 75% (48/64) of all patients.

ii. In an RCT of 23 patients, disability of the arm, shoulder and hand score (DASH: 0=no disability, 100=most severe disability) was not statistically significantly different between the PNA group (5±6.5) and the bovine graft group (8±6.3) at 12-month follow-up (p=0.318).

iii. In a case series of 108 patients needing nerve repair, there was no sensory recovery because of graft failure in 5% (4/76) of patients at last follow-up and surgical revision was needed.

iv. In the RCT of 23 patients, at 12-month follow-up, pain measured using a visual analogue scale (VAS, 0=no pain, 10=extreme pain) had improved from baseline in both groups (PNA group: from 4.7±3.4 to 0.5±0.6; treated bovine graft: from 4.4±2.1 to 0.9±1.0) but there was no statistically significant difference between the groups (p=0.432).

v. In another case series of 26 patients needing PNA after resection of neuromas of the foot and ankle, mean ordinal pain score (0=no pain to 10=worse pain) statistically significantly reduced from 7.5 points at baseline to 4.9 points at a mean 66-week follow-up (difference 2.6, range +2.0 to −8.0; p=0.016). In the same study, patient reported outcome measurement information system scores were used to assess the impact of pain on patients' behavior and daily function (reported as T-scores with a population mean of 50 and a standard deviation of 10). Pain behavior T-score decreased by 7.3 (range+2.0 to −22.0) from 63.0 at baseline (percentile decrease of 24%, p<0.003). Pain interference T-score decreased by 11.3 (range +2.0 to −27.0) from 68.0 at baseline (mean percentile change of 31%, p<0.003).

Other payer policies

1) **BCBS 2019**
    a. Peripheral Nerve Repair: There is insufficient scientific evidence in the peer-reviewed medical literature to support the efficacy of either acellular, allogeneic nerve grafts or nerve conduits for bridging defects resulting from peripheral nerve injuries. The published literature for processed, acellular nerve grafts consists of small case series and registry data, and for nerve conduits, a small randomized trial and small case series. Study limitations include non-standardized assessment of clinical outcomes, lack of comparator groups, small group size and lack of long-term follow-up.
2) **Aetna 2019**
    a. Considers peripheral nerve allografts to be experimental

HERC staff summary

The RANGER trial is a non randomized registry study with no comparison groups funded by industry. The RANGER trial found improvement in outcomes with all types of nerve allograft (sensory, motor, mixed) in multiple anatomic areas. The RANGER trial found the best outcomes for digital nerve repair, similar to the NICE evidence review. Smaller studies with randomized comparison groups find more mixed or negative results. NICE only recommends use of nerve allografts for digital nerve repair. Private insurers continue to find nerve allografts to be experimental.

HERC staff recommendations:

1) Add CPT 64912-64913 (Nerve repair; with nerve allograft) to line 536 PERIPHERAL NERVE DISORDERS Treatment SURGICAL TREATMENT
    a. Will pair with ICD10 S64.40X (Injury of digital nerve of unspecified finger)
    b. Consistent with our trusted source (NICE) and prioritization of relevant conditions
2) Add the following coding specification to line 536
    a. "CPT 64912-64913 is on this line only for pairing with ICD10 S64.40X"
3) Delete entry in GN173

GUIDELINE NOTE 173, TREATMENTS THAT HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS; UNPROVEN TREATMENTS

The following treatments are prioritized on Line 660, CONDITIONS FOR WHICH CERTAIN TREATMENTS HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS; UNPROVEN TREATMENTS for the conditions listed here:

CPT/HCPCS code	INTERVENTION	Rationale	Date of last Review
~~64912-64913~~	~~Nerve repair; with nerve allograft~~	~~Unproven treatment~~	~~November, 2017~~

Received: 26 June 2019 | Revised: 23 January 2020 | Accepted: 12 February 2020

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CLINICAL ARTICLE

MICROSURGERY WILEY

Peripheral nerve repair throughout the body with processed nerve allografts: Results from a large multicenter study

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Abstract

Background: Peripheral nerve damage resulting in pain, loss of sensation, or motor function may necessitate a reconstruction with a bridging material. The RANGER® Registry was designed to evaluate outcomes following nerve repair with processed nerve allograft (Avance® Nerve Graft; Axogen; Alachua, FL). Here we report on the results from the largest peripheral nerve registry to-date.

Methods: This multicenter IRB-approved registry study collected data from patients repaired with processed nerve allograft (PNA). Sites followed their own standard of care for patient treatment and follow-up. Data were assessed for meaningful recovery, defined as ≥S3/M3 to remain consistent with previously published results, and comparisons were made to reference literature.

Results: The study included 385 subjects and 624 nerve repairs. Overall, 82% meaningful recovery (MR) was achieved across sensory, mixed, and motor nerve repairs up to gaps of 70 mm. No related adverse events were reported. There were no significant differences in MR across the nerve type, age, time-to-repair, and smoking status subgroups in the upper extremity ($p > .05$). Significant differences were noted by the mechanism of injury subgroups between complex injures (74%) as compared to lacerations (85%) or neuroma resections (94%) ($p = .03$) and by gap length between the <15 mm and 50–70 mm gap subgroups, 91 and 69% MR, respectively ($p = .01$). Results were comparable to historical literature for nerve autograft and exceed that of conduit.

Conclusions: These findings provide clinical evidence to support the continued use of PNA up to 70 mm in sensory, mixed and motor nerve repair throughout the body and across a broad patient population.

1 | INTRODUCTION

Peripheral nerve damage due to traumatic injury is common and can result in loss of sensation and motor function impacting overall quality of life. Almost immediately after a nerve is severed, function directed by that nerve are lost unless proximal axon branches can be reconnected, which often requires appropriate surgical repair (Lundborg, 2000). While a tension-free direct repair with joints at extension is ideal, complex or extensive injuries may require a bridging material to support axonal regeneration across the nerve discontinuity for successful recovery (Lundborg, 2000; Mackinnon & Dellon, 1988).

Currently available bridging materials include nerve autografts, conduits, or processed nerve allografts (Dvali & Mackinnon, 2003; Safa & Buncke, 2016). Nerve autograft, preferred over a direct repair under tension, is a well-established method to manage nerve gap injuries (Safa & Buncke, 2016); however, there are drawbacks to this method. Nerve autografts require an additional surgical procedure, which increases costs, anesthesia time, surgical and healing complications (e.g., scarring, pain, and neuromas) (Ehretsman, Novak, & Mackinnon, 1999; Frykman & Gramyk, 1991; Ijpma, Nicolai, & Meek, 2006; Meek, Coert, & Robinson, 2005; Rappaport et al., 1993; Taras, Amin, Patel, & McCabe, 2013). Furthermore, tissue availability is limited and requires that a healthy, functional nerve be sacrificed to repair the damaged nerve. Conduits, hollow tubes made from various biological or synthetic materials, have been used clinically since the late 1990s. A recent systematic review found their outcomes to be highly variable and inconsistent from study to study with a recommendation for their use be limited to gaps <10 mm (Safa & Buncke, 2016). Recently, processed nerve allografts (PNAs) have been increasingly used as a viable option in clinical practice. These grafts possess many of the physiological characteristics of nerve autografts without the associated complications.

Avance® Nerve Graft (Axogen, Inc., Alachua, FL) is a decellularized, pre-degenerated, sterilized extracellular matrix (ECM) processed from donated human peripheral nerve tissue that serves as a scaffold for nerve regeneration. The benefits include a flexible, pliable, ECM that maintains the structure and laminin of native nerve, allows for revascularization and remodels into the patient's own tissue while supporting

NICE guidance

Processed nerve allografts to repair peripheral nerve discontinuities

Interventional procedures guidance
Published: 22 November 2017
www.nice.org.uk/guidance/ipg597

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Recommendations

1.1 Current evidence on the safety and efficacy of processed nerve allografts to

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repair peripheral nerve discontinuities is adequate to support the use of this procedure for digital nerves provided that standard arrangements are in place for clinical governance, consent and audit.

1.2 The evidence on the safety of processed nerve allografts to repair peripheral nerve discontinuities in other sites raises no major safety concerns. However, current evidence on its efficacy in these sites is limited in quantity. Therefore, for indications other than digital nerve repair, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.3 Clinicians wishing to do processed nerve allografts to repair peripheral nerve discontinuities in sites other than the digital nerves should:

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients understand the uncertainty about the procedure's efficacy on mixed nerve repair and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having processed nerve allografts to repair peripheral nerve discontinuities (see section 7.1).

1.4 This procedure should only be done by surgeons with training and experience in peripheral nerve repair.

1.5 Patient selection should take into consideration the site, type of nerve (motor, sensory, mixed) and the size of the defect.

1.6 NICE encourages further research into processed nerve allografts to repair peripheral nerve discontinuities. This should include information on the type of nerve repaired, the anatomical site, the size of the defect, patient reported outcome measures, functional outcomes, time to recovery and long-term outcomes (12 months to 18 months).

2 Indications and current treatments

2.1 Peripheral nerve damage can be caused by trauma or surgery, and can lead to reduced sensation and mobility of the affected limb or region. If direct repair is

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not possible because the section of nerve discontinuity is too long, grafts or artificial nerve conduits can be used.

2.2 Autologous nerve grafting (using another nerve from the same patient) is used most frequently (usually using the sural nerve from the leg). However, this can be associated with donor site morbidity. Untreated allografts (using a nerve from a donor) have also been used. However, postoperative immunosuppressive treatment is needed with untreated allografts.

3 The procedure

3.1 Acellular processed nerve allografts are nerves from deceased human donors that have had their immunogenic components removed using tissue processing techniques. They are stored frozen until implantation and are available in different sizes. Immunosuppressive treatment is not needed.

3.2 The procedure is done under general anaesthesia. The injured nerve is exposed, and the nerve ends are cleared of necrotic tissues and resected to allow for tension-free alignment with the graft. The graft is sutured to the exposed nerve ends. After grafting, limb splinting may be needed for several weeks to allow optimal nerve regeneration. The typical length of an allograft implant is 1 cm to 3 cm.

3.3 The aim of the procedure is to bridge the peripheral nerve discontinuity to allow axonal regeneration and growth through the allograft towards the distal nerve.

4 Efficacy

This section describes efficacy outcomes from the published literature that the committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the interventional procedure overview.

4.1 In a randomised controlled trial (RCT) of 23 patients needing digital nerve repair comparing processed nerve allograft (PNA) with treated bovine graft at 12-month follow-up, static 2-point discrimination assessment (s2PD, which tests the ability to discern the difference between 1 and 2 static pressure points) was statistically significantly better in the PNA group (n=5) than the

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bovine graft group (n=7; 5±1 mm versus 8±5 mm, p<0.05). In the same study, moving 2-point discrimination assessment (m2PD) was not statistically significantly different between the PNA group and the bovine graft group (5±1 mm versus 7±5 mm, p>0.05) at 12-month follow-up. In a non-randomised comparative study of 153 patients needing digital nerve repair comparing PNA repair (n=72) with tension-free suture nerve repair (n=81), s2PD scores (excellent plus good, defined as the ability to distinguish between 2 static pressure points at a maximum distance of 15 mm) were not statistically significantly different between the PNA group (67% [48/72]) and the tension-free suture group (64% [52/81]) at 6-month follow-up (p=0.749). In a case series of 17 patients with digital nerve injuries treated by PNA grafting, s2PD was excellent or good in 78% (14/18) of digits repaired, at a mean follow-up of 15 months. In the RCT of 23 patients, Semmes–Weinstein monofilament test (testing of pressure threshold using a monofilament; range: 2.833=normal sensation to 6.650=residual sensation) was statistically significantly better in the PNA group than the treated bovine graft group (3.6±0.7 versus 4.4±1.4, p<0.05) at 12-month follow-up. In the same study, thermal sensation was totally improved from baseline at 12-month follow-up and not statistically significantly different between the treatment (PNA group: from 7% [1/14] to 100% [6/6] and bovine graft group: from 33% [3/9] to 100% [7/7]).

4.2 In a case series of 64 patients needing nerve repair in the upper extremity and treated by grafting using PNA, there was meaningful recovery in 75% (48/64) of all patients. Univariate analysis showed that distal sites of injuries have a statistically significantly higher likelihood of recovery than proximal upper limb sites (odds ratio [OR] 5.606, 95% confidence interval [CI] 1.663 to 18.903; p<0.05). In the same study, discontinuities smaller than 30 mm had a statistically significantly greater likelihood of meaningful repair than those greater than 50 mm (OR 14.333, 95% CI 2.143 to 95.848; p<0.05). In a case series of 26 patients with lingual nerve and inferior alveolar nerve discontinuities treated by PNA grafting, meaningful sensory recovery was assessed using a neurosensory test improvement tool (ranging from normal=best, through mild, moderate and severe to complete=worse). At 12-month follow-up, neurosensory test improvement scores were normal in 52% (12/23), mild in 9% (2/23), moderate in 26% (6/23) and severe in 13% (3/23) of patients. In the same study, neurosensory improvement was reported in 86% (12/14) of patients with discontinuities 8–20 mm in length and 89% (8/9) of patients with discontinuities 30–70 mm in length.

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4.3 In the RCT of 23 patients, disability of the arm, shoulder and hand score (DASH: 0=no disability, 100=most severe disability) was not statistically significantly different between the PNA group (5±6.5) and the bovine graft group (8±6.3) at 12-month follow-up (p=0.318).

4.4 In a case series of 108 patients needing nerve repair, there was no sensory recovery because of graft failure in 5% (4/76) of patients at last follow-up and surgical revision was needed.

4.5 In the RCT of 23 patients, at 12-month follow-up, pain measured using a visual analogue scale (VAS, 0=no pain, 10=extreme pain) had improved from baseline in both groups (PNA group: from 4.7±3.4 to 0.5±0.6; treated bovine graft: from 4.4±2.1 to 0.9±1.0) but there was no statistically significant difference between the groups (p=0.432). In another case series of 26 patients needing PNA after resection of neuromas of the foot and ankle, mean ordinal pain score (0=no pain to 10=worse pain) statistically significantly reduced from 7.5 points at baseline to 4.9 points at a mean 66-week follow-up (difference 2.6, range +2.0 to −8.0; p=0.016). In the same study, patient reported outcome measurement information system scores were used to assess the impact of pain on patients' behaviour and daily function (reported as T-scores with a population mean of 50 and a standard deviation of 10). Pain behaviour T-score decreased by 7.3 (range+2.0 to −22.0) from 63.0 at baseline (percentile decrease of 24%, p<0.003). Pain interference T-score decreased by 11.3 (range +2.0 to −27.0) from 68.0 at baseline (mean percentile change of 31%, p<0.003). In a case series of 17 patients with digital nerve injury treated by grafting with PNA, pain (measured using a VAS: 0=no pain, 10=extreme pain) worsened in 1 patient (VAS score increased from 5 at baseline to 8 at 15-month follow).

4.6 In the non-randomised comparative study of 153 patients, difference in satisfaction rate was not statistically significantly different between the PNA group and the tension-free suture group (2.02%, 95% CI −6.07 to 10.87) at 6-month follow-up.

4.7 The specialist advisers listed key efficacy outcomes as re-innervation of target organs, nerve regeneration rate, clinical sensory and motor outcome scales, and patient reported outcomes.

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5 Safety

This section describes safety outcomes from the published literature that the committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the interventional procedure overview.

5.1 Tenolysis was needed in 3% (2/78) of patients at 6-month follow-up in a non-randomised comparative study of 153 patients needing digital nerve repair comparing processed nerve allograft (PNA) repair (n=72) with tension-free suture nerve repair (n=81).

5.2 Neuroma was reported after 1 nerve repair of 132 nerves in a case series of 108 patients needing nerve repair.

5.3 Local infection that improved after treatment (not specified) was reported in 1 patient in a case series of 15 patients treated by PNA grafting.

5.4 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers listed the following anecdotal adverse events: immunological reaction or rejection, and inflammatory reaction to preservatives. They considered that the following were theoretical adverse events: immunological reaction or rejection, inflammatory reaction to preservatives and sub-optimal results because of preference in using the allograft when patients could be treated by more established interventions.

6 Committee comments

6.1 The grafts used in this procedure are regulated by the Human Tissue Authority.

6.2 The grafts can be used in a variety of anatomical sites but most published evidence reviewed by the committee came from the repair of digital nerves.

6.3 The type of nerve being repaired (motor, sensory, mixed) and the size of the defect potentially affect the outcome.

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6.4 The use of this type of graft avoids the need to harvest a donor nerve from the same patient, and avoids the use of non-human-derived tissue and immunosuppression.

7 Further information

7.1 This guidance requires that clinicians doing the procedure make special arrangements for audit. NICE has identified relevant audit criteria and has developed an audit tool (which is for use at local discretion).

7.2 Patient commentary was not sought because the procedure is only being done in research setting in the UK.

7.3 For related NICE guidance, see the NICE website.

Information for patients

NICE has produced information on this procedure for patients and carers (information for the public). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

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Accreditation



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Simultaneous Kidney Liver Transplant

Question: Should indications for simultaneous kidney liver transplant be broadened on the Prioritized List?

Question source: Scott Naugler, MD, OHSU transplant medicine

Issue: Currently, the indications for simultaneous kidney liver transplant are limited on the Prioritized List to ICD10 Q44.6 (Cystic disease of liver), which is most commonly used for Caroli disease. Caroli disease is a rare inherited disorder characterized by cystic dilatation of the bile ducts within the liver. Caroli disease is also associated with liver failure and polycystic kidney disease.

From Dr. Naugler:

> Authorization for combined liver and kidney transplant. As it stands, the only code for which this is authorized is "Caroli's Disease." The truth is that this indication is so rare that I've never seen a patient transplant for it. However, we see a reasonable number of patients who need simultaneous liver and kidney transplants, a routine practice here and around the country. When such a patient comes through, we are always denied authorization stating the above ("only authorized for Caroli's Disease"), and the ensuing struggle (even to talk to someone) is monumental, frustrating, and sometimes results in bad outcomes for patients due to time lag. We need to work on changing this policy, and I would be happy to help with the language, etc.
>
> From Dr. Naugler:11 simultaneous liver kidney transplants have been done at OHSU from 2014-2019 (all payers). Only OHSU is accredited to do liver transplants in Oregon

HSC/HERC history

For many years, there was a transplant algorithm on the Prioritized List that included requirements for studies with more than 50 patients supporting the transplant, certain 3 and 5 year survival outcomes, and other criteria. There was wording in this algorithm limiting simultaneous solid organ transplants to certain situations. There was a transplant advisory group that helped to evaluate this algorithm and general OHP transplant coverage. At some point, this algorithm was deleted, although it is not clear from the minutes when this deletion occurred.

In 2009, second solid organ transplants were discussed and coverage for second solid organ transplants was added. As part of this discussion, the HSC decided to not dictate coverage in this area, but rather to leave decisions to national organ allocation groups, such as UNOS, and local transplant centers.

Review of the minutes from HSC and HOSC could not find mention of why Caroli's syndrome (ICD-10 Q44.6) was the only diagnosis included for liver-kidney transplant.

Simultaneous Kidney Liver Transplant

Current Prioritized List status

Line: 307

Condition: CIRRHOSIS OF LIVER OR BILIARY TRACT; BUDD-CHIARI SYNDROME; HEPATIC VEIN THROMBOSIS; INTRAHEPATIC VASCULAR MALFORMATIONS; CAROLI'S DISEASE (See Coding Specification Below)

Treatment: LIVER TRANSPLANT, LIVER-KIDNEY TRANSPLANT

ICD-10: I82.0,K65.2,K70.2,K70.30-K70.31,K74.0,K74.3-K74.5,K74.60-K74.69,K76.81,P59.1,P59.20-P59.29,P76.8-P76.9,P78.1,P78.81,P78.84,Q44.6,T86.40-T86.49,Z48.22-Z48.23,Z48.288, Z52.6

CPT: 47133-47147,50300,50323-50365,76776,86825-86835,93792,93793,96156-96159,96164-96171,98966-98972,99051,99060,99070,99078,99184,99201-99239,99281-99285,99291-99404,99408-99449,99451,99452,99468-99472,99475-99480,99487-99491,99495-99498, 99605-99607

HCPCS: G0068,G0071,G0248-G0250,G0396,G0397,G0406-G0408,G0425-G0427,G0463-G0467, G0490,G0508-G0511,G2010-G2012,G2058-G2065

Liver-kidney transplant only included on this line for a documented diagnosis of Q44.6 (cystic disease of the liver).

Other multiple organ transplant lines

1) Line 83 DIABETES MELLITUS WITH END STAGE RENAL DISEASE, Treatment: SIMULTANEOUS PANCREAS/KIDNEY (SPK) TRANSPLANT, PANCREAS AFTER KIDNEY (PAK) TRANSPLANT
    a. Coding specifications: SPK included for type I diabetes mellitus with end stage renal disease (E10.2), PAK only included for other type I diabetes mellitus with secondary diagnosis of Z94.0.
2) Line 239 SHORT BOWEL SYNDROME Treatment: INTESTINE AND INTESTINE/LIVER TRANSPLANT
    a. No coding specifications
    b. Guideline specifying when intestinal transplant is included on line
3) Line 240 CONDITIONS REQUIRING HEART-LUNG AND LUNG TRANSPLANTATION Treatment: HEART-LUNG AND LUNG TRANSPLANT
    a. No coding specifications or guidelines
4) Line 264 CONGESTIVE HEART FAILURE, CARDIOMYOPATHY, MALIGNANT ARRHYTHMIAS, AND COMPLEX CONGENITAL HEART DISEASE Treatment: CARDIAC TRANSPLANT; HEART/KIDNEY TRANSPLANT
    a. GUIDELINE NOTE 70, HEART-KIDNEY TRANSPLANTS
    Line 264

    Patients under consideration for heart/kidney transplant must qualify for each individual type of transplant under current DMAP administrative rules and transplant center criteria with the exception of any exclusions due to heart and/or kidney disease. Qualifying renal disease is limited to Stage V or VI.

Simultaneous Kidney Liver Transplant

Expert guidelines

1) **UNOS 2015,** Simultaneous Liver Kidney (SLK) Allocation Policy
    a. There seems to be a survival advantage of receiving a kidney along with the liver over receiving a liver alone, but only for those with renal failure.
    b. Recommend that for patients receiving a liver transplant, simultaneous kidney transplant should be considered for those patients who have:
        i. chronic renal disease requiring dialysis,
        ii. acute kidney injury requiring dialysis for 6 weeks or longer, or
        iii. one of the following metabolic diseases: Hyperoxaluria, atypical HUS from mutations in factor H and possibly factor I, familial non-neuropathic systemic amyloid, or methylmalonic aciduria

HERC staff summary

The HERC has relied on UNOS and the transplant centers to determine eligibility for organ transplant for some time. The current restriction on simultaneous liver kidney transplant contradicts UNOS recommendations and does not appear to be evidence based or sensible with advances in transplant outcomes in the last decade. Other lines with multiple organ transplants that include any restrictions are more general (e.g. "end stage renal disease"}.

HERC staff recommendation:

1) Delete the coding specification from line 307 and allow simultaneous liver-kidney transplant at the transplant center's clinical discretion. Not likely to be overutilized. Transplant centers can use UNOS criteria and their clinical best practices
    ~~a. Liver-kidney transplant only included on this line for a documented diagnosis of Q44.6 (cystic disease of the liver).~~

OPTN/UNOS Kidney Transplantation Committee

Simultaneous Liver Kidney (SLK) Allocation Policy

Prepared by:
Gena Boyle
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Simultaneous Liver Kidney (SLK) Allocation Policy

Executive Summary

Current OPTN policy prioritizes candidates seeking a simultaneous liver kidney (SLK) transplant *before* pediatric and adult transplant candidates who are listed only for a kidney ("kidney alone candidates") when the liver candidate and the deceased donor are in the same Donation Service Area (DSA). Unlike kidney alone allocation, in SLK allocation, the kidney is not allocated based on medical criteria assessing the kidney function of the candidate. Instead, geographic proximity between the liver-kidney candidate and the donor is the single factor for allocating the kidney with the liver. Organ Procurement Organizations (OPOs) are not required to allocate the kidney with the liver to a regional SLK candidate, although they have the discretion to do so.

The Kidney Transplantation Committee ("the Committee"), has identified several problems with this current policy:

- The current policy for SLK allocation is counter to requirements in the OPTN Final Rule ("Final Rule") specifying that organ allocation policies be based on sound medical judgment and standardized criteria. These requirements are in place to ensure equity and efficiency in the U.S. organ allocation system—to promote a system where all candidates are assessed and organs are allocated equitably based on some level of medical need.
- The lack of medical criteria results in the allocation of high quality kidneys to liver candidates who may regain renal function after liver transplant and decreased access for kidney alone candidates who would otherwise be highly prioritized in deceased donor kidney allocation.
- The lack of consistency for regional SLK allocation has been a tremendous concern for the liver transplant community, as deceased donor liver allocation prioritizes candidates with a certain medical urgency status or Model End Stage Liver Disease Score (MELD) score or Pediatric End Stage Liver Disease (PELD) score for regional allocation but regional SLK allocation is not required.

In order to provide more clarity and consistency in the rules for SLK allocation, the Committee is proposing the following new policies:

- Establish medical eligibility criteria for candidates seeking an SLK transplant. Because there is somewhat limited data to establish new rules, the Committee has relied on clinical consensus and feedback from experts in kidney and liver transplantation to establish the criteria.
- Establish a "safety net" (some match classification priority on the kidney alone waiting list for liver recipients with continued dialysis dependency or kidney dysfunction in the first year after liver transplant) as an added element to address concerns about limitations associated with the SLK medical eligibility criteria.

This proposal reflects feedback from the 11 OPTN regions, several professional transplant societies, patient advocacy groups, and various OPTN/UNOS committees. The proposal is intended to further the OPTN strategic goal to "provide equity in access to transplants" by addressing the objective to "establish clearer rules for allocation of multiple organs to a single candidate, especially liver-kidney candidates."

Because there is a tremendous amount of transplant community interest in the development of this policy and a need to ensure a high level of consensus for the final product, the Committee may utilize the Fall 2015 and Spring 2016 public comment periods to receive input on these changes, with an expectation that the OPTN/UNOS Board of Directors will consider final adoption at the June 2016 Board meeting.

Section 8.0

Coverage Guidances

Overview of Planned Out-Of-Hospital Birth

Value-based Benefits Subcommittee

Health Evidence Review Commission

August 13, 2020

Oregon Health Authority

High-level issues

- Out-of-hospital birth (OOHB) is generally safe and has benefits for women (e.g. fewer c-sections)
- Maternal and neonatal birth outcomes and safety related to birth settings continue to be a focus in Oregon
- Requirements for licensure for OOHB attendants vary and are set by a variety of professional boards
- OOHBs and birth attendants are not always well-integrated into hospital birth model in Oregon
- There are continued quality improvement efforts underway related to birth outcomes in Oregon, including but not limited to a focus on coordination between out of hospital providers and hospitals

Oregon OOHB Policy History 1993-2013

1993 legislation

- Created the Board of Direct Entry Midwifery (DEM board/LDM board); licensure was voluntary
- Oregon Medicaid coverage of OOHB began

2011 legislation

- Oregon Birth Certificate added intended location of the birth and the intended birth attendant
- Limited liability language to protect hospitals and physicians against risk following a patient transfer

2012-13

- Oregon Public Health Division reported a higher observed perinatal mortality rate among OOHBs compared to hospital births
- Legislation creating mandatory licensure of LDMs

Oregon OOHB Policy History 2014-2018

2014 Workgroup

- OHA created OOHB staff advisory workgroup; 8 recommendations
- Recommendation for OHP to cover only low-risk OOHB, HERC to create coverage guidance
- FFS option (Most CCOs did not and do not cover OHP OOHB)

2014-15 HERC

- HERC coverage guidance "Planned Out-of-Hospital Birth," defining low/high risk in detail
- Based on limited evidence as well as practices in other settings
- Implemented in Jan. 2016 as Guideline Note 153 in OHP

2017-18

- Out-of-Hospital Births workgroup published report; launched PA process review
- Public health report on out-of-hospital birth trends in Oregon 2012-2017 (published December 2018).
- Prior Authorization Workgroup recommendations addressed transparency, communication and process

HERC Coverage Guidance History

- 2015 coverage guidance
  - Contains many detailed criteria based on international guidelines as well as evidence
- In 2018, several stakeholders raised concerns
  - Concerns about new potential risk factors
  - Providers felt implementation was burdensome and inappropriately restricted care
  - EbGS recommended no review, but after hearing testimony, HERC requested a new review

OHP OOHB Policy History 2020

- From disenrollment to carveout
  - Previously, OOHB had been covered by transferring the mother to FFS/Open Card Medicaid then back to CCO at birth
    - Care was disrupted
  - Transition to carveout benefit
    - FFS pays for the OOHB costs
    - CCOs are responsible for coordinating other care for the mother and all care for the newborn

OHP OOHB Policy History 2020

- During COVID-19 emergency
  - OHP has adopted emergency rules regarding the PA criteria for OOHB that provide further flexibility during the COVID-19 pandemic, taking into consideration provider/hospital capacity, visitation guidelines and patient concerns regarding exposure to COVID-19
  - Based on the draft CG changes posted prior to the June 2020 EbGS meeting
  - OHA Health Services Division currently allows initiation of OOHB until 34 weeks (was previously 28 weeks)
  - Rule will be made permanent and revised if needed

Original Goals of Coverage Guidance Re-review

- Update list of high-risk coverage exclusion criteria based on evidence and guidelines
- Update list of consult and transfer criteria
  - Based on guidelines from locations with high quality out-of-hospital birth systems
  - Make the list of risk factors for consult and transfer more straightforward to implement, if possible

2019-20 EbGS Process Overview

- EbGS process began February 2019
  - Two orientation meetings
  - Added criteria from other sources
  - Reviewed updated evidence
  - Posted for comment first time
  - Based on comments, removed many criteria for several reasons
    - Already part of licensing standards
    - Difficult to implement, PA process and consultations burdensome
    - Criteria were vague, subject to interpretation, not considered appropriate for coverage, were more like a clinical guideline or practice standard
    - Removed all neonatal criteria
  - Posted for comment again
    - More limited changes to specific criteria

Scope Statement

- Population
  - Pregnant women
- Interventions
  - Planned out-of-hospital birth (home or birth center)
- Comparators
  - Planned birth in a hospital

Scope Statement

- Critical Outcomes
  - Delivery mode (cesarean, operative vaginal delivery, spontaneous vaginal delivery)
  - Perinatal mortality
  - Serious neonatal morbidity (e.g., seizures, NICU admission, low Apgar scores, hypoxic ischemic encephalopathy, sepsis)
  - Serious maternal harm (e.g., postpartum hemorrhage, serious infection, mortality)
- Important Outcomes
  - Breastfeeding

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Evidence Sources

- 42 comparative observational studies
  - 7 U.S. of good (1), fair (2), poor (4) methodological quality
  - 35 Non-U.S. of good (5), fair (9), poor (21) methodological quality
- 14 noncomparative observational studies, all poor methodological quality
  - 7 U.S. studies
  - 6 non-U.S. studies
  - 1 used combination of Canadian and U.S. data

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Guideline and Policy Sources

- American Academy of Pediatrics (AAP) (2016)
- American Association of Birth Centers (AABC) (2017)
- American College of Nurse Midwives (ACNM) (2015)
- American College of Obstetricians and Gynecologists (ACOG) (2017)

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Guideline and Policy Sources

- National Institute for Health and Care Excellence (NICE) (2017)
- Society of Obstetricians and Gynecologists of Canada (SOGC) (2019)
- Oregon Health Authority's State Board of Direct Entry Midwifery
- Washington Medicaid's *Planned Home Births & Births in Birthing Centers Billing Guide* (January 2019)

OOHB: U.S. vs. International Context

- Applying a proposed framework for OOHB integration (Comeau et al., 2017)
  - Recognition through regulation and legislation
  - Receipt of formal training
  - Suitable access to hospital facilities
    - Established system for emergency transport
    - Ability to provide care after emergency transport
  - Carries emergency equipment and supplies
- Well-integrated:
  - British Columbia, England, Iceland, Netherlands, New Zealand, Ontario, Washington State

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OOBH: Oregon Context

- *Intended* home or birth center birth
  - 14 licensed birth centers in Oregon (as of 4/29/20)
- OOHB decreasing slightly in Oregon
  - 4.6% (2012) to 4.1% (2017)
- Nationally, OOHB increased from 2004 to 2017

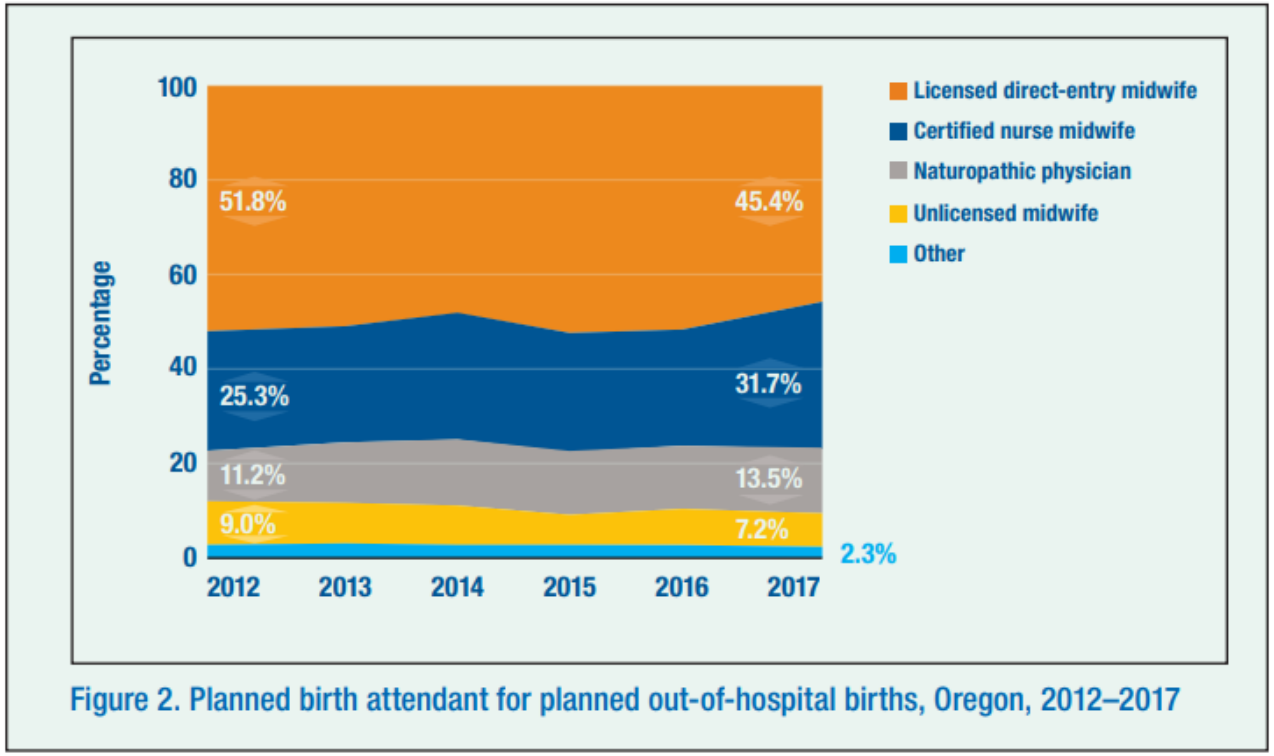

Figure 2. Planned birth attendant for planned out-of-hospital births, Oregon, 2012–2017

(MacDorman & Declercq, 2018)

Source: Oregon Health Authority, Out-of-hospital births in Oregon: 2012-2017

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OOHB: U.S. vs International, continued

- In countries with integrated registries, clinical information (e.g., gestational diabetes) adds useful detail to vital statistics data
  - Provide additional stratification by risk factors
- Population-level comparative registries not widely available in U.S.

Outcome: Mode of Delivery

●●○○ Low confidence that planned out-of-hospital birth is associated with improved delivery mode outcome compared to planned in-hospital birth, based on 4 good- or fair-methodological-quality observational studies, 1 from U.S.

GRADE Table: Mode of Birth

	Planned home or birth center vs. Planned hospital	
	U.S. Studies	**Non-U.S. Studies**
Nonoperative Vaginal Delivery	1 study 93.8% vs. 71.9% RD = 27.5 more NNT = 3 aOR 5.63, 95% CI 4.84 to 6.55	3 studies 81% to 92.8% vs. 64.7% to 86% RD = 3.0 to 19.0 NNT range from 5 to 33 aOR range from 1.57 to 3.61

GRADE Table: Mode of Birth

	Planned home or birth center vs. Planned hospital	
	U.S. Studies	**Non-U.S. Studies**
Cesarean Delivery	1 study 5.3% vs. 24.7% RD = 19.4 more NNT = 5 aOR = 0.18, 95% CI 0.16 to 0.22	2 studies 2.8% to 4.0% vs. 11.1% to 11.7% RD range from 7.6 to 8.3 more NNT range from 12 to 13 aOR range from 0.31 to 0.76

Outcome: Perinatal or Neonatal Mortality

●○○○ Very low confidence that planned out-of-hospital birth is associated with increase perinatal or neonatal mortality, based on 4 good- or fair-quality observational studies, 2 from U.S.

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GRADE Table: Mortality

	Planned home or birth center vs. Planned hospital	
	U.S. Studies	**Non-U.S. Studies**
Perinatal or Neonatal Mortality	Neonatal death from 0 to 27 days (2 studies) 0.12% to 0.16% vs. 0.03% to 0.06% RD from 0.09 to 0.1 more NNH range from 1,111 to 1,000 SMR 4.13, 95% CI 3.38 to 4.88; aOR 2.87, 95% CI 1.10 to 7.47 Perinatal death (≥ 20 weeks through 27 days of life) (1 study) 0.39% vs. 0.18%; RD = 0.15, NNH= 666; aOR 2.43, 95% CI 1.37 to 4.30	Intrapartum or neonatal death from 0 to 7 days (2 studies) 0.06% to 0.15% vs. 0.01% to 0.18% Adjusted odds ratios not statistically significant across both studies

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Outcome: Neonatal Morbidity

●○○○ Very low confidence that planned out-of-hospital birth associated with increased neonatal morbidity, based on 4 good- or fair-quality observational studies, 1 from U.S.

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GRADE Table: Neonatal Morbidity

	Planned home or birth center vs. Planned hospital	
	U.S. Studies	**Non-U.S. Studies**
Apgar < 7 at 5 minutes	1 study (Oregon) 2.3% vs. 1.8% aOR = 1.31, 95% CI 1.04 to 1.66	1 study 1.2% vs. 2.8% aOR 0.57, 95% CI 0.25 to 1.35
Apgar < 4 at 5 minutes	1 study (Oregon) 0.6% vs. 0.4% aOR = 1.56, 95% CI 0.98 to 2.47	No non-U.S. studies reported this outcome

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GRADE Table: Neonatal Morbidity

	Planned home or birth center birth vs. Planned hospital birth	
	U.S. Studies	**Non-U.S. Studies**
Neonatal Seizures	1 study (Oregon) 0.13% vs. 0.04% RD 0.06 to 0.07 (2 different methods) NNH 1,428 to 1,666 aOR 3.60, 95% CI 1.36 to 9.50	No non-U.S. studies reported this outcome

GRADE Table: Neonatal Morbidity

	Planned home or birth center birth vs. Planned hospital birth	
	U.S. Studies	**Non-U.S. Studies**
NICU Admission	1 study 1.7% vs. 2.9% RD = 0.95 to 0.85 less NNT = 105 to 117 aOR 0.71, 95% CI 0.55 to 0.92	No non-U.S. studies reported this outcome
Ventilator Support	1 study 3.8% vs. 3.3% RD: 0.97 to 1.05 more NNH = 95 to 103 aOR 1.36, 95% CI 1.14 to 1.62	No non-U.S. studies reported this outcome

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Outcome: Maternal Harm

●○○○ Very low confidence that planned out-of-hospital birth associated with less risk of third or fourth degree lacerations compared to planned in-hospital birth, evidence on risk of blood transfusion was conflicting (increased in U.S, similar or less from non-U.S. studies), and no U.S. findings on post-partum hemorrhage based on 5 good- or fair-quality observational studies, 1 from U.S.)

GRADE Table: Maternal Harm

	Planned home or birth center birth vs. Planned hospital birth	
	U.S. Studies	**Non-U.S. Studies**
Postpartum hemorrhage of ≥ 1000 ml	No U.S. studies of this outcome	4 studies 0.38% to 29.2% vs. 1.04% to 39.9% Range of finding across 3 with analysis aOR =0.88, 95% CI 0.52 to 1.47 aRR 1.10, 95% CI 0.67 to 1.79 aOR =0.4, 95% CI 0.3 to 0.6

GRADE Table: Maternal Harm

	Planned home or birth center birth vs. Planned hospital birth	
	U.S. Studies	**Non-U.S. Studies**
Blood transfusion	1 study 0.6% vs. 0.4% RD 0.27 to 0.28 more NNH = 357 to 370 aOR 1.91, 95% CI 1.25 to 2.93	1 study Home 0.5% vs. Hospital 1.2% aOR 0.72, 95% CI 0.47 to 1.12 Birth center 0.6% vs. Hospital 1.2% RD 0.6 less, NNT =166 aOR 0.48, 95% CI 0.32 to 0.73

GRADE Table: Maternal Harm

	Estimate of Effect for Outcome/*Confidence in Estimate*	
	U.S. Studies	**Non-U.S. Studies**
Third or fourth degree perineal laceration	1 study 0.9% vs. 1.3% RD to 0.45 to 0.54 less NNT = 185, adjusted 222 aOR 0.69 (95% CI 0.49 to 0.98)	2 studies 1.9% to 4.9% vs. 3.2% to 4.2% RD 0.45 to 0.54 less NNT = 76 to 166 aOR 0.77, 95% CI 0.57 to 1.05 to aOR 0.90, 95% CI 0.56 to 1.45

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GRADE Table: Breastfeeding

Estimate of Effect for Outcome/*Confidence in Estimate*	
U.S. Studies	**Non-U.S. Studies**
No U.S. studies with long-term outcomes identified	Exclusive breastfeeding at 6 months postpartum 4% to 22% for planned home or birth center birth vs. 1% to 9% for planned hospital birth ARD = 3 to 13 NNT = 7 to 33 aOR 2.24, 95% CI 1.14 to 4.03
●○○○ (very low confidence that exclusive breastfeeding at 6 months was more common for planned home or birth center birth compared to planned home birth, based on 1 fair-quality observational study)	

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Population Subgroups Summary

- Prior Cesarean Delivery, Breech Presentation
  - increased risk of adverse infant outcomes for OOHB
- Nulliparous women (women giving birth for the first time) in U.S. found to have increased risk of neonatal death for planned out-of-hospital births
  - Non-U.S. studies also observed higher rates of adverse outcomes for nulliparous women, but direct comparisons between settings cannot be made
- Additional groups at further increased risk, from findings of a single U.S. study
  - Advanced maternal age, later gestational age, and combinations of parity and maternal age, gestational age

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Evidence Review Limitations

- Only observational studies identified
  - Strength of evidence, confidence of effect implications
- Birth certificate data identifies planned home births
  - But planned home births transferred to hospital before delivery may be counted as hospital births (misattribution bias)
  - Only Oregon addresses transfer in birth certificate
- Residual confounding in U.S. studies
- System-level challenges

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GRADE table elements: Resource Allocation

- Lower cost for out-of-hospital birth attendance
- Offsets:
  - Transfers
  - Apparent higher rate of rare adverse events may cause longer-term expenses

GRADE table elements: Values and Preferences

- Women have strong preferences about where they give birth
- Preferences and values vary widely around:
  - risk for mother and infant/value on birth as a natural process
  - preference for institutional versus home/birthing center

GRADE table elements: Other factors

- Much of the evidence reviewed may not be relevant to Oregon setting
  - Differing levels of system integration
  - Variation in education and training of attendants
  - Regulatory standards differ among countries

GRADE table elements: Balance of benefits and harms

- Favors out-of-hospital birth for dyads without certain risk factors
- Common benefits for mother; rare catastrophic adverse events for infant
- Higher-risk conditions include advanced maternal age, postdates, nulliparity, prior cesarean delivery, multiple gestation, and breech presentation
- Guidelines in areas with robust systems of care suggest numerous specific risk criteria for which risks outweigh benefits.
- For women with certain risk factors, harms outweigh benefits

GRADE table elements: Rationale

- In Oregon, balance appears favorable for the mother but less favorable or unfavorable for the infant
- OOHBs are not universally well-integrated into the health system, potentially resulting in delays and poor coordination of care
- Standards of care and licensing board requirements for birth attendants are highly variable in Oregon

GRADE table elements: Rationale (cont'd)

In balancing these considerations, the Commission recommends coverage for out-of-hospital birth for pregnancies free of specified conditions or characteristics which increase the risk of adverse obstetric or birth outcomes. In addition, coverage is recommended with specific requirements for ongoing risk assessment, consultation or transfer for specific high-risk conditions. The recommendation is weak because of the very low confidence in the evidence and because our recommendation includes pregnancies with certain risk factors (nulliparity, advanced maternal age) for which evidence suggests planned out-of-hospital birth results in a higher infant death rate.
(continued on next slide)

GRADE table elements: Rationale (cont'd)

The Commission recommends noncoverage of planned out-of-hospital birth when the specified risk factors exist, when required risk assessments are not performed, or when criteria for consultation or transfer of care are not followed by the birth attendant. This is a strong recommendation because of concern about the serious risks to the infant and the likelihood that systems issues might further exacerbate these risks.

Recommendation

- Planned out-of-hospital birth is recommended for coverage for pregnant women who are at low risk for adverse obstetric or birth outcomes *(weak recommendation)*. The high-risk conditions outlined below would either preclude coverage of planned out-of-hospital birth, necessitate a consultation, or require transfer of the mother or infant to a hospital setting. When a condition requiring transfer arises during labor, an attempt should be made to transfer the mother and/or her newborn; however, imminent fetal delivery may delay or preclude actual transfer prior to birth.

Recommendation

- Coverage of prenatal, intrapartum, and postpartum care is recommended with the performance of appropriate risk assessments (at initiation of care and throughout pregnancy and delivery) and the out-of-hospital birth attendant's adherence to the consultation and transfer criteria as outlined below.
- Planned out-of-hospital birth is not recommended for coverage for pregnancies with identified high-risk factors necessitating a planned hospital birth, or when the listed criteria for consultation and transfer of care are not followed by the birth attendant *(strong recommendation)*.

Recommendation

- When a high-risk condition develops that requires transfer or planned hospital birth, coverage is recommended when appropriate care is provided until the point the high-risk condition is identified. For women who have a high-risk condition requiring consultation, ongoing coverage of planned out-of-hospital birth care is recommended as long as the consulting provider's recommendations are then appropriately managed by the out-of-hospital birth attendant in a planned out-of-hospital birth setting.

Recommendation

HIGH-RISK CONDITIONS

Conditions in the red (darker) boxes indicate high-risk conditions that require planned hospital birth (when present on intake) or transfer of the mother or infant to hospital-based care (when condition develops).

Conditions in the yellow (lighter) boxes indicate potentially risky conditions that require consultation. Consultations may be with 1) a provider (MD/DO or CNM) who has active admitting privileges to manage pregnancy in a hospital and/or 2) appropriate specialty consultation (e.g., maternal-fetal medicine, hepatologist, hematologist, psychiatrist).

This list of high-risk conditions is not exhaustive, and other, physical health, behavioral health, obstetric, or fetal high-risk conditions may arise that require consultation and/or transfer to hospital-based care. Having multiple risk conditions requiring consultation may increase the risk sufficiently to indicate the need for transfer of care.

Risk tables shown in guideline note

Risk Factor Changes from 2015

Added High-risk Exclusion Criteria

	Source
Active gynecologic cancer	2020 OR DEM WA
Cardiovascular disease causing functional impairment	4 guidelines
Collagen vascular diseases (Systemic lupus erythematous, Scleroderma, Rheumatoid arthritis)	WA
Significant endocrine conditions other than diabetes (e.g. hyperthyroidism)	WA

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Risk Factor Changes from 2015

Added High-risk Exclusion Criteria

	Source
Neurological disorders or active seizure disorders that would impact maternal or neonatal health	3 guidelines *(modification of 2015 exclusion)*
Renal disease requiring supervision by a renal specialist **Renal failure**	3 guidelines
Tuberculosis (other than latent)	2 guidelines

Risk Factor Changes from 2015

Added Consultation Criteria

	Source
Chronic pulmonary disease (e.g. cystic fibrosis)	NICE and WA
Anatomic anomaly (e.g. bicornuate, large fibroid impacting delivery)	Consultation in 2 guidelines
Prior myomectomy	OR 2020 LDEM final rule
Uncertain expected date of delivery	One guideline
Disorders including uncontrolled intrahepatic cholestasis of pregnancy and/or abnormal liver function tests	OR 2020 LDEM rule Note: exclusion in 2 guidelines
Acute pyelonephritis	1 guideline
Inappropriate uterine growth (size-date discrepancy). (An ultrasound read by a qualified physician constitutes a consultation).	3 guidelines

Risk Factor Changes from 2015

Modified Criteria – specific example

2015 Maternal mental illness requiring inpatient care	Transfer
2015 Maternal mental illness under outpatient psychiatric care with suspicion for psychosis or potential harm to self or infant	Consult
2020 Maternal mental illness requiring psychological or psychiatric intervention	Consult
2020 History of Postpartum mood disorder with high risk to the infant (e.g. psychosis)	Consult
2020 History of Schizophrenia, other psychotic disorders, bipolar I disorder or schizotypal disorders	Consult
2020 Patient currently taking psychotropic medications	Consult

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Risk Factor Changes from 2015

Examples of Removed or Modified Criteria

	Source	
Neonatal encephalopathy in prior pregnancy		Changed to consultation
Pre-labor amniotic membrane rupture >24 hrs	Consultation in WA guideline Exclusion for NICE	Changed to consultation
Refractory hyperemesis gravidarum	Consultation in WA guideline	Changed to consultation
Body mass index at first prenatal visit of greater than 35 kg/m2	NICE	Removed
Lack of informed consent on prophylaxis if mother is GBS positive and declines prophylaxis	Not in other guidelines	Removed

Risk Factor Changes from 2015

Examples of Removed or Modified Criteria

History of cerclage or cervical insufficiency in prior pregnancy	Removed
Prior delivery of a > 4.5 kg or 9 lbs 14 oz infant	Removed
Suspected fetal macrosomia (estimated weight >4.5 kg or 9 lbs 14 oz) in current pregnancy	Removed
Gestational diabetes, diet controlled	Removed
More than one preterm birth, or preterm birth less than 34 weeks 0 days in most recent pregnancy **ing pregnancy**	Removed

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Today's task

- Detailed language has been reviewed at EbGS multiple times and undergone extensive public comment
- Many criteria were added, then removed after first public comment period
- VbBS's primary task is to make a recommendation on how the coverage guidance recommendations could/should be implemented on the Prioritized List
- More extensive discussion planned for HERC this afternoon

VBBS Discussion

- Questions?
- VbBS feedback for HERC about EbGS overall direction?
- Concerns about specific language? Criteria?

Coverage Guidance: Planned Out-of-Hospital Birth

Question: How should GN153 PLANNED OUT-OF-HOSPITAL BIRTH be updated based on the updated Coverage Guidance on Planned Out-of-Hospital Birth?

Question source: Evidence-based Guidelines Subcommittee

Issue: The EbGS has approved a draft revision of the Coverage Guidance for when coverage is recommended for out of hospital birth. VbBS needs to evaluate application to the Prioritized List of Health Services.

The previous out-of-hospital birth coverage guidance in 2015 resulted in the creation of GN153 (see appendix A for wording of this guideline). The 2020 EGBS approved coverage guidance is significantly different that the 2015 version. The entire section on newborn transfer criteria was removed, as not relating to the pregnancy. Other parts were significantly edited to not appear to be clinical practice guidelines. There was also additional evidence that has been developed over the past 5 years that was taken into account.

Of note, during the COVID-19 emergency, HSD has been using the revised coverage guidance criteria in determining whether a patient has a low risk pregnancy and is therefore eligible for OHP payment for out of hospital birth.

Coverage Guidance: Planned Out-of-Hospital Birth

Changes from 2015 to 2020 in Out of Hospital Birth Criteria

Added Exclusion Criteria	**Rationale**	**Comments**
Active gynecologic cancer	Excluded in 2020 OR DEM final rule and in Washington	
Cardiovascular disease, causing functional impairment	Excluded in 4 guidelines	
Systemic lupus erythematous Scleroderma Rheumatoid arthritis Any collagen-vascular disease	Excluded in WA	
Significant endocrine conditions other than diabetes (e.g. hyperthyroidism)	Excluded in WA	
Hemoglobinopathies	Excluded in 3 guidelines	
Neurological disorders or active seizure disorders that would impact maternal or neonatal health	Excluded in 3 guidelines	
Renal disease requiring supervision by a renal specialist Renal failure	Excluded in 3 guidelines	
Amniotic membrane rupture before 37 weeks 0 days	Excluded in WA guideline	
Tuberculosis (other than latent)	Excluded in 2 guidelines	
Uterine inversion		
Development of any high-risk condition	Exclusion in WA and NICE	
Added Consultation Criteria		
Chronic pulmonary disease (e.g. cystic fibrosis)	NICE and WA exclusions	
Anatomic anomaly (e.g. bicornuate, large fibroid impacting delivery)	Consultation in 2 guidelines	
Prior myomectomy	OR 2020 LDEM rule	
Uncertain expected date of delivery	One guideline	
Disorders including uncontrolled intrahepatic cholestasis of pregnancy and/or abnormal liver function tests	OR 2020 LDEM rule Note: exclusion in 2 guidelines	
Acute pyelonephritis	In one guideline	
Inappropriate uterine growth (size-date discrepancy). (An ultrasound read by a qualified physician constitutes a consultation).	3 guidelines	
Deleted Exclusion Criteria		
Neonatal encephalopathy in prior pregnancy		Changed to consultation
Pre-labor amniotic membrane rupture >24 hrs	Consultation in WA guideline Exclusion for NICE	Changed to consultation

Refractory hyperemesis gravidarum	Consultation in WA guideline	Changed to consultation
Lack of informed consent on prophylaxis if mother is GBS positive and declines prophylaxis		
History of hypertensive disorders of pregnancy		
Cytomegalovirus	Not in other guidelines	
Deleted Consultation Criteria		
Cervical insufficiency/prior cerclage		
Suspected/estimated weight >4.5 kg or 9lbs 14 oz.)		
History of 3 or more 1st trimester spontaneous miscarriages		
History of 1 or more 2nd trimester spontaneous miscarriage		
Prior child with congenital or hereditary disorder		
Life-threatening congenital anomalies (unless non-resuscitation planned)		
Gestational – diet controlled		Still consultation criteria in 2020 LDM rule
Fetal demise (current pregnancy)		
Family history of genetic/heritable disorders that would impact labor, delivery or care of newborn		
Prior baby > 4.5 kg or 9 lbs 14 oz.		
Maternal seizure disorder (excluding eclampsia) (History of)		Included in new exclusion criteria
Inadequate prenatal care		
History of preterm birth (before 34 weeks)		
Laparotomy during pregnancy	Not in other guidelines	
Deleted Transfer Criteria		
Thick meconium		Still a transfer criteria in 2020 LDM rule
All Neonatal transfer and consultation criteria		

Coverage Guidance: Planned Out-of-Hospital Birth

HERC staff recommendations:
Replace current GN153 with the following guideline note

GUIDELINE NOTE 153 PLANNED OUT-OF-HOSPITAL BIRTH

Lines 1,2
Planned out-of-hospital birth is included on this line for pregnant women who are at low risk for adverse obstetric or birth outcomes. The high-risk conditions outlined below would either preclude coverage of planned out-of-hospital birth, necessitate a consultation, or require transfer of the mother or infant to a hospital setting. When a condition requiring transfer arises during labor, an attempt should be made to transfer the mother and/or her newborn; however, imminent fetal delivery may delay or preclude actual transfer prior to birth.

Coverage of prenatal, intrapartum, and postpartum care is recommended with the performance of appropriate risk assessments (at initiation of care and throughout pregnancy and delivery) and the out-of-hospital birth attendant's adherence to the consultation and transfer criteria as outlined below.

When a high-risk condition develops that requires transfer or planned hospital birth, coverage is recommended when appropriate care is provided until the point the high-risk condition is identified. For women who have a high-risk condition requiring consultation, ongoing coverage of planned out-of-hospital birth care is recommended as long as the consulting provider's recommendations are then appropriately managed by the out-of-hospital birth attendant in a planned out-of-hospital birth setting.

HIGH-RISK CONDITIONS
Conditions in the red (darker) boxes indicate high-risk conditions that require planned hospital birth (when present on intake) or transfer of the mother or infant to hospital-based care (when condition develops).

Conditions in the yellow (lighter) boxes indicate potentially risky conditions that require consultation. Consultations may be with 1) a provider (MD/DO or CNM) who has active admitting privileges to manage pregnancy in a hospital and/or 2) appropriate specialty consultation (e.g., maternal-fetal medicine, hepatologist, hematologist, psychiatrist).
This list of high-risk conditions is not exhaustive, and other, physical health, behavioral health, obstetric, or fetal high-risk conditions may arise that require consultation and/or transfer to hospital-based care. Having multiple risk conditions requiring consultation may increase the risk sufficiently to indicate the need for transfer of care.

MEDICAL HISTORY OR OBSTETRIC HISTORY ^ indicates transfer; ~ indicates consultation	
Cancer	• Active gynecologic cancer^
Cardiovascular Disease	• Cardiovascular disease causing functional impairment^
Connective Tissue Disorders	• Systemic lupus erythematous~ • Scleroderma~ • Rheumatoid arthritis~ • Any collagen-vascular disease~
Delivery History	• Prior cesarean section^
Diabetes Mellitus	• Type 1 diabetes^ • Type 2 diabetes^
Endocrine Conditions	• Significant endocrine conditions other than diabetes (e.g. hyperthyroidism)~
Fetal Demise or Stillbirth	• Prior stillbirth/neonatal death~
Hematologic Disorders	• Maternal bleeding disorder^
	• Hemoglobinopathies~ • History of thrombosis or thromboembolism~ • History of postpartum hemorrhage requiring transfusion or other advanced treatment (e.g. Bakri balloon)~
Hypertensive Disorders	• Eclampsia^ • Pre-eclampsia requiring preterm birth^ • HELLP syndrome (hemolysis, elevated liver enzymes, low platelets)^ • Pre-existing or chronic hypertension^
Infectious Diseases	• HIV positive^
Isoimmunization	• Blood group incompatibility and/or Rh sensitization in a prior pregnancy~
Neonatal Encephalopathy in prior pregnancy	• Neonatal encephalopathy in prior pregnancy~
Neurological disorders	• Neurological disorders or active seizure disorders that would impact maternal or neonatal health (e.g. epilepsy, myasthenia gravis, previous cerebrovascular accident)^
Placental Conditions	• History of retained placenta requiring surgical removal^
Psychiatric Conditions	• History of postpartum mood disorder with high risk to the infant (e.g. psychosis)~ • Schizophrenia, other psychotic disorders, bipolar I disorder or schizotypal disorders~

Coverage Guidance: Planned Out-of-Hospital Birth

MEDICAL HISTORY OR OBSTETRIC HISTORY **^ indicates transfer; ~ indicates consultation**	
Pulmonary Disease	• Chronic pulmonary disease (e.g. cystic fibrosis)~
Renal Disease	• Renal disease requiring supervision by a renal specialist^ • Renal failure^ *(Preeclampsia and related conditions are listed separately)*
Shoulder Dystocia	• History of, with or without fetal clavicular fracture~
Uterine Conditions	• Prior myomectomy~
	• Prior hysterotomy^

Coverage Guidance: Planned Out-of-Hospital Birth

CONDITIONS OF CURRENT PREGNANCY	
Abnormal Bleeding in pregnancy	• Antepartum hemorrhage, recurrent^ • Hemorrhage (hypovolemia, shock, need for transfusion, vital sign instability)^
Amniotic Membrane Rupture	• Before 37 weeks 0 days^
	• Pre-labor rupture > 24 hours~
Congenital or Hereditary Anomaly of the fetus	• Evidence of congenital anomalies requiring immediate assessment and/or management by a neonatal specialist~
Diabetes, Gestational	• Requiring medication or uncontrolled^
Fetal Growth	• Uteroplacental insufficiency^ • IUGR (defined as fetal weight less than fifth percentile using ethnically-appropriate growth tables, or concerning reduced growth velocity on ultrasound)^
	• Inappropriate uterine growth (size-date discrepancy). (An ultrasound read by a qualified physician constitutes a consultation)~
Fetal presentation	• Breech or noncephalic presentation^
Gestational age	• < 37 weeks 0 days^ • ≥42 weeks 0 days (unless already in active labor at 41 weeks 6 days)^
	• Expected date of delivery (EDD) uncertain~
Hematologic conditions	• Anemia with hemoglobin < 8.5 g/dL (current pregnancy)^ • Suspected or diagnosed thrombosis or thromboembolism^ • Thrombocytopenia (platelets < 100,000)^
	• Hemoglobin < 10 g/dL, unresponsive to treatment~
Hepatic disorders	• Disorders including uncontrolled intrahepatic cholestasis of pregnancy and/or abnormal liver function tests~
Hyperemesis gravidarum	• Refractory~

Hypertensive disorders	• Elevated blood pressure on two occasions 30 minutes apart (e.g. gestational hypertension or pregnancy-induced hypertension)^
	  ○ Systolic ≥ 140 or diastolic ≥ 90
	• Elevated blood pressure on one occasion^
	  ○ Systolic ≥ 160 or diastolic ≥ 110, or
	  ○ Systolic ≥ 140 or diastolic ≥ 90, with severe pre-eclampsia features
	• Pre-eclampsia^
	• Eclampsia^
	• HELLP syndrome^

Infectious conditions	• HIV, Hepatitis B or syphilis positive^ • Chorioamnionitis^ • Maternal temperature ≥ 38.0 C in labor/postpartum • Genital herpes at time of labor^ • Maternal infection postpartum (e.g., endometritis, sepsis, wound) requiring hospital treatment^ • Rubella^ • Tuberculosis (other than latent)^ • Toxoplasmosis^ • Varicella (active at labor)^
Isoimmunization	• Blood group incompatibility and/or Rh sensitization in current pregnancy^
Labor management	• Induction^ • Failure to progress/failure of head to engage in active labor^ • Lack of adequate progress in 2nd stage with cephalic presentation^
Miscarriage/non-viable pregnancy	• Molar^
Multiple gestations	• Multiple gestations^
Oligohydramnios or polyhydramnios	• Oligohydramnios^ • Polyhydramnios^
Perineal laceration or obstetric anal sphincter injury	• 3rd degree requiring hospital repair or beyond expertise of attendant^ • 4th degree^ • Enlarging hematoma^
Placental conditions	• Low lying placenta within 2 cm or less of cervical os at 38 weeks 0 days or later^ • Placenta previa^ • Vasa previa^ • Abruption^ • Retained placenta > 60 minutes^

Psychiatric conditions	• Maternal mental illness requiring psychological or psychiatric intervention~ • Patient currently taking psychotropic medications~
Renal	• Acute pyelonephritis~
Substance Use	• Drug or alcohol misuse with high risk for adverse effects to fetal or maternal health^
Umbilical cord	• Prolapse^
Uterine condition	• Anatomic anomaly (e.g. bicornuate, large fibroid impacting delivery)~ • Uterine prolapse~
	• Uterine rupture, inversion^

The development of this guideline note was informed by a HERC coverage guidance. See https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx.

Appendix A
Current guideline wording

GUIDELINE NOTE 153, PLANNED OUT-OF-HOSPITAL BIRTH

Lines 1,2

Planned out-of-hospital birth is included on these lines when appropriate risk assessments are performed, and the consultation and transfer criteria are followed, and no high risk coverage exclusion criteria exist. Risk assessment should be done initially when planning the location of birth, and updated throughout pregnancy, labor, and delivery to determine if out-of-hospital birth is still appropriate.

The clinical and/or diagnostic assessment of each criterion, with the exception of those marked with an asterisk, is necessary for planned out-of-hospital birth to be included on these lines. (Criteria marked with an asterisks may not be known or not be pertinent if there is no clinical indication for concern and additional diagnostic testing is not indicated.)

An ultrasound is required to rule out certain risk criteria (e.g. multiple gestation, placenta previa, and life threatening congenital anomalies). Certain risk criteria require serial measurements such as fundal height and blood pressure.

If a woman refuses a required clinical or diagnostic assessment, then ascertainment of her risk status is unknowable and she does not meet criteria for coverage for an out-of-hospital birth.

Documentation of continuing appropriate risk assessment and routine prenatal care is required.

I. High-risk coverage exclusion criteria:
   A. Complications in a previous pregnancy:
      1. Maternal surgical history
         a) Cesarean section or other hysterotomy
         b) Uterine rupture
         c) Retained placenta requiring surgical removal
         d) Fourth-degree laceration without satisfactory functional recovery

      2. Maternal medical history
         a) Pre-eclampsia requiring preterm birth
         b) Eclampsia
         c) HELLP syndrome

      3. Fetal and placental
         a) Unexplained stillbirth/neonatal death or previous death related to intrapartum difficulty
         b) Baby with neonatal encephalopathy
         c) Placental abruption with adverse outcome

   B. Complications of current pregnancy:

      1. Maternal

a) Induction of labor
b) Prelabor rupture of membranes > 24 hours
c) Pre-existing chronic hypertension; Pregnancy-induced hypertension with diastolic blood pressure greater than or equal to 90 mmHg or systolic blood pressure greater than or equal to 140 mmHg on two consecutive readings taken at least 30 minutes apart
d) Unknown group B strep carrier state
e) Lack of informed consent on group B strep prophylaxis, if mother is Group B strep positive.
f) Eclampsia or pre-eclampsia
g) Anemia – hemoglobin less than 8.5 g/dL
h) Thrombocytopenia (platelets <100,000)
i) Thrombosis/thromboembolism or other maternal bleeding disorder*
j) Maternal mental illness requiring inpatient care*
k) Drug or alcohol use with high risk for adverse effects to fetal or maternal health
l) Unknown, or positive, syphilis, HIV, or Hepatitis B status
m) Current active infection of varicella at the time of labor; rubella infection anytime during pregnancy; active infection (outbreak) of genital herpes at the time of labor*
n) Refractory hyperemesis gravidarum*
o) Diabetes, type I or II, uncontrolled gestational diabetes, or gestational diabetes controlled with medication

2. Placental
   a) Low lying placenta within 2 cm or less of cervical os at term; placenta previa, vasa previa
   b) Placental abruption/abnormal bleeding
   c) Recurrent antepartum hemorrhage
   d) Uteroplacental insufficiency*

3. Fetal
   a) Gestational age - preterm or postdates (defined as gestational age < 37 weeks + 0 days or > 41 weeks + 6 days)
   b) Multiple gestation
   c) Non-cephalic fetal presentation
   d) IUGR (defined as fetal weight less than fifth percentile using ethnically-appropriate growth tables, or concerning reduced growth velocity on ultrasound)*
   e) Oligohydramnios or polyhydramnios*
   f) Abnormal fetal heart rate/Doppler/surveillance studies
   g) Blood group incompatibility with atypical antibodies, or Rh sensitization
   h) Molar pregnancy

II. Transfer criteria:

A. If out-of-hospital birth is planned, certain intrapartum and postpartum complications may necessitate transfer to a hospital to meet coverage criteria. For these indications, an attempt should be made to transfer the mother and/or her newborn; however, imminent fetal delivery may delay or preclude actual transfer prior to birth.

1. Maternal
   a) Temperature ≥ 38.0 C
   b) Maternal infection requiring hospital treatment (e.g. endometritis or wound infection)
   c) Hemorrhage (hypovolemia, shock, need for transfusion)
   d) Retained placenta > 60 minutes
   e) Laceration requiring hospital repair (e.g., extensive vaginal, cervical or third- or fourth-degree trauma)
   f) Enlarging hematoma
   g) Bladder or rectal dysfunction
2. Fetal and uterine
   a) Repetitive or persistent abnormal fetal heart rate pattern
   b) Thick meconium staining of amniotic fluid
   c) Prolapsed umbilical cord
   d) Failure to progress (as defined by the American Congress of Obstetricians and Gynecologists, March 2014, found at http://www.acog.org/Resources-And-Publications/Obstetric-Care-Consensus-Series/Safe-Prevention-of-the-Primary-Cesarean-Delivery)/failure of head to engage in active labor
   e) Chorioamnionitis or other serious infection (including toxoplasmosis, rubella, CMV, HIV, etc.)
   f) Uterine rupture, inversion or prolapse

B. If the infant is delivered out-of-hospital, the following complications require transfer to a hospital for the out-of-hospital birth to meet coverage criteria:

1. Low Apgar score (< 5 at 5 minutes, < 7 at 10 minutes)
2. Weight less than 5th percentile for gestational age
3. Unexpected significant or life-threatening congenital anomalies
4. Respiratory or cardiac irregularities, cyanosis, pallor
5. Temperature instability, fever, suspected infection or dehydration
6. Hyperglycemia/hypoglycemia unresponsive to treatment
7. Hypotonia, tremors, seizures, hyperirritability
8. Excessive bruising, enlarging cephalohematoma, significant birth trauma
9. Vomiting/diarrhea

III. Consultation criteria:

Certain high-risk conditions require consultation (by a provider of maternity care who is credentialed to admit and manage pregnancies in a hospital) for coverage of a planned out-of-hospital birth to be recommended. These complications include (but are not limited to) patients with:

A. Complications in a previous pregnancy:

1. Maternal
   a) More than three first trimester spontaneous abortions, or more than one second trimester spontaneous abortion
   b) More than one preterm birth, or preterm birth less than 34 weeks 0 days in most recent pregnancy
   c) Pre-eclampsia, not requiring preterm birth
   d) Cervical insufficiency/prior cerclage
   e) Third degree laceration; fourth-degree laceration with satisfactory functional recovery
   f) Life-threatening congenital anomalies (unless fatal anomalies with nonresuscitation planned)
   g) Postpartum hemorrhage requiring additional pharmacologic treatment or blood transfusion
   h) Retained placenta requiring manual removal
2. Fetal
   a) Child with congenital and/or hereditary disorder
   b) Baby > 4.5 kg or 9 lbs 14 oz
   c) Shoulder dystocia, with or without fetal clavicular fracture
   d) Unexplained stillbirth/neonatal death or previous death unrelated to intrapartum difficulty
   e) Unresolved intrauterine growth restriction (IUGR) or small for gestational age (defined as fetal or birth weight less than fifth percentile using ethnically-appropriate growth tables)
   f) Blood group incompatibility, and/or Rh sensitization

B. Complications of current pregnancy:

1. Maternal
   a) Inadequate prenatal care (defined as less than five prenatal visits or care began in the third trimester)
   b) Body mass index at first prenatal visit of greater than 35 kg/m2
   c) History of maternal seizure disorder (excluding eclampsia)
   d) Gestational diabetes, diet-controlled
   e) Maternal mental illness with suspicion for psychosis or potential harm to self or infant under outpatient psychiatric care
   f) Maternal anemia with hemoglobin < 10.5 g/dL, unresponsive to treatment
   g) Third-degree laceration not requiring hospital repair
   h) Laparotomy during pregnancy
2. Fetal
   a) Fetal macrosomia (estimated weight >4.5 kg or 9 lbs 14 oz)
   b) Confirmed intrauterine death
   c) Family history of genetic/heritable disorders that would impact labor, delivery or newborn care

The development of this guideline note was informed by a HERC coverage guidance. See https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx.

Health Evidence Review Commission (HERC)

Coverage Guidance: Planned Out-of-Hospital Birth

DRAFT for 8/13/2020 HERC/VbBS Meeting Materials

HERC Coverage Guidance

Planned out-of-hospital birth is recommended for coverage for pregnant women who are at low risk for adverse obstetric or birth outcomes *(weak recommendation)*. The high-risk conditions outlined below would either preclude coverage of planned out-of-hospital birth, necessitate a consultation, or require transfer of the mother or infant to a hospital setting. When a condition requiring transfer arises during labor, an attempt should be made to transfer the mother and/or her newborn; however, imminent fetal delivery may delay or preclude actual transfer prior to birth.

Coverage of prenatal, intrapartum, and postpartum care is recommended with the performance of appropriate risk assessments (at initiation of care and throughout pregnancy and delivery) and the out-of-hospital birth attendant's adherence to the consultation and transfer criteria as outlined below.

Planned out-of-hospital birth is not recommended for coverage for pregnancies with identified high-risk factors necessitating a planned hospital birth, or when the listed criteria for consultation and transfer of care are not followed by the birth attendant *(strong recommendation)*.

When a high-risk condition develops that requires transfer or planned hospital birth, coverage is recommended when appropriate care is provided until the point the high-risk condition is identified. For women who have a high-risk condition requiring consultation, ongoing coverage of planned out-of-hospital birth care is recommended as long as the consulting provider's recommendations are then appropriately managed by the out-of-hospital birth attendant in a planned out-of-hospital birth setting.

HIGH-RISK CONDITIONS

Conditions in the red (darker) boxes indicate high-risk conditions that require planned hospital birth (when present on intake) or transfer of the mother or infant to hospital-based care (when condition develops).

Conditions in the yellow (lighter) boxes indicate potentially risky conditions that require consultation. Consultations may be with 1) a provider (MD/DO or CNM) who has active admitting privileges to manage pregnancy in a hospital and/or 2) appropriate specialty consultation (e.g., maternal-fetal medicine, hepatologist, hematologist, psychiatrist).

This list of high-risk conditions is not exhaustive, and other, physical health, behavioral health, obstetric, or fetal high-risk conditions may arise that require consultation and/or transfer to hospital-based care. Having multiple risk conditions requiring consultation may increase the risk sufficiently to indicate the need for transfer of care.

MEDICAL HISTORY OR OBSTETRIC HISTORY	
Cancer	• Active gynecologic cancer
Cardiovascular Disease	• Cardiovascular disease causing functional impairment
Connective Tissue Disorders	• Systemic lupus erythematous • Scleroderma • Rheumatoid arthritis • Any collagen-vascular disease
Delivery History	• Prior cesarean section
Diabetes Mellitus	• Type 1 diabetes • Type 2 diabetes
Endocrine Conditions	• Significant endocrine conditions other than diabetes (e.g. hyperthyroidism)
Fetal Demise or Stillbirth	• Prior stillbirth/neonatal death
Hematologic Disorders	• Maternal bleeding disorder
	• Hemoglobinopathies • History of thrombosis or thromboembolism • History of postpartum hemorrhage requiring transfusion or other advanced treatment (e.g. Bakri balloon)
Hypertensive Disorders	• Eclampsia • Pre-eclampsia requiring preterm birth • HELLP syndrome (hemolysis, elevated liver enzymes, low platelets) • Pre-existing or chronic hypertension
Infectious Diseases	• HIV positive
Isoimmunization	• Blood group incompatibility and/or Rh sensitization in a prior pregnancy
Neonatal Encephalopathy in prior pregnancy	• Neonatal encephalopathy in prior pregnancy
Neurological disorders	• Neurological disorders or active seizure disorders that would impact maternal or neonatal health (e.g. epilepsy, myasthenia gravis, previous cerebrovascular accident)
Placental Conditions	• History of retained placenta requiring surgical removal
Psychiatric Conditions	• History of postpartum mood disorder with high risk to the infant (e.g. psychosis) • Schizophrenia, other psychotic disorders, bipolar I disorder or schizotypal disorders

MEDICAL HISTORY OR OBSTETRIC HISTORY	
Pulmonary Disease	• Chronic pulmonary disease (e.g. cystic fibrosis)
Renal Disease	• Renal disease requiring supervision by a renal specialist • Renal failure *(Preeclampsia and related conditions are listed separately)*
Shoulder Dystocia	• History of, with or without fetal clavicular fracture
Uterine Conditions	• Prior myomectomy
	• Prior hysterotomy

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CONDITIONS OF CURRENT PREGNANCY	
Abnormal Bleeding in pregnancy	• Antepartum hemorrhage, recurrent • Hemorrhage (hypovolemia, shock, need for transfusion, vital sign instability)
Amniotic Membrane Rupture	• Before 37 weeks 0 days
	• Pre-labor rupture > 24 hours
Congenital or Hereditary Anomaly of the fetus	• Evidence of congenital anomalies requiring immediate assessment and/or management by a neonatal specialist
Diabetes, Gestational	• Requiring medication or uncontrolled
Fetal Growth	• Uteroplacental insufficiency • IUGR (defined as fetal weight less than fifth percentile using ethnically-appropriate growth tables, or concerning reduced growth velocity on ultrasound)
	• Inappropriate uterine growth (size-date discrepancy). (An ultrasound read by a qualified physician constitutes a consultation)
Fetal presentation	• Breech or noncephalic presentation
Gestational age	• < 37 weeks 0 days • ≥42 weeks 0 days (unless already in active labor at 41 weeks 6 days)
	• Expected date of delivery (EDD) uncertain
Hematologic conditions	• Anemia with hemoglobin < 8.5 g/dL (current pregnancy) • Suspected or diagnosed thrombosis or thromboembolism • Thrombocytopenia (platelets < 100,000)
	• Hemoglobin < 10 g/dL, unresponsive to treatment
Hepatic disorders	• Disorders including uncontrolled intrahepatic cholestasis of pregnancy and/or abnormal liver function tests
Hyperemesis gravidarum	• Refractory

Hypertensive disorders	• Elevated blood pressure on two occasions 30 minutes apart (e.g. gestational hypertension or pregnancy-induced hypertension)
	  ○ Systolic ≥ 140 or diastolic ≥ 90
	• Elevated blood pressure on one occasion
	  ○ Systolic ≥ 160 or diastolic ≥ 110, or
	  ○ Systolic ≥ 140 or diastolic ≥ 90, with severe pre-eclampsia features
	• Pre-eclampsia
	• Eclampsia
	• HELLP syndrome

Infectious conditions	• HIV, Hepatitis B or syphilis positive • Chorioamnionitis • Maternal temperature ≥ 38.0 C in labor/postpartum • Genital herpes at time of labor • Maternal infection postpartum (e.g., endometritis, sepsis, wound) requiring hospital treatment • Rubella • Tuberculosis (other than latent) • Toxoplasmosis • Varicella (active at labor)
Isoimmunization	• Blood group incompatibility and/or Rh sensitization in current pregnancy
Labor management	• Induction • Failure to progress/failure of head to engage in active labor • Lack of adequate progress in 2nd stage with cephalic presentation
Miscarriage/non-viable pregnancy	• Molar
Multiple gestations	• Multiple gestations
Oligohydramnios or polyhydramnios	• Oligohydramnios • Polyhydramnios
Perineal laceration or obstetric anal sphincter injury	• 3rd degree requiring hospital repair or beyond expertise of attendant • 4th degree • Enlarging hematoma

Placental conditions	• Low lying placenta within 2 cm or less of cervical os at 38 weeks 0 days or later • Placenta previa • Vasa previa • Abruption • Retained placenta > 60 minutes
Psychiatric conditions	• Maternal mental illness requiring psychological or psychiatric intervention • Patient currently taking psychotropic medications
Renal	• Acute pyelonephritis
Substance Use	• Drug or alcohol misuse with high risk for adverse effects to fetal or maternal health
Umbilical cord	• Prolapse
Uterine condition	• Anatomic anomaly (e.g. bicornuate, large fibroid impacting delivery) • Uterine prolapse
	• Uterine rupture, inversion

Note: Definitions for strength of recommendation are in Appendix A. *GRADE Table Element Descriptions*.

Rationales for each recommendation appear below in the GRADE table.

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Rationale for development of coverage guidances and multisector intervention reports

Coverage guidances are developed to inform coverage recommendations for public and private health plans in Oregon as plan administrators seek to improve patients' experience of care, population health, and the cost-effectiveness of health care. In the era of public and private sector health system transformation, reaching these goals requires a focus on maximizing the benefits and minimizing the harms and costs of health interventions.

HERC uses the following principles in selecting topics for its reports to guide public and private payers:

- Represents a significant burden of disease or health problem
- Represents important uncertainty with regard to effectiveness or harms
- Represents important variation or controversy in implementation or practice
- Represents high costs or significant economic impact
- Topic is of high public interest

HERC bases its reports on a review of the best available research applicable to the intervention(s) in question. For coverage guidances, which focus on diagnostic and clinical interventions, evidence is evaluated using an adaptation of the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) methodology. For more information on coverage guidance methodology, see Appendix A.

Multisector interventions can be effective ways to prevent, treat, or manage disease at a population level. In some cases, HERC has reviewed evidence and identified effective interventions, but has not made formal coverage recommendations when these policies are implemented in settings other than traditional health care delivery systems because effectiveness could depend on the environment in which the intervention is implemented.

Use of GRADE System

HERC develops recommendations by using the concepts of the GRADE system. GRADE is a transparent and structured process for developing and presenting evidence and for performing the steps involved in developing recommendations. The table below lists the elements that determine the strength of a recommendation. HERC reviews the evidence and assesses each element, which in turn is used to develop the recommendations presented in the coverage guidance box. Estimates of effect are derived from the evidence presented in this document. The level of confidence in the estimate is determined by HERC based on the assessment of two independent reviewers from the Center for Evidence-based Policy.

In some cases, no systematic reviews or meta-analyses encompass the most current literature. In those cases, HERC may describe the additional evidence or alter the assessments of confidence in light of all available information. Such assessments are informed by clinical epidemiologists from the Center for Evidence-based Policy. Unless otherwise noted, statements regarding resource allocation, values and preferences, and other considerations are the assessments of HERC, as informed by the evidence reviewed, public testimony, and subcommittee discussion.

Recommendations for coverage are based on the balance of benefit and harms, resource allocation, values and preferences and other considerations. See Appendix A for more details about the factors that constitute the GRADE table.

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GRADE Table

The Resource Allocation, Values and Preferences, and Other Considerations columns of this table appear as rows at the bottom of this table to improve readability.

Outcomes	**Estimate of Effect for Outcome/ *Confidence in Estimate***	
	U.S. Studies	**Non-U.S. Studies**
Mode of Delivery *(Critical outcome)* Data from comparative studies of good (3) and fair (1) methodological quality reported. Findings from poor-methodological-quality studies (14) not included in GRADE table.	Nonoperative Vaginal Delivery (1 study) 93.8% vs. 71.9% for planned home or birth center birth compared to planned hospital birth Absolute risk difference (ARD) = 27.5 Number needed to treat (NNT) = 3 Adjusted Odds Ratio (aOR) 5.63, 95% CI 4.84 to 6.55 Cesarean Delivery (1 study) 5.3% vs. 24.7% for planned home or birth center birth compared to planned hospital birth ARD = 19.4 favoring planned home or birth center birth NNT = 5 aOR = 0.18, 95% CI 0.16 to 0.22	Nonoperative Vaginal Delivery (3 studies) Range from 81% to 92.8% for planned home or birth center birth vs. 64.7% to 86% for planned hospital birth ARD range from 3.0 to 19.0 NNT range from 5 to 33 aOR range from 1.57 to 3.61 in favor of planned home or birth center birth Cesarean Delivery (2 studies) Range from 2.8% to 4.0% for planned home or birth center birth vs. 11.1% to 11.7% for planned hospital birth ARD range from 7.6 to 8.3 favoring planned home or birth center birth NNT range from 12 to 13 aOR range from 0.31 to 0.76 in favor of planned home or birth center birth
	●●○○ (*low confidence, based on 4 good- or fair-methodological-quality observational studies, 1 from U.S.)*	

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Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	
	U.S. Studies	**Non-U.S. Studies**
Perinatal or neonatal mortality *(Critical outcome)* Data from comparative studies of good (2) and fair (2) methodological quality reported. Findings from poor-methodological-quality studies (11) not included in GRADE table.	Neonatal death from 0 to 27 days (2 studies) Range from 0.12% to 0.16% for planned home or birth center vs. 0.03% to 0.06% for planned hospital births ARD range from 0.09 to 0.1 in favor of planned hospital birth Number needed to harm (NNH) range from 1,111 to 1,000 Standardized mortality ratio (SMR) 4.13, 95% CI 3.38 to 4.88; aOR 2.87, 95% CI 1.10 to 7.47	Intrapartum or neonatal death from 0 to 7 days (2 studies) Range from 0.06% to 0.15% for planned home or birth center vs. 0.01% to 0.18% for planned hospital birth Adjusted odds ratios not statistically significant across both studies
	●○○○ *(very low confidence, based on 4 good- or fair-quality observational studies, 2 from U.S.)*	
Neonatal Morbidity *(Important outcome)* Data from comparative studies of good (2) and fair (2) methodological quality reported. Findings from poor-methodological-quality studies (16) not included in GRADE table.	Apgar < 7 at 5 minutes (1 study [Oregon]) 2.3% vs. 1.8% for planned home or birth center birth compared to planned hospital birth aOR = 1.31, 95% CI 1.04 to 1.66 Apgar < 4 at 5 minutes (1 study [Oregon]) 0.6% vs. 0.4% for planned home or birth center birth compared to planned hospital birth aOR = 1.56, 95% CI 0.98 to 2.47 Neonatal seizures (1 study [Oregon]) 0.13% vs. 0.04% for planned home or birth center birth compared to planned hospital birth ARD = 0.09 Adjusted risk difference (RD) estimates from two different methods: 0.07, 0.06 in favor of planned hospital birth NNH = 1,111 (from adjusted RD 1,428 to 1,666) aOR 3.60, 95% CI 1.36 to 9.50	Apgar < 7 at 5 minutes (1 study) 1.2% vs. 2.8%, aOR 0.57, 95% CI 0.25 to 1.35 Birthplace Composite (stillbirth after onset of labor care, neonatal death 0 to 7 days, neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured humerus or clavicle) International (2 studies): 0.05% to 3.5% for planned home or birth center birth vs. 0.05% to 4.4% for planned hospital birth Adjusted odds ratios not statistically significantly different across both studies

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Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	
	U.S. Studies	**Non-U.S. Studies**
	Neonatal intensive care unit (NICU) admission (1 study) 1.7% vs. 2.9% for planned home or birth center birth compared to planned hospital birth ARD = 1.2 favoring planned home or birth center birth Adjusted RD estimates from two different methods 0.95, 0.85 in favor of planned hospital birth NNT = 83 (from adjusted RD 105 to 117) home or birth center births to avoid 1 NICU admission aOR 0.71, 95% CI 0.55 to 0.92 Ventilator support (1 study) 3.8% vs. 3.3% for planned home or birth center birth compared to planned hospital birth ARD = 0.5 in favor of planned hospital birth Adjusted RD estimates from two different methods: 0.97. 1.05 in favor of planned hospital birth NNH = 200 (adjusted 95 to 103) aOR 1.36, 95% CI 1.14 to 1.62	
	●○○○ *(very low confidence, based on 4 good- or fair-quality observational studies, 1 from U.S.)*	

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Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	
	U.S. Studies	**Non-U.S. Studies**
Maternal Harm (Important outcome) Data from comparative studies of good (2) and fair (3) methodological quality reported. Findings from poor-methodological-quality studies (15) are not included in GRADE table.	Postpartum hemorrhage of ≥ 1000 ml No U.S. studies of this outcome Maternal blood transfusion (1 study) Unadjusted 0.6% vs. 0.4% for planned home or birth center birth compared to planned hospital birth ARD = 0.2 in favor of planned hospital birth Adjusted RD estimates from two different methods 0.27, 0.28 in favor of planned hospital birth NNH = 500 (adjusted 357 to 370) aOR 1.91, 95% CI 1.25 to 2.93 Third or fourth degree perineal laceration (1 study) 0.9% vs. 1.3% for planned home or birth center birth compared to planned hospital birth ARD = 0.54, in favor of planned home or birth center birth Adjusted RD from two different methods 0.45, 0.54 in favor of planned home or birth center birth NNT = 185, adjusted 222 aOR 0.69 (95% CI 0.49 to 0.98)	Postpartum hemorrhage of ≥ 1000 ml (4 studies) 0.38% to 29.2% for planned home or birth center birth vs. 1.04% to 39.9% for planned hospital birth ARD = 0.66 to 10.7 NNT = 9 to 151 aOR ranged from 0.4, 95% CI 0.3 to 0.6, to 0.88, 95% CI 0.52 to 1.47 Adjusted risk ratio (aRR) 1.10, 95% CI 0.67 to 1.79, p = 0.23 Maternal blood transfusion (1 study) 0.5% to 0.6% for planned home or birth center birth compared to 1.2% for planned hospital birth ARD = 0.2 in favor of planned hospital birth (adjusted 0.27 to 0.28) NNT = 142 to 166 aOR 0.48 (95% CI 0.32 to 0.73) to aOR 1.91 (95% CI 1.25 to 2.93) Third or fourth degree perineal laceration (2 studies) Range from 1.9% to 4.9% for planned home or birth center birth vs. 3.2% to 4.2% for planned hospital birth ARD = 0.6 to 1.3 (adjusted 0.45 to 0.54) NNT = 76 to 166 aOR 0.77, 95% CI 0.57 to 1.05 to aOR 0.90, 95% CI 0.56 to 1.45
	●○○○ *(very low confidence, based on 5 good- or fair-quality observational studies, 1 from U.S.)*	

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Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	
	U.S. Studies	**Non-U.S. Studies**
Breastfeeding *(Important outcome)* Longest outcome data from a single fair-methodological-quality studies (1) reported (non-U.S.). Findings from poor-methodological-quality studies (7) or of short follow-up duration (1) not included in GRADE table.	*No U.S. studies with long-term outcomes identified.*	Exclusive breastfeeding at 6 months postpartum 4% to 22% for planned home or birth center birth vs. 1% to 9% ARD = 3 to 13 NNT = 7 to 33 aOR 2.24, 95% CI 1.14 to 4.03
	●○○○ *(very low confidence, based on 1 fair-quality observational study)*	
Resource Allocation: Planned out-of-hospital birth is likely to cost much less than planned hospital birth given both the lower number of maternal surgical interventions and decreased costs associated with setting. Serious neonatal morbidity could result in highly expensive and potentially long-term expensive care, but these events are rare. Transfers of care from the out-of-hospital to hospital setting, both intrapartum and postpartum, would also decrease the cost favorability. However, overall, resource allocation is expected to be in favor of planned out-of-hospital birth.		
Values and Preferences: Women deciding about birth setting are likely to have strong values and preferences toward a specific place (out-of-hospital or hospital). Women would prefer health care choices that improve the health of both the mother and the infant. In the context of informed consent, women's values vary widely in how they weigh the rare—but sometimes severe—risks to the infant associated with out-of-hospital birth in the U.S. against the less severe—but more common—maternal harms associated with hospital birth. For women who prefer out-of-hospital birth, their assessment of the benefit to the mother from reduced medical interventions may outweigh any risk of harms to the infant, since these harms are quite rare. Women who prefer out-of-hospital birth often have strongly held values about birth as a natural process and preferences to give birth in a less institutional setting. For women who prefer hospital birth, the increased risk of harms to the infant and availability of obstetric interventions, including pain management and emergency interventions, may weigh much more strongly than a higher chance of vaginal delivery. Overall, there is high variability in values and preferences regarding planned out-of-hospital birth.		

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	
	U.S. Studies	**Non-U.S. Studies**
Other Considerations: Much of the evidence and guidelines informing this coverage guidance might not have direct applicability in the Oregon setting. Some of the guidelines are based in places where out-of-hospital birth and out-of-hospital birth attendants are well-integrated into the health care delivery system, which is not uniformly the case in Oregon. In addition, minimum requirements for education and training are less stringent in Oregon than in these other contexts. Expectations and regulatory standards for birth attendants regarding acceptable risk levels for out-of-hospital births are different and less variable in other health systems reviewed in this coverage guidance.		
Balance of benefits and harms: An assessment of the balance of benefits and harms is significantly limited by the low or very low confidence in the outcomes. The balance of benefits and harms favors planned out-of-hospital birth in dyads without significant risk factors. The evidence suggests a benefit to the mother (with lower rates of cesarean section) for planned out-of-hospital birth. However, evidence also suggests harms to the neonate (a significantly increased fetal/neonatal death rate with planned out-of-hospital birth, although these events remain rare). Some higher-risk conditions are associated with even greater risk of fetal/neonatal death including (but not limited to) advanced maternal age, postdates, nulliparity, prior cesarean delivery, multiple gestation, and breech presentation. Guidelines in areas with robust systems of care suggest numerous specific risk criteria for which risks outweigh benefits. In consideration of the limited evidence and current guidelines, for women with certain risk factors, the balance of benefits and harms weighs against coverage of out-of-hospital birth.		
Rationale: In the Oregon setting, the balance of benefits and harms for out-of-hospital birth appears favorable for the mother, but less favorable or unfavorable to the infant, depending on risk factors. This assessment is largely based on very low-quality but consistent evidence. The Commission recognizes the high value many women place on choosing their birth setting and holds that value in tension with concerns about the personal and societal costs of potential catastrophic harms to the infant in the out-of-hospital setting. Resource allocation favors out-of-hospital birth as less costly for low-risk births, although frequent transfers of care and rare severe harms to the infant could affect the population-level cost. In Oregon, out-of-hospital births are not universally well-integrated into the health care system, potentially resulting in delays and poor coordination of care at critical times during pregnancy, labor, and delivery. In addition, standards of care and educational requirements for birth attendants are highly variable in Oregon. In balancing these considerations, the Commission recommends coverage for out-of-hospital birth for pregnancies free of specified conditions or characteristics which increase the risk of adverse obstetric or birth outcomes. In addition, coverage is recommended with specific requirements for ongoing risk assessment, consultation or transfer for specific high-risk conditions. The recommendation is weak because of		

Outcomes	Estimate of Effect for Outcome/ *Confidence in Estimate*	
	U.S. Studies	**Non-U.S. Studies**
the very low confidence in the evidence and because our recommendation includes pregnancies with certain risk factors (nulliparity, advanced maternal age) for which evidence suggests planned out-of-hospital birth results in a higher infant death rate. The Commission recommends noncoverage of planned out-of-hospital birth when the specified risk factors exist, when required risk assessments are not performed, or when criteria for consultation or transfer of care are not followed by the birth attendant. This is a strong recommendation because of concern about the serious risks to the infant and the likelihood that systems issues might further exacerbate these risks.		
Coverage Recommendation: See box language for details.		

Note: GRADE table elements are described in Appendix A. A GRADE Evidence Profile is in Appendix B.

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Background

The vast majority of births in Oregon and the U.S. occur in hospitals, although an increasing number of women choose to give birth in settings outside the hospital, including in homes or birthing centers. In the U.S., out-of-hospital births (planned or unplanned) represented 1.6% of all live births in 2017, an 85% increase from 2004 to 2017. The rate of out-of-hospital births varied greatly from state to state: the lowest rates were in Alabama (0.43%), Louisiana (0.46%), New Jersey (0.51%), and Rhode Island (0.51%). The highest rates of out-of-hospital births occurred in Alaska (7.9%), Montana (4.1%), Washington (3.8%), Idaho (3.8%), Oregon (3.6%), and Pennsylvania (3.5%) (MacDorman & Declercq, 2016). While the 2003 revision of the U.S. Standard Certificate of Live Birth included language clarifying if a birth location in the home was planned or unplanned, the implementation was staggered over the next fifteen years (Center for Disease Control and Prevention [CDC], 2017a). While this addition may help to identify the population of births intentionally occurring in the home or birth center, women planning an out of hospital birth but who transferred to and ultimately delivered in a hospital setting may be misattributed as having had a planned hospital birth.

The Oregon legislature passed a bill in 2011 (HB 2380) requiring birth certificates to include the question, "Did you go into labor planning to deliver at home or at a freestanding birthing center?" In 2017, planned out-of-hospital births accounted for 1,758 (4.0%) of the 44,160 births in Oregon. Compared to women who planned hospital births, women who planned out-of-hospital births were more likely to be 30 years or older (61% vs. 49%), White non-Hispanic (85 vs. 67%), and college-educated (49% vs. 32%) (Oregon Health Authority [OHA], 2019).

Table 1. Planned Attendant for Planned Out-of-Hospital Births, Oregon, 2017

Attendant	Number	Percentage
Doctors (MDs) and Doctors of Osteopathic Medicine (DOs)	0	0%
Naturopathic Physicians	238	14%
Certified Nurse Midwives	548	31%
Licensed Direct-Entry Midwives	794	45%
Unlicensed Direct-Entry Midwives	136	8%
Other	42	2%
TOTAL	**1,758**	**100%**

Table 1 shows the planned attendants for 2017 planned out-of-hospital births and that 85% of births were attended by one of the three types of midwives. Among planned hospital births, 79% were attended by MDs or DOs, and 21% (n = 8,937) were attended by midwives, all of whom were certified nurse midwives (CNMs). Among the planned out-of-hospital births, 280 (16%) resulted in an intrapartum transfer to a hospital, and another 30 (2%) involved a neonatal transfer (OHA, 2018).

In the U.S., birth attendants with a range of education and training requirements can practice in out-of-hospital settings. Table 2 shows the training and licensing requirements for various birth attendants in Oregon. With prior authorization, the Oregon Health Plan reimburses licensed out-of-hospital birth

providers for prenatal, labor and delivery, and postpartum care (OHA, 2017). Thus, unlicensed direct-entry midwives are not eligible Oregon Health Plan providers. However, unlicensed direct-entry midwives and other attendants constitute nearly 10% of all planned out of hospital births (OHA, 2019).

Table 2. Training and Licensing Requirements for Birth Attendants in Oregon

	Unlicensed Direct-Entry Midwives	Licensed Direct-Entry Midwives (LDEMs)	Certified Nurse Midwives (CNMs)	Naturopathic Doctors (NDs)	Osteopathic or Allopathic Doctors (DOs/MDs)	Chiropractors (DCs)
Accredited Training Program		√* *or judged to have equivalent training		√* *Additional training that meets board standards		√* *Additional training that meets board standards
Undergraduate Degree			√	√	√	√ * Chiropractic school or college
Graduate Degree			√	√	√	
Postgraduate Training					√	
Settings	Home	Home, birth center	Home, birth center, hospital	Home, birth center	Hospital	Home, birth center
Licensing Board	None	Board of Direct-Entry Midwifery	Oregon State Board of Nursing	Oregon Board of Naturopathic Medicine	Oregon Medical Board	Board of Chiropractic Examiners

About 60% of out-of-hospital births were in the mother's home, and about 40% were in freestanding birth centers. There are 15 licensed birth centers in Oregon, mostly located in the Willamette Valley, in the cities of Portland, Aurora, Dundee, Salem, Corvallis, and Lebanon. Southern Oregon birth centers are located in Springfield, Medford, Grants Pass, and Gold Beach (not currently providing birthing services at the center); Klamath Falls and Bend also have birth centers (OHA 2019b). Licensed birth centers in Oregon must have policies and procedures that meet North American Registry of Midwives standards (OAR 333-076-0670). Nine of the 15 licensed birth centers in Oregon are accredited by the American Association of Birth Centers, which has national standards for birth centers.

The level of integration of home birth within health care systems can be a factor in the differences in outcomes among studies of out-of-hospital births from different countries. Regulations of out-of-hospital births, provider qualifications, and accessibility of emergency care could affect the safety of out-of-hospital births. For example, there are stronger midwifery education and training requirements in some countries compared to the U.S., including Iceland (two-year Master of Midwifery after completion of a Bachelor of Science in Nursing), the Netherlands (four-year direct-entry baccalaureate program), and England (18-month postgraduate program after completion of Bachelor of Science in Nursing or three-year direct-entry baccalaureate program). In contrast, Oregon does not have any requirements for college completion for licensed or unlicensed direct-entry midwives (see Table 2 above). Midwives have hospital admitting privileges in some countries (Canada, New Zealand, Norway), and that is not always the case in the U.S. In Oregon, hospitals can grant CNMs admitting privileges. This ability is not granted to licensed or unlicensed direct-entry midwives. Requirements for midwives to carry emergency medical supplies varies across countries, and sometimes varies within a country. These contextual differences could limit the generalizability of findings from international settings to the U.S. (Comeau et al., 2018).

The differences in antenatal model of care further complicate the interpretation of birth outcomes by intended place of birth. The care provided by certified nurse midwives, certified midwives, and direct-entry midwives differs from care delivered by most physicians in its foundational view of birth as a natural process, midwifery's holistic approach to care of women, and avoidance of intervention (Rooks, 1999). A 2016 systematic review of birth outcomes for low-risk women by model of care reinforces this difference (Sandal et al., 2016). In this study, midwife-led models were associated with reduced risk of epidural anesthesia, episiotomy, instrumental delivery, and reduced risk fetal loss or neonatal death compared to physician led models (Sandal et al., 2016).

Federal Innovations- Strong Start

The Strong Start for Mothers and Newborns initiative is an example of the role of antenatal care models on birth outcomes, specifically for Medicaid enrollees (Hill et al., 2018). Funded through the Patient Protection and Affordable Care Act, Strong Start supported three models of enhanced prenatal care for Medicaid enrollees: accredited birth centers, group prenatal care, and maternity care homes (Hill et al., 2018). Strong Start participants receiving antenatal care at an accredited birth center were less likely to have a preterm delivery, a low birth weight infant, or cesarean section (17.5% versus 29.0%) compared to a similar risk cohort of Medicaid enrollees receiving traditional care regardless of place of birth. Costs were lower for birth center attendees as well (Hill et al., 2018). Additionally, Strong Start recipients received more prenatal education, psychosocial support, and referrals to non-medical services (e.g., nutritional support, housing, transportation, childcare) compared to women receiving traditional care under Medicaid. Based on these findings, the Centers for Medicare and Medicaid Services (CMS) suggests state Medicaid programs may consider expanding access to accredited birth centers to improve outcomes for enrollees (CMS, 2018).

Oregon Public Health Data

Planned out-of-hospital births in Oregon have decreased from 1,903 births (4.6%) in 2012 to 1,636 (4.1%) in 2017 (OHA, 2018). By county, planned out-of-hospital births range from 0.7% (Lake) to 10.1% (Curry) of all births (OHA, 2018). Women planning out-of-hospital birth are more often older, white, married, college-educated, and self-paying for delivery (OHA, 2018). They are also more likely to have inadequate (8.0% vs. 5.1%) or no (1.9% vs. 0.4%) prenatal care (OHA, 2018).

Infants born to low-risk women planning an out-of-hospital birth (i.e., gestational age ≥ 37 weeks to < 42 weeks, singleton, no history of prior cesarean section) have a decreased risk of neonatal intensive care unit (NICU) admission consistently, most recently 17 per 1,000 compared to 31.2 per 1,000 births for planned in-hospital births (OHA 2018). Fetal and neonatal deaths through 6 days of life (i.e., perinatal deaths) remain a rare event for births planned to be in and or out of a hospital. From 2012 to 2017, Oregon perinatal mortality rates were 2.0 per 1,000 for planned out-of-hospital birth compared to 1.7 per 1,000 for planned hospital births (absolute risk difference [ARD 0.03], number needed to harm [NNH] 3,333) (OHA, 2018).

A previous investigation into Oregon perinatal death disparities for planned out-of-hospital births was conducted in 2012 after the Oregon birth certificate was changed to record information about the planned place of birth. In the 2012 analysis, the perinatal mortality rate was 4.0 per 1,000 deaths (compared to 2.1 per 1,000 for planned hospital birth). The analysis revealed that for the eight perinatal deaths in 2012 that occurred in out- of- hospital settings, two of the mothers had inadequate or no prenatal care, four declined ultrasound in pregnancy, five declined group B streptococcal (GBS) screening, and two declined intrapartum GBS prophylaxis for positive carrier status (OHA, 2013). Additionally, for six of the eight deaths, the mothers did not meet the criteria for having a low-risk pregnancy because of either multiple gestations, advanced gestational age (> 41 weeks), or morbid obesity (> 40 body mass index) (OHA, 2013).

Evidence Review

Comparative Studies

Studies reporting findings for each of the five outcomes selected for this coverage guidance are summarized below. A summary of identified comparative studies and methodological quality is reported, followed by a high-level summary of the findings. Greater detail is available in the subsequent paragraphs by U.S.-based or international setting or different birth location (home or birth center if available). Findings from subgroups are reported in a separate section.

Outcome: Mode of Delivery

Summary

Table F1 in Appendix F provides findings of the 19 comparative cohort studies reporting mode of delivery for planned home or birth center births compared to planned hospital births. The majority (14) of studies were of poor methodological quality (Davies-Tuck et al., 2018; Halfdansdottir et al., 2018; Halfdansdottir et al., 2015; Hutton et al., 2016; Hutton et al., 2009; Janssen et al., 2009; Katoaka et al., 2018; Kennare et al., 2010; Laws et al., 2014; Øian et al., 2018; Schroeder et al., 2017; Sprague et al., 2018; Thornton et al., 2017; Wiegerinck et al., 2015). One study was assessed as having fair methodological quality (Monk et al., 2014), and three of good methodological quality (Birthplace in England Collaborative, 2011; Snowden et al., 2015; van der Kooy et al., 2017). An additional seven studies reporting findings only by parity, the most common subgroup reported across studies, are in Table F1 (Bailey, 2017; Bolten et al., 2016; Christensen & Overgaard, 2017; Hermus et al., 2017; Hollowell et al., 2017 Li et al., 2015; van Haaren-ten Haken et al., 2015).

Planned home or birth center birth was consistently associated with a greater likelihood of vaginal birth and reduction in cesarean or operative vaginal delivery compared to planned hospital birth. Studies of

higher methodological quality were more likely to account for planned home or birth center transfers to a hospital, thus eliminating differential misclassification bias that would have favored planned home or birth center birth, as negative outcomes would be attributed to hospitals in the event of transfer.

Estimates of spontaneous vaginal birth from fair- or good-methodologic-l quality studies reported an absolute risk difference of 20 to 27% in favor of planned home or birth center birth (four to five women needed to treat with planned out-of-hospital birth compared to planned hospital birth to avoid one non-spontaneous vaginal birth). Estimates of operative vaginal or cesarean deliveries from good- or fair-methodological-quality studies observed an absolute risk difference in favor of planned home birth (3% to 17% or 5 to 33 women with planned delivery at home or birth center to avoid one operative vaginal or cesarean delivery). However, comparative evidence on delivery mode for U.S. women is limited. Notably, aside from a single Australian study with a 27% hospital cesarean rate (Kennare et al., 2010), all studies were conducted in sites with fewer hospital cesarean deliveries than typically observed in U.S. hospitals where the cesarean delivery rate was 31% in 2016 (CDC, 2017b).

U.S. Studies

Two studies reported mode of delivery for U.S.-based settings (Snowden et al., 2015; Thornton et al., 2017). In a good-quality study from Oregon, planned home or birth center births were associated with a reduced risk of cesarean delivery compared to planned hospital delivery (absolute risk difference -24%, 95% CI -26.6 to -21.4, $p < 0.001$) and operative vaginal delivery (absolute risk difference -4.7%, 95% CI -5.8 to -3.5%, $p < 0.001$) with greater rates of spontaneous vaginal delivery (absolute risk difference 27.5%, 95% CI 24.9 to 30.2, $p < 0.001$) (Snowden et al., 2015). In a poor-quality separate analysis of planned home or birth center births in 43 states, cesarean deliveries were less common for planned home or birth center births compared to planned hospital births (aOR 0.63, 95% CI 0.50 to 0.79) (Thornton, et al., 2017).

Non-U.S. Studies

Fifteen studies reported comparative mode of delivery outcomes for women by intended place of birth in non-U.S. based settings (Birthplace, 2011; Davies-Tuck et al., 2018; Halfdansdottir et al., 2018; Halfdansdottir et al., 2015; Hutton et al., 2009; Hutton et al., 2016; Janssen et al., 2009; Katoaka et al., 2018; Kennare et al., 2010; Laws et al., 2014; Monk et al., 2014; Schroeder et al., 2017; Sprague et al., 2018; van der Kooy et al., 2017; Wiergerinck et al., 2015). Findings from the two good-quality studies demonstrated increased rates of spontaneous vaginal deliveries (aOR 3.61, 95% CI 2.97 to 4.38) (Birthplace, 2011) and decreased risk of operative or cesarean delivery (aOR 0.77, 95% CI 0.75 to 0.78) (van der Kooy et al., 2017).

Vaginal birth rates were consistently higher for planned home or planned birth center births (over 90% across studies) compared to hospital births in non-U.S. settings. Estimates ranged across studies comparing planned home to planned hospital births from a 30% to 60% reduced odds of cesarean delivery for planned home or birth center births compared to planned hospital birth. Rates of operative vaginal delivery (forceps, vacuum, or both) were reduced for planned home or birth center births compared to planned hospital deliveries. The magnitude of effect ranged across studies from 20% to 60% reduced odds of an operative delivery.

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Outcome: Perinatal or Neonatal Mortality

Estimates of fetal or neonatal mortality were not consistently defined across identified studies, encompassing definitions that ranged from 20 weeks gestation through 27 days of life. As able, we provided specific timing of mortality to allow more direct comparisons across studies. If the study authors provided absolute numbers and used an unadjusted odds ratio as their estimate of effect, we provided a calculated unadjusted risk ratio (relative risk) estimate.

Summary

Table F2 provides findings of the 16 comparative studies reporting perinatal mortality outcomes for planned home or birth center births compared to planned hospital births. The majority of these studies were of poor methodological quality (Davies-Tuck et al., 2018; Grigg et al., 2017; Grunebaum, McCullough, Arabin et al., 2017; Hutton et al., 2016; Hutton et al., 2009; Janssen et al., 2009; Katoaka et al., 2018; Kennare et al., 2010; Thornton et al., 2017; Wiegerinck et al., 2015). We assessed four studies as having fair methodological quality (Grunebaum, McCullough, Sapra et al., 2017; Halfdansdottir et al., 2015; Homer et al., 2014; van der Kooy et al., 2011), and two as having good methodological quality (Birthplace, 2011; Snowden, et al., 2015). An additional three studies, reporting findings only by parity, the most common subgroup, are also in Table F2 (Bailey et al., 2017; de Jonge et al., 2013; van Haaren-ten Haken et al., 2015).

International studies consistently observe very low rates of intrauterine, intrapartum, and neonatal mortality that are similar for home, birth center, and hospital settings for all women. However, U.S.-based studies reported increased risks of neonatal death (from 0 to 27 days) for planned home births compared to planned hospital births using national vital statistics data (Grunebaum, McCullough, Sapra et al., 2017; Snowden et al., 2015). Comparisons of U.S. studies to international settings are limited by differences in outcome definition, provider types, health system delivery, and the reliance on administrative vital statistics in the U.S. that limits ability of authors to adjust for confounding.

U.S. Studies

Three studies reported comparative mortality outcomes for births in U.S.-based settings (Grunebaum, McCullough, Sapra et al., 2017; Snowden, et al., 2015; Thornton et al., 2017). In the first study, a fair-quality study of national vital statistics data, neonatal death from 0 to 27 days was more common in planned home births attended by a midwife (provider type confirmed by personal communication, A. Grunebaum, June 4, 2019) compared to planned hospital birth attended by a certified nurse midwife from 2009 to 2013 (0.12% vs. 0.03%, standardized mortality ratio 4.13, 95% CI 3.38 to 4.88) (Grunebaum, McCullough, Sapra et al., 2017).

The second study, a good-quality study conducted in Oregon, the risk of fetal death (≥ 20 weeks), intrapartum, or neonatal death (0 to 27 days) was higher for planned home and birth center births compared to planned hospital births from 2012 to 2013 (absolute difference 0.158 percentage points, 95% CI 0.055 to 0.261, p = 0.003) (Snowden et al., 2015). Overall, 634 women would need to have a planned hospital birth to avoid one fetal or neonatal death in the planned home or birth center setting.

In the third study, which we rated as poor quality, intrapartum or newborn death (days of life not reported) was similar for planned birth centers and planned hospital births in data from 43 states and 79 birth centers from 2006 to 2011 (OR 0.86, 95% CI 0.09 to 8.3, p = 0.99; RR calculated 0.96, 95% CI 0.54 to 1.70) (Thornton et al., 2017).

Non-U.S. Studies

Seven studies reported comparative mortality outcomes for births in settings outside the U.S. (Davies-Tuck et al., 2018; Grigg et al., 2017; Janssen et al., 2009; Katoaka et al., 208; Kennare et al., 2010; van der Kooy et al., 2011; Wiegerinck, et al., 2015). In a good quality study from the Netherlands, from 2000 to 2007 intrapartum or neonatal deaths (0 to 7 days) did not differ for planned home and planned hospital births attended by a midwife (aOR 1.05, 95% CI 0.91 to 1.21) (van der Kooy et al., 2011).

Estimates from poor-quality studies reported similar findings from the Netherlands (Wiegerinck et al., 2015), British Columbia (Janssen et al., 2009), Australia (Davies-Tuck et al., 2018; Kennare et al., 2010), New Zealand (Grigg et al., 2017), and Japan (Katoaka et al., 2018)..

A cohort of Dutch women from 2005 to 2008 observed similar intrapartum or neonatal deaths (OR 1.30, 95% CI 0.63 to 2.67) (Wiegerinck et al., 2015). Planned home births in British Columbia, Canada, had similar rates of fetal (≥ 20 weeks), intrapartum, or neonatal deaths (0 to 7 days) compared to planned hospital births attended by midwives and a cohort of births attended by physicians, matched for maternal demographics (RR 0.61, 95% CI 0.06 to 5.88; RR 0.55, 95% CI 0.06 to 5.25; respectively) (Janssen et al., 2009). Rates of intrauterine or neonatal death were not statistically different for planned home births compared to planned hospital births in two studies from two states in Australia (Victoria, South Australia) with over 10 years of registry data (Davies-Tuck et al., 2018; Kennare et al., 2010). In a small study (n < 1,000) from New Zealand, there were no intrauterine, intrapartum, or neonatal deaths (0 to 27 days) for hospital births compared to 3 (0.74%) for planned birth center births (Grigg et al., 2017). No intrauterine or intrapartum deaths were observed for planned birth center births in Japan, compared to 11 (0.3%) for planned hospital births (Katoaka et al., 2018).

Outcome: Neonatal Morbidity

Summary

Neonatal morbidity encompasses a range of outcomes including but not limited to admission to a hospital, admission to a specialized neonatal unit or NICU, low Apgar score at birth, neonatal seizures, hypoxic ischemic encephalopathy, and sepsis. These outcomes were reported individually or as composites, depending on the study.

Table F3 provides findings of the 20 comparative studies reporting neonatal morbidity outcomes for planned home or birth center births compared to planned hospital births. The majority of studies were of poor methodological quality (Davies-Tuck et al., 2018; Grigg et al., 2017; Halfdansdottir et al., 2018; Halfdansdottir et al., 2015; Hitzert et al., 2016; Hutton et al., 2016; Hutton et al., 2009; Janssen et al., 2009; Katoaka et al., 2018; Kennare et al., 2010; Li et al., 2017; Øian et al., 2018; Schroeder et al., 2017; Sprague et al., 2018; Thornton et al., 2017; Wiegerinck et al., 2015).We rated two studies as fair methodological quality (Homer et al., 2014; Monk et al., 2014), and two of good methodological quality (Birthplace in England Collaborative, 2011; Snowden, et al., 2015). An additional five studies reporting findings only by parity, the most common subgroup, are in Table F3 (Bailey et al., 2017; Christensen & Overgaard, 2017; de Jonge et al., 2015; Hollowell et al., 2017; Li et al., 2015; van Haaren-ten Haken et al., 2015).

Three studies reported comparative neonatal morbidity outcomes for women in U.S. settings. Two reported single state findings from Oregon (Snowden et al., 2015) and South Carolina (Li et al., 2017). The third reported outcomes from freestanding birth centers in 43 states (Thornton et al., 2017).

Findings from these U.S. studies demonstrated a small but increased risk of seizures and need for ventilator support in Oregon from 2012 to 2013 data (Snowden et al., 2015). Older data from South Carolina also demonstrated greater rates of neonatal morbidity for planned home or birth center births versus planned hospital births without formal statistical analysis, including neonatal seizures (0.15% vs. 0.0% vs. 0.02%) and convulsions (0.61% vs. 0.24% vs. 0.24%) (Li et al., 2017).

Generally, findings from international studies of planned home or birth center births compared to planned hospital births did not observe statistically significant differences across neonatal morbidity outcomes. However, in subgroup analyses, nulliparous women appeared to experience a greater likelihood of neonatal morbidity in the Birthplace study from England (i.e., Birthplace composite outcome) even after restricting to the lowest-risk group (Birthplace et al., 2011; Hollowell et al., 2017). However, that relationship was not consistent across a study from Australia (Homer et al., 2014).

U.S. Studies: Planned Home and Birth Center Settings

A study conducted in Oregon from 2012 to 2013 found that the risk of admission to an NICU was lower for planned home or birth center births compared to planned hospital births (absolute difference -0.85 percentage points, 95% CI -1.57 to -0.14, NNT = 117) (Snowden et al., 2015). The risk of all the following outcomes was higher for planned home or birth center births compared to planned hospital births:

- A lower Apgar score at five minutes of less than seven (unadjusted 2.3% vs. 1.8%, adjusted absolute difference 0.50, 95% CI 0.07 to 0.93, NNH = 200) and less than four (unadjusted 0.6% vs. 0.4%, adjusted absolute difference 0.18, 95% CI 0.00 to 0.37, NNH = 555)
- Neonatal seizures (unadjusted 0.13% vs. 0.04%, absolute difference, 0.07 percentage points, 95% CI 0.02 to 0.13, calculated NNH = 1,428)
- Ventilator support (unadjusted 3.8% vs. 3.3%, adjusted absolute difference, 1.05 percentage points, 95% CI 0.48 to 1.62, calculated NNH = 95) (Snowden et al., 2015)

In a study conducted in South Carolina from 2003 to 2013, the frequency of neonatal seizures and convulsions was higher for planned home births (0.15%, 0.61% respectively) compared to planned birth center (none, 0.24%) and hospital settings (0.02%, 0.24%); no formal statistical analysis was reported (Li et al., 2017).

U.S. Studies: Birth Center Setting

In a poor-quality study of birth centers in 43 states, women planning a birth center birth experienced similar odds of a lower Apgar score at five minutes (score 3 to 7; aOR 1.60, 95% CI 0.82 to 3.16), and short-term positive pressure ventilation (< 10 minutes; aOR 1.31, 95% CI 0.95 to 1.82) compared to those planning a hospital birth (Thornton et al., 2017). The odds of needing a newborn sepsis evaluation was reduced for planned birth center birth (aOR 0.51, 95% CI 0.32 to 0.81). The odds of a composite outcome consisting of mortality, hypoxic injury, low Apgar, seizure, respiration support, and meconium aspiration syndrome were also similar across settings (aOR 1.44, 95% CI 0.95 to 1.82).

Non-U.S. Studies: Home Birth Setting

The odds of a composite outcome encompassing death after the start of care in labor, early neonatal death, neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, and fractured humerus or clavicle were similar across planned home and planned hospital births in a good-quality study from England (aOR 1.16, 95% CI 0.76 to 1.77) (Birthplace, 2011) and a fair-quality study from Australia (aOR 1.06, 95% CI 0.44 to 2.56) (Homer et al., 2014). The odds of a composite outcome of

Apgar score less than four at five minutes and need for positive pressure ventilation or chest compressions were similar for planned home and planned hospital births in two poor-quality studies from Ontario, Canada (RR 0.95, 95% CI 0.6 to 1.48) (Hutton et al., 2016), which is consistent with findings from an earlier cohort (RR 0.82, 95% CI 0.66 to 1.01) (Hutton et al., 2009).

In a poor-quality study conducted in the Netherlands, planned home births were associated with decreased odds of NICU admission for over 24 hours (OR 0.64, 95% CI 0.43 to 0.95), and similar odds of an Apgar score less than seven at five minutes (OR 0.93, 95% CI 0.75 to 1.15) (Wiegerinck et al., 2015). In a poor-quality study from the state of South Australia conducted in a 14-year period, the odds of Apgar score less than seven at five minutes (aOR 1.43, 95% CI 0.66 to 3.07) and needs for specialized neonatal care (aOR 0.80, 95% CI 0.62 to 1.03) were not different for planned home and planned hospital births (Kennare et al., 2010). The odds of an Apgar score less than seven at five minutes (aOR 0.82, 95% CI 0.27 to 2.52), need for respiratory support (aOR 0.97, 95% CI 0.63 to 1.50), and admission to a neonatal nursery unit (aOR 1.44, 95% CI 0.70 to 2.96) were similar for planned midwifery birth center births and planned obstetric hospital births in a small, poor-quality study from New Zealand (n < 1,000) (Grigg et al., 2017).

Infants whose mothers had planned home births in British Columbia, Canada, experienced a decreased risk of birth weight < 2,500g (RR 0.44, 95% CI 0.25 to 0.78), a lower rate of need for resuscitation (RR 0.23, 95% CI 0.14 to 0.37), and birth trauma (RR 0.26, 95% CI 0.11 to 0.58) compared to midwife-attended hospital births. Relative risk of an Apgar score less than seven at five minutes (RR 0.92, 95% CI 0.58 to 1.47), asphyxia (RR 0.79, 95% CI 0.30 to 2.05), meconium aspiration (RR 0.83, 95% CI 0.38 to 1.81), seizures (RR 0.61, 95% CI 0.12 to 3.03), and assisted ventilation over 24 hours (RR 1.02, 95% CI 0.34 to 3.04) were not statistically different across settings in a poor-quality study (Janssen et al., 2009).

The frequency of Apgar scores < five at five minutes (0.9% vs. 1.2%, p = 0.08), hypoxic ischemic encephalopathy (0% vs. 0.2%, p = 0.44), and other perinatal morbidities were not statistically different in a poor-quality study conducted in the state of Victoria in Australia from 2000 to 2008; no formal statistical analysis was reported (Davies-Tuck et al., 2018). There were more admissions to an NICU (0.4% vs. 0.2%, p = 0.03) among planned home births. Admission to a special care nursery 1.8% vs. 8.3%, p < 0.001), birth trauma (1.4% vs. 6.6%, p < 0.001*),* intrauterine hypoxia (1.5% vs. 5.8%, p < 0.001), and composite morbidity (e.g., NICU admissions, birth trauma, hypoxia) (3.6% vs. 13.4%, p < 0.001) were less common in planned home births than planned hospital births.

Non-U.S. Studies: Birth Center Settings

In fair- to good-quality studies, the odds of a composite outcome encompassing stillbirth after the start of care in labor, early neonatal death, neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, and fractured humerus or clavicle were similar across planned birth center and planned hospital births in England (aOR 0.92, 95% CI 0.58 to 1.46) (Birthplace, 2011) and Australia (aOR 0.87, 95% CI 0.69 to 1.10) (Homer et al., 2014).

In a poor-quality study, admission to an NICU was similar (aRR 1.3, 95% CI 0.9 to 2.0) for planned birth center births and planned midwife-attended hospital births in Ontario, Canada, in the first year after the introduction of the birth center (2014 to 2015) (Sprague et al., 2018).

DRAFT

Outcome: Maternal Harm

Summary

Outcomes related to maternal harm include but are not limited to third or fourth degree perineal injuries or obstetric anal sphincter injuries, immediate postpartum hemorrhage, blood transfusion, admission to a hospital or an intensive care unit (ICU), infection, uterine rupture, and manual removal of the placenta. Definitions for outcomes varied across studies, particularly for postpartum hemorrhage and blood transfusion; some studies only reported findings for large transfusion volume (i.e., over 4 units).

Table F4 provides findings of the 20 comparative studies reporting maternal harm outcomes for planned home or birth center births compared to planned hospital births. The methodological quality of the included studies was largely poor (Davies-Tuck et al., 2018; Grigg et al., 2017; Halfdansdottir et al., 2018; Halfdansdottir et al., 2015; Hutton et al., 2016; Hutton et al., 2009; Janssen et al., 2009; Katoaka et al., 2018; Kennare et al., 2010; Laws et al., 2014; Øian et al., 2018; Schroeder et al., 2017; Thornton et al., 2017; Wiegerinck et al., 2015). We assessed four studies as having fair methodological quality (de Jonge et al., 2013; Davis et al., 2012; Monk et al., 2014; Nove et al., 2012;) and two as good methodological quality (Birthplace in England Collaborative, 2011; Snowden et al., 2015). An additional five studies reported findings only by parity and are also in Table F4 (Bailey, 2017; Bolten et al., 2016; Christensen & Overgaard, 2017; Hollowell et al., 2017; van Haaren-ten Haken et al., 2015).

Only two of the 20 included studies reported outcomes for U.S.-based settings (Snowden et al., 2015; Tilden et al., 2017). Overall, estimates of maternal harm for planned home or birth center births are limited in the U.S. because they rely on vital statistics data. In the two included studies, planned home or birth center births observed a decreased risk of third or fourth degree perineal tear with an increased risk of blood transfusion (Snowden et al., 2015; Tilden et al., 2017). In international studies, the authors observed mixed results in estimates of maternal harm, often with no statistical differences in harms or a reduced frequency in the home birth group.

U.S. Studies

In a good-quality study conducted in Oregon using data from 2012 to 2013, women planning a home or birth center birth experienced a decreased risk of severe perineal lacerations (adjusted risk difference 0.54 in favor of planned home or birth center, 95% CI −0.98 to −0.11, p = 0.02), but also had an increased risk of blood transfusion (adjusted risk difference 0.27 favoring planned hospital birth, 95% CI 0.08 to 0.46 p = 0.006) (Snowden et al., 2015). In a poor-quality study, postpartum hemorrhage frequency was not statistically different for planned birth center and planned hospital groups (aOR 1.25, 95% CI 0.99 to 1.58) (Thornton et al., 2017).

Non-U.S. Studies: Home Births

Estimates of third or fourth degree tears were similar in one good-quality study (1.9% vs. 3.2%, aOR 0.77, 95% CI 0.57 to 1.05)((Birthplace, 2011) and one poor-quality study (1.0% vs. 1.8%, aOR 0.77, 95% CI 0.34 to 1.74, p = 0.53 (Kennare et al., 2010) and decreased in three poor-quality studies (1.0% vs. 2.0%, p < 0.001; 1.3% vs. 2.3%, RR 0.57, 95% CI 0.47 to 0.69; 1.2% vs. 2.9%, RR 0.43, 95% CI 0.29 to 0.63) (Davies-Tuck et al., 2018; Hutton et al., 2016; Janssen et al., 2009) for women in planned home birth settings compared to planned hospital births. Obstetric anal sphincter injuries were less common in

planned home birth groups in two poor-quality studies (2.5% vs. 3.1%, p = NR; 2.6% vs. 3.0%, aOR 0.97, 95% CI 0.41 to 2.27) (Halfdansdottir et al., 2018; Halfdansdottir et al., 2015).

In eight poor- to fair-quality studies conducted in multiple countries, women in the planned home birth group were less likely to have a documented postpartum hemorrhage (9.1% vs. 12.9%, p < 0.001; 29.2% vs. 39.9%, p = NR; 3.0% vs. 3.7%, aOR 0.64, 95% CI 0.24 to 1.67; 0.8% vs. 1.2%, RR 0.68, 95% CI 0.49 to 0.96; 2.5% vs. 3.0%, RR 0.82, 95 % CI 0.70 to 0.96; 3.8% vs. 6.0%, RR 0.43, 95% CI 0.29 to 0.63; 0.38% vs. 1.04%, aOR 0.4, 95% CI 0.3 to 0.6, p < 0.001; 4% vs. 5%, OR 0.68, 95% CI 0.62 to 0.74, p < 0.001)(Davies-Tuck et al., 2018; de Jonge et al., 2013; Halfdansdottir et al., 2015; Hutton et al., 2009; Hutton et al., 2016; Janssen et al., 2009; Nove et al., 2012; Wiegerinck et al., 2015). The frequency of estimated blood loss at time of delivery of ≥ 1000 mL was not statistically different in 2 poor to fair quality studies (1.0% vs. 1.1%, aRR 0.93, 95% CI 0.49 to 1.74, p = 0.97; 4.4% vs. 5.5%, aOR 0.72, 95% CI 0.47 to 1.11, p = 0.14)(Davis et al., 2012; Kennare et al., 2010).

Estimates of the need for blood transfusion were similar for planned home and hospital births (0.6% vs. 1.2%, aOR 0.72, 95% CI 0.47 to 1.12) in a good-quality study (Birthplace, 2011). The frequency of blood transfusion was less common in two poor- to fair-quality studies (de Jonge et al., 2013; no formal statistical analysis reported; Halfdansdottir et al., 2015). Manual removal of the placenta was less frequent for planned home birth groups; however, neither study reported statistical analysis (de Jonge et al., 2013; Janssen et al., 2009).

In 2 poor to fair quality studies, women in the planned home birth group were less likely to be admitted to a hospital or an ICU (0.2% vs. 0.6%, p = 0.002; 0.3% vs. 0.7%, p = NR) (Davies-Tuck et al., 2018; de Jonge et al., 2013). Frequency of maternal postpartum infection was similar for planned home and hospital births in a single poor-quality study without statistical analysis (Janssen et al., 2009).

Non-U.S. Studies: Birth Centers

Findings from birth centers related to third or fourth degree perineal lacerations observed similar rates (2.2% vs. 1.8%, aOR 1.43, 95% CI 0.46 to 4.42, p > 0.05) (Grigg et al., 2017) or lower rates compared to planned hospital births (2.5% vs. 3.0%, aOR 0.85, 95% CI 0.74 to 0.99) (Law et al., 2014). Overall, perineal laceration rates were lower in the birth center setting compared to planned hospital (40.9% vs. 66.1%, aOR 0.38, 95% CI 0.35 to 0.42; Katoaka et al., 2018).

Studies demonstrated conflicting outcomes for frequency of blood loss ≥ 1,000 ml for planned birth center births compared to planned hospital births: higher in one study (3.6% vs. 2.4%, aOR 1.77, 95% CI 1.35 to 2.32) (Katoaka et al., 2018), similar in two studies (5.9% vs. 4.6%, aOR 1.74, 95% CI 0.85 to 3.59, p > 0.05; 3.6% vs. 139 4.4%, aOR 0.88, 95% CI 0.52 to 1.47, p = 0.618) (Grigg et al., 2017; Monk et al., 2014), and lower in another study (8.6% vs. 10.6%, aOR 0.79, 95% CI 0.73 to 0.86) (Laws et al., 2014). Women planning birth center births were also less likely to have a uterine rupture (0.03% vs. 0.08%, aOR 0.17, 95% CI 0.04 to 0.73), postpartum infection (1.0% vs. 1.4%, aOR 0.74, 95% CI 0.59 to 0.92), and ICU admission (0.02% vs. 0.08%, aOR 0.12, 95% CI 0.02 to 0.89) (Laws et al., 2014).

Outcome: Breastfeeding

Summary

Table F5 provides findings of the nine comparative studies reporting breastfeeding outcomes for planned home or birth center births compared to planned hospital births. The majority of the identified studies are of poor methodological quality (de Cock et al., 2015; Grigg et al., 2017; Hutton et al., 2016;

Hutton et al., 2009; Laws et al., 2014; MacDorman & Declercq, 2016; Thornton et al., 2017); two are of fair methodological quality (Monk et al., 2014; Quigley et al., 2016).

Two of the studies provided outcomes for U.S.-based settings (MacDorman & Declercq, 2016; Thornton et al., 2017). Across all studies, the timing of breastfeeding outcomes ranged from rates of initiation in the birth setting to exclusive breastfeeding at six months. Only two studies (Hutton et al., 2016; Hutton et al., 2009) provided outcomes for nulliparous and multiparous women separately, with the remaining studies reporting aggregate outcomes for all women.

Early rates of breastfeeding (initiation, at time of discharge, or within the first two weeks) were consistently higher for planned home or birth centers compared to hospital births. However, estimates that control for confounding and examine breastfeeding at a time point further from delivery did not observe differences between planned home birth, birth center, and planned hospital groups in international settings. There were no U.S.-based studies with comparative breastfeeding outcomes that reported data past discharge from the birth setting. A retrospective survey reported that rates of exclusive breastfeeding at six months were higher for individuals reporting a planned home birth, but the findings were well below World Health Organization (WHO) goals and based on two surveys with low participation rates (Quigley et al., 2016).

U.S. Studies

Two poor-quality studies reported comparative estimates of breastfeeding by place of birth in the U.S. (MacDorman & Declercq, 2016; Thornton et al., 2017). Breastfeeding initiation rates from birth certificate data from 2004 to 2014 were higher for planned home or birth center births, 97.9% and 98.1% respectively, compared to 80.8% for planned hospital births; no formal statistical analysis was provided (MacDorman & Declercq, 2016). Analysis of data from the American Association of Birth Centers from 2006 to 2011 observed that infants born in a planned birth center were more likely to be breastfed at the time of discharge compared to infants born in a planned hospital birth (94.5% vs. 72.2%, aOR 9.12, 95% CI 7.45 to 11.16, p = NR) (Thornton et al., 2017).

Non-U.S. Studies

Seven poor- to fair-quality studies reported comparative estimates of breastfeeding by place of birth in Australia, Canada, Ireland, the Netherlands, New Zealand, and the United Kingdom (de Cock et al., 2015; Grigg et al., 2017; Hutton et al., 2016; Hutton et al., 2009; Laws et al., 2014; Monk et al., 2014; Quigley et al., 2016). Largely, rates of breastfeeding were higher for planned home birth groups compared to planned hospital births across all time points. Exclusive breastfeeding at six months of life was reported by a single fair-quality study using retrospective data from Irish and UK national surveys (Quigley et al., 2016). In Ireland, 22% of infants from a planned home birth group compared to 9% of those with planned hospital births were exclusively breastfed at six months (aOR 2.77, 95% CI 1.78 to 4.33, p = 0.0073). In the United Kingdom, the proportion of infants with exclusive breastfeeding at six months declined, but was still higher for the planned home birth cohort compared to the planned hospital cohort (4% vs. 1%, aOR 2.24, 95% CI 1.14 to 4.03, p < 0.001).

Although the proportion of infants exclusively breastfed at a median of five weeks postpartum was lower for planned hospital births compared to planned home births in a small study from the Netherlands (n = 712), the difference was not statistically significant after adjusting for potential confounders of age, parity, education level, ethnicity, smoking, and birth weight (68.5% vs. 75%, aOR 0.79, 95% CI 0.53 to 1.18) (de Cock et al., 2015). Similarly, in New Zealand, rates of exclusive

breastfeeding at six weeks were statistically similar for planned birth in primary midwifery units (i.e., birth centers) compared to tertiary maternity hospitals (i.e., hospital births) after adjusting for potential confounders of age, smoking, parity, term, and need for augmentation or induction (80.6% vs. 78.6%, aOR 1.14, 95% CI 0.76 to 1.70, p > 0.05) (Grigg et al., 2017).

A study from Canada found that breastfeeding rates were higher at 10 days for planned home compared to planned hospital births (87.8% vs. 78.9%, RR 1.11, 95% CI 1.10 to 1.13) (Hutton et al., 2016). The likelihood of breastfeeding at discharge was higher for planned home births in Australia in both the studies by Laws et al. (aOR 2.32, 95% CI 2.04 to 2.65, p = NR) and Monk et al. (aOR 1.59, 95% CI 1.14 to 2.24 p = 0.007), after adjusting for potential confounders.

Subgroup Findings

The following section outlines comparative findings across identified subpopulations or subgroups for all outcomes prioritized for this coverage guidance. Reported subgroups are parity, maternal age, other risk factors, history of cesarean section, breech position, gestational age, and race/ethnicity. Studies commonly reported outcomes for all participants, then separately reported outcomes for nulliparous and multiparous women. Additionally, studies reported outcomes for a specific subpopulation (e.g. women with a prior cesarean delivery, high-risk pregnancy [based on differing definitions]).

A summary is provided for each subgroup, followed by specifics for each outcome. As above, findings are reported for U.S-based studies separately from non-U.S. studies. Findings from U.S-based studies by subgroup only report neonatal mortality or morbidity outcomes. Please see the tables in Appendix G for detailed findings.

Subgroup: Parity

Summary

Comparisons by parity were the most commonly reported subgroup and included mode of delivery, fetal or neonatal mortality, neonatal harm, maternal harm, and breastfeeding. Findings from U.S. settings were limited to neonatal mortality rates from two studies. Both studies observed higher rates of neonatal death for all women; nulliparous women were at the highest risk. International studies consistently observed more optimal delivery mode outcomes and similar intrapartum and early neonatal death rates across birth settings for nulliparous and multiparous women.

Rates of neonatal harm, specifically the Birthplace composite outcome, were higher for nulliparous women in the planned home but not planned birth center setting compared to planned hospital setting in the original Birthplace cohort study. This finding was not observed in a study of similar quality conducted in Australia.

Mode of Delivery

No U.S.-based study reported comparative mode of delivery outcomes by parity. In non-U.S. studies, nulliparous and multiparous women were likely to experience more optimal delivery mode outcomes (i.e., increased odds of vaginal delivery, lower odds of instrumental [forceps or vacuum assisted] or cesarean delivery) in the planned home or birth center groups compared to women in planned hospital births, based on good- or fair-methodological-quality studies.

Non-U.S. Studies: Home Birth Settings

Ten non-U.S.-based studies reported mode of delivery outcomes by parity (Bailey et al., 2017; Bolten et al., 2016; Christensen & Overgaard, 2017; Halfdansdottir et al., 2017; Hollowell et al., 2017; Hutton et al., 2009; Hutton et al., 2016; Janssen et al., 2009; Li et al., 2015; van Haaren-ten Haken et al., 2015).

Nulliparous and multiparous women planning a home birth were more likely to experience a straightforward vaginal birth (one without instrumentation, a third or fourth degree tear, or requiring blood transfusion) than similar women planning hospital birth in the good-quality Birthplace study conducted in England (aRR 1.63, 95% CI 1.47 to 1.81 for nulliparous women; aRR 1.20, 95% CI 1.16 to 1.23 for multiparous) (Li et al., 2015).

Across studies of poor quality, nulliparous and multiparous women experienced more optimal delivery mode outcomes in the planned home birth group (i.e., increased odds of vaginal delivery, lower odds of instrumental or cesarean delivery) compared to planned hospital birth; the magnitude of the benefit was greater for multiparous women across all modes for planned home birth compared to planned hospital birth; for example, a study conducted in the Netherlands found greater odds of spontaneous vaginal delivery for multiparous women (aOR 2.29, 95% CI 1.21 to 4.36 compared to aOR 1.38, 95% CI 1.08 to 1.76 for nulliparous women, no formal statistical comparison reported) (Bolten et al., 2016). Similar benefits were observed in nulliparous and multiparous women in Ontario, Canada (Hutton et al., 2016). In studies only reporting comparative rates, with no formal statistical analysis, women who had planned home births experienced lower cesarean delivery rates in British Columbia (Janssen et al., 2009) and Iceland (Halfdansdottir et al., 2015), and in older data from Ontario, Canada (Hutton et al., 2009).

Non-U.S. Studies: Birth Center Settings

Four non-U.S. based studies reported outcomes from birth center settings: two studies were poor quality (Bailey et al., 2017; Christensen & Overgaard, 2017) and one was fair quality (Hollowell et al., 2017) and one was good quality (Hermus et al., 2017). In the Netherlands, nulliparous and multiparous women experienced similar rates of vaginal delivery in a birth center as in a hospital or home setting (Hermus et al., 2017). Rates of instrumental delivery also did not differ by planned place of birth (Hermus et al., 2017).Nulliparous and multiparous women planning to give birth at a freestanding birth center in the United Kingdom were more likely to have a spontaneous vaginal delivery and less likely to have an instrumental delivery, but had similar odds of cesarean delivery compared to planned hospital births after adjusting for maternal characteristics and complicating conditions at the start of labor (Hollowell et al., 2017).

Unadjusted estimates from Denmark demonstrated greater odds of uncomplicated birth, one “leaving both mother and infant in good condition” and lower odds of instrumental delivery for nulliparous and multiparous women planning a birth center birth compared to a matched hospital birth group. The odds of uncomplicated birth were greater for multiparous women than for nulliparous women (OR 2.9, 95% CI 2.0 to 4.2 compared to OR 2.2, 95% CI 1.4 to 3.3); nulliparous women experienced a greater reduction in the odds of cesarean delivery (OR 0.4, 95% CI 0.2 to 0.9 compared to OR 0.8, 95% CI 0.3 to 2.2). The reduction in instrumental delivery was similar for both groups (OR 0.4, 95% CI 0.2 to 0.7 nulliparous, OR 0.3, 95% CI 0.1 to 0.9 multiparous) (Christensen & Overgaard, 2017).

Nulliparous and multiparous women planning a birth center birth in New Zealand experienced similar reductions in odds of instrumental delivery, with a small reduction in the risk of cesarean delivery for

multiparous women (aOR 0.34, 95% CI 0.26 to 0.46) compared to that for nulliparous women (aOR 0.51, 95% CI 0.44 to 0.59) (Bailey et al., 2017).

Fetal or Neonatal Mortality

Two studies of poor and fair quality reported comparative mortality outcomes by parity in the U.S. from 2008 to 2012 (Grunebaum, McCullough, Arabin et al., 2017) and 2009 to 2013 (Grunebaum, McCullough, Sapra et al., 2017). In the first study, neonatal death (0 to 27 days) was higher in the planned home birth group (attended by a certified nurse or other midwife) compared to hospital births attended by a certified nurse midwife for nulliparous (RR 5.34, 95% CI 3.9 to 7.4) and multiparous women (RR 3.1, 95% CI 2.4 to 4) (Grunebaum, McCullough, Arabin et al., 2017). The authors did not report adjusted estimates to account for possible confounding.

The findings were similar for the later time period (2009 to 2013) with a higher standardized mortality ratio (SMR) in planned home births for nulliparous (SMR 6.06, 95% CI 4.30 to 7.83) and multiparous women (SMR 3.49, 95% CI 2.68 to 4.30) (Grunebaum, McCullough, Sapra et al., 2017). The planned home birth cohort in this analysis was not limited by provider type to certified nurse or other midwife, as above, and included births that were purposely not attended by a trained professional. Estimates in this study were reported as standardized mortality ratios, attempting to account for parity and other maternal demographics in comparisons.

Eight non-U.S.-based studies reported comparative perinatal mortality outcomes by parity in Australia (Homer et al., 2014), Iceland (Halfdansdottir et al., 2015), New Zealand (Bailey et al., 2017), the Netherlands (de Jonge et al., 2015; Hermus et al., 2017; van Haaren-ten Haken et al., 2015) and Ontario, Canada (Hutton et al., 2016; Hutton et al., 2009). Of these, one good-quality (Hermus et al., 2017) and two fair-quality studies reported findings by parity (Homer et al., 2014; de Jonge et al., 2015).

Nulliparous women in Australia did not experience statistically different rates of neonatal death across birth settings (home vs. hospital: aOR 2.48, 95% CI 0.34 to 18.02; birth center vs. hospital: aOR 0.99, 95% CI 0.52 to 1.88 (Homer et al., 2014). No cases of intrapartum or neonatal deaths (0 to 7 days) were observed for multiparous women in home or birth center settings. In the same eight-year time period, 96 events were observed in planned hospital births for multiparous women (0.103% of births; due to absence of deaths in the home and birth center groups, no further statistical analysis was performed).

In a large study conducted in the Netherlands (N = 743,070), the risk of intrapartum death was similar across settings for nulliparous (aOR 1.02, 95% CI 0.76 to 1.37) and multiparous women (aOR 1.31, 95% CI 0.89 to 1.94) (de Jonge et al., 2015). Neonatal death, 0 to 7 days, was also similar across settings by parity (nulliparous: aOR 0.98, 95% CI 0.70 to 1.36; multiparous: aOR 1.07, 95% CI 0.70 to 1.65)(de Jonge et al., 2015). Neonatal death, 0 to 27 days, also did not differ by setting for nulliparous and multiparous women (aOR 0.97, 95% CI 0.70 to 1.34; aOR 1.07, 95% CI 0.70 to 1.62, respectively) (de Jonge et al., 2015). In a small study from the Netherlands (N = 3455), rates of perinatal mortality within 24 hours were extremely rare (n = 1) and did not differ significantly by planned place of birth for nulliparous or multiparous women (Hermus et al., 2017).

Additional findings from poor-quality studies either observed similar rates of neonatal death or no cases of death. Intrapartum and neonatal death from 0 to 27 days were similar for planned home and planned hospital births for nulliparous women (RR 1.17, 95% CI 0.39 to 3.47) and multiparous women (unadjusted RR 0.67, 95% CI 0.11 to 3.99) in Ontario, Canada (Hutton et al., 2016). Death from

peripartum hypoxia was similar in planned birth center and planned hospital births for nulliparous women (unadjusted OR 1.30, 95% CI 0.46 to 3.23; calculated RR 1.27, 95% CI 0.65 to 2.49) and multiparous women in New Zealand (OR 1.70, 95% CI 0.47 to 5.90) (Bailey et al., 2017). Two small studies (n < 500) did not observe any deaths across birth settings for multiparous women in the Netherlands or Iceland (van Haaren-ten Haken et al., 2015; Halfdansdottir et al., 2015).

Neonatal Morbidity

No U.S. studies reported comparative neonatal morbidity outcomes by parity. Six non-U.S. studies provided comparative neonatal morbidity outcomes by parity (Bailey et al., 2017; Christensen & Overgaard, 2017; de Jonge et al., 2015; Hollowell et al., 2017; Li et al., 2015; van Haaren-ten Haken et al., 2015). Five studies provided overall estimates with separate analyses by parity (Birthplace, 2011; Homer et al., 2014; Halfdansdottir et al., 2015; Hutton et al., 2016; Hutton et al., 2009). Reported outcomes included the Birthplace composite outcome (stillbirth after the start of care in labor, early neonatal death, neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured humerus or clavicle), NICU admission, and Apgar scores.

Home Birth Setting

In the good-quality Birthplace study (Birthplace, 2011) the composite outcome did not differ by setting (see Outcome: Neonatal Morbidity section). When stratified by parity, for multiparous women, there was no difference across birth settings (aOR 0.72, 0.41 to 1.27) compared to all study participants (aOR 1.16, 95% CI 0.76 to 1.77). Infants of nulliparous women were at increased odds for the composite outcome in the planned home birth group compared to planned hospital group (9.3% vs. 5.3%, aOR 1.75, 1.07 to 2.86). In a fair-quality study conducted in Australia (2000 to 2008), the Birthplace composite for all births was not different in planned home compared to planned hospital births when stratified by parity (nulliparous women: aOR 1.72, 95% CI 0.64 to 4.63 compared to aOR 0.47, 95% CI 0.07 to 3.38) (Homer et al., 2014).

In a good-quality secondary analysis of the Birthplace cohort, adding admission to an NICU for over 48 hours (beginning within 48 hours of birth) to the composite outcomes for nulliparous and multiparous women did not result in a difference across planned home and planned hospital settings for nulliparous women (aRR 0.60, 95% CI 0.25 to 1.43); multiparous women remained at lower risk (aRR 0.47, 95% CI 0.25 to 0.88) (Li et al., 2015).

In a fair-quality study conducted in the Netherlands, low Apgar scores and admission to NICU (within 28 days) did not differ across birth settings for nulliparous women (aOR 0.95, 95% CI 0.87 to 1.02; aOR 1.05, 95% CI 0.92 to 1.18 respectively). Multiparous women were at decreased odds of an Apgar score less than seven at five minutes (aOR 0.77, 95% CI 0.69 to 0.86), similar odds for an Apgar score less than four at five minutes (aOR 0.92, 95% CI 0.70 to 1.20), and decreased odds of admission to NICU within 28 days (aOR 0.79, 95% CI 0.66 to 0.93) (de Jonge et al., 2015).

In a poor-quality study from Ontario, Canada, the odds of a composite outcome consisting of intrapartum or neonatal mortality, Apgar score less than four at five, positive pressure ventilation, or chest compressions remained similar in subgroup analyses by parity (nulliparous: RR 1.04, 95% CI 0.61 to 1.78; multiparous: RR 0.79, 95% CI 0.36 to 1.73) (Hutton et al., 2016).

In a poor-quality study, the frequency of NICU admission, an Apgar score less than seven at five minutes, and need for resuscitation was quantitatively similar (no statistical analysis provided) in planned home

and planned hospital settings in Iceland. When stratified by parity, nulliparous women experienced greater frequency of NICU admission (18.8% vs. 12%), an Apgar score less than seven at five minutes (6.3% vs. 3.1%), and need for neonatal resuscitation (6.3% vs. 1.6%); however, no formal statistical analysis was reported (Halfdansdottir et al., 2015).

Birth Center Setting

In the fair-quality Birthplace study, the composite outcome was similar for planned birth center and planned hospital births for nulliparous women (0.045% vs. 0.027%, aOR 0.96, 95% CI 0.51 to 1.82, p = 0.91) and multiparous women (0.047% vs. 0.024%, aOR 1.14, 95% CI 0.52 to 2.50, p = 0.745) (Hollowell et al., 2017).

In a fair-quality study from Australia analyzing data from 2000 to 2008, the Birthplace composite outcome) for all women (aOR 0.87, 95% CI 0.69 to 1.10) remained similar for nulliparous women in planned birth center births compared to planned hospital births (nulliparous women: aOR 1.04, 95% CI 0.81 to 1.34). Infants of multiparous women experienced a reduction in the odds of the composite outcome (aOR 0.45, 95% CI 0.26 to 0.81) (Homer et al., 2014).

Admissions to NICUs were lower for planned birth center births compared to planned hospital births in a poor-quality New Zealand study, but the difference was only statistically significant for nulliparous women (aOR 0.70, 0.58 to 0.86 compared to aOR 0.85, 95% CI 0.71 to 1.01 for multiparous women) (Bailey et al., 2017).

Maternal Harm

No U.S-based studies reported comparative maternal harm outcomes by parity. In one large, fair-quality non-U.S. study, a composite measure of severe acute maternal morbidity was lower for planned home birth compared to planned hospital birth (1.5% vs. 2.7%, no statistical analysis reported) (de Jonge et al., 2013). When analyzed by parity, there was no statistically significant difference for nulliparous women (aOR 0.77, 95% CI 0.56 to 1.06); reduced odds were observed for multiparous women (aOR 0.43, 95% CI 0.29 to 0.63, RRR 58.3%, 95% CI 33.2% to 87.5%) (de Jonge et al., 2013). Similarly, for the following outcomes, a statistically significant reduction in the odds was only observed in multiparous women in the planned home birth group compared to planned hospital birth:

- Need for a blood transfusion of four or more units (0.09% vs. 0.19%, aOR 0.45, 0.30 to 0.68, RRR 52.7, 95% CI 24.9 to 85.3)
- Postpartum hemorrhage (1.96% vs. 3.76%, aOR 0.50, 95% CI 0.46 to 0.55, RRR 47.9%, 95% CI 41.2% to 54.7%)
- Manual removal of the placenta (0.85% vs. 1.96%, aOR 0.41, 95% CI 0.36 to 0.47, RRR 56.9%, 95% CI 47.9% to 66.3%) (de Jonge et al., 2013).

In a good-quality study from the Netherlands, Hermus et al. observed significantly lower rates of third or fourth degree lacerations for women with a planned hospital birth (0.9%, 2 out of 348) compared to birth center (4%, 38 out of 939) (p < 0.01). Rates of blood loss (> 1000 mL), need for blood transfusion, and need for manual placental removal did not differ by planned place of birth (Hermus et al., 2017).

In one poor-quality study, the need for blood transfusion was lower for planned birth center births compared to planned hospital births for nulliparous (0.9% vs. 2.4%, aOR 0.40, 95% CI 0.25 to 0.62) and multiparous women (0.4% vs. 1.0%, aOR 0.54, 95% CI 0.35 to 0.83) (Bailey et al., 2017).

Estimates of obstetric anal sphincter injury were inconsistent. Two poor-quality studies observed either an increased risk in planned home birth groups compared to planned hospital for nulliparous women (5.3% vs. 3.2%, aOR 1.75, 95% CI 1.01 to 3.03) (Bolten et al., 2016) or decreased risk (3.1% vs. 4.7%, RR 0.67, 95% CI 0.53 to 0.83) (Hutton et al., 2016). One poor-quality study observed similar rates of obstetric anal sphincter injury in the planned birth center group compared to planned hospital birth for nulliparous (OR 0.9, 95% CI 0.4 to 2.0) and multiparous women (OR 0.6, 95% CI 0.2 to 1.7) (Christensen & Overgaard, 2017). One poor-quality study observed similar rates for planned home birth group compared to planned hospital birth group in Iceland for nulliparous (6.3% vs. 6.3%, aOR 1.37, 95% CI 0.40 to 4.63) and multiparous women (1.6% vs. 2.2%, aOR 0.73, 95% CI 0.20 to 2.59) (Halfdansdottir et al., 2015).

Studies observed statistically similar rates of postpartum hemorrhage in planned home and planned hospital births for nulliparous and multiparous women (Bolten et al., 2016; van Haaren-ten Haken et al., 2015). Postpartum hemorrhage was similar in planned home births compared to planned hospital births for nulliparous (3.2% vs. 3.6%, RR 0.89, 95% CI 0.71 to 1.12) and reduced in multiparous women (2.1% vs. 2.7%, RR 0.77, 95% CI 0.63 to 0.95) in one poor-quality study (Hutton et al., 2016).

Breastfeeding

No U.S-based studies reported comparative breastfeeding outcomes by parity. Two poor-quality studies reported comparative breastfeeding outcomes for nulliparous women in Ontario, Canada (Hutton et al., 2009; Hutton et al., 2016). At day 10 of life, infants in the planned home birth group were more likely to be breastfed compared to infants in the planned hospital birth group (84.8% vs. 75.9%, RR 1.13, 95% CI 1.11 to 1.16) (Hutton, et al., 2016). Exclusive breastfeeding at six weeks of life was reported for 89.1% of planned home birth infants compared to 76.7% for planned hospital births; no formal statistical analysis was reported (Hutton et al., 2009). These two studies also reported comparative breastfeeding outcomes for multiparous women (Hutton et al., 2009; Hutton et al., 2016). At day 10 of life, infants in the planned home birth group were more likely to be breastfed compared to infants in the planned hospital birth group (89.6% vs. 81.2%, RR 1.10, 95% CI 1.09 to 1.12) (Hutton, et al., 2016). Exclusive breastfeeding at six weeks of life was reported for 91.1% of infants in the planned home birth group compared to 82.2% for infants in the planned hospital birth group; no formal statistical analysis was reported (Hutton et al., 2009).

Subgroup: Maternal Age

Summary

Findings from U.S.-based studies reporting outcomes by maternal age are limited to neonatal mortality. Neonatal mortality in U.S. studies was higher for all women; women 35 years and older had higher risk than younger women.

International studies reported mode of delivery, neonatal harm, and maternal harm findings by maternal age. Overall, increasing maternal age was associated with a slightly increased risk in operative or cesarean delivery across birth settings, but actual rates of operative or cesarean delivery were lower across age groups. Similarly, risk of neonatal harm increased for every five-year increase in age; nulliparous women over 40 were at the highest risk of neonatal harm (including death or NICU admission).

Mode of Delivery

No U.S. based study reported comparative mode of birth outcomes by maternal age. A single good-quality study from England (Birthplace) reported mode of delivery outcomes for women by age and parity (Li, et al., 2014). The risk of instrumental and cesarean delivery increased with every five-year increment in age for nulliparous and multiparous women after controlling for maternal characteristics and intended birth setting (aRR ranged from 1.15 to 1.27, 95% CI ranged 1.05 to 1.32). The risk of a maternal composite outcome, incorporating delivery mode and maternal harms, increased with every five-year increase in age from 16 to 40 years, and was greater for planned out-of-hospital births (all non-hospital planned settings: aRR 1.21, 95% CI 1.18 to 1.25) compared to planned hospital births (aRR 1.12, 95% CI 1.10 to 1.15) (Li et al., 2014). The composite included augmentation, instrument delivery, intrapartum cesarean delivery, general anesthesia, blood transfusion, third or fourth degree tear, and admission to a higher level of care. However, the absolute rates of the maternal composite outcome were lower for nulliparous and multiparous women in the planned out-of-hospital group than the planned hospital group. The magnitude of the benefit decreased with increasing age (nulliparous women age 16 to 19: aRR 0.49, 95% 0.42 to 0.58 and women 40 and older: aRR 0.70, 95% CI 0.53 to 0.93).

Fetal or Neonatal Mortality

Two studies of poor to fair quality reported comparative U.S. estimates of neonatal death (0 to 27 days) by maternal age, from 2008 to 2012 (Grunebaum, McCullough, Arabin et al., 2017) and 2009 to 2013 (Grunebaum, McCullough, Sapra et al., 2017). Across both time periods, the risk of neonatal death was higher in planned home births compared to planned hospital births. When stratified by age, older women (≥ 35 years) experienced greater neonatal mortality than younger women. The two studies used different effect estimates (unadjusted relative risk and standardized mortality ratios (SMR), respectively) (≥ 35 years: RR 4.1, 95% CI 2.6 to 6.5; <35 years: RR 3.9, 95% CI 2.8 to 4.4) (Grunebaum, McCullough, Arabin et al., 2017); (≥ 35 years: SMR 5.11, 95% CI 3.19 to 7.03; < 35 years: SMR 3.72, 95% CI 2.95 to 4.50) (Grunebaum, McCullough, Sapra et al., 2017).

Neonatal Harm

We identified no studies that reported neonatal morbidity by maternal age in a U.S. setting. In a good-quality non-U.S. study, the risk of a composite outcome consisting of NICU admission over 48 hours (within 48 hours or birth) and the Birthplace composite (i.e., stillbirth after the start of care in labor, early neonatal death, neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured humerus or clavicle) was increased for nulliparous women over 40 compared to women aged 25 to 29 (aRR 2.29, 95% CI 1.28 to 4.09). For every 5 year increase in age, the adjusted relative risk was not statistically significant for nulliparous (aRR 1.06, 95% CI 0.95 to 1.17) and multiparous women (aRR 0.98, 95% CI 0.84 to 1.15) (Li et al., 2014).

Maternal Harm

No studies reported maternal harm by maternal age in U.S. settings. In a single good-quality study from England, controlling for birth setting, nulliparous women experienced a small, but statistically significant, increased risk of third or fourth degree tear for every five-year increase in age (aRR 1.12, 95% CI 1.02 to 1.23) (Li et al., 2014). The need for blood transfusion, controlling for place of birth, was not increased for nulliparous or multiparous women with higher maternal age.

Breastfeeding

No studies from U.S. or non-U.S. settings reported breastfeeding by maternal age.

Subgroup: Prior Cesarean Delivery

Summary

Findings from two U.S.-based studies observed conflicting estimates of effect: one study showed increased risk of neonatal death in planned home or birth center settings and the other did not observe a statistically significant difference. International studies observed greater frequency of neonatal harms in planned home or birth center settings, but the findings were not statistically significantly different. International studies observed that women with a history of cesarean delivery had higher rates of vaginal delivery in planned home or birth center settings.

Mode of Delivery

No U.S.-based study reported comparative mode of delivery outcomes for women with a prior cesarean delivery. A single good-quality, non-U.S.-based study reported comparative delivery mode outcomes for women with a prior cesarean section in England (Rowe et al., 2016). Compared to planned hospital birth, women with a history of cesarean delivery planning home birth were more likely to have a vaginal birth, including spontaneous vertex or breech vaginal births, or vaginal births assisted by forceps or vacuum (aRR 1.19, 95% CI 1.06 to 1.24).

Fetal or Neonatal Mortality

A single fair-quality study reported comparative mortality outcomes for women planning home birth with a prior cesarean delivery in U.S. settings (Grunebaum, McCullough, Sapra et al., 2017). The standardized perinatal mortality ratio (birth to day 27) for women with a prior cesarean delivery (SMR 8.33, 95% CI 2.59 to 14.07) was higher compared to women without a prior cesarean delivery (SMR 3.72, 95% CI 3.01 to 4.43).

A single fair-quality study reported comparative mortality outcomes for women planning home or birth center birth with a prior cesarean delivery (Tilden et al., 2017). Women planning home or birth center births experienced a greater frequency of neonatal death (0.13% vs. 0.08%), but the difference was not statistically significant (aOR 2.10, 95% CI 0.73 to 6.05, $p > 0.05$). No non-U.S. based studies reported comparative fetal or neonatal mortality outcomes for women with a prior cesarean delivery.

No non-U.S. based studies reported comparative fetal or neonatal mortality outcomes for women with a prior cesarean delivery.

Neonatal Harm

A single fair-quality study conducted in the U.S. reported comparative neonatal morbidity outcomes for women with a prior cesarean section (Tilden et al., 2017). Poor neonatal outcomes were more common for home or birth center births compared to planned hospital births for the following outcomes: Apgar scores less than four (0.73% vs. 0.40%, aOR 1.77, 95% CI 1.12 to 2.79, $p = 0.016$), Apgar scores less than seven (4.42% vs. 2.68%, aOR 1.62, 95% CI 1.35 to 1.96, $p < 0.001$), and neonatal seizures (0.19% vs. 0.02%, aOR 8.53, 95% CI 2.87 to 25.4, $p = 0.003$). Rates of NICU admission were lower for planned home or birth center births compared to planned hospital births (1.11% vs. 3.10%, aOR 0.40, 95% CI 0.29 to

0.57, p < 0.001). There were no statistically significant differences across groups in the need for ventilator support (0.38% vs. 0.29%, aOR 1.36, 95% CI 0.75 to 2.46, p = 0.31).

A single good-quality study reported comparative neonatal morbidity outcomes for women with a prior cesarean section in England (Rowe et al., 2016). Comparing planned home versus planned hospital births, the risk of a composite of intrapartum death or an Apgar score less than seven at five minutes (1.87% vs. 1.57%, RR 1.19, 95% CI 0.41 to 3.44) and admission to a neonatal unit (3.71% vs. 3.04%, RR 1.22, 95% CI 0.57 to 2.59) did not differ among women with a history of cesarean delivery in the planned home birth group compared to planned hospital birth

Subgroup: Breech Position of Fetus

Summary

Outcomes for breech position are limited to fetal or neonatal mortality. Breech position was associated with an increased risk of neonatal death in a single U.S. study.

Fetal or Neonatal Mortality

A single fair-quality study conducted in the U.S. observed higher standardized mortality ratios for cephalic and breech infants in planned home birth groups compared to planned hospital births attended by midwives (Grunebaum, McCullough, Sapra et al., 2017). The point estimate for breech presentation was over a twofold increase (SMR 8.14, 95% 2.17 to 14.11) compared to cephalic (SMR 3.61, 95% CI 2.92 to 4.31).

Subgroup: Other Factors

Summary

This section includes outcomes for several combinations of risk factors for low- and high-risk groups. Studies attempting to examine the most low-risk group, women without complicating conditions at the start of labor, excluded women with meconium-stained fluids, preeclampsia, non-cephalic position, abnormal fetal heartrate, or prolonged rupture of membranes. Other definitions of risk were not consistent across settings, which limited comparisons across studies.

Findings for U.S.-based studies were limited to fetal or neonatal mortality outcomes and observed higher risk for several combinations of factors, particularly for nulliparous women of older age, or advanced gestational age. International studies reported delivery mode, fetal or neonatal mortality, and neonatal harm outcomes by risk factor groupings. Nulliparous women without complicating conditions at the start of labor experienced a small but statistically significant increased odds of neonatal harm in planned home birth groups that was similar to that observed for all nulliparous women; from international studies.

Mode of Delivery

No U.S.-based study reported comparative delivery mode outcomes for women by other risk factor groupings. Three studies conducted outside of the U.S. reported delivery mode outcomes for women with or without an array of risk factors: we rated one as good quality (Birthplace, 2011) and two as poor quality (Halfdansdottir et al., 2018; Davies-Tuck et al., 2018)..

Women without a complicating condition at the start of labor (e.g., meconium-stained amniotic fluid) were more likely to experience a birth without induction, epidural or spinal analgesia, general

anesthesia, or assisted or cesarean delivery in planned home or planned birth center settings than in planned hospital settings (aOR 4.12, 95% CI 3.37 to 5.04 for home births, aOR 3.42, 95% CI 2.74 to 4.27 for birth centers, both compared to hospital birth) (Birthplace, 2011). However, as the authors noted, the use of an odds ratio for this common outcome likely overstated the actual magnitude of the effect.

Women with a known contraindication to home birth (e.g., BMI > 35, after 42 weeks completed gestation, chronic diseases, prematurity, previous cesarean delivery) were no more likely to have an operative delivery compared to women planning home birth without a contraindication in a small study of 1,228 women in Iceland (OR 5.42, 95% CI 0.60 to 48.99) (Halfdansdottir et al., 2018).

In a study conducted in Australia, high-risk women also experienced beneficial delivery mode outcomes more often in planned home birth settings compared to a planned hospital setting (i.e., lower rates of cesarean delivery, instrumental deliveries, and higher rates of spontaneous vaginal deliveries; no formal statistical analysis reported) (Davies-Tuck et al., 2018). Although there were higher NICU admission rates for the infants (1.6% vs. 0.4%, $p < 0.001$) and intrauterine hypoxia (3.2% vs. 6.6%, $p < 0.001$), rates of other maternal and neonatal outcomes were not statistically significantly different (i.e., perinatal morbidity (meconium aspiration syndrome, pneumonia, or respiratory distress syndrome), Apgar score less than seven at five minutes, composite morbidity). Rates of birth trauma (brachial plexus injury, fractured clavicle or humerus) were reduced for high-risk planned home births compared to planned hospital births (3.1% vs. 7.6%, $p < 0.001$).

Fetal or Neonatal Mortality

A single fair-quality study from the U.S. observed increased risk of neonatal mortality (0 to 27 days) for several combinations of risk factors for planned home births (all providers) compared to planned hospital births attended by a midwife (Grunebaum, McCullough, Sapra et al., 2017). The greatest risk was seen in nulliparous women, 35 years and older (SMR 12.41, 95% CI 4.33 to 20.49) and nulliparous women at 41 weeks of pregnancy or later (SMR 9.57, 95% CI 5.84 to 13.30); other groups experienced increased risk.

A single fair-quality Australian study limited to women without complicating conditions at the start of labor (i.e., prolonged rupture of membranes, preeclampsia, gestational hypertension, antepartum hemorrhage, eclampsia, gestational diabetes or pre-pregnancy diabetes; 8.9% of entire study sample), observed no cases of intrapartum or early neonatal death (0 to 7 days) for planned home births from 2000 to 2008. Estimates after adjusting for negative values (by adding 0.5 to all counts) were not statistically significantly different for all home, birth center, and planned hospital births (Homer et al., 2014).

Neonatal Harm

No U.S. based study reported comparative neonatal harm outcomes for women by other risk factor groupings. In a subgroup comparison from the good-quality Birthplace study limited to nulliparous women without complicating conditions at the start of labor (e.g., meconium-stained fluids) experienced increased odds of the Birthplace composite outcome (stillbirth after start of care in labor, early neonatal death, neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured humerus or clavicle) in planned home birth (unadjusted aOR 2.80, 95% CI 1.59 to 4.92 compared to aOR 1.75, 95% CI 1.07 to 2.86 for all nulliparous women planned home compared to planned hospital). Although the effect estimate was higher, the incidence was similar (3.5 per 1,000 vs. 9.5 per 1,000; the wider confidence interval is likely a result of the smaller sample in the analysis of

women without complicating conditions.. Risk the Birthplace composite was similar in planned birth center settings compared to planned hospital (aOR 1.40, 95% CI 0.74 to 2.65) (Birthplace, 2011).

In a fair-quality Australian study of women without complications at the start of labor, there were no statistically significant differences in the composite outcome comparing planned home to planned hospital births (aOR 0.87, 95% CI 0.33 to 2.35) or comparing planned birth center to planned hospital births (aOR 0.82, 95% CI 0.64 to 1.05) (Homer et al., 2014).

For women at higher risk at the start of labor (e.g., gestational diabetes, BMI > 35, 42 to 44 weeks gestation, known high-risk medical conditions), but without complicating conditions at the start of labor (e.g., meconium-stained fluids), in the Birthplace cohort, the small number of nulliparous women (n = 288) fared similarly in home and hospital settings (aRR 0.43, 95% CI 0.16 to 1.16); multiparous women (n = 1,201) were at a lower risk of adverse perinatal outcomes (i.e., Birthplace composite) (aRR 0.41, 95% CI 0.18 to 0.89) (Li et al., 2015).

In a poor-quality study conducted in Australia, high-risk women (e.g., obese, with chronic medical conditions, non-cephalic presentation, prior cesarean delivery) in the planned home birth group more commonly experienced NICU admissions for their infants (1.6% vs. 0.4%, p < 0.001). Rates of other outcomes were not statistically significantly different or favored home birth for reduced composite morbidity (7.8% vs. 16.9%, p < 0.001), intrauterine hypoxia (3.2% vs. 6.6%, p < 0.001), and birth trauma (3.1% vs. 7.6%, p < 0.001) (Davies-Tuck, et al., 2018).

In a poor-quality study conducted in Iceland, women with a known contraindication to home birth, but who elected to proceed with home birth, experienced similar odds of NICU admission (OR 1.88, 95% CI 0.41 to 8.64), Apgar score of less than seven at five minutes (OR 8.37, 95% CI 0.37 to 189.36), neonatal resuscitation (OR 1.89, 95% CI 0.14 to 9.68), and overall morbidity (OR 1.16, 95% CI 0.65 to 5.51) compared to women without a contraindication, but the results were all imprecise (i.e., had wide confidence intervals) (Halfdansdottir et al., 2018)

Subgroup: Gestational Age

Summary

Outcomes by gestational age were limited to fetal or neonatal mortality from a single U.S. study.

Fetal or Neonatal Mortality

Estimates of neonatal mortality by gestational age in U.S. settings were reported by two studies of poor to fair quality that had overlapping time periods (Grunebaum, McCullough, Arabin et al., 2017; Grunebaum, McCullough, Sapra et al., 2017). Neonatal mortality (0 to 27 days) was higher for planned home births across both gestational age groups (≥ 37 to < 41 weeks, and ≥41 weeks) in both studies. In the 2009 to 2013 dataset, both groups experienced increased rates of neonatal mortality at ≥ 37 to < 41 weeks (SMR 3.37, 95% CI 2.95 to 4.50) and ≥41 weeks (SMR 4.78, 95% CI 3.43 to 6.12) (Grunebaum, McCullough, Sapra et al., 2017). The 2008 to 2012 dataset also demonstrated higher risk of neonatal mortality for home birth attended by a CNM or other midwife compared to hospital birth attended by a midwife at ≥ 37 to < 41 weeks (RR 3.25, 95% CI 2.6 to 4.2) and ≥41 weeks (RR 4.43, 95% CI 3.1 to 6.3) (Grunebaum, McCullough, Arabin, et al., 2017).

Subgroup: Race or Ethnicity

Summary

Outcomes by race or ethnicity were limited to fetal or neonatal mortality from a single U.S. study.

Fetal or Neonatal Mortality

A single poor-quality study reported standardized mortality ratios for white, non-Hispanic women and women of all other races or ethnicities combined. Both groups experienced an increased risk of neonatal death (0 to 27 days) compared to planned hospital births attended by a midwife, but the estimates overlapped (RR 3.71, 95% CI 3 to 4.6 for white women; RR 2.65, 95% CI 1.4 to 5 for all other race/ethnicities combined) (Grunebaum, McCullough, Arabin et al., 2017).

Noncomparative Studies

We identified 14 noncomparative studies that reported on relevant outcomes from planned home or birth center births. Seven of the studies analyzed U.S. data (Bachilova et al., 2018; Bovbjerg et al., 2017; Cheyney et al., 2014; Cox et al., 2015; Nethery et al., 2017; Stapleton et al., 2013; Stephenson-Famy et al., 2017), and four of these studies relied on data from the Midwives Alliance of North America Statistics Project (MANA Stats), which combines outcome data from planned home and birth center births (Bovbjerg et al., 2017; Cheyney et al., 2014; Cox et al., 2015; Nethery et al., 2017). One study used a combination of Canadian and U.S. data (Johnson & Daviss, 2005), and the remaining six studies were based in Australia (Catling-Paull et al., 2013), Japan (Eto et al., 2017; Suto et al., 2015), the Netherlands (Schuit et al., 2016), and Nordic countries (Blix et al., 2015; Edqvist et al., 2016). Sample sizes across the studies ranged from 1,521 (Suto et al., 2015) to 746,642 (Schuit et al., 2016). There were high levels of heterogeneity in the outcomes reported across studies. At least six of the 14 noncomparative studies reported on delivery mode, maternal genital tract trauma, perinatal mortality, and neonatal morbidity.

The noncomparative studies demonstrated favorable delivery mode outcomes (i.e., high rates of vaginal deliveries, low rates of assisted or cesarean deliveries). In general, the studies reported greater risks of maternal and neonatal harms for nulliparous women and women with a previous history of cesarean or instrument-assisted vaginal delivery. In addition, breech presentation, multiple gestation, and high-risk maternal conditions (e.g., hypertension) were associated with higher risks of adverse neonatal events. Many of the noncomparative studies excluded high-risk populations, and thus these findings might not be directly applicable to typical populations of planned home and birth center births. Appendix H provides additional details on the study characteristics of the included noncomparative observational studies.

Evidence Summary

Planned out-of-hospital birth is associated with favorable outcomes for women, but with increased risk of harm to neonates in U.S. studies. Rates of vaginal births for women having planned home or birth center births were consistently greater than for women having planned hospital births, as reported across U.S. and international studies of fair to good methodological quality. Maternal harms were also more favorable in planned out-of-hospital settings. Estimates of breastfeeding by planned place of birth tended to favor out-of-hospital settings, but the quality of evidence is very low.

Although overall rates of infant harm were similar from fair- to good-methodological-quality international studies, there were estimates of increased harm, particularly higher rates of death, for infants in planned out-of-hospital births compared to planned hospital births as observed in U.S.-based studies of similar methodological quality.

The risk of neonatal morbidity or death within subgroups was higher for nulliparous women in U.S-studies, whereas non-U.S.-based studies observed higher or similar risks. In U.S. studies, higher maternal age, later gestational stage, breech position, and prior cesarean delivery were associated with increased risk of neonatal death. In the U.S., rates of death for newborns also increased for combinations of risk, notably for nulliparous older women or at advanced gestational age. The magnitude of the neonatal risk difference was greater in U.S.-based studies than international studies because neonatal death was less common across international studies.

Policy Landscape

Guidelines from Others

A search of MEDLINE, Center core sources, and professional societies relevant to planned out-of-hospital birth identified documents from the American Academy of Pediatrics (AAP) (2016), American Association of Birth Centers (AABC) (2017), American College of Nurse Midwives (ACNM) (2015), American College of Obstetricians and Gynecologists (ACOG) (2017), the National Institute for Health and Care Excellence (NICE) (2017), and the Society of Obstetricians and Gynecologists of Canada (SOGC) (2019). In-person public comment from the June 2019 EBGS meeting identified guidance from the Oregon Midwifery Council (OMC) (2019). The Midwives Alliance of North America (2005) and the National Association of Certified Professional Midwives (2004) had no updated guidance in the last 15 years.

The 2015 HERC Coverage Guidance used guidance from NICE (2014), the College of Midwives of British Columbia (CMBC) (2014), the College of Midwives of Ontario (2015), and the Obstetric Working Group of the National Insurance Board of the Netherlands (n.d.). Updated documents were only identified from the College of Midwives of British Columbia (2018) and NICE (2017). The College of Midwives of Ontario published *Professional Standards for Midwives* in 2018, but this document does not make specific recommendations about clinical care, eligibility, or transfers (College of Midwives of Ontario, 2018). The most current standards for consultation and transfers from the College of Midwives of Ontario remain the 2015 guidance, included in the prior HERC coverage guidance (College of Midwives of Ontario, 2015).

Only the NICE guideline included information on evidence review methods for the guideline *Intrapartum Care for Healthy Women and Babies*, which was updated in 2017 and is available publicly at: https://www.nice.org.uk/guidance/cg190 (NICE, 2017). This guideline was assessed as having good methodological quality. No other identified documents included the methods of development. These documents should be considered expert opinion and of poor methodological quality.

The information contained within the identified documents is vast in scope. Specific guidance on system-level practices, emergency planning, and life support training requirements for birth attendants is summarized in this section; specific risk assessment levels are abstracted in Appendix I for maternal indications and Appendix J for newborn indications.

Regulatory Guidance

An additional source is included in this Coverage Guidance because it is relevant to the Oregon regulatory environment. The proposed administrative rules (as of May 2019) from the Oregon Health Authority's State Board of Direct Entry Midwifery (OR DEM) are also included for reference in Appendices I and J (OR DEM, 2019).

Guidelines and Regulatory Guidance Summary

Table 3 lists all included guidelines and regulatory guidance, along with a billing guide from the state of Washington's Medicaid program (WA) identified in the policy search (see below). The Washington guide is included in this section because it provides specific guidance on risk assessment, consultation, and referrals criteria for planned home or birth center births. The policy search did not identify any guidance on out-of-hospital birth from chiropractic or naturopathic professional societies.

Table 3. Included Guidelines, Regulations, and Professional Society Guidance

Organization	Year	Specific Risk Assessment Protocols
American Academy of Pediatrics	2013 (reaffirmed 2016)	Yes
American Association of Birth Centers	2017	Yes
American College of Nurse-Midwives	2015	Yes
American College of Obstetricians and Gynecologists	2017	Yes
College of Midwives of British Columbia	2018	Yes
College of Midwives of Ontario	2018	No
National Institute for Health and Care Excellence	2014, updated 2017	Yes
Oregon Midwifery Council	2019	No
Society of Obstetricians and Gynecologists of Canada	2019	No
State Board of Direct Entry Midwifery, Oregon	2019, proposed	Yes
Washington Medicaid Billing Guide	2017	Yes

System-Level Recommendations

This section summarizes recommendations on health system-level practices to improve outcomes for planned out-of-hospital births. Canada's "systems-based approach," supporting safety for home birth within its integrated health system, is posited as the reason for improved perinatal and obstetric outcomes observed in Canada compared to the United States (SOGC, 2019).

Regarding transfer, multiple organizations recommend that a relationship with a medical facility should be in place in the event of transfer, and the attendant should have readily available consultation (AAP, 2016; ACNM, 2015; ACOG, 2017). The AABC standards include recommendations for an established system for consultation, collaboration, or referral for emergency and non-emergency events (AABC, 2017). Transfers should occur in a timely and safe fashion (AAP, 2016; ACNM, 215; ACOG, 2017).

The AAP and the ACOG both recommend hospitals or birth centers as the safest place of birth in the U.S (AAP, 2016; ACOG, 2017). Acknowledging that women may, after participating in an informed risk and

benefit discussion, elect to pursue a home birth, the AAP and ACOG recommend that to reduce perinatal mortality, the birth should be within an integrated and regulated health system attended by a certified nurse midwife, certified midwife, or midwife meeting International Confederation of Midwives' Global Standards for Midwifery Education (AAP, 2016; ACOG, 2017).

According to the AAP, care of the newborn immediately after birth should adhere to the *Guidelines for Perinatal Care* published by the ACOG and AAP, including but not limited to transitional care after birth, monitoring for group B streptococcal disease, glucose screening, eye gonococcal prophylaxis, vaccination for hepatitis B, provision of vitamin K prophylaxis, assessment of feeding, screening for hyperbilirubinemia, and newborn screening (AAP, 2016). Additionally, all infants should receive an evaluation by a "health care professional who is knowledgeable and experienced in pediatrics within 24 hours of birth and subsequently within 48 hours of that first evaluation" (AAP pg. 1019, 2016). This evaluation should also include an assessment for congenital heart disease in addition to but not limited to hydration, jaundice, integration of clinical laboratory testing, and breastfeeding (AAP, 2016).

Emergency Planning and Life Support Training

The AAP recommends that each delivery, regardless of location, be attended by 2 individuals, 1 with training in infant resuscitation (i.e., Neonatal Resuscitation Program) whose sole responsibility is the newborn, allowing the other to attend to the mother (AAP, 2016). This is similar to guidance from the SOCG, which notes that a second care provider is required to accompany a registered midwife for a home birth (SOCG, 2019). The SOGC also notes that registered midwives attending homebirths are required to maintain hospital privileges, bring emergency equipment and supplies, and have emergency transportation protocols (SOGC, 2019, pg. 224). Similarly, NICE recommends that protocols be in place for patient transfer with development oversight by a multidisciplinary regulatory body with midwifery, obstetric, anesthesia, and neonatal experts (NICE, 2017).

Specifically in the case of the presence of meconium, NICE recommends transfer to hospital setting, with providers trained in fetal blood sampling and neonatal life support present at the delivery (NICE, 2017).

Eligibility and Risk Assessment, Transfer or Consultation Criteria

The majority of identified guideline documents concur that women planning an out-of-hospital birth should be at low risk and have uncomplicated pregnancies, but vary in the level of detail with which they describe low-risk candidates (AABC 2017; AAP 2016; ACNM 2015; ACOG 2017; CMBC 2017; NICE 2017; SOGC 2019;). Ongoing risk assessment over the course of pregnancy is recommended (AABC 2017; ACNM 2015; CMBC 2017; NICE 2017; OR DEM 2019; OMC 2019; SOGC 2019). Specific instructive language on what to do in the event of a risk factor varies across documents. For example, a consultation in the Washington guidance may include telephone, written, or electronic mail with an MD/DO, co-management, referral for exam or treatment, or transfer (WA, 2017). In the guidance from CMBC, a consultation is an in-person evaluation by a consultant resulting in recommendations for continuing care with a registered midwife, co-management, or transfer (CMBC, 2018). This recommendation language would be a "referral" in the Washington guidance. For the purposes of this document, conditions are categorized as high-risk historical conditions or complications of current pregnancy requiring hospital birth (3), conditions requiring consultation (2), or eligible for planned out-of-hospital birth provided there are no other complications (1).

Specific risk criteria for consultation, transfer, or contraindications/exclusions vary in level of detail across documents. When language aligned, similar recommendations are summarized together on the same line within Appendices I and J. In an attempt to ease comparisons across guidance documents, recommendations were color and number coded as described in Appendices I and J. When no formal recommendation for a condition was identified (--) was placed in the cell. At times, a recommendation for one condition may be superseded by another, which is denoted by the abbreviation for non-applicable, NA. For example, a recommendation for consultation with rupture of membranes at 35 weeks by one guideline (i.e., category 2), might not be applicable to a different organization that lists gestational age under 36 weeks as high-risk exclusion (i.e., category 3). When it was possible, we attempted to clarify whether a listed condition referred to a history of the condition or as a new condition arising in the current pregnancy. Risk criteria recommendations also reflect variation in the integration of out-of-hospital birth and the scope of midwife practice. For example, within the National Health Service of the United Kingdom when risk factors are identified that suggest birth in a hospital setting is safer than out of hospital, the midwife is compelled to inform the woman and engage in an informed consent process but not required to transfer. Ensuring women are informed of the risk is required, balanced by personal autonomy of the woman to make the decision to transfer (NICE, 2017).

Appendix I catalogues maternal risk factor recommendations from the 2015 Coverage Guidance, additional guidance published in the interim, and relevant documents from Washington State (2017) and the Oregon Health Authority, OR DEM Board proposed rules (2019). Appendix J provides the same details for neonatal conditions.

Fetal malpresentation, multiple gestation, and prior cesarean are high-risk contraindications to planned out-of-hospital birth by the AAP, AABC, ACNM, ACOG, CMBC, NICE, and the Washington guidance, which concurs with the 2015 HERC Coverage Guidance (AAP 2016; AABC 2017; ACOG 2017; CMBC 2017; NICE 2017; WA 2017). The OR DEM Board (2019) considers frank or complete breech and/or prior cesarean delivery to be acceptable risk factors for out-of-hospital birth (OR DEM, 2019). The OMC lists out-of-hospital birth past 42 completed weeks of gestation (i.e., 43 weeks 0 days) as “outside of our community standard of care” and recommends starting fetal surveillance testing at 41 weeks and 3 days gestation (OMC 2019, pg. 11).

Across most guidelines are statements regarding the general medical health of the women attempting a planned out-of-hospital birth, specifically that they be free of chronic medical conditions or conditions that would be expected to worsen during pregnancy, or require treatment with pharmacotherapy (AABC 2017; ACNM 2015; CMBC 2018; NICE 2017).

Payer Coverage Policies

Medicaid

The policy for the Washington Medicaid Program (effective 1/1/2019) covers planned home births and births in agency-approved, licensed birthing centers attended by a qualified licensed midwife, a certified nurse midwife, or a physician. For coverage, the pregnancy must be low risk (see criteria below) and the woman must be expected to deliver the child vaginally and without complication.

Planned home birth providers and birthing center providers must:

- Have evidence of current cardiopulmonary resuscitation (CPR) training for adult CPR and neonatal resuscitation
- Have written, appropriate plans for consultation, emergency transfer, and transport of client and newborn to a hospital
- Obtain from the client a signed informed consent form

Home birth providers must also provide documentation of:

- Names and national provider identifier (NPI) number of back-up midwives that are current Washington Apple Health providers and will provide 24 hour-per-day coverage
- Local emergency medical services and emergency response capability in the area
- Professional consultation plan and referral
- Midwife's informed consent that includes newborn screening, prophylactic eye ointment, and vitamin K injection
- Participation in a formal, state sanctioned, quality assurance/improvement program or professional liability review process
- Midwife's or birthing center's professional liability policy

Washington Medicaid does not cover planned home births or births in birthing centers for women with a history of or identified with any of these factors:

- Cesarean section delivery
- Known multiple gestation
- Known breech presentation in labor with delivery not imminent
- Significant hematological disorders/coagulopathies
- Deep venous thrombosis or pulmonary embolism
- Cardiovascular disease causing functional impairment
- Chronic hypertension
- Significant endocrine disorders including pre-existing diabetes
- Hepatic disorders including uncontrolled intrahepatic cholestasis of pregnancy or abnormal liver function tests
- Isoimmunization, including evidence of Rh sensitization/platelet sensitization
- Neurologic disorders or active seizure disorders
- Pulmonary disease
- Renal disease
- Collagen-vascular diseases
- Cancer affecting site of delivery
- Other significant deviations from normal as assessed by the provider

In addition, coverage is not provided to women with current alcohol/drug addiction or abuse or current severe psychiatric illness.

Washington Medicaid requires consultation with a physician (MD/DO) and may require referral to a physician when any of the following conditions arise during the pregnancy:

- Breech at 37 weeks
- Polyhydramnios/Oligohydramnios
- Significant vaginal bleeding

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- Persistent nausea and vomiting causing a weight loss of > 15 lbs.
- Post-dates pregnancy (> 42 completed weeks)
- Fetal demise after 12 completed weeks gestation
- Significant size/dates discrepancies
- Abnormal fetal non-stress test (NST)
- Abnormal ultrasound findings
- Acute pyelonephritis
- Infections whose treatment is beyond the scope of the provider
- Evidence of large uterine fibroid that may obstruct delivery or significant structural uterine abnormality
- No prenatal care prior to the third trimester
- Other significant deviations from normal, as assessed by the provider

Referral to a physician is required when any of the following conditions arise during pregnancy:

- Evidence of pregnancy-induced hypertension (BP>140/90 for >6 hours with client at rest)
- Hydatidiform mole (molar pregnancy)
- Gestational diabetes not controlled by diet
- Severe anemia unresponsive to treatment (Hgb<10, Hct (hematocrit)< 28)
- Known fetal anomalies or conditions affected by site of birth
- Documented placental abnormalities, significant abruption past the first trimester, or any evidence of previa in the third trimester
- Rupture of membranes before the completion of 37 weeks gestation
- Positive HIV antibody test
- Documented intrauterine growth retardation (IUGR)
- Primary genital herpes past the first trimester
- Noncompliance with the plan of care (e.g., frequent missed prenatal visits)
- Development of any of the high-risk conditions that result in non-coverage of planned home birth or birthing center births

Washington Medicaid requires consultation with a physician and may require referral to a physician when any of the following conditions arise intrapartum:

- Prolonged rupture of membranes, >24 hours and not in active labor
- Other significant deviations from normal as assessed by the provider

Referral to a physician or hospital is required when any of the following emergency conditions arise intrapartum:

- Labor before the completion of 37 weeks gestation, with known dates
- Abnormal presentation or lie at time of delivery, including breech
- Persistent non-reassuring fetal heart rate (requires emergency transport)
- Active genital herpes at the onset of labor
- Thick meconium-stained fluid with delivery not imminent
- Prolapse of the umbilical cord (requires emergency transport)
- Sustained maternal fever
- Maternal seizure (requires emergency transport)

- Abnormal bleeding (hemorrhage requires emergent transfer)
- Hypertension with or without additional signs or symptoms of pre-eclampsia
- Prolonged failure to progress in active labor
- Sustained maternal vital sign instability or shock (requires emergency transport)
- Maternal desire for pain medication, consultation, or referral

Washington Medicaid requires consultation with a physician and may require referral to a physician when any of the following conditions arise postpartum in the first 24 hours after delivery of the placenta:

- Development of any of the applicable conditions listed for prenatal or intrapartum referral
- Significant maternal confusion or disorientation
- Other significant deviations from normal as assessed by the provider

Referral to a physician is required when any of the following conditions arise postpartum:

- Anaphylaxis or shock (requires emergency transport)
- Undelivered adhered or retained placenta with or without bleeding
- Significant hemorrhage not responsive to treatment (requires emergency transport)
- Maternal seizure (requires emergency transport)
- Third or fourth degree lacerations, if repair is beyond provider's level of expertise
- Sustained maternal vital sign instability and/or shock (requires emergency transport)
- Development of maternal fever, signs/symptoms of infection or sepsis
- Acute respiratory distress (requires emergency transport)
- Uterine prolapse or inversion (requires emergency transport)

Washington Medicaid requires consultation with a pediatric physician and may require referral to a pediatric physician when any of the following conditions arise in a neonate:

- Apgar score ≤ 6 at five minutes of age
- Birth weight < 2,500 grams
- Abnormal jaundice
- Other significant deviations from normal as assessed by the provider

Referral to a pediatric physician is required when any of the following conditions arise in a neonate:

- Birth weight < 2,000 grams
- Persistent respiratory distress (requires emergency transport)
- Persistent cardiac abnormalities or irregularities (requires emergency transport)
- Persistent central cyanosis or pallor (requires emergency transport)
- Prolonged temperature instability when intervention has failed
- Prolonged glycemic instability (requires emergency transport)
- Neonatal seizure (requires emergency transport)
- Clinical evidence of prematurity (gestational age < 35 weeks)
- Loss of > 10% of birth weight/failure to thrive
- Birth injury requiring medical attention
- Major apparent congenital anomalies
- Jaundice prior to 24 hours

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Medicare

No National Coverage Determinations or Local Coverage Determinations were identified for out-of-hospital births.

Private Payers

Coverage policies for out-of-hospital births were assessed for four private payers: Aetna, Cigna, Moda, and Regence. All four payers cover deliveries in birthing centers. The policy for Aetna (last review 3/28/2019) considers planned home births not medically appropriate. The policies for Cigna (effective 1/15/2019), Moda (last review 4/3/2018), and Regence (webpage dated 2019) cover planned home births attend by certified nurse midwives. None of these private payers include coverage criteria regarding low-risk pregnancies, other than requiring that attending midwifes need to be performing duties within the scope of their licensure.

Cigna

Midwife Services

Coverage of professional fees for midwife services is subject to the terms, conditions, and limitations of the applicable benefit plan and may be limited based on health care professional certification/licensure requirements. In addition, coverage of midwife services may be governed by state mandates; please note that licensure and regulations related to midwifery practice and prescriptive authority vary among states.

In addition, midwife services and/or birthing centers are excluded from network adequacy/network exception or transition of care provisions.

Services provided by a Licensed/Certified Nurse Midwife are eligible for coverage. Services provided by non-nurse midwives (e.g., Certified Midwife [CM], Certified Professional Midwife [CPM], Direct-Entry Midwife, Lay Midwife), may be covered depending on state requirements.

Licensed/Certified Nurse Midwife

Cigna covers services provided by a Licensed/Certified Nurse Midwife acting within the scope of license or certification under the applicable state law

Non-Nurse Midwife

Cigna ONLY covers services provided by a non-nurse midwife (e.g., Certified Midwife [CM)] Certified Professional Midwife [CPM], Direct-Entry Midwife, Lay Midwife) when acting within the scope of license or certification under the applicable state law.

Not Covered

Cigna does not cover ANY of the following:

- Services provided by an out-of-network midwife (e.g., Licensed/Certified Nurse Midwife, Certified Midwife) when out-of-network benefits are not available.
- Services at the in-network benefit level, for services provided by an out-of-network health care provider (i.e., network exception) when a qualified in-network health care professional who provides obstetrical services is available, unless required by state regulations or mandates.

- Services provided by a midwife (e.g., Licensed Certified Midwife, Certified Midwife) acting outside the scope of license or certification under the applicable state law.
- Doula services (e.g., childbirth education and support services during pregnancy by a trained non-clinician), absent state mandates.

Home Birth Services

Coverage of a planned home birth may be governed by state mandates.

A planned home birth is an elective alternative to delivery in a birthing center or hospital setting. Coverage of professional fees for a home birth (i.e., elective, planned delivery in the home setting) is subject to the terms, conditions, and limitations of the applicable benefit plan and may be limited based on health care professional certification/licensure requirements.

Cigna covers the professional fee for services provided to a mother eligible for coverage under a Cigna health benefit plan for a home birth, including delivery and immediate medically necessary postpartum care, when services are provided by a health care provider who is acting within the scope of his/her license or certification under the applicable state law.

Cigna does not cover any of the following services associated with a home birth:

- Services provided by an out-of-network provider when out-of-network benefits are not available
- Services at the in-network benefit level, for services provided by an out-of-network health care provider (i.e., network exception) when a qualified in-network health care professional who provides obstetrical services is available, unless required by state regulations
- Services that are not considered eligible for reimbursement (e.g., other than a health care provider who is acting within the scope of that provider's license or certification under the applicable state law)
- Duplication of services (e.g., services provided by a licensed physician and licensed certified nurse-midwife simultaneously [i.e., at the same time])
- Services considered not medically necessary (e.g., non-routine maternity services, additional prenatal counseling sessions, prenatal evaluation and management services specifically related to home birth)
- Items that are excluded or otherwise not covered under the benefit plan (e.g., equipment, supplies [e.g., emergency kits], supplies specifically related to home birth, modifications to the home, standby services [e.g., support personnel])
- Facility charges for the home setting

Moda

Home Births

Eligible professional fees by the Certified Nurse Midwife or Nurse Practitioner Midwife are eligible for coverage. Other home birth expenses are not eligible for reimbursement and are generally excluded by the member's contract. This includes but is not limited to travel, portable hot tubs, supplies, and transportation of equipment, etc.

Regence

Home/birthing center deliveries and postpartum services are subject to this reimbursement policy in the same manner as services performed by physicians and other health care professionals who deliver in the hospital setting.

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Appendix A. GRADE Table Element Descriptions

Element	Description
Balance of benefits and harms	The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. An estimate that is not statistically significant or has a confidence interval crossing a predetermined clinical decision threshold will be downgraded.
Quality of evidence	The higher the quality of evidence, the higher the likelihood that a strong recommendation is warranted
Resource allocation	The higher the costs of an intervention—that is, the greater the resources consumed in the absence of likely cost offsets—the lower the likelihood that a strong recommendation is warranted
Values and preferences	The more values and preferences vary, or the greater the uncertainty in values and preferences, the higher the likelihood that a weak recommendation is warranted
Other considerations	Other considerations include issues about the implementation and operationalization of the technology or intervention in health systems and practices within Oregon.

Strong recommendation

In Favor: The subcommittee concludes that the desirable effects of adherence to a recommendation outweigh the undesirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors.

Against: The subcommittee concludes that the undesirable effects of adherence to a recommendation outweigh the desirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors.

Weak recommendation

In Favor: The subcommittee concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors., but further research or additional information could lead to a different conclusion.

Against: The subcommittee concludes that the undesirable effects of adherence to a recommendation probably outweigh the desirable effects, considering the balance of benefits and harms, cost and resource allocation, and values and preferences, but further research or additional information could lead to a different conclusion.

Confidence in estimate rating across studies for the intervention/outcome

Assessment of confidence in estimate includes factors such as risk of bias, precision, directness, consistency and publication bias.

High: The subcommittee is very confident that the true effect lies close to that of the estimate of the effect. Typical sets of studies are RCTs with few or no limitations and the estimate of effect is likely stable.

Moderate: The subcommittee is moderately confident in the estimate of effect: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. Typical sets of studies are RCTs with some limitations or well-performed nonrandomized studies with additional strengths that guard against potential bias and have large estimates of effects.

Low: The subcommittee's confidence in the estimate of effect is limited: The true effect may be substantially different from the estimate of the effect. Typical sets of studies are RCTs with serious limitations or nonrandomized studies without special strengths.

Very low: The subcommittee has very little confidence in the estimate of effect: The true effect is likely to be substantially different from the estimate of effect. Typical sets of studies are nonrandomized studies with serious limitations or inconsistent results across studies.

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Appendix B. GRADE Evidence Profile

Quality Assessment (Confidence in Estimate of Effect)							
No. of Studies	**Study Design(s)**	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Factors**	**Quality**
Mode of Delivery							
18	Observational	Not serious	Not serious	Serious	Not Serious		Low ●●○○
Perinatal or Neonatal Mortality							
16	Observational	Not serious	Serious	Serious	Serious		Very Low ●○○○
Neonatal Morbidity							
20	Observational	Not serious	Serious	Serious	Not serious		Very Low ●○○○
Maternal Harm							
20	Observational	Not serious	Serious	Serious	Not serious		Very Low ●○○○
Breastfeeding							
9	Observational	Serious	Serious	Serious	Not serious		Very Low ●○○○

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Appendix C. Methods

Scope Statement

Populations

Pregnant women

Population scoping notes: None

Interventions

Planned out-of-hospital birth (home or birth center)

Intervention exclusions: None

Comparators

Planned birth in a hospital

Outcomes

Critical: Delivery mode (cesarean, operative vaginal delivery, spontaneous vaginal delivery), perinatal mortality, serious neonatal morbidity (e.g., seizures, NICU admission, low Apgar's, hypoxic ischemic encephalopathy, sepsis), serious maternal harm (e.g., postpartum hemorrhage, serious infection, mortality)

Important: Breastfeeding

Considered but not selected for the GRADE table: None

Key Questions

KQ1: What is the comparative effectiveness of planned out-of-hospital birth compared to hospital birth?

KQ2: Does the comparative effectiveness of planned out-of-hospital birth vary by:

a. Patient characteristics (demographics)
b. Risk factors (pregnancy or pre-pregnancy) and comorbidities
c. Setting (including home, out-of-hospital birth center)
d. Location (U.S. vs. non-U.S.)

KQ3: What are the harms of planned out-of-hospital birth compared to hospital birth?

KQ4: Do the harms of planned out-of-hospital birth vary by:

a. Patient characteristics (demographics)
b. Risk factors (pregnancy or pre-pregnancy) and comorbidities
c. Setting (including home, out-of-hospital birth center)
d. Location (U.S. vs. non-U.S.)
e. Provider characteristics

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Contextual Questions

CQ1: What do applicable guidelines recommend as standards for consultation and referral or transfer of patients planning out-of-hospital birth?

a. What conditions require consultation?
b. What conditions require transfer?

CQ2: What systems factors (e.g., coordination with consultants, hospitals, and emergency transportation) are associated with differential outcomes in out-of-hospital birth?

CQ3: What is the rate of expected transfer to a hospital setting with a planned out-of-hospital birth?

CQ4: What are example coverage criteria from other public and private payers?

Search Strategy

Sources from the previous Coverage Guidance: Planned Out-of-Hospital Birth (2015) were included in this evidence review. Then, a full search of the core sources was conducted to identify systematic reviews, meta-analyses, and technology assessments that met the criteria for the scope described above. Searches of core sources were limited to citations published since 2015.

The following core sources were searched:

- Agency for Healthcare Research and Quality (AHRQ)
- Canadian Agency for Drugs and Technologies in Health (CADTH)
- Cochrane Library (Wiley Online Library)
- Institute for Clinical and Economic Review (ICER)
- Medicaid Evidence-based Decisions Project (MED)
- National Institute for Health and Care Excellence (NICE)
- Tufts Cost-effectiveness Analysis Registry
- Veterans Administration Evidence-based Synthesis Program (ESP)
- Washington State Health Technology Assessment Program

A MEDLINE® search was also conducted to identify systematic reviews, meta-analyses, and technology assessments, randomized controlled trials, and comparative and noncomparative observational studies using the search terms for home births, birth centers, and out-of-hospital births. The search was limited to publications in English published since 2015.

Searches for clinical practice guidelines were limited to those published since 2013. A search for relevant clinical practice guidelines was also conducted using MEDLINE® and the following sources:

- Australian Government National Health and Medical Research Council (NHMRC)
- Canadian Agency for Drugs and Technologies in Health (CADTH)
- Centers for Disease Control and Prevention (CDC), Community Preventive Services
- National Institute for Health and Care Excellence (NICE)
- Scottish Intercollegiate Guidelines Network (SIGN)
- United States Preventive Services Task Force (USPSTF)

- Veterans Administration/Department of Defense (VA/DoD) Clinical Practice Guidelines

Inclusion/Exclusion Criteria

Studies were excluded if they were not published in English, did not address the scope statement, or were study designs other than systematic reviews, meta-analyses, technology assessments, randomized controlled trials, comparative or noncomparative observational studies, or clinical practice guidelines.

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Appendix D. Applicable Codes

CODES	DESCRIPTION
CPT Codes	
59400	Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care
59409	Vaginal delivery only (with or without episiotomy and/or forceps);
59410	Vaginal delivery only (with or without episiotomy and/or forceps); including postpartum care
59412	External cephalic version, with or without tocolysis
59414	Delivery of placenta (separate procedure)
59425	Antepartum care only; 4-6 visits
59426	Antepartum care only; 7 or more visits
59430	Postpartum care only (separate procedure)
59510	Routine obstetric care including antepartum care, cesarean delivery, and postpartum care
59514	Cesarean delivery only;
59515	Cesarean delivery only; including postpartum care
59525	Subtotal or total hysterectomy after cesarean delivery (List separately in addition to code for primary procedure)
59610	Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care, after previous cesarean delivery
59612	Vaginal delivery only, after previous cesarean delivery (with or without episiotomy and/or forceps);
59614	Vaginal delivery only, after previous cesarean delivery (with or without episiotomy and/or forceps); including postpartum care
59618	Routine obstetric care including antepartum care, cesarean delivery, and postpartum care, following attempted vaginal delivery after previous cesarean delivery
59620	Cesarean delivery only, following attempted vaginal delivery after previous cesarean delivery;
59622	Cesarean delivery only, following attempted vaginal delivery after previous cesarean delivery; including postpartum care
HCPCS Codes	
H1000-5	Prenatal care, at risk assessment

Note: Inclusion on this list does not guarantee coverage.

Appendix E. Characteristics of Comparative Observational Studies

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
Bailey, 2017 New Zealand Routinely collected maternity outcome data compiled from Counties-Manukau District Health Board (CMDHB) maternity facilities 2003 to 2010 Poor quality	N = 47,381 Planned Birth Center n = 10,448 Planned Hospital n = 36,933	Inclusion criteria: Single pregnancy, cephalic presentation, labored spontaneously at ≥37 weeks gestation Exclusion criteria: Previous cesarean delivery, specific indications for a cesarean delivery, pregestational or gestational diabetes, malpresentation, lethal congenital abnormality, multiple pregnancy, intrauterine fetal death before onset of labor, preterm labor, induction of labor	Planned Birth Center (n = 10,448) vs. Planned Hospital (n = 36,933) Parity Nulliparous: 3,438 (32.9%) vs. 11,915 (32.3%) Parity ≥5: 363 (3.5%) vs. 2,149 (5.8%) Maternal age Age <20 years: 1,100 (10.5%) vs. 3,777 (10.2%) Age ≥35 years: 1,436 (13.7%) vs. 4,868 (13.2%) Ethnicity European: 5,086 (48.7%) vs. 4,868 (22.5%) Maori: 3,258 (31.2%) vs. 8,884 (24.1%) Pacific Island: ,1363 (13.0%) vs. 14,029 (38.0%) Other: 926 (7.1%) vs. 5,714 (15.4%) Deprivation score Decile 1-4: 2,510 (24.3%) vs. 4,427 (12.3%) Decile 5-8: 3,230 (31.2%) vs. 7,538 (20.9%) Decile 9-10: 4,603 (44.5%) vs. 24,110 (66.8%) New Zealand Deprivation index based on domicile, using socioeconomic measures from census data, then stratified into deciles

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
Birthplace in England Collaborative, 2011 United Kingdom Birthplace April 2008 to April 2010 Good quality	N = 64,538 Planned Home n = 16,840 Planned Freestanding Midwifery Unit n = 11,282 Planned Obstetric Unit n = 19,706 Planned Alongside Midwifery Unit n = 16,710	Inclusion criteria: Any NHS midwife attendance in part or all of labor, at 37 or more weeks in spontaneous labor Exclusion criteria: Elective cesarean delivery, prior cesarean delivery, preterm labor, multiple gestations, no prenatal care, fetal demise before onset of labor (i.e., stillbirth), presence of any medical or obstetric risk factor listed in the NICE intrapartum care guideline	Planned Home vs. Planned Freestanding Midwifery Unit vs. Planned Alongside Midwifery Unit vs. Planned Obstetric Unit Maternal age (years) <20: 218 (1.3%) vs. 677 (6.0%) vs. 1,069 (6.4%) vs. 1,506 (7.7%) 20–24: 1,706 (10.2%) vs. 2,132 (18.9%) vs. 3,489 (20.9%) vs. 4,251 (21.6%) 25–29: 4,346 (25.9%) vs. 3,267 (29.0%) vs. 5,001 (30.0%) vs. 5,701 (29.0%) 30–34: 5,848 (34.8%) vs. 3,248 (28.8%) vs. 4,582 (27.5%) vs. 5063 (25.7%) 35–39: 4,017 (23.9%) vs. 1,690 (15.0%) vs. 2,232 (13.4%) vs. 2,640 (13.4%) ≥40: 671 (4.0%) vs. 254 (2.3%) vs. 299 (1.8%) vs. 520 (2.6%) Ethnic group White: 15,937 (94.8%) vs. 10,329 (91.6%) vs. 13485 (80.9%) vs. 16068 (81.7%) Indian: 67 (0.4%) vs. 87 (0.8%) vs. 509 (3.1%) vs. 477 (2.4%) Pakistani: 41 (0.2%) vs. 164 (1.5%) vs. 545 (3.3%) vs. 636 (3.2%) Bangladeshi: 14 (0.1%) vs. 147 (1.3%) vs. 130 (0.8%) vs. 297 (1.5%) Black Caribbean: 127 (0.8%) vs. 48 (0.4%) vs. 198 (1.2%) vs. 265 (1.3%) Black African: 112 (0.7%) vs. 94 (0.8%) vs. 520 (3.1%) vs. 670 (3.4%)

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			Mixed: 280 (1.7%) vs. 124 (1.1%) vs. 293 (1.8%) vs. 328 (1.7%) Other: 241 (1.4%) vs. 284 (2.5%) vs. 993 (6.0%) vs. 938 (4.8%) Understanding of English Fluent: 16,724 (99.5%) vs. 10,927 (97.1%) vs. 15,196 (91.3%) vs. 18,044 (92.3%) Some: 75 (0.4%) vs. 273 (2.4%) vs. 1176 (7.1%) vs. 1,130 (5.8%) None: 15 (0.1%) vs. 55 (0.5%) vs. 274 (1.6%) vs. 380 (1.9%) Marital or partner status Married or living with partner: 16,056 (96.0%) vs. 10,444 (93.6%) vs. 15,014 (91.2%) vs. 17,097 (88.2%) Single or unsupported by partner: 673 (4.0%) vs. 718 (6.4%) vs. 1,453 (8.8%) vs. 2,289 (11.8%) Mean BMI in pregnancy: 24.0 ± 3.7 vs. 24.1 ± 3.7 vs. 24.0 ± 3.8 vs. 24.4 ± 4.0 Mean gestation (completed weeks: 39.8 ± 1.0 vs. 39.8 ± 1.0 vs. 39.7 ± 1.0 vs. 39.8 ± 1.1) Complications per woman 0: 15 757 (94.6%) vs. 10,643 (94.5%) vs. 15,512 (93.1%) vs. 15,794 (80.5%) 1: 847 (5.1%) vs. 572 (5.1%) vs. 1,078 (6.5%) vs. 3345 (17.0%)

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			≥2: 51 (0.3%) vs. 50 (0.4%) vs. 78 (0.5%) vs. 490 (2.5%)
Bolten et al., 2016 The Netherlands DELIVER (Data EersteLIjns VERloskunde) Study 2009 to 2010 Poor quality	N = 3,495 Planned Home n = 2,050 Planned Hospital n = 1,445	Inclusion criteria: Low-risk women who were in midwife-led care at the onset of labor Exclusion criteria: Women who were transferred to obstetrician-led care during pregnancy, and who received midwife-led care but had a 'medium risk' indication (according to VIL), including a history of postpartum hemorrhage or manual removal of the placenta, and who had prolonged rupture of membranes without contractions	Nulliparous, Planned Home (n = 868) vs. Planned Hospital (n = 717) Maternal age <25: 145 (16.7%) vs. 131 (18.3%) 25 to 35: 651 (75.0%) vs. 490 (68.3%) ≥35: 72 (8.3%) vs. 96 (13.4%) Ethnic background Dutch: 785 (90.4%) vs. 540 (75.3%) Non-Dutch Western: 37 (4.3%) vs. 82 (11.4%) Non-Western: 43 (5.0%) vs. 92 (12.8%) Prepregnancy BMI <25: 654 (75.3%) vs. 511 (71.3%) ≥25: 182 (21.0%) vs. 170 (23.7%) Socioeconomic status High: 187 (21.5%) vs. 180 (25.1%) Middle: 389 (44.8%) vs. 319 (44.5%) Low: 288 (33.2%) vs. 215 (30.0%) Parous, Home (n = 1,182) vs. Hospital (n = 728) Maternal age <25: 48 (4.1%) vs. 36 (4.9%) 25 to 35: 870 (73.6%) vs. 506 (69.5%) ≥35: 264 (22.3%) vs. 186 (25.5%) Ethnic background

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			Dutch: 1,030 (87.1%) vs. 532 (73.1%) Non-Dutch Western: 82 (6.9%) vs. 69 (9.5%) Non-Western: 65 (5.5%) vs. 125 (17.2%) Prepregnancy BMI <25: 842 (71.2%) vs. 481 (66.1%) ≥25: 292 (24.7%) vs. 216 (29.7%) Socioeconomic status High: 321 (27.2%) vs. 205 (28.2%) Middle: 581 (49.2%) vs. 325 (44.6%) Low: 277 (23.4%) vs. 194 (26.6%)
Christensen & Overgaard, 2017 Denmark Data collected on sociodemographic characteristics, present and previous pregnancies and births, neonatal outcomes and transfers March 2004 to October 2008 Poor quality	N = 1,678 Planned Birth Center n = 839 Planned Obstetric Unit n = 839	Inclusion criteria: Freestanding Midwifery Unit - considered low obstetric risk, presented with spontaneous onset of labor between 37 + 0 and 41 + 6 weeks of gestation following an uncomplicated pregnancy Obstetric Unit- included in the control group only if they represented a strict match on all nine criteria at the start of care in labor (e.g., BMI, age, parity) Exclusion criteria: NR	Planned Birth Center (n = 839) vs. Planned Obstetric Unit (n = 839) Parity Primiparous: 215 (25.6%) vs. 215 (25.6%) Multiparous: 624 (74.4%) vs. 624 (74.4%) Ethnicity Nordic or Western European: 805 (96%) vs. 809 (96.4%) Other ethnicity: 34 (4.0%) vs. 30 (3.6%) Education level No postsecondary education 230 (27.4%) vs. 230 (27.4%) Postsecondary education 609 (72.6%) vs. 609 (72.6%) Occupation level

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			Low level of employment: 535 (63.8%) vs. 535 (63.8%) High level of employment 304 (36.2%) vs. 304 (36.2%) Mean BMI: 24.2 ± 3.9 vs. 24.0 ± 3.9 Mean age: 29.4 ± 4.6 vs. 30.2 ± 4.5
Davies-Tuck et al., 2018 Australia Victorian Perinatal Data Collection 2000 to 2015 Poor quality	N = 833,231 Planned Home n = 3,945 Planned Hospital n = 829,286 High Risk N = 128,971 Planned Home n = 743 Planned Hospital n = 128,228 Low Risk N = 704,260 Planned Home n = 3,202 Planned Hospital n = 701,058 High risk defined as any of the following: multiple pregnancy, post-term (> 41 and 6 weeks), non-cephalic	Inclusion criteria: Women who gave birth from 2000 to 2015 who had planned before the onset of labor to give birth either at home with a midwife or in a hospital, who delivered at or past 37 weeks gestation. Pregnancies were classified as high or low risk: high risk pregnancy was defined as: a multiple pregnancy, a post-term (> 41 + 6 weeks of gestation) pregnancy, a non-cephalic presentation in labor, obesity, a prior cesarean delivery, previous uterine surgery, grand multiparity (≥5 previous births), any significant maternal medical condition such as preexisting diabetes, hypertension, renal, cardiac, liver, respiratory, endocrine, immunological, renal, or gastrointestinal disease	Low risk, Planned Home (n = 3,202) vs. Planned Hospital (n = 701,058) Maternal Age <20: 19 (0.6%) vs. 21,845 (3.1%) 20 to 30: 870 (27.2%) vs. 292,891 (41.8%) ≥30: 2,269 (70.9%) vs. 385,833 (55%) BMI < 18.5: 74 (2.3%) vs. 9,642 (1.4%) 18.5 to 24.9: 902 (28.2%) vs. 155,936 (22.2%) 25 to 29.9: 284 (8.9%) vs. 74,788 (10.7%) ≥30: 98 (3.1%) vs. 30,515 (4.4%) Country of Birth Australian/NZ: 2,515 (78.5%) vs. 500,945 (71.5%) Non-Australian: 481 (15.0%) vs. 175,420 (25.0%) Parity Nulliparous: 1,103 (34.5%) vs. 347,079 (49.5%) Second birth: 1,187 (37.1%) vs. 218,790 (31.2%)

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
	presentation in labor, obesity (BMI Class 2 or greater), a prior cesarean, previous uterine surgery, grand multiparity (≥5 previous births), any significant maternal medical condition such as preexisting diabetes, hypertension, renal, cardiac, liver, respiratory, endocrine, immunological, renal, or gastrointestinal disease as determined by individual ICD-10 codes. Low risk defined as absence of any high risk condition.		3rd or subsequent birth: 912 (82.5%) vs. 135,181 (19.3%) Index of Relative Social Disadvantage quintile 1 Most Disadvantaged: 365 (11.4%) vs. 130,638 (18.6%) 2: 544 (17.0%) vs. 130,782 (18.7%) 3: 567 (17.7%) vs. 135,146 (19.3%) 4: 740 (21.1%) vs. 132,770 (18.9%) 5 Least Disadvantaged: 846 (26.4%) vs. 132,991 (19.0%) High risk, Planned Home (n = 743) vs. Planned Hospital (n = 128,228) Maternal Age <20: 2 (0.3%) vs. 2,051 (1.6%) 20 to 30: 162 (21.8%) vs. 44,543 (34.7%) ≥30: 573 (77.1%) vs. 81,605 (63.6%) BMI < 18.5: 15 (2.0%) vs. 1,310 (1.0%) 18.5 to 24.9: 196 (26.4%) vs. 25,437 (19.8%) 25 to 29.9: 85 (11.4%) vs. 16,288 (12.7%) ≥30: 73 (9.8%) vs. 32,406 (25.3%) Country of Birth Australian/NZ: 606 (81.6%) vs. 87,369 (68.1%) Non-Australian: 91 (12.3%) vs. 35,301 (27.5%) Parity Nulliparous: 142 (19.1%) vs. 41,499 (32.4%)

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			Second birth: 294 (39.6%) vs. 48,341 (37.7%) 3rd or subsequent birth: 306 (41.2%) vs. 36,829 (28.7%) <u>Index of Relative Social Disadvantage quintile</u> 1 Most Disadvantaged: 84 (11.3%) vs. 29,013 (22.6%) 2: 110 (14.8%) vs. 26,024 (10.3%) 3: 134 (18.0%) vs. 23,966 (18.7%) 4: 177 (23.8%) vs. 21,320 (16.6%) 5 Least Disadvantaged: 176 (23.7%) vs. 19,244 (15.0%)
Davis et al., 2012 New Zealand New Zealand College of Midwives research database, managed by the Midwifery Maternity Provider Organisation 2006 to 2007 Fair quality	N = 16,210 Planned Home n = 1,830 Planned Primary Unit n = 2,877 Planned Secondary Hospital n = 7,380 Planned Tertiary Hospital n = 4,123	Inclusion criteria: Low risk - see exclusion criteria <u>Exclusion criteria</u>: Previous cesarean delivery, stillbirth, fetal death before commencement of labor, multiple birth, labor on or before 36 weeks + 6 days or after 41 weeks + 6 days, induced labor, breech or shoulder presentation, transverse lie, and elective cesarean delivery, previous postpartum hemorrhage (>1,000 mL), severe pregnancy-induced hypertension, gestational diabetes, Rh sensitization, ABO incompatibility, essential hypertension, diabetes, thyroid disease, drug or alcohol abuse, heart disease, pulmonary disease/asthma,	Planned Home (n = 1,830) vs. Planned Primary Unit (n = 2,877) vs. Planned Secondary Hospital (n = 7,380) vs. Planned Tertiary Hospital (n = 4,123) <u>Mean age</u>: 30.4 ± 5.4 vs. 27.9 ± 6.0 vs. 27.7 ± 6.0 vs. 29.3 ± 5.9, $p < 0.001$ <u>Mean parity</u>: 1.4 ± 1.4 vs. 1.1 ± 1.2 vs. 0.9 ± 1.2 vs. 0.7 ± 1.0, $p < 0.001$ <u>Mean length of labor</u>: 5.1 ± 4.8 vs. 6.1 ± 4.8 vs. 6.39 ± 4.6 vs. 7.4 ± 5.3, $p < 0.001$ <u>Proportion of unassisted vaginal births</u>: 95.4% vs. 94.7% vs. 84.5% vs. 72.7%, $p < 0.001$ <u>Proportion of emergency cesarean deliveries</u>: 2.6% vs. 3.2% vs. 8.5% vs. 14.9%, $p < 0.001$

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
		hematological disorder, neurological disorder, renal/urinary tract disorder, muscular skeletal disorder, consultation with or transfer of care to another practitioner during antenatal period	Proportion of active management: 25.9% vs. 47.1% vs. 73.2% vs. 77.8%, p < 0.001
de Cock et al., 2015 The Netherlands Survey data, DELIVER study September 2009 to April 2011 Poor quality	N = 712 Home: n = 547 Planned hospital-Midwife: n = 165	Inclusion criteria: Singleton pregnancy, fetus in cephalic presentation, low-risk and in primary care at the onset of labor, started labor spontaneously between 37 and 42 weeks, stated intention to breastfeed prior to birth Exclusion criteria: Previous cesarean delivery, medical or obstetric risk factors that are an indication for secondary care, women who gave birth in hospital under the supervision of an obstetrician, place of birth unknown, child had congenital anomaly, completed questionnaire in the first week postpartum or after six months postpartum	Planned Home (n = 547) vs. Planned Hospital-Midwife (n = 165) Ethnic background (p = 0.15) Dutch/other western: 529 (96.9%) vs. 154 (94.5%) Non-western: 17 (3.1%) vs. 9 (5.5%) Education level woman (p = 0.34) Low/medium 203 (37.1%) vs. 68 (41.2%) High 344 (62.9%) vs. 97 58.8%) Education level partner (p = 0.42) Low/medium: 263 (48.5%) vs. 85 (52.1%) High: 279 (51.5%) vs. 78 (47.9%) Age (p = 0.35) ≤24 years: 32 (5.9%) vs. 8 (4.8%) 25–34 years: 422 (77.1%) vs. 121 (73.3%) ≥35 years: 93 (17.0%) vs. 36 (21.8%) Smoking before or during pregnancy (p = 0.31) Yes: 80 (14.6%) vs. 19 (11.5%) No: 467 (85.4%) vs. 146 (88.5%) Parity (p = 0.24)

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			Nulliparous: 172 (31.4%) vs. 60 (36.4%) Parous: 375 (68.6%) vs. 105 (63.6%)
de Jonge et al., 2015 The Netherlands Netherlands Perinatal Registry 2000 to 2009 Fair quality	N = 743,070 Planned Home n = 466,112 Planned Hospital-Midwife n = 276,958	Inclusion criteria: Low-risk women in midwife-led care at the onset of labor, single pregnancy, spontaneous labor at ≥37 weeks gestation, no medical indication for hospital birth Exclusion criteria: Medium-risk women, women who had not received prenatal care, missing national perinatal database-1 form, unknown planned place of birth, prolonged ruptured membranes for more than 24 hours without contractions, an intrauterine death before labor began, a child with a congenital abnormality, gestational age <37 or >42 weeks	Planned Home (n = 466,112) vs. Planned Hospital-Midwife (n = 276,958) Parity Nulliparous: 198,515 (42.5%) vs. 137,168 (49.5%) Parous: 267,526 (57.5%) vs. 139,740 (50.5%) Maternal age <25 years: 44,621 (9.6%) vs. 48,083 (17.4%) 25 to 34 years: 341,617 (73.3%) vs. 181,763 (65.6%) ≥35 years: 79,700 (17.1%) vs. 47,006 (17.0%) Ethnicity Dutch: 423,853 (90.9%) vs. 184,433 (66.6%) Non-Dutch: 38,999 (8.3%) vs. 90,276 (32.6%) Socioeconomic status Low: 113,091 (24.3%) vs. 103,230 (37.3%) Medium: 230,767 (49.5%) vs. 106,461 (38.4%) High: 116,641 (25.0%) vs. 62,635 (22.6%) Missing: 5,542 (1.2%) vs. 4,582 (1.7%)
de Jonge, et al., 2013 The Netherlands LEMMoN study merged with Netherlands Perinatal Registry	N = 146,752 Planned Home n = 92,333	Inclusion criteria: Singleton, cephalic, without medical or obstetric risk factors (e.g., history of prior	Planned Home (n = 92,333) vs. Planned Hospital (n = 54,419) Parity 0: 38,728 (41.9%) vs. 26,499 (48.7%)

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
August 2004 to August 2006 Fair quality	Planned Hospital n = 54,419	cesarean delivery), spontaneous onset of labor between 37 and 42 weeks Exclusion criteria: ROM > 24 hours without contractions, "medium risk" history: prior postpartum hemorrhage or retained placenta, unknown planned place of birth	1+: 53,602 (58.1%) vs. 27,919 (51.3%) Gestational age 37+0 to 37+6: 3,404 (3.7%) vs. 2,296 (4.2%) 38+0 to 40+6: 67,507 (73.1%) vs. 40,256 (74.0%) 41+0 to 41+6: 21,422 (23.2%) vs. 11,867 (21.8%) Maternal age (years) <25: 9,142 (9.9%) vs. 9,407 (17.3%) 25-34: 66,554 (72.1%) vs. 35,137 (64.6%) ≥35: 16,630 (18.0%) vs. 9,868 (18.1%) Ethnicity Dutch: 83,629 (90.9%) vs. 36,126 (66.9%) Non-Dutch: 8,385 (9.1%) vs. 17,904 (33.1%) Socioeconomic position High: 23,243 (25.5%) vs. 12,324 (23.0%) Medium: 45,320 (49.7%) vs. 21,099 (39.4%) Low: 22,671 (24.8%) vs. 20,190 (37.7%)
Grigg et al., 2017 New Zealand Maternity and Midwifery Provider Organization data 2010 to 2011 Poor quality	N = 692 PMUs n = 407 TMH n = 285 Freestanding Primary Level Midwife-led Maternity Units (PMUs) vs. Tertiary-level Obstetric-led	Inclusion criteria: All women booked to give birth at birthing centers near Christchurch, New Zealand between March 2010 and August 2011 Exclusion criteria: Previous cesarean delivery, expecting twins, BMI > 40, neurological disorder	Planned Birthing Center (n = 407) vs. Planned Hospital (n = 285) Mean age: 30.8 vs. 32.1 <25: 56 (13.8%) vs. 26 (9.2%) 25 to 29: 127 (31.2%) vs. 67 (23.6%) 30 to 34: 142 (34.9%) vs. 120 (42.3%) ≥35: 83 (20.2%) vs. 71 (25.0%) Median parity: 1 (0.9) vs. 0 (0.5)

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
	Maternity Hospital (TMH)		Nulliparous: 167 (41.0%) vs. 157 (54.1%) Ethnicity NZ European: 308 (75.7%) vs. 226 (79.3%) Māori: 30 (7.4%) vs. 6 (2.1%) Other: 69 (17.0%) vs. 53 (18.6%) Smoker: 31 (7.6%) vs. 15 (5.3%) Residence City or semirural: 308 (75.7%) vs. 248 (87.0%) Rural or remote rural: 99 (25.3%) vs. 37 (13.0%) Has a partner: 377 (92.4%) vs. 260 (91.6%) BMI <25: 233 (58.7%) vs. 196 (69.3%) 25 to 35: 149 (37.5%) vs. 79 (27.9%) >35: 15 (3.8%) vs. 8 (2.8%) Income <$25,000 per annum before tax: 20/326 (6.1%) vs. 14/226 (6.2%) $25,000 to $50,000: 95/326 (29.1%) vs. 34/226 (15.0%) $50,000 to $75,000: 99/326 (30.4%) vs. 70/226 (31.0%) >NZ$75,000: 112/326 (34.4%) vs. 108/226 (47.8%) Education

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			No post school completed: 67/331 (20.2%) vs. 36/230 (15.7%) Apprenticeship, certificate: 55/331 (16.6%) vs. 32/230 (13.9%) Diploma: 56/331 (16.9%) vs. 41/230 (17.8%) Degree: 153/331 (46.2%) vs. 121/230 (52.6%)
Grunebaum, McCullough, Arabin et al., 2017 U.S. CDC-linked birth-infant death data set 2008 to 2012 Poor quality	N = 15,906,211 Planned Home n = 95,657 Planned Hospital-CNM n = 1,363,199 Planned Hospital-Physician n = 14,447,355	Inclusion criteria: Liveborn, singleton, term (≥ 37 weeks), birth weight ≥ 2500g, delivered by physician, CNM, or other midwife. Exclusion criteria: Preterm, low birthweight (<2,500g), other deliverer, other location than home or hospital	Planned Home (n = 95,657) vs. Planned Hospital-CNM (n = 1,363, 199) vs. Planned Hospital-Physician (n = 14,447,355) Unmarried: 8685 (9.1%) vs. 587,688 (43.1%) vs. 5,721,977 (39.6%) White non-Hispanic: 84,759 (88.6%) vs. 728,918 (53.5%) vs. 7,779,467 (53.8%) Nulliparous: 22,773 (23.8%) vs. 540,582 (39.7%) vs. 5,896,748 (40.8%) 41+ weeks: 27,825 (29.1%) vs. 297,534 (20.5%) vs. 2,252,777 (15.6%) Maternal age ≥35: 20,807 (21.8%) vs. 146,339 (10.7%) vs. 2,087,544 (14.4%)
Grunebaum, McCullough, Sapra et al., 2017 U.S. CDC-linked birth-infant death files 2009 to 2013 Fair quality	N = 12,953,671 Planned Home n = 96,815 Planned Hospital-CNM n = 1,077,197 Planned Hospital-Physician n = 11,779,659	Inclusion criteria: Term (≥37 weeks), weight ≥2,500 g, singleton, nonanomalous, states using the 2003 revised birth certificate Exclusion criteria: Birthplace outside hospital or home, unintended home birth, multiple gestations, residents of a foreign country	Planned Home Birth (n = 96, 815) vs. Planned Hospital-CNM (n = 1,077,197) vs. Planned Hospital-Physician (n = 11,779,659) Maternal ethnicity Non-Hispanic white: 87,253 (90.1%) vs. 577,665 (53.6%) vs. 6,276,662 (53.3%) Black: 1,890 (2.0%) vs. 137,484 (12.8%) vs. 1,539,889 (13.1%)

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			Hispanic: 4,643 (4.8%) vs. 283,687 (26.3%) vs. 3,042,950 (25.8%) Other: 1,614 (1.7%) vs. 71,335 (6.6%) vs. 828,184 (7.0%) Unknown: 1,415 (1.5%) vs. 7,026 (0.7%) vs. 91,974 (0.8%) <u>Maternal age, years</u> <25: 15,294 (15.8%) vs. 390,660 (36.3%) vs. 3,745,494 (31.8%) 25 to 34: 61,409 (63.4%) vs. 567,481 (52.7%) vs. 6,336,325 (53.8%) ≥35: 20,106 (20.8%) vs. 119,030 (11.0%) vs. 1,697,022 (14.4%) <u>Maternal education, years</u> <13: 38,443 (39.7%) vs. 496,538 (46.1%) vs. 4,998,057 (42.4%) ≥13: 57,729 (59.6%) vs. 566,134 (52.6%) vs. 6,642,060 (56.4%) <u>Prenatal visits, n</u> 0: 2,652 (2.7%) vs. 8,839 (0.8%) vs. 145,689 (1.2%) 1-5: 13,255 (13.7%) vs. 49,372 (5.6%) vs. 519,504 (4.4%) ≥6: 79,765 (82.4%) vs. 973,834 (90.4%) vs. 10,679,376 (90.7%) <u>Insurance</u> Private: 12,174 (12.6%) vs. 294,262 (27.3%) vs. 3,464,544 (29.4%)

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			Government: 6,145 (6.3%) vs. 319,590 (29.7%) vs. 3,337,667 (28.3%) Self-pay/other: 42,808 (44.2%) vs. 47,071 (4.4%) vs. 423,746 (3.6%) Unknown: 3,055 (3.2%) vs. 12,945 (1.2%) vs. 89,663 (0.8%) Not reported: 32,633 (33.7%) vs. 89,663 (0.8%) vs. 4,464,039 (37.9%) <u>Parity</u> Nulliparous: 20,125 (20.8%) vs. 424,060 (39.4%) vs. 4,756,609 (40.4%) Parous: 75,809 (78.3%) vs. 641,625 (59.6%) vs. 6,952,531 (59.0%) Unknown: 881 (0.9%) vs. 11,512 (1.1%) vs. 70,519 (0.6%) <u>Previous cesarean delivery</u> No: 92,199 (95.2%) vs. 1,048,436 (97.3%) vs. 9,961,948 (84.6%) Yes: 4,273 (4.4%) vs. 22,176 (2.1%) vs. 1,782,055 (15.1%) Unknown: 343 (0.4%) vs. 6,585 (0.6%) vs. 35,656 (0.3%) <u>Newborn weight, g</u> 2,500 to 3,900: 76,428 (78.9%) vs. 982,994 (91.3%) vs. 10,744,142 (92.2%) ≥ 4,000: 20,387 (21.1%) vs. 94,203 (8.7%) vs. 1,035,517 (8.8%) <u>Gestational age (week)</u>

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			37-38: 14,205 (14.7%) vs. 256,151 (23.8%) vs. 3,341,327 (28.4%) 39-40: 54,232 (56.0%) vs. 606,165 (56.3%) vs. 6,645,173 (56.4%) ≥41: 28,378 (29.3%) vs. 214,881 (19.9%) vs. 1,793,159 (15.2%) Presentation Cephalic: 93,462 (96.5%) vs. 1,036,683 (96.2%) vs. 10,977,624 (93.2%) Breech: 553 (0.6%) vs. 1,921 (0.2%) vs. 300,204 (2.5%) Other: 470 (0.5%) vs. 11,189 (1.0%) vs. 259,162 (2.2%) Unknown: 2,330 (2.4%) vs. 27,404 (2.5%) vs. 242,669 (2.1%) Risk composite No risk present: 37,286 (38.5%) vs. 414,744 (38.5%) vs. 3,464,701 (29.4%) Any risk present: 57,831 (59.7%) vs.637,530 (59.2%) vs. 8,124,803 (69.0%) Unknown: 1,698 (1.8%) vs. 24,923 (2.3%) vs. 190,155 (1.6%)
Halfdansdottir et al., 2018 Iceland Maternity notes review 2005 to 2009 Poor quality	N = 1,228 Low Risk N = 1,129 Planned Home n = 278	Inclusion criteria: Women who intended to give birth at a home under the care of a midwife in Iceland before the onset of labor in 2005 to 2009, and hospital births matched on parity, maternal age, residence, known	Overall Mean age: 30.3 ± 4.7 < 25: 136 (11.1%) 25 to 34: 857 (69.8%) ≥35: 235 (19.1%)

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
	Planned Hospital n = 851 High Risk N = 99 Planned Home n = 29 Planned Hospital n = 70	risks, and year of birth to similar hospital births Exclusion criteria: Hospital births that did not meet the criteria for home birth, unless matched on specific risk to a contraindicated home birth	Residence Capital (all ≤ 20 min): 931 (75.8%) Rural ≤ 20 min: 196 (16.0%) Rural > 20 min: 101 (8.2%) Marital status Married: 505 (41.2%) Cohabiting: 650 (53.0%) Single: 72 (5.9%) Occupation Specialist: 569 (56.1%) Semi-specialist: 304 (30.0%) Non-specialist: 142 (14.0%) Citizenship Non-Icelandic: 105 (8.8%) Parity Primiparous: 256 (20.8%) Multiparous: 972 (79.2%) Previous home births: 70 (5.7%) Previous instrumental births: 137 (11.2%) BMI <25: 676 (56.9%) 25 to 29.99: 356 (30.0%) ≥30: 156 (13.1%) Maternal smoking: 35 (2.9%) Place of birth

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			Hospital: 921 (75.0%) Home: 307 (25.0%) Mean gestation: 2,81.4 ± 7.4 Mean birthweight: 3,764 ± 475 Congenital anomalies: 57 (4.6%)
Halfdansdottir et al., 2015 Iceland Review of midwives' and doctors' original hand-written maternity notes 2005 to 2009 Poor quality	N = 1,228 Planned Home n = 307 Planned Hospital n = 921	Inclusion criteria: All planned home births accepted for midwifery care in Iceland at the onset of labor in 2005–2009, and births in a hospital or alongside midwifery unit matched on matched on parity (primipara vs. multipara); contraindications (if present in the home birth); residence (capital vs. rural, by transfer time to hospital); maternal age (±2 years); and year of birth (next in chronological order) Exclusion criteria: Unplanned and unattended home births, births in a hospital or midwifery unit that were not matched to the include home birth cases, women with any of 67 predefined contraindications (supporting information), based on the Directorate of Health's guidelines for home births, were excluded when matching low-risk home births without contraindications	Planned Home (n = 307) vs. Planned Hospital or Midwifery Alongside Unit (n = 921) Mean age: 30.6 ± 4.9 vs. 30.2 ± 4.7, p = 0.120 <25: 33 (10.7%) vs. 103 (11.2%) 25 to 34: 202 (65.8%) vs. 655 (71.1%) ≥35: 72 (23.5%) vs. 163 (17.7%), p = 0.084 Marital status Married: 143 (46.6%) vs. 362 (39.3%) Cohabiting: 156 (50.8%) vs. 494 (53.7%) Single: 8 (2.6%) vs. 64 (7.0%) Occupation Specialist: 170 (59.4%) vs. 399 (54.7%) Semispecialist: 89 (31.1%) vs. 215 (29.5%) Nonspecialist: 27 (9.4%) 115 vs. (15.8%) Citizenship Icelandic: 286 (93.8%) vs. 799 (90.3%) Non-Icelandic: 19 (6.2%) vs. 86 (9.7%) Parity Primipara: 64 (20.8%) vs. 192 (20.8%)

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			Multipara: 243 (79.2%) vs. 729 (79.2%) <u>Previous home births</u> No: 235 (77.0%) vs. 920 (100.0%) Yes: 70 (23.0%) vs. 0 (0.0%) <u>Previous instrumental births</u> No: 275 (90.2%) vs. 813 (88.4%) Yes: 30 (9.8%) vs. 107 (11.6%) <u>BMI</u> <25: 171 (59.2%) vs. 505 (56.2%) 25 to 29.99: 88 (30.4%) vs. 268 (29.8%) ≥30: 30 (10.4%) vs. 126 (14.0%) <u>Smoking</u> No: 294 (97.0%) vs. 895 (97.2%) Little: 9 (3.0%) vs. 26 (2.8%) Mental health problems No: 290 (94.5%) vs. 885 (96.1%) Yes: 17 (5.5%) vs. 36 (3.9%) <u>Contraindications</u> No: 278 (90.6%) vs. 851 (92.4%) Yes: 29 (9.4%) vs. 70 (7.6%) Contraindications: hypertensive disorders; previous cesarean delivery; isoimmunization; prolonged pregnancy; hyperthyroidism; bipolar affective disorder; abnormal findings on antenatal screening; macrosomia or anticipated maternal–fetal disproportion; BMI >35 or <18

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
Hermus et al., 2017 The Netherlands July to December 2013 Good quality	N = 3455 Planned Home n = 1086 Planned Birth Center n = 1668 Planned Hospital n = 701	Inclusion criteria: Term (≥ 37 weeks) starting labor under care of a community midwife Exclusion criteria: Any woman with a medium-risk or higher condition on the List of Obstetric Indications. Any woman with no specific planned place of birth at one set of labor	Planned Home (n = 1086) vs. Planned Birth Center (n = 1668) vs. Planned Hospital (n = 701) (Birth center reference group) Maternal background Dutch: 1035 (95.3%) vs. 1274 (76.4%) vs. 531 (75.7%) Non-Dutch: 51 (4.7%) vs. 394 (23.6%) vs. 170 (24.3%) Socioeconomic status Low: 53 (4.9%) vs. 244 (14.6%) vs. 80 (11.4%) Medium: 888 (81.8%) vs. 1113 (66.7%) vs. 482 (68.8%) High: 136 (12.5%) vs. 278 (16.6%) vs. 109 (15.5%)
Hitzert et al., 2016 The Netherlands Dutch Birth Centre Study August to December 2013 Poor quality	N = 990 Planned Home n = 350 Planned Birth Center n = 263 Planned Hospital-Midwife n = 262 Planned Hospital-Obstetrician n = 115	Inclusion criteria: Postpartum women under the care of community midwives in 82 randomly recruited midwifery practices between August 1 and December 31, 2013	Planned Home (n = 350) vs. Planned Birth Center (n = 263) vs. Planned Hospital-Midwife (n = 262) vs. Hospital-Obstetrician (n = 115) Age ≤25: 21 (6.5%) vs. 12 (4.6%) vs. 14 (5.8%) vs. 3 (2.7%) 26 to 35: 238 (73.2%) vs. 195 (75.0%) vs. 174 (72.5%) vs. 76 (69.1%) ≥36: 66 (20.3%) vs. 53 (20.4%) vs. 52 (21.7%) vs. 31 (28.2%) Parity Primiparous: 126 (38.0%) vs. 154 (58.8%) vs. 113 (46.5%) vs. 47 (42.3%)

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			Multiparous: 206 (62.0%) vs. 108 (41.2%) vs. 130 (53.5%) vs. 64 (57.7%) <u>Education</u> Low: 26 (8.0%) vs. 16 (6.1%) vs. 14 (6.0%) vs. 10 (9.4%) Middle: 120 (36.9%) vs. 64 (24.4%) vs. 72 (30.9%) vs. 35 (33.0%) High: 179 (55.1%) vs. 182 (69.5%) vs. 147 (63.1%) vs. 61 (57.5%) <u>Ethnicity</u> Dutch: 312 (96.3%) vs. 247 (93.9%) vs. 203 (84.6%) vs. 93 (85.3%) Non-Dutch: 12 (3.7%) vs. 16 (6.1%) vs. 37 (15.4%) vs. 16 (14.7%)
Hollowell et al., 2017 England Birthplace in England national prospective cohort study April 2008 to April 2010 Fair quality	N = 27,938 Planned Birthing Center n = 11,265 Planned Hospital n = 16,673	<u>Inclusion criteria</u>: Low-risk single pregnancy, received prenatal care from an NHS midwife, not known to have any medical or obstetric risk factors <u>Exclusion criteria</u>: Presented with labor <37 weeks, no prenatal care, experienced stillbirth prior to onset of labor	Planned Birthing Center (n = 11,265) vs. Planned Hospital (n = 16,673) <u>Parity</u> Nulliparous: 5,187 (46.0%) vs. 8,350 (50.1%) Multiparous: 6,078 (54.0%) vs. 8,323 (49.9%) <u>Maternal age</u> < 20 years: 676 (6%) vs. 1,054 (6%) 20 to 24 years: 2,129 (19%) vs. 3,208 (19%) 25-29 years: 3,258 (29%) vs. 4,994 (30%) 30-34 years: 3,244 (29%) vs. 4,574 (27%) 35 to 39 years: 1,690 (15%) vs. 2,227 (13%) 40+: 254 (2%) vs. 298 (2%)

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			BMI 10 to 18.4: 234 (2.1%) vs. 437 (2.6%) 18.5 to 24.9: 5,596 (50%) vs. 8,202 (49.2%) 25.0 to 29.9: 2,648 (23.5%) vs. 3,784 (22.7%) 30.0 to 35.0: 911 (8.1%) vs. 1,269 (7.6%) Not Recorded: 1,861 (16.5%) vs. 2,915 (17.5%)
Homer et al., 2014 Australia Perinatal Data Collection, Admitted Patient Data Collection, Register of Congenital Conditions, Registry of Birth Deaths and Marriages, and the Australian Bureau of Statistics 2000 to 2008 Fair quality	N = 258,161 Planned Home n = 742 Planned Birth Center n = 14,483 Planned Hospital n = 242,936	Inclusion criteria: Women who gave birth to a singleton baby in a cephalic presentation following spontaneous labor at >37 weeks gestation from July 1, 2000, up to and including June 30, 2008 Exclusion criteria: Women who had an elective cesarean delivery, the baby was born before arrival to hospital, the birth occurred before 37 completed weeks gestation, had received no antenatal care, were attempting a vaginal birth after previous cesarean delivery (VBAC) for this birth, the baby was diagnosed with a congenital abnormality (that is, registered on the NSW Register of Congenital Conditions), had labor induced for any reason, or had a baby who had received a diagnosis (as recorded on the birth and subsequent admission data on the Admitted Patient Data Collection) of a congenital condition	Planned Home (n = 742) vs. Planned Birth Center (n = 14,483) vs. Planned Hospital (n = 242,936) Age <20: 7 (0.9%) vs. 513 (3.5%) vs. 15,280 (6.3%) 20 to 24: 54 (7.3%) vs. 2,122 (14.7%) vs. 42,544 (17.5%) 25 to 29: 159 (21.4%) vs. 4,529 (31.3%) vs. 73,440 (30.2%), p < 0.001 30 to 34: 249 (33.6%) vs. 4,788 (33.1%) vs. 73,404 (30.2%) 35 to 39: 185 (24.9%) vs. 2,181 (15.1%) vs. 32,058 (13.2%) ≥40: 49 (6.6%) vs. 349 (2.4%) vs. 6,134 (2.5%) Previous pregnancies (≥20 weeks) 0: 313 (42.2%) vs. 9,145 (63.1%) vs. 149,459 (61.5%) 1: 219 (29.5%) vs. 3,328 (23.0%) vs. 54,445 (22.4%), p < 0.001 2: 143 (19.3%) vs. 1,453 (10.0%) vs. 24,627 (10.1%)

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
		and who died within the first week of life resulted in that woman and baby pair being excluded from the cohort	≥3: 59 (8.0%) vs. 552 (3.8%) vs. 14,259 (5.9%)
Hutton et al., 2016 Ontario, Canada Chart review March 2016 to April 2009 Poor quality	N = 22,986 Planned Home n = 11,493 Planned Hospital n = 11,493	Inclusion criteria: Term (≥ 37 weeks), single prior cesarean delivery Exclusion criteria: Alcohol or drug dependency, chronic hypertension, diabetes, heart condition, hepatitis B, HIV, isoimmunization, anemia unresponsive to treatment, antepartum bleeding, eclampsia, gestational diabetes, IUGR, SGA, oligohydramnios, pregnancy-induced hypertension, preterm delivery (<37 weeks), breech presentation, multiple gestations, medical induction (oxytocin or prostaglandin), lethal congenital anomaly	Planned Home (n = 11,493) vs. Planned Hospital (n = 11,493) Age < 25: 1,512 (13.2%) vs. 1,821 (15.8%) 25–34: 7,802 (67.9%) vs. 8,015 (69.7%) ≥ 35: 2,177 (18.9%) vs. 1,656 (14.4%) Parity 0: 4,027 (35.0%) vs. 4,027 (35.0%) 1–4: 7,084 (61.6%) vs. 7,311 (63.6%) > 4: 382 (3.3%) vs. 155 (1.3%) Previous cesarean deliveries 0: 11,206 (97.5%) vs. 11,206 (97.5%) 1: 271 (2.4%) vs. 287 (2.5%) > 1: 16 (0.1%) vs. 0 (0.0%) Maternal smoking: 477 (4.3%) vs. 647 (5.8%) Multiple birth: 2 (0.02%) vs. 0 (0.0%) Breech presentation: 35 (0.3%) vs. 0 (0.0%) Gestational age < 37 weeks: 101 (0.9%) vs. 0 (0.0%) 37 to 41 weeks, 6 days: 11,210 (97.5%) vs. 11,414 (99.3%) > 41 weeks, 6 days: 182 (1.6%) vs. 79 (0.7%)

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
Hutton et al., 2009 Canada Ontario Ministry of Health database 2003 to 2006 Poor quality	N = 13,384 Planned Home n = 6,692 Planned Hospital n = 6,692	Inclusion criteria: Midwife-attended births that occurred between April 1, 2003, and March 31, 2006 who planned a home birth at the outset of labor, and a comparable low-risk group of women who planned a hospital birth at the outset of labor, and groups were matched with respect to parity and previous lower segment cesarean delivery	Planned Home (n = 6,692) vs. Planned Hospital Midwife (n = 6,692) Age <25: 729 (10.9%) vs. 844 (12.6%) 25 to 34: 4,428 (66.1%) vs. 4,630 (69.2%) ≥35: 1,503 (22.5%) vs. 1,199 (17.9%) Parity 0: 2,293 (34.3%) vs. 2,298 (34.3%) 1 to 4: 4,172 (62.3%) vs. 4,289 (64.1%) >4: 221 (3.3%) vs. 105 (1.6%) Previous cesarean delivery 0: 6,479 (96.8%) vs. 6,485 (96.9%) 1: 200 (3.0%) vs. 207 (3.1%) >1: 6 (0.1%) vs. 0 (0%)
Janssen et al., 2009 British Columbia, Canada Perinatal Database Registry and vital statistics 2000 to 2004 Poor quality	N = 12,982 Planned Home n = 2,889 Planned Hospital-Midwife n = 4,752 Matched Sample of Physician-attended Hospital Births n = 5,331	Inclusion criteria: Planned home birth - Singleton fetus, cephalic presentation, gestational age greater than 36 and less than 41 completed weeks, no more than 1 previous cesarean delivery, labor is spontaneous or induced on an outpatient basis, absence of significant preexisting disease (including heart disease, hypertensive chronic renal disease or type 1 diabetes), absence of significant disease arising during pregnancy (including pregnancy-induced hypertension with proteinuria,	Planned Home (n = 2,889) vs. Planned Hospital-Midwife (n = 4,752) vs. Matched Sample of Physician-attended Hospital Births (n = 5,331) Age 15 to 19: 48 (1.7%%) vs. 116 (2.4%) vs. 92 (1.7%) 20 to 24: 336 (11.6%) vs. 584 (12.3%) vs. 629 (11.8%) 25 to 29: 892 (30.8%) vs. 1,371 (28.9%) vs. 1,644 (30.8%) 30 to 34: 1,025 (35.4%) vs. 1,682 (35.4%) vs. 1,883 (35.3%)

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
		antepartum hemorrhage after 20 weeks' gestation, gestational diabetes requiring insulin, active genital herpes, placenta previa or placental abruption), mother has not been transferred to the delivery hospital from a referring hospital Hospital attended by registered midwife - Met eligibility criteria for home birth, midwife was in attendance during labor, rosters of the College of Midwives indicated that birth was planned to be in hospital Hospital attending by physician - Matched births that met eligibility criteria for home birth to each home birth on a 2:1 ratio - parameters were year of birth, parity, single parent, maternal age and hospital where the midwife conducting the index home birth had hospital privileges; women did not require oxytocin for induction of labor Exclusion criteria: NR	≥ 35: 598 (20.6%) vs. 999 (21.0%) vs. 1,083 (20.3%) Nulliparous: 1,215 (41.9%) vs. 2,428 (51.1%) vs. 2,204 (41.3%) Mean gestational age at first prenatal contact: 12.2 ± 7.0 vs. 12.2 ± 6.8 vs. 11.8 ± 5.9 Mean number of antenatal visits: 11.8 ± 3.3 vs. 11.2 ± 3.6 vs. 9.3 ± 2.7 Mean BMI: 22.8 ± 4.0 vs. 23.3 ± 4.3 vs. 23.2 ± 4.3 Single parent: 91 (3.1%) vs. 252 (5.3%) vs. 163 (3.1%) Use of illicit drugs during pregnancy: 39 (1.3%) vs. 57 (1.2%) vs. 71 (1.3%) Use of alcohol during pregnancy: 10 (0.3%) vs. 25 (0.5%) vs. 35 (0.7%) Smoking status Current: 166 (5.7%) vs. 375 (7.9%) vs. 487 (9.1%) Former: 256 (8.8%) vs. 417 (8.8%) vs. 211 (4.0%) Never: 2,477 (85.4%) vs. 3,960 (83.3%) vs. 4,633 (86.9%) Income quintile 1 (lowest): 650 (23.4%) vs. 906 (19.8%) vs. 1,088 (21.1%)

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			2: 593 (21.3%) vs. 910 (19.9%) vs. 1,163 (22.6%) 3: 525 (18.9%) vs. 913 (20.0%) vs. 1,006 (19.5%) 4: 543 (19.5%) vs. 984 (21.5%) vs. 1,020 (19.8%) 5 (highest): 460 (16.5%) vs. 862 (18.8%) vs. 875 (17.0%)
Katoaka et al., 2018 Japan Review of medical records Birth centers: 2001 to 2006, one hospital: 2004 to 2006, other hospital: 2008 Poor quality	N = 9,588 Planned Birth Center n = 5,379 Planned Hospital n = 4,209	Inclusion criteria: Vaginal delivery, gestation at ≥22 weeks, singleton, and cephalic presentation Exclusion criteria: Transportation to other facilities, cesarean delivery, and twin pregnancies	Planned Birth Center (n = 5,379) vs. Planned Hospital (n = 4,209) Age <20: 20 (0.4%) vs. 20 (0.5%) 20 to 29: 1,537 (28.7%) vs. 1,273 (30.3%) 30 to 39: 3,669 (68.6%) vs. 2,762 (65.7%) ≥40: 122 (2.3%) vs. 147 (3.5%) Parity 0: 1,579 (29.4%) vs. 2,675 (63.6%) 1: 2,345 (43.6%) vs. 1,235 (29.3%) 2: 1,132 (21.0%) vs. 252 (6.0%) 3: 246 (4.6%) vs. 42 (1.0%) ≥4: 77 (1.4%) vs. 5 (0.1%)
Kennare et al., 2010 Australia Pregnancy Outcome Unit of South Australia Health perinatal data for all births and data on perinatal deaths	N = 298,333 Planned Home n = 1,141 Planned Hospital n = 297,192	Inclusion criteria: Live births and stillbirths of at least 400 g birthweight or 20 weeks' gestation Exclusion criteria: No antenatal care, termination of pregnancy	Planned Home (n = 1,141) vs. Planned Hospital (n = 297,192) Mean age: 31.3 ± 5.5 vs. 29.2 ± 5.5 Nulliparous: NR (31.2%) vs. NR (41.0%), $p < 0.001$)

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
1991 to 2006 Poor quality			Indigenous: NR (1.0%) vs. NR (2.2%), p = 0.003 Live in the metropolitan area: NR (79.8%) vs. NR (76.0%), p = 0.003) Post-term pregnancies (42 weeks' gestation): NR (3.8%) vs. NR (1.2%), p < 0.001
Laws et al., 2014 Australia Registry of Births, Deaths, and Marriages, Midwives Data Collection, Admitted Patient Data Collection 2001 to 2009 Poor quality	N = 81,932 Planned Birth Center n = 15,742 Planned Hospital n = 66,190	Inclusion criteria: All women intending to give birth in birth centers, to singleton babies at 37 or more weeks' gestation, with a spontaneous onset of labor, born between January 1, 2001, and December 31, 2009, plus 66,190 women intending to give birth in the co-located hospitals during the same period	Planned Birth Center (n = 15,742) vs. Planned Hospital (n = 66,190) Maternal age <20: 508 (3.2%) vs. 3,267 (4.9%) 20 to 24: 2,256 (14.3%) vs. 10,154 (15.3%) 25 to 29: 4,873 (31.0%) vs. 19,264 (29.1%) 30 to 34: 5,222 (33.2%) vs. 20,985 (31.7%) ≥35: 2,883 (18.3%) vs. 12,519 (18.9%) Country of birth Australia: 8,795 (55.9%) vs. 28,787 (43.5%) Overseas: 3,828 (24.3%) vs. 24,936 (37.7%) SEIFA Index of Disadvantage 1 (least): 3,496 (22.2%) vs. 15,074 (22.9%) 2: 4,690 (29.8%) vs. 18,640 (28.3%) 3: 4,085 (26.0%) vs. 14,011 (21.3%) 4: 2,156 (13.7%) vs. 9,316 (14.2%) 5 (most): 1,286 (8.2%) vs. 8,715 (13.3%) Parity Primiparous: 9,694 (61.6%) vs. 40,669 (61.4%)

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			Multiparous: 6,048 (38.4%) vs. 25,428 (38.4%) Smoke during pregnancy: 1,440 (9.1%) vs. 8,959 (13.5%)
Li et al., 2017 South Carolina Birth certificates 1996 to 2013 Poor quality	N = 948,343 2004 to 2013 n = 550,239 1996 to 2003 n = 398,104 Planned Home n = 2,562 Planned Birth Center n = 1,274 Planned Clinic n = 22 Planned Hospital n = 944,299	Inclusion criteria: Live births born from 1996 to 2013 (of at least 20 weeks of gestation and 500 g birthweight) with linked datasets, including birth certificates and death certificates, statewide hospital discharge abstracts for inpatient and emergency room visits, and Medicaid claims data for both inpatient and outpatient visits and physician office visits in South Carolina Exclusion criteria: NR	NR
Li et al., 2015 United Kingdom Birthplace national prospective cohort study April 2008 to April 2010 Good quality	N = 8,180 higher risk Planned Home n = 1,489 Planned Hospital (i.e., obstetric unit) n = 6,691 n = 16,619 "low risk" women	Inclusion criteria: Birthplace cohort limited to "those with specified medical or obstetric risk factors known prior to the onset of labor or with post-term pregnancies (gestational age 42+1 weeks or more)" Exclusion criteria: Planned induction of labor	Patient characteristics stratified by nulliparous and parous women, then by planned home and planned obstetric unit. See table 1 in original study for details. *Medical and obstetrics risk factors known prior to onset of labor* Nulliparous- Planned Home (n = 288) vs. Planned Hospital (n = 2,524) Confirmed cardiac disease: 5 (1.54%) vs. 49 (2.00%)

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			Hypertensive disorders: 7 (2.17%) vs. 225 (8.59%) Asthma: 9 (3.55%) vs. 64 (2.40%) Group B strep: 22 (7.43%) vs. 337 (13.07%) Hyperthyroidism: 12 (4.14%) vs. 45 (1.72%) Diabetes: 1 (0.27%) vs. 89 (3.62%) Epilepsy: 3 (0.67%) vs. 60 (2.27%) 'Other' medical: 20 (7.84%) vs. 78 (3.10%) Any medical: 108 (37.93%) vs. 1102 (43.29%) *Current pregnancy* Pre-eclampsia or pregnancy-induced hypertension: 6 (2.37%) vs. 369 (14.60%) Gestational diabetes: 8 (2.63%) vs. 119 (4.68%) BMI at booking >35 kg/m^2: 70 (24.60%) vs. 557 (22.24%) Post-term (42+1–44 weeks): 78 (26.80%) vs. 198 (8.20%) Small for gestational age: 5 (1.67%) vs. 107 (4.11%) 'Other' obstetric/fetal: 15 (4.62%) vs. 120 (4.84%) Any obstetric/fetal: 187 (64.36%) vs. 1570 (62.64%)

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			Medical and obstetric/fetal risk factors per women 1: 272 (95.05%) vs. 2,222 (88.20%) 2+: 6 (4.95%) vs. 302 (11.80%) Parous- Planned Home (n = 1,201) vs. Planned Hospital (n = 4,167) Confirmed cardiac disease: 10 (0.75) vs. 44 (1.05%) Hypertensive disorders: 16 (1.26%) vs. 150 (3.50%) Asthma: 6 (2.40%) vs. 50 (1.19%) Group B strep: 81 (6.17%) vs. 495 (11.95%) Hyperthyroidism: 35 (2.87% vs. 69 (1.63%) Diabetes: 4 (0.32%) vs. 95 (2.19%) Epilepsy: 24 (1.96%) vs. 81 (1.80%) 'Other' medical: 55 (4.30%) vs. 76 (1.73%) Any medical: 310 (24.81%) vs. 1273 (30.21%) *Complications in previous pregnancies* Postpartum hemorrhage with treatment/transfusion: 61 (4.86%) vs. 179 (4.43%) Retained placenta: 66 (5.87%) vs. 123 (3.14%) Caesarean delivery: 209 (18.21%) vs. 1,227 (30.35%)

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			Current pregnancy Pre-eclampsia or pregnancy-induced hypertension: 16 (1.20%) vs. 176 (4.13%) Gestational diabetes: 175 (4.33%) vs. 33 (3.14%) BMI at booking >35 kg/m^2: 828 (19.48%) vs. 314 (26.23%) Post-term (42+1–44 weeks): 132 (3.11%) vs. 114 (8.92%) Small for gestational age: 136 (2.96%) vs. 18 (1.58%) 'Other' obstetric/fetal: 143 (3.55%) vs. 78 (6.56%) Any obstetric/fetal: 3213 (77.44%) vs. 936 (78.93%) Medical and obstetric/fetal risk factors per women 1: 1,079 (90.23%) vs. 3,415 (82.00%) 2+: 122 (9.77%) vs. 752 (18.00%)
Li et al., 2014 United Kingdom Birthplace April 2008 to April 2010 Good quality	N = 63,371 16 to 19 n = 3354 20 to 24 n = 11,395 25 to 29 n = 18,091 30 to 34 n = 18,453 35 to 39 n = 10,397 40 and over n =1,681	Inclusion criteria: Age 16 year and older, 37 and 0 weeks to 42 and 0 weeks gestation, parity less than 6, "low-risk" Exclusion criteria: elective cesarean delivery or cesarean delivery before onset of labor, presented in preterm labor (<37 weeks' gestation),	Previously described in Birthplace, 2011

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
		multiple pregnancy, unplanned home birth, received no antenatal care	
MacDorman & Declercq, 2016 U.S. Birth certificates in 47 states and DC 2004 to 2014 Poor quality	Planned Home n = 29,021 Planned Birthing Center n = 18,047 Planned Hospital n = 3,773,115	Inclusion criteria: Births in states that had implemented the revised birth certificate Exclusion criteria: NR	Planned Home (n = 29,021) vs. Planned Birthing Center (n = 18,047) vs. Planned Hospital (n = 3,773,115) Not all states report on every population characteristic Pre-pregnancy BMI < 18.5: 4.3% vs. 4.4% vs. 3.8% 18.5 to 24.9: 62.9% vs. 61.9% vs. 45.6% 25.0 to 29.9: 21.2% vs. 21.9% vs. 25.6% 30+: 11.6% vs. 11.8% vs. 25.0% Smoked during pregnancy: 0.9% vs. 1.3% vs. 8.5% First live birth: 20.5% vs. 36.1% vs. 39.2% Percent VBAC: 4.6% vs. 1.6% vs. 1.6% Maternal education Less than high school diploma: 22.8% vs. 13.8 vs. 15.1% High school diploma: 13.0% vs. 11.9% vs. 25.3% Some college: 26.5% vs. 27.8% vs. 29.6% Bachelor's degree: 26.4% vs. 31.2% vs. 19.0% Master's degree or higher: 11.2% vs. 15.3% vs. 11.0%

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			Prenatal care: Began during first trimester: 54.3% vs. 66.9% vs. 76.9% Began during second trimester: 34.4% vs. 27.0% vs. 17.2% Late or no prenatal care: 11.4% vs. 6.0% vs. 5.9% Receipt of WIC food: 8.2% vs. 11.8% vs. 44.2% Method of payment for this delivery: Medicaid: 8.5% vs. 18.4% vs. 44.2% Private insurance: 19.7% vs. 47.0% vs. 48.0% Self-pay: 67.1% vs. 31.9% vs. 3.4% Other: 4.7% vs. 2.6% vs. 4.4% Attendant at birth: Physician: 0.9% vs. 3.1% vs. 91.5% CNM/CM: 28.1% vs. 53.6% vs. 8.0% Other midwife: 49.6% vs. 39.0% vs. 0.2% Other: 21.5% vs. 4.3% vs. 0.4%
Monk et al., 2014 Australia ObstetriX surveillance system of point-of-care maternity data collection across the antenatal, intrapartum, and immediate postnatal periods 2005 to 2006 Fair quality	N = 3,651 Planned Birth Center n = 494 Planned Tertiary Maternity Unit n = 3,157	Inclusion criteria: All women booked to give birth at the freestanding midwifery units were considered low risk and were included in the study, regardless of their specific ACM risk classification Exclusion criteria: NR	Planned Birth Center (n = 494) vs. Planned Tertiary Maternity Unit (n = 3,157) Mean age: 29.6 vs. 28.5 Median parity: 1 (0.9) vs. 1 (1.0) Nulliparous: 208 (42.1%) vs. 1,364 (43.2%) Ethnicity African: 5 (1.0%) vs. 40 (1.3%)

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			Asian: 100 (20.2%) vs. 140 (4.4%) European: 27 (5.5%) vs. 92 (2.9%) Oceania: 350 (70.9%) vs. 2,856 (90.5%) Aboriginal/Torres Strait Islander: 12 (3.4%) vs. 165 (5.8%) South American: 4 (0.8%) vs. 5 (0.2%) North American: 7 (1.4%) vs. 20 (0.6%) Smoker: 27 (5.5%) vs. 546 (17.3%) Risk level at booking B/C or C: 27 (5.5) vs. 0 (0%) Risk level at labor B/C or C: 65 (13.2%) vs. 598 (18.9%) Previous cesarean delivery: 2 (0.4%) vs. 430 (13.6%)
Nove et al., 2012 United Kingdom St Mary's Maternity Information System 1988 to 2000 Fair quality	N = 273,872 Planned Home n = 5,998 Planned Hospital n = 267,874	Inclusion criteria: Pregnancy ended in live birth or stillbirth Exclusion criteria: Elective Cesarean delivery, medical induction, gestation < 37 weeks, high-risk pregnancy, unplanned home birth, unattended in labor, baby of indeterminate sex	Combined N = 273,872 Pregnancy risk status Medium: 73,862 (27%) Low: 200,010 (73%) Parity Primipara: 125,963 (46%) Multipara: 147,909 (54%) Mother's age at delivery <20: 13,881 (5%) 20 to 24: 51,640 (20%) 25 to 29: 93,757 (34%)

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			30 to 34: 81,332 (30%) 35 to 39: 29,031 (11%) 40+: 4,231 (2%) Mother's ethnic group Black African: 7,516 (3%) Black Caribbean: 6,587 (2%) Mediterranean: 6,808 (3%) Asian: 39,024 (14%) White European: 195,498 (71%) Other: 11,064 (4%) Pregnancy risk status based on a 2007 clinical guideline from the National Institute for Health and Clinical Excellence
Øian et al., 2018 Norway Medical Birth Registry with supplementary data collection January 2008 to December 2010 Poor quality	N = 107,876 Births in Midwife-led Birth Units, Planned n = 2,298 Births Planned for Midwife-led Birth Unit, Took Place Elsewhere n = 220 Births in Hospital, Low Risk n = 105,358	Inclusion Criteria: Planned Birth Center Births - Planned births in midwife-led birth units between 2008 and 2010 Planned Low-Risk Hospital Births - Infants born after 36 weeks gestation Exclusion Criteria: Planned Birth Center Births - NR Planned Low-Risk Hospital Births - planned cesarean deliveries, deliveries that were induced, women with chronic diseases such as hypertension, kidney disease, rheumatoid arthritis or heart disease; had suffered pregnancy	Births in Midwife-Led Birth Centers, Planned (n = 2,298) vs. Births Planned for a Midwife-led Birth Unit, Took Place Elsewhere (n = 220) vs. Births in Hospital, Low Risk (n = 105,358) Parity Nulliparous: 225 (14.5%) vs. 90 (50.6%) vs. 45,700 (43.4%) Multiparous: 1,332 (85.5%) vs. 88 (49.4%) vs. 59,658 (56.6%) Presentation Normal, Vertex: 1,470 (94.4%) vs. 150 (84.3%) vs. 98,182 (93.2%) Breech: 19 (1.2%) vs. 6 (3.4%) vs. 1,929 (1.8%)

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
		complications such as gestational diabetes and hypertensive complaints	Other: 67 (4.3%) vs. 22 (12.4%) vs. 5,229 (5.0%) Missing Data: 1 (.0%) vs. 0 vs. 18 (0%)
Quigley et al., 2016 Ireland and United Kingdom Growing Up in Ireland study, 2008 to 2009 United Kingdom Millennium Cohort Study, 2001 to 2002 Fair quality	N = 28,125 Ireland: n = 10,604, Planned Home (n = 157), Planned Hospital (n = 10,447) United Kingdom: n = 17,521, Planned Home (n = 340), Planned Hospital (n = 17,181)	Inclusion criteria: Ireland: Mother-infant pairs, born between December 2007 and May 2008 United Kingdom: Mother-infant pairs, born between 2000 and 2001 Exclusion criteria: NR	Ireland (n = 10,604) vs. United Kingdom (n = 17,521) Place of birth Home: 157 (1.0%) vs. 340 (2.0%) Hospital: 10,447 (99%) vs. 17,181 (98%) Parity Primiparous: 4,312 (41%) vs. 8,596 (49%) Multiparous: 6,292 (59%) vs. 8,975 (51%) Maternal age < 30 years: 3,453 (33%) vs. 9,762 (56%) 30 to 35 years: 3,662 (35%) vs. 5,042 (27%) ≥ 35 years: 3,489 (33%) vs. 2,764 (16%) Socioeconomic status Never worked: 1,193 (11%) vs. 2,114 (12%) Manager/Professional: 5,172 (49%) vs. 4,556 (26%) BMI < 25: 5,496 (52%) vs. 9,303 (53%) 25 to 30: 2,967 (28%) vs. 3,920 (22%) ≥30: 1,634 (15%) vs. 1,982 (11%) Missing: 534 (5.0%) vs. 2,316 (13%)
Rowe et al., 2016 England	N = 1,436	Inclusion criteria:	Planned Home (n = 209) vs. Planned Obstetric Unit (n = 1,227)

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
Birthplace in England national prospective cohort study April 2008 to April 2010 Good quality	Planned Home n = 209 Planned Obstetric Unit n = 1,227	Women planning vaginal birth after cesarean delivery Exclusion criteria: Elective cesarean delivery before the onset of labor, presented in preterm labor (<37 weeks' gestation), multiple pregnancy, unplanned home birth, received no antenatal care	Parity Para 1: 87 (6.1%) vs. 787 (55%) Para 2+: 122 (8.5%) vs. 440 (30.6%) Maternal age < 20 years: 0 vs. 10 (0.8%) 20 to 24 years: 12 (5.4%) vs. 140 (11.1%) 25 to 29 years: 27 (13.6%) vs. 340 (27%) 30 to 34 years: 72 (36%) vs. 382 (31.1%) 35 to 39 years: 74 (34%) vs. 296 (25%) 40+ years: 24 (11%) vs. 58 (5.1%) Ethnicity White: 191 (92.4%) vs. 877 (68.6%) Non-white: 18 (7.6%) vs. 347 (31.4%) BMI Not recorded: 45 (20.4%) vs. 191 (16.6%) < 18.5: 4 (1.7%) vs. 24 (2.0%) 18.5 to 24.9: 81 (42.1%) vs. 431 (34.3%) 25.0 to 29.9: 56 (25.7%) vs. 326 (26.6%) 30.0 to 34.9: 17 (7.4%) vs. 165 (13.6%) 35.0 to 39.9: 1 (0.5%) vs. 54 (4.3%) 40.0+: 5 (2.2%) vs. 33 (2.7%) IMD quintiles 1st least deprived: 43 (21.4%) vs. 206 (15.6%) 2nd: 45 (20.8%) vs. 206 (15.9%) 3rd: 39 (18.5%) vs. 216 (17%) 4th: 38 (19%) vs. 222 (18.5%)

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			5th most deprived: 44 (20.3%) vs. 365 (33%)
Schroeder et al., 2017 England Interviews and medical records from Barkantine Birth Centre and Royal London Hospital's obstetric unit in Tower Hamlets, a low-income borough in east London 2008 to 2009 Poor quality	N = 333 Planned Birth Center n = 167 Planned Hospital n = 166	Inclusion criteria: Resident of Tower Hamlets, low risk of obstetric complications, satisfied criteria to use the birth center Exclusion criteria: NR	Planned Birth Center vs. Planned Hospital Marital status Living with partner/married: 123/141 (87.2%) vs. 90/104 (86.5%) Partner living away from home: 8/141 (5.7%) vs. 7/104 (6.7%) Single/no partner: 1/141 (0.7%) vs. 0/104 (0.0%) Other marital statuses: 9/141 (6.4%) vs. 7/104 (6.7%) Mother's ethnic group White British: 72/215 (33.5%) vs. 10 (5.7%) All white non-British ethnic groups: 21/215 (9.8%) vs. (10 5.7%) White European: 18/215 (8.4%) vs. 6 (3.4%) White other: 3/215 (1.4%) vs. 4 (2.3%) Black: 10/215 (4.7%) vs. 5 (2.9%) South Asian (Indian/Pakistani/Bangladeshi): 33/215 (15.3%) vs. 127 (73.0%) All other ethnic groups: 29/215 (13.5%) vs. 6 (3.4%) Interpreter needed: Yes: 5/160 (3.1%) vs. 43/104 (41.3%)
Snowden, et al., 2015 Oregon, U.S. State vital statistics	N = 79,727	Inclusion criteria: Cephalic, singleton, term, non-anomalous deliveries	Planned Out-of-Hospital birth (n = 3,804) vs. Planned Hospital Birth (n = 75,923)

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
January 2012 to December 2013 Good quality	Planned Out-of-Hospital Birth n = 3,804 Planned Hospital Birth n = 75,923	Exclusion criteria: Unplanned home births, unknown intended place of birth, other location of birth (e.g., clinic or doctor's office)	Race or ethnic group White: 3,317 (87.2%) vs. 51,238 (67.5%) Black: 34 (0.9%) vs. 1,945 (2.6%) Hispanic: 192 (5%) vs. 14,882 (19.6%) Asian: 97 (2.5%) vs. 4,896 (6.4%) American Indian or Alaskan native: 87 (2.3%) vs. 1,940 (2.6%) Other: 77 (2.0%) vs. 1,022 (1.3%) Parity 0: 1,514 (39.8%) vs. 30,758 (40.5%) 1: 1,219 (32.0) vs. 24,739 (32.6%) 2: 548 (14.4% vs. 12,136 (16.0%) ≥3: 523 (13.7%) vs. 8,290 (10.9%) Insurance status (n = 3,710 vs. n = 75,523) Public: 872 (23.5%) vs. 35,243 (46.7%) Private: 1,718 (46.3%) vs. 39,507 (52.3%) Self-pay: 1,120 (30.2%) of vs. 773 (1.0%) Maternal age <20: 47 (1.2%) vs. 4,887 (6.4) 20 to 34: 2,932 (77.1%) vs. 59,383 (78.2) ≥35: 825 (21.7%) vs. 11,653 (15.3)
Sprague et al., 2018 Ontario, Canada Better Outcomes Registry & Network, Canadian Institute of Health Information Discharge Abstracts Database, Statistics	N = 2,475 Planned Birth Center: n = 495 Planned Hospital: n = 1,980	All birth center births matched on 1:4 basis to singleton pregnancies in spontaneous labor in hospital midwifery care, additional matching based on gestational age at birth (within 2 weeks), parity and maternal age (<30, 30 to 34,	Planned Birthing Center (n = 495) vs. Planned Hospital (n = 1,980) Age (years) <20: 10 (2.0%) vs. 25 (1.3%) 20 to 24: 38 (7.7%) vs. 151 (7.6%)

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
Canada census data, birth center records January 2014 to February 2015 Poor quality		35+), location of residence, and pregnancy complications (gestational diabetes and hypertension)	25 to 29: 113 (22.8%) vs. 468 (23.6%) 30 to 34: 209 (42.2%) vs. 836 (42.0%) 35 to39: 115 (23.2%) vs. 452 (22.8%) ≥40: 10 (2.0%) vs. 48 (2.4%) Parity Nulliparous: 292 (59.0%) vs. 1,168 (59.0%) Multiparous: 201 (41.0%) vs. 812 (41.0%) Previous cesarean delivery: 8 (1.6%) vs. 108 (5.5%) BMI category <21: 192 (38.8%) vs. 533 (26.9%) 21 to 25: 217 (43.8%) vs. 928 (46.9%) 26 to 30: 64 (12.9%) vs. 337 (17.0%) 31 to 35: 14 (2.8%) vs. 110 (5.6%) 36 to 40: 4 (0.8%) vs. 44 (2.2%) ≥41: 4 (0.8%) vs. 28 (1.4%) Spontaneous labor: 486 (98.2%) vs. 1,973 (99.6%) Women giving birth in the birth center: 373 (75.4%) vs. 0 (0.0%) Intermittent auscultation use: 487 (98.4%) vs. 839 (42.4%)
Thornton et al., 2017 U.S. Uniform Data Set from American Association of Birth	N = 11,303 Planned Birth Center n = 8,776	Inclusion criteria: Received prenatal care in birth center, reached 37 weeks' gestation, admitted in	Planned Birth Center (n = 8,776) vs. Planned Hospital (n = 2,527) Parous: 4,698 (53.53%) vs. 1,521 (60.19%), p < 0.001

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
Centers at 79 U.S. birth centers in 43 states 2006 to 2011 Poor quality	Planned Hospital n = 2,527	spontaneous labor to birth center or affiliated hospital Exclusion criteria: Twin gestation, labor was pharmacologically induced, nonvertex presentations, history of cesarean delivery, anomalous fetuses, neonates weighing < 2500 grams or > 6000 grams at birth, BMI less than 20 or greater than 27, hypertension, diabetes, renal disease, asthma, seizure history, treated psychiatric disorders including depression, tobacco or other substance abuse, sexual or other physical victimization, gestational diabetes or hypertension, preeclampsia, anemia (hematocrit 30), infection, preterm labor or rupture of membranes, placental abruption or previa, nonreassuring antepartum fetal testing	Mean age: 28.96 ± 5.17 vs. 26.81 ± 5.89, p < 0.001 Payment, p < 0.001 Private: 4,685 (53.38%) vs. 953 (37.71%) Medicaid: 2,192 (24.98%) vs. 1,174 (46.46%) Military: 240 (2.73%) vs. 25 (0.99%) Self-pay: 1,337 (15.23%) vs. 282 (11.16%) Race, p < 0.001 White: 7,490 (85.35%) vs. 1,871 (74.04%) Black: 428 (4.88%) vs. 275 (10.88%) Asian Pacific Islander: 220 (2.51%) vs. 131 (5.18%) Native American: 48 (0.55%) vs. 14 (0.55%) Lives with partner: 7,907 (90.10%) vs. 1,888 (74.71%); p < 0.001 Mean gestational age at birth: 39.90 ± 1.05 vs. 39.73 ± 1.09, p < 0.001 Trimester care began, p < 0.001 First trimester: (1 to 13 weeks): 6,581 (74.99%) vs. 1,674 (66.24%) Second trimester: (14 to27 weeks) 1,643 (18.72%) vs. 637 (25.21%) Third trimester: (28+ weeks) 163 (1.86%) vs. 69 (2.73%) Missing: 389 (4.43%) vs. 147 (5.82%)

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
Tilden et al., 2017 U.S. Birth and death certificates 2007 to 2010 Fair quality	N = 109,970 Planned Home n = 2,352 Planned Birth Center n = 795 Planned Hospital n = 106,823	Inclusion criteria: Women with singleton, term, vertex, nonanomolous, liveborn neonates who were delivered by VBAC in or out-of-hospital between 2007 and 2010 in the U.S. Exclusion criteria: No prior cesarean delivery, delivered by repeat cesarean delivery, multiple gestation, delivered preterm (<37 weeks) or extremely postterm (>43 weeks), breech fetus, fetus with congenital anomalies, stillbirth, obvious data miscoding	Planned Home and Birth Center (n = 3,147) vs. Planned Hospital (n = 106,823) Race/ethnicity White: 2,728 (86.69%) vs. 53,226 (49.83%) Black: 94 (2.99%) vs. 15,396 (14.41%) Hispanic: 273 (8.67%) vs. 31,030 (29.05%) Asian: 42 (1.33%) vs. 6,106 (5.72%) American Indian/Alaska Native: 10 (0.32%) vs. 1,065 (1.00%) Parity 1: 648 (20.59%) vs. 33,813 (31.65%) 2: 660 (20.97%) vs. 28,423 (26.61%) ≥ 3: 1785 (56.72%) vs. 43,237 (40.48%) Tobacco use: 25 (0.79%) vs. 7,842 (7.34%) Maternal age ≤20: 5 (0.16%) vs. 2,302 (2.15%) 21 to 34: 2,192 (69.65%) vs. 81,386 (76.19%) ≥35: 950 (30.19%) vs. 23,135 (21.66%) Education Not completed high school: 673 (21.39%) vs. 9,044 (8.47%) High school: 585 (18.59%) vs. 41,668 (39.01%) College: 1,587 (50.43%) vs. 45,093 (42.21%)

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			Graduate school: 283 (8.99%) vs. 9,744 (9.12%) Previous cesarean deliveries 1: 2,791 (88.69%) vs. 94,478 (88.44%) 2: 232 (7.37%) vs. 7,916 (7.41%) ≥3: 42 (1.33%) vs. 1,676 (1.57%) History of vaginal birth: 2,392 (76.01%) vs. 67,217 (62.92%) Prenatal care initiation after 1st trimester: 1,584 (50.33%) vs. 31,415 (29.41%) Kotelchuck Index Adequate Plus: 208 (6.61%) vs. 21,011 (19.67%) Adequate: 998 (31.71%) vs. 35,629 (33.35%) Intermediate: 722 (22.94%) vs. 20,748 (19.42%) Inadequate: 1,131 (35.94%) vs. 22,486 (21.05%) Weight gain >40 pounds: 569 (18.08%) vs. 20,477 (19.17%)
van der Kooy et al., 2017 The Netherlands Netherlands Perinatal Registry 2000 to 2007 Good quality	N = 622,017 Planned Home n = 402,912 Planned Hospital n = 219,105	Inclusion criteria: Low-risk women in midwife-led care at the onset of labor, single pregnancy, spontaneous labor Exclusion criteria:	Planned Home (n = 402,912) vs. Planned Hospital (n = 219,105) Parity Primiparous: 171,986 (42.7%) vs. 104,249 (47.6%) Multiparous: 230,926 (57.3%) vs. 114,856 (52.4%)

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
		Medium-risk women, defined by Dutch guidelines (e.g., women with a history of postpartum hemorrhage or obesity)	Maternal age < 19 years: 4,036 (1.0%) vs. 6,713 (3.1%) 20 to 25 years: 34,661 (8.6%) vs. 32,617 (14.9%) 25 to 34 years: 296,128 (73.5%) vs. 142,597 (65.1%) > 35 years: 68,087 (16.9%) vs. 37,178 (17.0%) Ethnicity Dutch: 370,647 (96.3%) vs. 196,659 (89.8%) Non-Dutch: 32,265 (8.0%) vs. 65,533 (29.9%) Socioeconomic status Privileged neighborhood: 388,089 (96.3%) vs. 196,659 (89.8%) Underprivileged neighborhood: 14,823 (3.7%) vs. 22,446 (10.2%)
van der Kooy et al., 2011 The Netherlands Netherlands Perinatal Registry 2000 to 2007 Fair quality	N = 622,017 Planned Home n = 402,912 Planned Hospital-Midwife n = 219,105	Inclusion criteria: Singleton pregnancy, under the supervision of a community midwife at the onset of labor Exclusion criteria: Medium-risk women (e.g., a history of postpartum hemorrhage, BMI > 30)	Planned Home (n = 402,912) vs. Planned Hospital-Midwife (n = 219,105) Parity Primiparous: 171,986 (42.69%) vs. 104,249 (47.58%) Multiparous: 230,926 (57.31%) vs. 114,856 (52.42%) Maternal age Younger than 19: 4,036 (1.00%) vs. 6,713 (3.06%) 20 to 25: 34,661 (8.60%) vs. 32,617 (14.89%)

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			25 to 34: 296,128 (73.50%) 267 vs. 142,597 (65.08%) Older than 35: 68,087 (16.90%) vs. 37,178 (16.97%) <u>Ethnic background</u> Western: 364,796 (90.54%) vs. 143,677 (65.57%) Non-Western: 38,116 (9.46%) vs. 75,428 (34.43%) Neighborhood Privileged neighborhood: 388,089 (96.32%) vs. 196,659 (89.76%) Underprivileged neighborhood: 14,823 (3.68%) vs. 22,446 (10.24%) <u>Gestational age (weeks)</u> Less than 34: 2,409 (0.60%) vs. 1,702 (0.78%) 35 to 36: 6,510 (1.62%) vs. 4,064 (1.85%) 37: 15,203 (3.77%) vs. 9,603 (4.38%) 38 to 41: 368,926 (91.56%) vs. 193,816 (88.46%) More than 41: 9,864 (2.45%) vs. 9,920 (4.53%)
van Haaren-ten Haken et al., 2015 The Netherlands Self-reported questionnaires, medical records, and birth registration forms	N = 576 Planned Home n = 226 Planned Hospital-Midwife n = 168	<u>Inclusion criteria</u>: Low-risk nulliparous women who started their pregnancy in midwife-led care or in obstetrician-led care by 8 to 12 weeks gestation who indicated a preferred place of birth during pregnancy at that time	Planned Home (n = 226) vs. Planned Hospital-Midwife (n = 168) vs. Planned Hospital-Obstetrician (n = 182) <u>Mean age</u>: 28.8 (3.9) vs. 29.1 (3.8) vs. 30.9 (4.8), $p < 0.01$

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
2007 to 2011 Poor quality	Planned Hospital-Obstetrician n = 182	Exclusion criteria: Women with an obstetric or medical indication according to the List of Obstetric Indications (high risk), women who had previously given birth, women who miscarried, women who began prenatal care at 20 weeks gestation or later, women who did not report a preferred place of birth, women whose deliveries did not result in a birth registration form	BMI <18.5: 10 (4.5%) vs. 5 (3.1%) vs. 7 (3.9%) 18.5 to 24.99: 139 (63.2%) vs. 115 (71.4%) vs. 121 (68.0%) 25.00 to 29.99: 55 (25.0%) vs. 33 (20.5%) vs. 40 (22.5%) ≥30.0: 16 (7.3%) vs. 8 (5.0%) vs. 10 (5.6%) Ethnic background Dutch: 225 (99.6%) vs. 160 (95.2%) vs. 174 (95.6%) Non-Dutch: 1 (0.4%) vs. 8 (4.8%) vs. 8 (4.4%) Highest completed level of education Low: 19 (8.4%) vs. 18 (10.7%) vs. 19 (10.4%) Middle: 86 (38.1%) vs. 56 (33.3%) vs. 71 (39.0%) High: 121 (53.5%) vs. 94 (56.0%) vs. 92 (50.5%) Distance to hospital 0 to 15 minutes: 170 (75.6%) vs. 135 (80.8%) vs. 135 (74.6%) >15 minutes: 55 (24.4%) vs. 32 (19.2%) vs. 46 (25.4%) First pregnancy Yes: 181 (80.1%) vs. 142 (84.5%) vs. 112 (61.9%), $p < 0.01$ No: 45 (19.9%) vs. 26 (15.5%) vs. 69 (38.1%)

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			Mean gestation (days) at birth: 278 (15) vs. 278 (13) vs. 274 (15), p < 0.01
Wiegerinck et al., 2018 The Netherlands National Perinatal Register 2005 to 2008 Poor quality	N = 57,396 Midwife-led care n = 46,764 Obstetrician-led care n = 10,632	Inclusion criteria: Women who gave birth after 37 weeks gestation and before 42 weeks gestation between January 1, 2005 and December 31, 2007 in the Amsterdam region Exclusion criteria: Planned cesarean delivery, induced labor, congenital anomalies, antepartum fetal death, non-vertex position of the fetus, a previous cesarean delivery, hypertension, gestational diabetes, prolonged rupture of membranes, vaginal bleeding in the second half of pregnancy	Midwife-led care (n = 46,764) vs. Obstetrician-led care (n = 10,632) Maternal age <25: 6,060 (13.0%) vs. 1,305 (12.3%) 25 to 29: 12,995 (27.8%) vs. 2,361 (22.2%) 30 to 34: 17,562 (37.5%) vs. 3,719 (35.0%) ≥35: 10,147 (21.7%) vs. 3,247 (30.5%) Parity Nulliparous: 21,074 (45.1%) vs. 4,376 (41.2%) Multiparous: 25,690 (54.9%) vs. 6,256 (58.8%) Ethnicity Western: 35,358 (75.6%) vs. 7,406 (69.7%) Non-Western: 11,406 (24.4%) vs. 3,226 (30.3%) Socioeconomic status Low: 11,752 (25.1%) vs. 3,079 (29.0%) Mid: 22,973 (49.1%) vs. 4,785 (45.0%) High: 12,039 (25.8%) vs. 2,768 (26.0%) Mean birth weight (grams): 3,552 ± 458 vs. 3,474 ± 500 Gestational age, median (range): 40 (37 to 41) vs. 40 (37 to 41)

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			Propensity Score Matched Cohort† Home (n = 10,632) vs. Hospital (n = 10,632) Maternal age <25: 1,308 (12.3%) vs. 1,305 (12.3%) 25 to 29: 2,454 (23.1%) vs. 2,361 (22.2%) 30 to 34: 3,611 (34.0%) vs. 3,719 (35.0%) ≥35: 3,259 (30.7%) vs. 3,247 (30.5%) Parity Nulliparous: 4,344 (40.9%) vs. 4,376 (41.2%) Multiparous: 6,288 (59.1%) vs. 6,256 (58.8%) Ethnicity Western: 7,379 (69.4%) vs. 7,406 (69.7%) Non-Western: 3,253 (30.6%) vs. 3,226 (30.3%) Socioeconomic status Low: 3,023 (28.4%) vs. 3,079 (29.0%) Mid: 4,796 (45.1%) vs. 4,785 (45.0%) High: 2,813 (26.5%) vs. 2,768 (26.0%) Mean birthweight: 3,483 ± 463 vs. 3,474 ± 500 Median gestational age (range): 40 (37 to 41) vs. 40 (37 to 41) †Matched on maternal age, birth weight, parity, ethnicity, gestational age, socioeconomic status and gender of the child

Citation, Location,Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
Wiegerinck et al., 2015 The Netherlands Netherlands Perinatal Register with additionally retrieved data from hospitals and midwife practices 2005 to 2008 Poor quality	N = 47,490 Planned Home n = 26,128 Planned Hospital n = 21,362	Inclusion criteria: In the perinatal region of Amsterdam, singleton pregnancy, gave birth beyond 37+0 weeks gestation, in primary care (led by midwives or general practitioners) at onset of labor Exclusion criteria: Preplanned cesarean delivery, pregnancy complicated by congenital anomalies or antepartum fetal death (antenatal testing showed significant chromosomal anomaly, multiple anomalies were established at physical examination suggesting an underlying syndrome, or underlying syndrome was documented in the autopsy report)	Planned Home (n = 26,128) vs. Planned Hospital (n = 21,362) Mean maternal age: 30.8 ± 4.7 vs. 30.0 ± 5.3, p < 0.001 Primiparous: 11,214 (43%) vs. 11,022 (52%), p < 0.001 Mean gestational age: 40 (range, 37 to 42) vs. 40 (range, 37 to 42), p = 0.81 Ethnicity, p < 0.001 Non-Western: 4,278 (16%) vs. 7,282 (34%) Western 21,850 84% vs. 14,080 (66%) Socioeconomic status, p < 0.001 Low: 6,129 (23%) vs. 6,128 (29%) Mid: 13,494 (52%) vs. 9,768 (46%) High: 6,505 (25%) vs. 5,466 (26%)

Appendix F. Outcome Data from Comparative Observational Studies

Table F1. Outcome Data from Comparative Studies: Delivery Mode

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
U.S. Studies			
Snowden, et al., 2015 Oregon, U.S. State vital statistics January 2012 to December 2013 Good quality	Planned Out-of-Hospital birth (n = 3,804) vs. Planned Hospital Birth (n = 75,923) <u>Absolute difference in risk percentage points</u> Unassisted vaginal delivery: 27.5, 95% CI 24.9 to 30.2, p < 0.001 Operative vaginal delivery: −4.7, 95% CI −5.8 to −3.5, p < 0.001 Cesarean delivery: −24.0, 95% CI −26.6 to −21.4, p < 0.001	NR	NR
Thornton et al., 2017 U.S. Uniform Data Set from American Association of Birth Centers at 79 U.S. birth centers in 43 states 2006 to 2011 Poor quality	Planned Birth Center (n = 8,776) vs. Planned Hospital (n = 2,527) Cesarean delivery: 363 (4.14%) vs. 126 (4.99%), aOR 0.63, 95% CI 0.50 to 0.79, p = NR Propensity weight adjustment using maternal age, parity, race, payment method, cohabitation status, trimester prenatal care began, gestational age at birth, newborn weight	NR	NR

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
Non-U.S. Studies			
Birthplace in England Collaborative, 2011 England Birthplace study April 2008 to April 2010 Good quality	Planned Home (n = 16,825) vs. Planned Hospital (n = 19,688) Spontaneous vertex: 15,590 (92.8%) vs. 14,645 (73.8%), aOR 3.61, 95% CI 2.97 to 4.38 Cesarean delivery 458 (2.8%) vs. 2158 (11.1%), aOR 0.31, 95% CI 0.23 to 0.41 Forceps: 372 (2.1%) vs. 1307 (6.8%), aOR 0.43, 95% CI 0.32 to 0.57 Vaginal breech: 63 (0.4%) vs. 43 (0.2%), aOR 2.13, 95% CI 1.15 to 3.96 Planned Freestanding Midwifery Unit (n = 11,280) vs. Planned Hospital (n = 19,688) Spontaneous vertex: 10,150 (90.7%) vs. 14,645 (73.8%), aOR 3.38, 95% CI 2.70 to 4.25 Cesarean delivery: 405(3.5%) vs. 2158 (11.1%), aOR 0.32, 95% CI 0.24 to 0.42 Forceps: 365 (2.9%) vs. 1307 (6.8%), aOR 0.45, 95% CI 0.32 to 0.63 Vaginal breech: 39 (0.4%) vs. 43 (0.2%), aOR 2.00, 95% CI 1.00 to 3.99 Adjusted for maternal age, ethnic group, understanding of English, marital or partner status, BMI, deprivation score quintile, previous pregnancies, weeks of gestation	NR	NR

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
Davies-Tuck et al., 2018 Australia Victorian Perinatal Data Collection 2000 to 2015 Poor quality	Low risk, Planned Home (n = 3,202) vs. Planned Hospital (n = 701,058) Unplanned cesarean delivery: 81 (2.5%) vs. 87,716 (12.5%), p < 0.001 Instrumental delivery: 79 (2.5%) vs. 122,517 (17.5%), p < 0.001 Spontaneous vaginal: 3,038 (94.9%) vs. 490,748 (70.0%), p < 0.001	NR	NR
Halfdansdottir et al., 2018 Iceland Maternity notes review 2005 to 2009 Poor quality	No home birth contraindication Planned Home (n = 278) vs. Planned Hospital (n = 851) Operative: 12 (4.3%) vs. 60 (7.1%) Home birth contraindication present Planned Home (n = 29) vs. Planned Hospital (n = 70) Operative: 7 (24.1%) vs. 9 (12.9%)	NR	NR
Halfdansdottir et al., 2015 Iceland Review of midwives' and doctors' original hand-written maternity notes 2005 to 2009 Poor quality	Planned Home (n = 307) vs. Planned Hospital or Midwifery Alongside Unit (n = 921) Spontaneous vaginal birth: 288 (93.8%) vs. 852 (92.5%) Instrumental birth: 12 (3.9%) vs. 42 (4.6%) Cesarean delivery: 7 (2.3%) vs. 27 (2.9%)	Planned Home (n = 64) vs. Planned Hospital or Midwifery Alongside Unit (n = 192) Spontaneous vaginal birth: 52 (81.3%) vs. 154 (80.2%) Instrumental birth: 7 (10.9%) vs. 24 (12.5%) Cesarean delivery: 5 (7.8%) vs. 14 (7.3%)	Planned Home (n = 243) vs. Planned Hospital or Midwifery Alongside Unit (n = 729) Spontaneous vaginal birth: 236 (97.1%) vs. 698 (95.7%) Instrumental birth: 5 (2.1%) vs. 18 (2.5%) Cesarean delivery: 2 (0.8%) vs. 13 (1.8%)
Hermus et al., 2017 The Netherlands	NR	Planned Home (n = 348) vs. Planned Birth Center (n = 939) vs. Planned	Planned Home (n = 687) vs. Planned Birth Center (n = 729) vs. Planned

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
July to December 2013 Good quality		Hospital (n = 399) (Birth Center reference group) Vaginal (non-instrumental): 314 (78.7%) vs. 730 (77.7%) vs. 279 (80.2%) Vaginal (spontaneous or instrumental): 377 (94.5%) vs. 864 (92.0%) vs. 330 (94.8%)	Hospital (n = 353) (Birth center reference group) Vaginal (non-instrumental): 674 (98.1%) vs. 709 (97.3%) vs. 337 (95.5%) Vaginal (spontaneous or instrumental): 684 (99.6%) vs. 722 (99.0%) vs. 347 (98.3%)
Hutton et al., 2016 Ontario, Canada Chart review March 2016 to April 2009 Poor quality	Planned home (n = 11,493) vs. Planned hospital (n = 11,493) Assisted vaginal: 370 (3.2%) vs. 591 (5.1%), RR 0.61, 95% CI 0.54–0.70 Cesarean delivery: 672 (5.8%) vs. 903 (7.9%), RR 0.74, 95% CI 0.67–0.82	Planned Home (n = 4,027) vs. Planned Hospital (n = 4,027) Assisted vaginal: 313 (8.9%) vs. 452 (13.2%), RR 0.68, 95% CI 0.59 to 0.78 Cesarean delivery: 531 (13.2%) vs. 611 (15.2%), RR 0.87, 95% CI 0.78 to 0.97	Planned Home (n = 7,466) vs. Planned Hospital (n = 7,466) Assisted vaginal: 57 (0.8%) vs. 139 (1.9%), RR 0.40, 95% CI 0.30 to 0.55 Cesarean delivery: 141 (1.9%) vs. 292 (3.9%), RR 0.48, 95% CI 0.40 to 0.59
Hutton et al., 2009 Canada Ontario Ministry of Health database 2003 to 2006 Poor quality	Planned Home (n = 6,692) vs. Planned Hospital-Midwife (n = 6,692) Spontaneous vaginal: 6,146 (91.8%) vs. 5,852 (87.4%) Assisted vaginal: 195 (2.9%) vs. 293 (4.4%); RR 0.67, 95% CI 0.56 to 0.80 Cesarean delivery: 348 (5.2%) vs. 544 (8.1%), RR 0.64, 95% CI 0.56 to 0.73	Planned Home (n = 2,293) vs. Planned Hospital-Midwife (n = 2,298) Assisted vaginal delivery: 166 (7.2%) vs. 221 (9.6%) Cesarean delivery: 276 (12.0%) vs. 365 (15.9%)	Planned Home (n = 4,393) vs. Planned Hospital-Midwife (n = 4,394) Assisted vaginal delivery: 28 (0.6%) vs. 72 (1.6%) Cesarean delivery: 71 (1.6%) vs. 179 (4.1%)
Janssen et al., 2009 British Columbia, Canada Perinatal Database Registry and vital statistics 2000 to 2004 Poor quality	Planned Home vs. Planned Hospital-Midwife vs. Matched Sample of Physician-Attended Hospital Births Cesarean delivery: 208 /2899 (7.2%) vs. 498/4,752 (10.5%) vs. 588/5,331 (11.0%)	Planned Home vs. Planned Hospital-Midwife vs. Matched Sample of Physician-Attended Hospital Births Cesarean delivery: 158/1,215 (13.0%) vs. 453/2,428 (18.7%) vs. 481/2,204 (21.8%)	Planned Home vs. Planned Hospital-Midwife vs. Matched Sample of Physician-Attended Hospital Births Cesarean delivery: 50/1,684 (3.0%) vs. 45/2,324 (1.9%) vs. 107/3,127 (3.4%)

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
	Spontaneous vaginal: 2,605/2,899 (89.9%) vs. 3910/4752 (82.3%) vs. 4,007/5,331 (75.2%)		
Katoaka et al., 2018 Japan Review of medical records Birth centers: 2001 to 2006, one hospital: 2004 to 2006, other hospital: 2008 Poor quality	Planned Birth center (n = 5,379) vs. Planned Hospital (n = 4,209) Spontaneous vaginal delivery: 5,379 (100%) vs. 4,011 (95.3%) Vacuum extraction: 0 (0%) vs. 178 (4.2%) Forceps delivery: 0 (0%) vs. 20 (0.5%)	NR	NR
Kennare et al., 2010 Australia Pregnancy Outcome Unit of South Australia Health perinatal data 1991 to 2006 Poor quality	Planned Home vs. Planned Hospital Cesarean delivery: 104/1136 (9.2%) vs. 79,238/292,469 (27.1%), aOR 0.27, 95% CI 0.22 to 0.34, p < 0.001 Instrumental delivery: 50/1136 (4.4%) vs. 37,386/292,469 (12.8%), aOR 0.33, 95% CI 0.25 to 0.44, p < 0.001 Adjusted for maternal age, parity, occupational status, smoking, plurality, medical and obstetric complications (e.g., antepartum hemorrhage, diabetes, hypertension), gestational age, small for gestational age, congenital anomalies, city or country hospital, mode of delivery	NR	NR
Laws et al., 2014 Australia	Planned Birth Center (n = 14,707) vs. Planned Hospital (n = 29,414)	NR	NR

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
Registry of Births, Deaths, and Marriages, Midwives Data Collection, Admitted Patient Data Collection 2001 to 2009 Poor quality	Assisted vaginal: 980 (6.7%) vs. 4,137 (14.1%), aOR 0.32, 95% CI 0.29 to 0.35 Emergency cesarean delivery: 575 (3.9%) vs. 3,702 (12.6), aOR 0.23, 95% CI 0.20 to 0.25 Adjusted for maternal age, Australian/overseas-born, socioeconomic disadvantage, smoking during pregnancy, parity, preexisting medical conditions, admitted patient insurance status, obstetric complications, level of hospital, day of the week, and holidays.		
Monk et al., 2014 Australia ObstetriX surveillance system of point-of-care maternity data collection across the antenatal, intrapartum, and immediate postnatal periods 2005 to 2006 Fair quality	Planned Birth Center (n = 494) vs. Planned Tertiary Maternity Unit (n = 3,157) Spontaneous vaginal: 400 (81.0%) vs. 2,044 (64.7%), aOR 1.57, 95% CI 1.20 to 2.06, p = 0.001 Instrumental: 34 (6.9%) vs. 331 (10.5%), aOR 0.79, 95% CI 0.53 to 1.17, p = 0.237 Elective cesarean delivery: 20 (4.0%) vs. 369 (11.7%), aOR 0.50, 95% CI 0.29 to 0.88, p = 0.02 Intrapartum cesarean delivery: 40 (8.1%) vs. 413 (13.1%), aOR 0.76, 95% CI 0.53 to 1.10, p = 0.151 Adjusted for maternal age, smoking status, parity, risk at the onset of	NR	NR

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
	labor, previous cesarean delivery and gestation at the time of birth		
Øian et al., 2018 Norway Medical Birth Registry with supplementary data collection January 2008 to December 2010 Poor quality	Births in Midwife-Led Birth Centers, Planned (n = 2,298) vs. Births Planned for a Midwife-led Birth Unit, Took Place Elsewhere (n = 220) vs. Births in Hospital, Low Risk (n = 105,358) Vacuum: 7 (.4%) vs. 25 (14.0%) vs. 9,218 (8.7%) Forceps: 0 vs. 1 (.6%) vs. 1,761 (1.7%) Cesarean, Elective: 0 vs. 0 vs. 0 Cesarean, Acute: 1 (.1%) vs. 21 (11.8%) vs. 6,564 (6.2%) Unspecified: 1 (.1%) vs. 0 vs. 8 (0%)	NR	NR
Schroeder et al., 2017 England Interviews and medical records from Barkantine Birth Centre and Royal London Hospital's obstetric unit in Tower Hamlets, a low-income borough in east London 2008 to 2009 Poor quality	Planned Birth Center (n = 167) vs. Planned Hospital (n = 164) Spontaneous vaginal delivery: 142 (85%) vs. 120 (73%), p = 0.006 Assisted delivery with ventouse: 8 (5%) vs. 9 (6%), p = 0.78 Assisted delivery with forceps: 7 (4%) vs. 8 (5%), p = 0.57 Lower segment cesarean delivery: 12 (7%) vs. 28 (17%), p = 0.003	NR	NR

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
Sprague et al., 2018 Ontario, Canada Better Outcomes Registry & Network, Canadian Institute of Health Information Discharge Abstracts Database, Statistics Canada census data, birth center records January 2014 to February 2015 Poor quality	<u>Mode of Delivery</u> Spontaneous vaginal: 435 (87.9%) vs. 1567 (79.1%), aRR 1.0 Reference Assisted (vacuum or forceps): 22 (4.4%) vs. 174 (8.8%), aRR 1.9, 95% CI 1.3 to 3.0 Cesarean: 38 (7.7%) vs. 239 (12.1%) aRR 1.5, 95% CI 1.1 to 2.1 Adjusted for BMI (<30, >30) and prior Cesarean delivery (yes, no)	NR	NR
van der Kooy et al., 2017 The Netherlands Netherlands Perinatal Registry 2000 to 2007 Good quality	Planned Home (n = 402,912) vs. Planned Hospital (n = 219,105) Vaginal Delivery: 359,146 (89%) vs. 188,970 (86%) Operative vaginal delivery and cesarean section: 43,766 (10.9%) vs. 30,135 (13.8%), aOR 0.77, 95% CI 0.75 to 0.78, p = NR Adjusted for maternal factors, child factors, health care factors	NR	NR
Wiegerinck et al., 2015 The Netherlands Netherlands Perinatal Register with additionally retrieved data from hospitals and midwife practices	Planned Home (n = 26,128) vs. Planned Hospital (n = 21,362) <u>Mode of delivery</u> Spontaneous: 23,055 (88%) vs. 18,166 (85%), OR 1.32, 95% CI 1.25 to 1.39, p < 0.001	NR	NR

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
2005 to 2008 Poor quality	Cesarean delivery: 988 (4%) vs. 1,131 (5%), OR 0.70, 95% CI 0.64 to 0.77, p < 0.001 Instrumental vaginal delivery: 2,085 (8%) vs. 2,065 (10%), OR 0.81, 95% CI 0.76 to 0.86, p < 0.001		
Non-U.S. Studies, by parity only			
Bailey, 2017 New Zealand Routinely collected maternity outcome data compiled from Counties-Manukau District Health Board (CMDHB) maternity facilities 2003 to 2010 Poor quality	NR	Planned Birth Center (n = 3,438) vs. Planned Hospital (n = 11,195) Instrumental delivery: 495 (14.4%) vs. 1981 (16.6%), aOR 0.47, 95% CI 0.41 to 0.53 Cesarean delivery: 247 (7.2%) vs. 1500 (12.6%), aOR 0.51, 95% CI 0.44 to 0.59 Adjusted for maternal age, ethnicity, and deprivation score	Planned Birth Center (n = 7,010) vs. Planned Hospital (n = 25,018) Instrumental delivery: 45 (0.6%) vs. 322 (1.3%), aOR 0.45, 95% CI 0.32 to 0.61 Cesarean delivery: 50 (0.7%) vs. 570 (2.3%), aOR 0.34, 95% CI 0.26 to 0.46 Adjusted for maternal age, ethnicity, and deprivation score
Bolten et al., 2016 The Netherlands DELIVER (Data EersteLIjns VERloskunde) Study 2009 to 2010 Poor quality	NR	Planned Home (n = 868) vs. Planned Hospital (n = 717) Spontaneous: 651 (75.0%) vs. 498 (69.5%), aOR 1.38, 95% CI 1.08 to 1.76 Instrumental: 156 (18%) vs. 150 (20.9%), aOR 0.77, 95% CI 0.60 to 1.01 Unplanned cesarean delivery: 61 (7.0%) vs. 69 (9.6%), aOR 0.72, 95% CI 0.48 to 1.09 Adjusted for maternal age, gestational age, ethnic background (Dutch/western background/non-	Planned Home (n = 1,182) vs. Planned Hospital (n = 728) Spontaneous: 1,164 (98.5) vs. 703 (96.6%), aOR 2.29, 95% CI 1.21 to 4.36 Instrumental: 11 (0.9%) vs. 13 (1.8%), aOR 0.46, 95% CI 0.20 to 1.07 Unplanned cesarean delivery: 7 (0.6%) vs. 12 (1.7%), aOR 0.42, 95% CI 0.16 to 1.10 Adjusted for maternal age, gestational age, ethnic background (Dutch/western background/non-

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
		western background), BMI, socio-economic position	western background), BMI, socio-economic position
Christensen & Overgaard, 2017 Denmark Data collected on sociodemographic characteristics, present and previous pregnancies and births, neonatal outcomes and transfers March 2004 to October 2008 Poor quality	NR	Planned Birth Center (n = 215) vs. Planned Obstetric Unit (n = 215) Uncomplicated birth: OR 2.2, 95% CI 1.4 to 3.3 Cesarean delivery: OR 0.4, 95% CI 0.2 to 0.9 Instrumental delivery: OR 0.4, 95% CI 0.2 to 0.7	Planned Birth Center (n = 624) vs. Planned Obstetric Unit (n = 624) Uncomplicated birth: OR 2.9, 95% CI 2.0 to 4.2 Cesarean delivery: OR 0.8, 95% CI 0.3 to 2.2 Instrumental delivery: OR 0.3, 95% CI 0.1 to 0.9
Hollowell et al., 2017 England Birthplace in England national prospective cohort study April 2008 to April 2010 Fair quality	NR	Planned Birthing Center (n = 5,187) vs. Planned Hospital (n = 8.,350) SVD: 78.8% vs. 71.5%, aOR 1.47, 99% CI 1.17 to 1.85, p < 0.001 Instrumental delivery (ventouse or forceps): 10.8% vs. 16.3%, aOR 0.63, 99% CI 0.46 to 0.86, p < 0.001 Intrapartum cesarean delivery: 6.7% vs. 7.7%, aOR 0.84, 99% CI 0.63 to 1.14, p = 0.15 Adjusted for maternal characteristics and complicating conditions identified at the start of care in labor	Planned Birthing Center (n = 6,078) vs. Planned Hospital (n = 8,323) SVD: 97.0% vs. 94.6%, aOR 1.86, 99% CI 1.35 to 2.57, p < 0.001 Instrumental delivery (ventouse or forceps): 1.1% vs. 2.5%, aOR 0.41, 99% CI 0.25 to 0.68, p < 0.001 Intrapartum cesarean delivery: 0.7% vs. 0.1%, aOR 0.75, 99% CI 0.41 to 1.38, p = 0.224 Adjusted for maternal characteristics and complicating conditions identified at the start of care in labor

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
Li et al., 2015 England Birthplace national prospective cohort study April 2008 to April 2010 Good quality	NR	Planned Home (n = 201) vs. Planned Hospital (n = 2,504) Straightforward vaginal birth: 201 (73.5%) vs. 1305 (51.7%), aRR 1.63, 95% CI 1.47 to 1.81 Birth without intrapartum cesarean delivery, instrumental delivery, 3rd or 4th degree tear, blood transfusion. Adjusted for maternal age, ethnic group, marital/partner status, BMI in pregnancy, index of multiple deprivation score quintile, gestation at delivery and parity where appropriate.	Planned Home (n = 1,189) vs. Planned Hospital (n = 4,138) Straightforward vaginal birth: 1101 (92.7%) vs. 3109 (74.7%), aRR 1.20, 95% CI 1.16 to 1.23 Birth without intrapartum cesarean delivery, instrumental delivery, 3rd or 4th degree tear, blood transfusion. Adjusted for maternal age, ethnic group, marital/partner status, BMI in pregnancy, index of multiple deprivation score quintile, gestation at delivery and parity where appropriate
van Haaren-ten Haken et al., 2015 The Netherlands Self-reported questionnaires, medical records, and birth registration forms 2007 to 2011 Fair quality	NR	Planned Home with Midwife (n = 226) vs. Planned Hospital with Midwife (n = 168) vs. Planned Hospital with Obstetrician (n = 182) Spontaneous vaginal: 161 (74.5%) vs. 104 (66.2%) vs. 103 (63.6%) (reference) Assisted vaginal (VE/FE): 37 (17.1%) vs. 29 (18.5%) vs. 37 (22.8%) Midwife at Home vs. Midwife at Hospital: aOR 0.94, 95% CI 0.49 to 1.83, Midwife at Home vs. Obstetrician at Hospital: aOR 0.83, 95% CI 0.45 to 1.53	NR (included nulliparous only)

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
		Cesarean delivery (unplanned): 18 (8.3%) vs. 24 (15.3%) vs. 22 (13.6%) Midwife at Home vs. Midwife at Hospital: aOR 0.48, 95% CI 0.23 to 1.02, Midwife at Home vs. Obstetrician at Hospital: aOR 0.75, 95% CI 0.35 to 1.59 Midwife at Hospital vs. Obstetrician at Hospital: aOR 1.55, 95% CI 0.76 to 3.17	

Table F2. Outcome Data from Comparative Studies: Perinatal Mortality

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
U.S. Studies			
Grunebaum, McCullough, Sapra et al., 2017 U.S. CDC-linked birth-infant death files 2009 to 2013 Fair quality	Planned home birth (all providers) (n = 96,815) vs. Planned Hospital-Midwife (n = 1,077,197) Neonatal death, 0 to 27 days: 118 (0.12%) vs. 334 (0.03%) Standardized mortality ratio, 4.13, 95% CI 3.38 to 4.88 Indirectly standardized for maternal age (<35 or ≥35, parity (nulliparous vs. parous), and gestational age (37 to 40 vs. ≥41 weeks)	Planned home birth (n = 20,125) vs. Hospital-Midwife (n = 424,060) 45 (0.22%) vs. 157 (0.04%) SMR 6.06, 95% CI 4.30 to 7.83	Planned home birth (n = 75,809) vs. Hospital-Midwife (n = 641,625) 70 (0.09%) vs. 171 (0.03%) SMR 3.49, 95% CI 2.68 to 4.30
Grunebaum, McCullough, Arabin et al., 2017 U.S. CDC-linked birth-infant death data set 2008 to 2012 Poor quality	Planned Home (certified nurse or other midwife) vs. Planned Hospital-Midwife Neonatal mortality (birth through 27 days): 122/95,657 (0.127%) vs. 480/1,363,199 (0.035%)	Planned Home vs. Planned Hospital-Midwife Neonatal death, 0 to 27 days: 45/22,773 (0.198%) vs. 200/540,582 (0.037%) RR 5.34, 95% CI 3.9 to 7.4	Planned home vs. Planned Hospital-Midwife Neonatal death, 0 to 27 days: 77/72,884 (0.106%) vs. (280/822,617 (0.034%) RR 3.1, 95% CI 2.4 to 4

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
Snowden, et al., 2015 Oregon, U.S. State vital statistics January 2012 to December 2013 Good quality	Planned Home or Birth Center (n = 3,804) vs. Planned Hospital (n = 75,923) Fetal death ≥20 weeks, intrapartum, or neonatal death, 0 to 27 days: 15 (0.39%) vs. 137 (0.18%) Absolute difference in risk (percentage points), propensity score adjusted 0.158, 95% CI 0.055 to 0.261, p = 0.003 Fetal death ≥20 weeks: 9 (0.24%) vs. 91 (0.12%) Absolute difference in risk (percentage points), propensity score adjusted 0.088, 95% CI 0.005 to 0.171, p = 0.04 Neonatal death, 0 to 27 days: 6 (0.16%) vs. 46 (0.06%) Absolute difference in risk (percentage points), propensity score adjusted 0.077, 95% CI 0.013 to 0.140, p = 0.02	NR	NR
Thornton et al., 2017 U.S. Uniform Data Set from American Association of Birth Centers at 79 US birth centers in 43 states 2006 to 2011 Poor quality	Planned Birth Center (n = 8,776) vs. Planned Hospital (n = 2,527) Intrapartum or newborn death, days of life not reported: 3 (0.03%) vs. 1 (0.04%), OR 0.86, 95% CI 0.09 to 8.3, p = 0.99 RR calculated, 0.96, 95% CI 0.54 to 1.70	NR	NR
Non-U.S. Studies			

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
Birthplace in England Collaborative, 2011 England Birthplace study April 2008 to April 2010 Good quality	Planned Home vs. Planned Birth Center vs. Planned Hospital Intrapartum death 6/16,839 (0.04%) vs. 4/11,282 (0.04%) vs. 3/19,706 (0.02%) Neonatal death (0 to 7 days) 5/16,759 (0.03%) vs. 5/11,263 (0.04%) vs. 5/19,637 (0.03%) No statistical analysis provided, data from Appendix 8, table 8.4	Planned Home vs. Planned Birth Center vs. Planned Hospital Intrapartum death 4/4,568 (0.09%) vs. 1/5,187 (0.02%) vs. 1/10,626 (0.01%) Neonatal death (0 to 7 days) 2/4,544 (0.04%) vs. 3/5,180 (0.06%) vs. 4/10,593 (0.04%) No statistical analysis provided, data from Appendix 8, table 8.5	Planned Home vs. Planned Birth Center vs. Planned Hospital Intrapartum death 2/12,255 (0.02%) vs. 3/6,078 (0.05%) vs. 2/9,049 (0.02%) Neonatal death (0 to 7 days) 3/12,199 (0.02%) vs. 2/6,066 (0.03%) vs. 1/9,013 (0.01%) No statistical analysis provided, data from Appendix 8, table 8.5
Davies-Tuck et al., 2018 Australia Victorian Perinatal Data Collection 2000 to 2015 Poor quality	Low risk, Planned Home (n = 3,202) vs. Planned Hospital (n = 701,058) Stillbirth: 2 (0.062%) vs. 906 (0.129%), p = 0.29 Neonatal death: 3 (0.094%) vs. 262 (0.037%), p = 0.10 Still birth or neonatal death: 5 (0.16%) vs. 1,168 (0.17%), p = 0.90 Timing of stillbirth nor neonatal death reported.	NR	NR

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
Grigg et al., 2017 New Zealand Maternity and Midwifery Provider Organization data 2010 to 2011 Poor quality	Planned Birthing Center (n = 407) vs. Planned Hospital (n = 285) Intrauterine or intrapartum death: 2 (0.5%) vs. 0 (0.0%) Neonatal death, 0 to 27 days: 1 (0.26%) vs. 0 (0.0%) Intrauterine demise identified at 38 weeks during antenatal care visit. Freestanding Primary Level Midwife-led Maternity Units (PMUs) vs. Tertiary-level Obstetric-led Maternity Hospital (TMH)	NR	NR
Halfdansdottir et al., 2015 Iceland Review of midwives' and doctors' original hand-written maternity notes 2005 to 2009 Poor quality	Planned Home (n = 307) vs. Planned Hospital or Midwifery Alongside Unit (n = 921) Neonatal mortality: 0 (0%) vs. 0 (0%)	Planned Home (n = 64) vs. Planned Hospital or Midwifery Alongside Unit (n = 192) Neonatal mortality: 0 (0.0%) vs. 0 (0.0%)	Planned Home (n = 243) vs. Planned Hospital or Midwifery Alongside Unit (n = 729) Neonatal mortality: 0 (0.0%) vs. 0 (0.0%)
Hermus et al., 2017 The Netherlands July to December 2013 Good quality	NR	Planned Home (n = 348) vs. Planned Birth Center (n = 939) vs. Planned Hospital (n = 399) (Birth Center reference group) Perinatal mortality in 24 hours: 0 (0%) vs. 0 (0%) vs. 1 (0.3%)	Planned Home (n = 687) vs. Planned Birth Center (n = 729) vs. Planned Hospital (n = 353) (Birth Center reference group) Perinatal mortality in 24 hours: 0 (0%) vs. 0 (0%) vs. 0 (0%)

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
Homer et al., 2014 Australia Perinatal Data Collection, Admitted Patient Data Collection, Register of Congenital Conditions, Registry of Birth Deaths and Marriages, and the Australian Bureau of Statistics 2000 to 2008 Fair quality	Planned Home vs. Planned Birth Center vs. Planned Hospital Intrapartum or neonatal death, 0 to 7 days: 1/693 (0.14%) vs. 10/14,476 (0.06%) vs. 255/242,665 (0.01%) Planned Home vs. Planned Hospital: aOR 1.29, 95% CI 0.18 to 9.23 Planned Birth Center vs. Planned Hospital: aOR 0.66, 95% CI 0.35 to 1.24 Adjusted for maternal age, gestational age in weeks at delivery and parity. Any case with missing data was excluded from the regression.	Planned Home vs. Planned Birth Center vs. Planned Hospital Intrapartum or neonatal death, 0 to 7 days: 1/304 (0.329%) vs. 10/9,145 (0.109%) vs. 158/149,417 (0.106%) Planned Home vs. Planned Hospital: aOR 2.48, 95% CI 0.34 to 18.02 Birth center vs. Hospital: aOR 0.99, 95% CI 0.52 to 1.88 Adjusted for maternal age, gestational age in weeks at delivery and parity. Any case with missing data was excluded from the regression.	Planned Home vs. Planned Birth Center vs. Planned Hospital Intrapartum and neonatal death, 0 to 7 days: 0/392 (0%) vs. 0/5,332 (0%) vs. 96/93,298 (0.103%) Planned Home vs. Planned Hospital: Unable to calculate due to zero events Planned Birth center vs. Planned Hospital: Unable to calculate due to zero events
Hutton et al., 2016 Ontario, Canada Chart review March 2016 to April 2009 Poor quality	Planned Home (n = 11,493) vs. Planned Hospital (n = 11,493) Intrapartum or neonatal death, 0 to 27 days: 9 (0.1%) vs. 9 (0.1%), RR 1.00, 95% CI 0.40 to 2.52	Planned Home (n = 4,027) vs. Planned Hospital (n = 4,027) Intrapartum or neonatal death, 0 to 27 days: 7 (0.2%) vs. 6 (0.1%), RR 1.17, 95% CI 0.39 to 3.47	Planned Home (n = 7,466) vs. Planned Hospital (n = 7,466) Intrapartum or neonatal death, 0 to 27 days: 2 (0.03%) vs. 3 (0.04%), RR 0.67, 95% CI 0.11 to 3.99
Hutton et al., 2009 Canada Ontario Ministry of Health database 2003 to 2006 Poor quality	Planned Home (n = 6,692) vs. Planned Hospital-Midwife (n = 6,692) Intrapartum or neonatal death, 0 to 27 days: 9 (0.1%) vs. 6 (0.1%); RR 1.50, 95% CI 0.53 to 4.21	Planned Home (n = 2,293) vs. Planned Hospital-Midwife (n = 2,298) Intrapartum or neonatal death, 0 to 27 days: 5 (0.2%) vs. 4 (0.2%), no additional analysis reported	Planned Home (n = 4,393) vs. Matched, Planned Hospital-Midwife (n = 4,394) Intrapartum or neonatal death, 0 to 27 days: 4 (0.1%) vs. 2 (0.1%)

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
Janssen et al., 2009 British Columbia, Canada Perinatal Database Registry and vital statistics 2000 to 2004 Poor quality	Planned Home (n = 2,889) vs. Planned Hospital-Midwife (n = 4,752) vs. Matched Sample of Physician-attended Hospital Births (n = 5,331) Fetal death ≥ 20 weeks, intrapartum, or neonatal death, 0 to 7 days: 1 (0.035%) vs. 3 (0.057%) vs. 3 (0.064%) Planned Home vs. Planned Hospital-Midwife RR 0.61, 95% CI 0.06 to 5.88, p = NR Planned Home vs. Matched Hospital-Physician RR 0.55, 95% CI 0.06 to 5.25, p = NR	NR	NR
Katoaka et al., 2018 Japan Review of medical records Birth centers: 2001 to 2006, one hospital: 2004 to 2006, other hospital: 2008 Poor quality	Planned Birth Center (n = 5,379) vs. Planned Hospital (n = 4,209) Fetal death ≥22 weeks or intrapartum death: 0 (0%) vs. 11 (0.3%)	NR	NR

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
Kennare et al., 2010 Australia Pregnancy Outcome Unit of South Australia Health perinatal data for all births and data on perinatal deaths 1991 to 2006 Poor quality	Planned Home (n = 1,141) vs. Planned Hospital (n = 297,192) Fetal death ≥ 20 weeks, intrapartum, or neonatal deaths, 0 to 28 days: 9 (0.079%) vs. 2,440 (0.082%), aOR 1.38, 95% CI 0.56 to 3.41, p = 0.48 Adjusted for maternal age, parity, occupational status, smoking, plurality, medical and obstetric complications (e.g., antepartum hemorrhage, diabetes, hypertension), gestational age, small for gestational age, congenital anomalies, city or country hospital, mode of delivery	NR	NR
van der Kooy et al., 2011 The Netherlands Netherlands Perinatal Registry 2000 to 2007 Fair quality	Planned Home (n = 402,912) vs. Planned Hospital-Midwife (n = 219,105) Intrapartum or neonatal deaths, 0 to 7 days: 594 (0.15%) vs. 403 (0.18%), aOR 1.05, 95% CI 0.91 to 1.21 Adjusted for parity, age, ethnic background, and neighborhood, gestational age, congenital abnormalities, preterm birth, low Apgar score, small for gestational age	NR	NR

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
Wiegerinck et al., 2015 The Netherlands Netherlands Perinatal Register with additionally retrieved data from hospitals and midwife practices 2005 to 2008 Poor quality	Planned Home (n = 26,128) vs. Planned Hospital (n = 21,362) Intrapartum or neonatal death, 0 to 27 days: 19 (0.073%) vs. 12 (0.056%), OR 1.30, 95% CI 0.63 to 2.67, p = 0.61 RR calculated: 1.11, 95% CI 0.84 to 1.47	NR	NR
Non-U.S. Studies, by parity only			
New Zealand Routinely collected maternity outcome data compiled from Counties-Manukau District Health Board (CMDHB) maternity facilities 2003 to 2010 Poor quality	NR	Planned Birth Center (n = 3,438) vs. Planned Hospital (n = 11,195) Hypoxic peripartum mortality: 6 (0.17%) vs. 14 (0.12%), OR 1.30, 95% CI 0.46 to 3.23 Unadjusted OR because of small numbers RR calculated, 1.277, 95% CI 0.65 to 2.49	Planned Birth Center (n = 7,010) vs. Planned Hospital (n = 25,018) Hypoxic peripartum mortality: 4 (0.06%) vs. 8 (0.03%), OR 1.79, 95% CI 0.47 to 5.90 Unadjusted OR because of small numbers RR calculated, 1.52, 95% CI 0.68 to 3.39

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
de Jonge et al., 2015 The Netherlands Netherlands Perinatal Registry 2000 to 2009 Fair quality	NR	Planned Home vs. Planned Hospital-Midwife Intrapartum death: 113/198,515 (0.06%) vs. 86/137,168 (0.06%), aOR 1.02, 95% CI 0.76 to 1.37 Neonatal death, 0 to 7 days: 95/198,412 (0.05%) vs. 67/137,088 (0.05%), aOR 0.98, 95% CI 0.70 to 1.36 Neonatal death, 0 to 28 days: 100/198,412 (0.05%) vs. 70/137,088 (0.05%), aOR 0.97, 95% CI 0.70 to 1.34 Adjusted for gestational age, maternal age, socioeconomic status, ethnicity	Planned Home vs. Planned Hospital-Midwife Intrapartum death: 87/267,526 (0.03%) vs. 44/139,740 (0.03%), aOR 1.31, 95% CI 0.89 to 1.94 Neonatal death, 0 to 7 days: 72/267,444 (0.03%) vs. 36/139,697 (0.03%), aOR 1.07, 95% CI 0.70 to 1.65 Neonatal death, 0 to 28 days: 76/267,444 (0.03%) vs. 38/139,697 (0.03%), aOR 1.07, 95% CI 0.70 to 1.62 Adjusted for gestational age, maternal age, socioeconomic status, ethnicity
van Haaren-ten Haken et al., 2015 The Netherlands Self-reported questionnaires, medical records, and birth registration forms 2007 to 2011 Poor quality	NR	Planned Home (n = 226) vs. Planned Hospital-Midwife (n = 168) vs. Planned Hospital-Obstetrician (n = 182) Intrapartum or neonatal death, 0 to 7 days: 0 (0%) vs. 0 (0%) vs. 0 (0%)	NR (included only nulliparous)

Table F3. Outcome Data from Comparative Studies: Neonatal Morbidity

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
U.S. Studies			
Li et al., 2017 South Carolina Birth certificates 1996 to 2013 Poor quality	2004 to 2013 birth certificate data, Medicaid claims, or discharge abstracts Planned Home (n = 661) vs. Planned Birth Center (n = 1,233) vs. Planned Clinic (n = 9) vs. Planned Hospital (n = 547,523) Neonatal seizures: 1 (0.15%) vs. 0 (0.0%) vs. 0 (0.0%) vs. 131 (0.02%) Neonatal convulsions: 4 (0.61%) vs. 3 (0.24%) vs. 0 vs. 1,290 (0.24%)	NR	NR
Snowden, et al., 2015 Oregon, U.S. State vital statistics January 2012 to December 2013 Good quality	Absolute difference in risk percentage points 5-Minute Apgar score < 7: 0.50, 95% CI 0.07 to 0.93, p = 0.02 5-Minute Apgar < 4: 0.18, 95% CI 0.00 to 0.37, p = 0.05 Neonatal seizures: 0.07, 95% CI 0.02 to 0.13, p = 0.007 Ventilator support: 1.05, 95% CI 0.48 to 1.62, p < 0.001 NICU admission: −0.85, 95% CI -1.57 to -0.14, p = 0.02 Propensity score adjusted result	NR	NR
Thornton et al., 2017 U.S. Uniform Data Set from American Association of	Planned Birth Center (n = 8,776) vs. Planned Hospital (n = 2,527)	NR	NR

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
Birth Centers at 79 U.S. birth centers in 43 states 2006 to 2011 Poor quality	5-minute Apgar score 3 to 7: 70 (0.80%) vs. 13 (0.51%), aOR 1.60, 95% CI 0.82 to 3.16, p = NR Newborn septic workup: 62 (0.71%) vs. 35 (1.39%), aOR 0.51, 95% CI 0.32 to 0.81, p = NR Positive pressure ventilation < 10 minutes: 268 (3.05%) vs. 57 (2.26%), aOR 1.31, 95% CI 0.95 to 1.82, p = NR Neonatal composite: 39 (0.44%) vs. 11 (0.44%), aOR 1.44, 95% CI 0.66 to 3.14 Composite definition: intrapartum and newborn mortality, hypoxic neurologic injury, Apgar score less than 4 at 5 minutes, seizures, persistent pulmonary hypertension, positive pressure ventilation greater than 10 minutes, and meconium aspiration syndrome Propensity score adjustment with a covariate considering maternal age, parity, race, payment method, cohabitation status, trimester prenatal care began, gestational age at birth, and newborn weight		

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
Non-U.S. Studies			
Birthplace in England Collaborative, 2011 England Birthplace study April 2008 to April 2010 Good quality	Planned Home (n = 16,553) vs. Planned Hospital (n = 19,551) Birthplace composite: 70 (4.2%) vs. 81 (4.4%), aOR 1.16, 95 % CI 0.76 to 1.77 Planned Freestanding Midwifery Unit (n = 11,199) vs. Planned Hospital (n = 19,551) Birthplace composite: 41 (3.5%) vs. 81 (4.4%), aOR 0.92, 95 % CI 0.58 to 1.46 Adjusted for maternal age, ethnic group, understanding of English, marital or partner status, BMI, deprivation score quintile, previous pregnancies, weeks of gestation Birthplace composite definition: stillbirth after the start of care in labor, early neonatal death, neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured humerus or clavicle	Planned Home (n = 4,488) vs. Planned Hospital (n = 10,541) Birthplace composite: 39 (9.3%) vs. 52 (5.3%), aOR 1.75, 95 % CI 1.07 to 2.86 Planned Freestanding Midwifery Unit (n = 5,158) vs. Planned Hospital (n = 10,541) Birthplace composite: 24 (4.5%) vs. 52 (5.3%), aOR 0.91, 95 % CI 0.52 to 1.60 Adjusted for maternal age, ethnic group, understanding of English, marital or partner status, BMI, deprivation score quintile, previous pregnancies, weeks of gestation.	Planned Home (n = 12,050) vs. Planned Hospital (n = 8,980) Birthplace composite: 31 (2.3%) vs. 29 (3.3%), aOR 0.72, 95% CI 0.41 to 1.27 Planned Freestanding Midwifery Unit (n = 6,025) vs. Planned Hospital (n = 8,980) Birthplace composite: 17 (2.7%) vs. 29 (3.3%), aOR 0.91, 95% CI 0.46 to 1.80 Adjusted for maternal age, ethnic group, understanding of English, marital or partner status, BMI, deprivation score quintile, previous pregnancies, weeks of gestation

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
Davies-Tuck et al., 2018 Australia Victorian Perinatal Data Collection 2000 to 2015 Poor quality	Low risk, Planned Home (n = 3,202) vs. Planned Hospital (n = 701,058) Admission to SCN: 58 (1.8%) vs. 58,303 (8.3%), p < 0.001 NICU admission: 14 (0.4%) vs. 1,721 (0.2%), p = 0.03 5-minute Apgar < 7: 29 (0.9%) vs. 8,739 (1.2%), p = 0.08 HIE: 0 (0%) 133 vs. (0.2%), p = 0.44 Birth trauma: 46 (1.4%) vs. 46,502 (6.6%), p < 0.001 Intrauterine hypoxia: 47 (1.5%) vs. 40,760 (5.8%), p < 0.001 Other perinatal morbidity: 8 (0.3%) vs. 1,113 (0.2%), p = 0.20 Composite morbidity: 115 (3.6%) vs. 94,094 (13.4%), p < 0.001 Birth trauma: brachial plexus injury, fractured clavicle or humerus Other perinatal morbidity: meconium aspiration syndrome, congenital pneumonia or respiratory distress syndrome	NR	NR

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
Grigg et al., 2017 New Zealand Maternity and Midwifery Provider Organization data 2010 to 2011 Poor quality	Planned Birthing Center (n = 407) vs. Planned Hospital (n = 285) 5-minute Apgar score < 7: 8 (2.0%) vs. 6 (2.1%), aOR 0.82, 95% CI 0.27 to 2.52 Resuscitation not needed: 345 (84.8%) vs. 234 (82.1%), aOR 0.97, 95% CI 0.63 to 1.50‡ Admission to NNU: 24 (5.9%) vs. 14 (4.9%), aOR 1.44, 95% CI 0.70 to 2.96, p > 0.05 Freestanding Primary Level Midwife-led Maternity Units (PMUs) vs. Tertiary-level Obstetric-led Maternity Hospital (TMH) ‡Refers to a dichotomous outcome of "resuscitation or not" adjusted for maternal age, smoking status, parity, augmentation, induction, term	NR	NR

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
Halfdansdottir et al., 2018 Iceland Maternity notes review 2005 to 2009 Poor quality	No home birth contraindication Planned Home (n = 278) vs. Planned Hospital (n = 851) NICU admission: 16 (5.8%) vs. 57 (6.7%) 5-minute Apgar < 7: 2 (0.7%) vs. 14 (1.6%) Neonatal resuscitation: 6 (2.2%) vs. 15 (1.8%) Neonatal morbidity, 7 days: 28 (10.1%) vs. 116 (13.6%) Home birth contraindication present Planned Home (n = 29) vs. Planned Hospital (n = 70) NICU admission: 6 (20.7%) vs. 6 (8.6%) 5-minute Apgar < 7: 3 (10.3%) vs. 1 (1.4%) Neonatal resuscitation: 2 (6.9%) vs. 2 (2.9%) Neonatal morbidity, 7 days: 7 (24.1%) vs. 10 (14.3%)	NR	NR
Halfdansdottir et al., 2015 Iceland Review of midwives' and doctors' original hand-written maternity notes 2005 to 2009 Poor quality	Planned Home (n = 307) vs. Planned Hospital or Midwifery Alongside Unit (n = 921) NICU admission: 22 (7.2%) vs. 63 (6.8%) aOR 1.34, 95% CI 0.78 to 2.32 5-minute Apgar < 7: 5 (1.6%) vs. 15 (1.6%) aOR 0.98, 95% CI 0.30 to 3.19	Planned Home (n = 64) vs. Planned Hospital or Midwifery Alongside Unit (n = 192) NICU admission: 12 (18.8%) vs. 23 (12.0%); aOR 1.88, 95% Ci 0.81 to 4.36 5 minute Apgar < 7: 4 (6.3%) vs. 6 (3.1%), aOR 1.24, 95% Ci 0.25 to 6.28 Neonatal resuscitation: 4 (6.3%) vs. 3 (1.6%)	Planned Home (n = 243) vs. Planned Hospital or Midwifery Alongside Unit (n = 729) NICU admission: 10 (4.1%) vs. 40 (5.5%), aOR 1.04, 95% Ci 0.46 to 2.34 5 minute Apgar < 7: 1 (0.4%) vs. 9 (1.2%), aOR 0.38, 95% Ci 0.04 to 3.60 Neonatal resuscitation: 4 (1.7%) vs. 14 (1.9%)

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
Hitzert et al., 2016 The Netherlands Dutch Birth Centre Study August to December 2013 Poor quality	Planned Home (n = 350) vs. Planned Birth Center (n = 263) vs. Planned Hospital-Midwife (n = 262) vs. Planned Hospital-Obstetrician (n = 115) Hospital admission of the child after birth No: 304 (87.4%) vs. 188 (72.3%) vs. 196 (74.8%) vs. 58 (50.9%) Yes, at the maternity ward: 38 (10.9%) vs. 63 (24.2%) vs. 58 (22.1%) vs. 41 (36.0%) Yes, high care: 6 (1.7%) vs. 9 (3.5%) vs. 8 (3.1%) vs. 15 (13.2%) Experienced health baby after birth Healthy: 318 (91.4%) vs. 229 (87.4%) vs. 229 (87.4%) vs. 93 (80.9%) Small problems: 22 (6.3%) vs. 29 (11.1%) vs. 25 (9.5%) vs. 20 (17.4%) Big problems/problems with impact unclear: 8 (2.3%) vs. 4 (1.6%) vs. 8 (3.1%) vs. 2 (1.8%)	NR	NR

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
Homer et al., 2014 Australia Perinatal Data Collection, Admitted Patient Data Collection, Register of Congenital Conditions, Registry of Birth Deaths and Marriages, and the Australian Bureau of Statistics 2000 to 2008 Fair quality	Planned Home vs. Planned Birth Center vs. Planned Hospital Composite morbidity or mortality: 5/703 (0.07%) vs. 77/14,482 (0.05%) vs. 1,399/242,860 (0.05%) Home vs. Hospital: aOR 1.06, 95% CI 0.44 to 2.56 Birth center vs. Hospital: aOR 0.87, 95% CI 0.69 to 1.10 Composite represented any of the following: stillbirth, early neonatal death (<7 days), neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured clavicle, fractured humerus. Adjusted for maternal age, gestational age in weeks at delivery and parity	Planned Home vs. Planned Birth Center vs. Planned Hospital Composite morbidity or mortality: 4/304 (1.32%) vs. 65/9,145 (0.71%) vs. 949/149,417 (0.64%) Home vs. Hospital: aOR 1.72, 95% CI 0.64 to 4.63 Birth center vs. Hospital: aOR 1.04, 95% CI 0.81 to 1.34 Composite represented any of the following: stillbirth, early neonatal death (<7 days), neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured clavicle, fractured humerus. Adjusted for maternal age, gestational age in weeks at delivery and parity	Planned Home vs. Planned Birth Center vs. Planned Hospital Composite morbidity or mortality: 1/392 (0.26%) vs. 12/5,332 (0.23%) vs. 448/93,298 (0.48%) Home vs. Hospital: aOR 0.47, 95% CI 0.07 to 3.38 Birth center vs. Hospital: aOR 0.45, 95% CI 0.26 to 0.81 Composite represented any of the following: stillbirth, early neonatal death (<7 days), neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured clavicle, fractured humerus Adjusted for maternal age, gestational age in weeks at delivery, parity
Hutton et al., 2016 Ontario, Canada Chart review March 2016 to April 2009 Poor quality	Planned Home (n = 11,493) vs. Planned Hospital (n = 11,493) Neonatal morbidity: 38 (0.3%) vs. 40 (0.3%), RR 0.95, 95% CI 0.6 to 1.48 5 minute Apgar < 4, positive pressure ventilation, or chest compressions	Planned Home (n = 4,027) vs. Planned Hospital (n = 4,027) Neonatal morbidity: 27 (0.7%) vs. 26 (0.6%), RR 1.04, 95% CI 0.61 to 1.78 5 minute Apgar < 4, positive pressure ventilation, or chest compressions	Planned Home (n = 7,466) vs. Planned Hospital (n = 7,466) Neonatal morbidity: 11 (0.2%) vs. 14 (0.2%), RR 0.79, 95% CI 0.36 to 1.73 5 minute Apgar < 4, positive pressure ventilation, or chest compressions

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
Hutton et al., 2009 Canada Ontario Ministry of Health database 2003 to 2006 Poor quality	Planned Home (n = 6,692) vs. Planned Hospital-Midwife (n = 6,692) Neonatal morbidity: 155 (2.3%) vs. 189 (2.8%), RR 0.82, 95% CI 0.66 to 1.01 Birthweight <2,500: 38 (0.6%) vs. 56 (0.8%) 5-minutes Apgar < 4: 10 (0.1%) vs. 8 (0.1%) positive pressure ventilation and cardiac compressions: 21 (0.3%) vs. 23 (0.3%) NICU >4 days: 102 (1.5%) vs. 115 (1.7%)	Planned Home (n = 2,293) vs. Planned Hospital-Midwife (n = 2,298) Neonatal morbidity: 78 (3.4%) vs. 84 (3.7%)	Planned Home (n = 4,393) vs. Planned Hospital-Midwife (n = 4,394) Neonatal morbidity: 77 (1.8%) vs. 105 (2.4%)
Janssen et al., 2009 British Columbia, Canada Perinatal Database Registry and vital statistics 2000 to 2004 Poor quality	Planned Home (n = 2,889) vs. Planned Hospital-Midwife (n = 4,752) RR - Planned Home vs. Hospital with Midwife 1-minute Apgar score < 7: RR 0.76, 95% CI 0.66 to 0.88 5-minute Apgar score < 7: RR 0.92, 95% CI 0.58 to 1.47 Meconium aspiration: RR 0.83, 95% CI 0.38 to 1.81 Asphyxia at birth: RR 0.79, 95% CI 0.30 to 2.05 Birth trauma: RR 0.26, 95% CI 0.11 to 0.58 Resuscitation at birth: RR 0.23, 95% CI 0.14 to 0.37 Birth weight < 2500 g: RR 0.44, 95% CI 0.25 to 0.78 Seizures: RR 0.61, 95% CI 0.12 to 3.03	NR	NR

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
	Assisted ventilation > 24 h: RR 1.02, 95% CI 0.34 to 3.04 Birth trauma: subdural or cerebral hemorrhage, fracture of clavicle, long bones or skull, facial nerve injury, Erb palsy, or unspecified birth trauma		
Katoaka et al., 2018 Japan Review of medical records Birth centers: 2001 to 2006, one hospital: 2004 to 2006, other hospital: 2008 Poor quality	Planned Birth Center (n = 5,379) vs. Planned Hospital (n = 4,209) Birth weight (grams) <2,500: 171 (3.2%) vs. 234 (5.6%), aOR 0.67, 95% CI 0.55 to 0.82 2,500 to 3,999: 5,120 (95.3%) vs. 3,896 (92.7%), aOR = Reference >4,000: 82 (1.5%) vs. 72 (1.7%), aOR 0.65, 95% CI 0.46 to 0.92 Apgar score <7 at 1 minute: 20 (0.4%) vs. 115 (2.7%), aOR 0.17, 95% CI 0.10 to 0.28 <7 at 5 minutes: 5 (0.1%) vs. 26 (0.6%), aOR 0.23, 95% CI 0.10 to 0.63 Adjusted for age, parity, mode of delivery, and gestational weeks	NR	NR

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
Kennare et al., 2010 Australia Pregnancy Outcome Unit of South Australia Health perinatal data for all births and data on perinatal deaths 1991 to 2006 Poor quality	Planned Home (n = 1,136) vs. Planned Hospital (n = 295,568) 5-minute Apgar score < 7: 12 (1.1%) vs. 4,243 (1.4%), aOR 1.43, 95% CI 0.66 to 3.07, p = 0.36 Specialized neonatal care: 88 (7.7%) vs. 44,410 (15.0%), aOR 0.80, 95% CI 0.62 to 1.03), p = 0.08 Adjusted for maternal age, parity, occupational status, smoking, plurality, medical and obstetric complications (e.g., antepartum hemorrhage, diabetes, hypertension), gestational age, small for gestational age, congenital anomalies, city or country hospital, mode of delivery	NR	NR

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
Monk et al., 2014 Australia ObstetriX surveillance system of point-of-care maternity data collection across the antenatal, intrapartum, and immediate postnatal periods 2005 to 2006 Fair quality	Planned Birth Center (n = 494) vs. Planned Tertiary Maternity Unit (n = 3,157) 5-minute Apgar < 7: 6 (1.2%) vs. 88 (2.8%), aOR 0.57, 95% CI 0.25 to 1.35, p = 0.203 Admitted to SCN/NICU: 33 (6.7%) vs. 432 (13.7%), aOR 0.60, 95% CI 0.39 to 0.91, p = 0.017 Birth weight <2,500: 9 (1.8) vs. 176 (5.6), aOR 0.38, 95% CI 0.16 to 0.89, p = 0.026 2,500 to 4,500: 472 (96.3) vs. 2,899 (92.2%), aOR 1.74, 95% CI 1.00 to 3.03, p = 0.050 >4500: 9 (1.8%) vs. 70 (2.2%), aOR 0.77, 95% CI 0.37 to 1.58, p = 0.473 Adjusted for maternal age, smoking status, parity, augmentation, induction, previous cesarean delivery and risk at the onset of labor	NR	NR
Øian et al., 2018 Norway Medical Birth Registry with supplementary data collection January 2008 to December 2010 Poor quality	Births in Midwife-Led Birth Centers, Planned (n = 2,298) vs. Births Planned for a Midwife-led Birth Unit, Took Place Elsewhere (n = 220) vs. Births in Hospital, Low Risk (n = 105,358) 5-minute Apgar Score < 7: 1 (.1%) vs. 2 (1.1%) vs. 1,029 (1.0%)	NR	NR

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
Schroeder et al., 2017 England Interviews and medical records from Barkantine Birth Centre and Royal London Hospital's obstetric unit in Tower Hamlets, a low-income borough in east London 2008 to 2009 Poor quality	Planned Birth Center (n = 167) vs. Planned Hospital (n = 164) Mean Days in NICU: 0.00 ± 0.0 vs. 0.01 ± 0.1, p = NR	NR	NR
Sprague et al., 2018 Ontario, Canada Better Outcomes Registry & Network, Canadian Institute of Health Information Discharge Abstracts Database, Statistics Canada census data, birth center records January 2014 to February 2015 Poor quality	Planned birth center (n = 495) vs. Matched Planned Midwifery (n = 1980) NICU admission: 27 (5.5%) vs. 141 (7.1%), aRR 1.3, 95% CI 0.9 to 2.0	NR	NR

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
Wiegerinck et al., 2015 The Netherlands Netherlands Perinatal Register with additionally retrieved data from hospitals and midwife practices 2005 to 2008 Poor quality	Planned Home (n = 26,128) vs. Planned Hospital (n = 21,362) 5-minute Apgar score: < 7: 181 (0.693%) vs. 159 (0.744%), OR 0.93, 95% CI 0.75 to 1.15, p = 0.54 NICU admittance >24 hours: 43 (0.165%) vs. 55 (0.258%), OR 0.64, 95% CI 0.43 to 0.95, p = 0.03	NR	NR
Non- U.S., by parity only			
Bailey, 2017 New Zealand Routinely collected maternity outcome data compiled from Counties-Manukau District Health Board (CMDHB) maternity facilities 2003 to 2010 Poor quality	NR	Planned Birth Center (n = 3,438) vs. Planned Hospital (n = 11,195) Neonatal unit admission: 155 (4.5%) vs. 226 (6.4%), aOR 0.70, 95% CI 0.58 to 0.86 Adjusted for maternal age, ethnicity, and deprivation score	Planned Birthing Center (n = 7,010) vs. Planned Hospital (n = 25,018) Neonatal unit admission 168 (2.4%) vs. 718 (2.9%), aOR 0.85, 95% CI 0.71 to 1.01 Adjusted for maternal age, ethnicity, deprivation score

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
Christensen & Overgaard, 2017 Denmark Data collected on sociodemographic characteristics, present and previous pregnancies and births, neonatal outcomes and transfers March 2004 to October 2008 Poor quality	NR	Planned Birth Center (n = 215) vs. Planned Obstetric Unit (n = 215) 5-minute Apgar score < 9: OR 0.6, 95% CI 0.2 to 1.9 NICU admission <24 h: 0.8, 95% CI 0.4 to 1.9 Infant readmission: 0.4, 95% CI 0.1 to 1.4	Planned Birth Center (n = 624) vs. Planned Obstetric Unit (n = 624) 5-minutes Apgar score < 9: OR 0.8, 95% CI 0.4 to 1.9 NICU admission <24 h: OR 0.7, 95% CI 0.3 to 1.8 Infant readmission: OR 0.7, 95% CI 0.4 to 1.3

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
de Jonge et al., 2015 The Netherlands Netherlands Perinatal Registry 2000 to 2009 Fair quality	NR	Planned Home vs. Planned Hospital-Midwife 5-minute Apgar score < 7: 1,568/198,372 (0.80%) vs. 1,213/137,054 (0.90%), aOR 0.95, 95% CI 0.87 to 1.02 5-minute Apgar score < 4: 209/198,372 (0.11%) vs. 166/137,054 (0.12%), aOR 0.91, 95% CI 0.74 to 1.14 Admission to NICU within 7 days: 644/198,412 (0.03%) vs. 476/137,088 (0.03%), aOR 1.04, 95% CI 0.91 to 1.18 Admission to NICU within 28 days: 677/198,412 (0.03%) vs. 495/137,088 (0.04%), aOR 1.05, 95% CI 0.92 to 1.18 Adjusted for gestational age, maternal age, socioeconomic status, and ethnicity	Planned Home vs. Planned Hospital-Midwife 5-minute Apgar score < 7: 855/267,371 (0.32%) vs. 638/139,656 (0.46%), aOR 0.77, 95% CI 0.69 to 0.86 5-minute Apgar score < 4: 167/267,371 (0.06%) vs. 100/139,656 (0.07%), aOR 0.92, 95% CI 0.70 to 1.20 Admission to NICU within 7 days: 327/267,444 (0.12%) vs. 232/139,697 (0.17%), aOR 0.84, 95% CI 0.70 to 1.01 Admission to NICU within 28 days: 363/267,444 (0.14%) vs. 272/139,697 (0.20%), aOR 0.79, 95% CI 0.66 to 0.93 Adjusted for gestational age, maternal age, socioeconomic status, and ethnicity

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
Hollowell et al., 2017 England Birthplace in England national prospective cohort study April 2008 to April 2010 Fair quality	NR	Planned Birthing Center (n = 5,187) vs. Planned Hospital (n = 8.,350) Birthplace primary perinatal outcome: 0.045% vs. 0.027%, aOR 0.96, 95% CI 0.51 to 1.82, p = 0.91 Composite measure defined as any of: stillbirth after the start of care in labor, early neonatal death, neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured humerus or clavicle Adjusted for maternal characteristics and complicating conditions identified at the start of care in labor	Planned Birthing Center (n = 6,078) vs. Planned Hospital (n = 8,323) Birthplace primary perinatal outcome: 0.047% vs. 0.024%, aOR 1.14, 95% CI 0.52 to 2.50, p = 0.745 Composite measure defined as any of: stillbirth after the start of care in labor, early neonatal death, neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured humerus or clavicle Adjusted for maternal characteristics and complicating conditions identified at the start of care in labor

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
Li et al., 2015 United Kingdom Birthplace national prospective cohort study April 2008 to April 2010 Good quality	NR	Planned Home (n = 283) vs. Planned Hospital (n = 2,503) Adverse perinatal outcomes (main composite): 9 (27.7%) vs. 107 (19.3%), aRR 0.60, 95% CI 0.25 to 1.43 A composite consisting of the birthplace intrapartum and admission to a neonatal unit within 48 hours of birth for more than 48 hours. Adjusted for maternal age, ethnic group, marital/partner status, BMI in pregnancy, index of multiple deprivation score quintile, gestation at delivery, parity where appropriate	Planned Home (n = 1,186) vs. Planned Hospital (n = 4,133) Adverse perinatal outcomes (main composite): 16 (12.3%) vs. 108 (26.8%), aRR 0.47, 95% CI 0.25 to 0.88 Composite consisting of the birthplace intrapartum and admission to a neonatal unit within 48 hours of birth for more than 48 hours Adjusted for maternal age, ethnic group, marital/partner status, BMI in pregnancy, index of multiple deprivation score quintile, gestation at delivery and parity where appropriate
van Haaren-ten Haken et al., 2015 The Netherlands Self-reported questionnaires, medical records, and birth registration forms 2007 to 2011 Poor quality	NR	Planned Home (n = 226) vs. Planned Hospital-Midwife (n = 168) vs. Planned Hospital-Obstetrician (n = 182) 5-minute Apgar score < 7: 4 (1.8%) vs. 3 (1.8%) vs. 4 (2.2%) Resuscitation: 1 (0.4%) vs. 0 (0%) vs. 0 (0%) Birth weight M (SD): 3,365 (543) vs. 3,401 (575) vs. 3210 (555)	NR (included only nulliparous)

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
		2500 to 3999 gram: 195 (86.3%) vs. 135 (80.4%) vs. 155 (85.2%) (reference) <2500 grams: 11 (4.9%) vs. 10 (6.0%) vs. 15 (8.2) Midwife at Home vs. Midwife at Hospital: aOR 0.68, 95% CI 0.16 to 2.84 Midwife at Home vs. Obstetrician at Hospital: aOR 0.83, 95% CI 0.22 to 3.12 ≥4000 grams: 20 (8.8) 23 (13.7) 12 (6.6) Midwife at Home vs. Midwife at Hospital: aOR 0.69, CI 0.32 to 1.52 Midwife at Home vs. Obstetrician at Hospital: aOR 1.02, 95% CI 0.44 to 2.40 Adjusted for maternal age, method of conception, first pregnancy (previous miscarriage or ectopic pregnancy), gestational age at birth, medical indications pregnancy	

Table F4. Outcome Data from Comparative Studies: Maternal Morbidity

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
U.S. Studies			
Snowden, et al., 2015 Oregon, U.S. State vital statistics January 2012 to December 2013 Good quality	Absolute difference in risk percentage points Maternal ICU admission: −0.04, 95% CI −0.18 to 0.10, p = 0.58 Maternal blood transfusion: 0.27, 95% CI 0.08 to 0.46, p = 0.006 Severe perineal lacerations: −0.54, 95% CI −0.98 to −0.11, p = 0.02 Propensity score adjusted result	NR	NR
Thornton et al., 2017 U.S. Uniform Data Set from American Association of Birth Centers at 79 U.S. birth centers in 43 states 2006 to 2011 Poor quality	Planned Birth Center (n = 8,776) vs. Planned Hospital (n = 2,527) Postpartum hemorrhage: 542 (6.18%) vs. 117 (4.63%), aOR 1.25, 95% CI 0.99 to 1.58, p = NR Propensity score adjustment with a covariate considering maternal age, parity, race, payment method, cohabitation status, trimester prenatal care began, gestational age at birth, newborn weight	NR	NR
Non-U.S. Studies			

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
Birthplace in England Collaborative, 2011 United Kingdom Birthplace April 2008 to April 2010 Good quality	Planned Home (n = 16,800) vs. Planned Hospital (n = 19,638) Third or fourth degree perineal: 318 (1.9%) vs. 625 (3.2%), aOR 0.77, 95% CI 0.57 to 1.05 Planned Freestanding Midwifery Unit (n = 11,262) vs. Planned Hospital (n = 19,638) Third or fourth degree perineal: 259 (2.3%) vs. 625 (3.2%), aOR 0.78, 95% CI 0.58 to 1.05 Planned Home (n = 16,687) vs. Planned Hospital (n = 19,579) Blood transfusion: 101 (0.6%) vs. 241 (1.2%), aOR 0.72, 95% CI 0.47 to 1.12 Planned Freestanding Midwifery Unit (n = 11,230) vs. Planned Hospital (n = 19,579) Blood transfusion:67 (0.5%) vs. 241 (1.2%), aOR 0.48, 95% CI 0.32 to 0.73	NR	NR
Davis et al., 2012 New Zealand New Zealand College of Midwives research database, managed by the Midwifery Maternity Provider Organisation 2006 to 2007 Fair quality	Planned Home (n = 1,830) vs. Planned Primary Unit (n = 2,877) vs. Planned Secondary Hospital (n = 7,380) vs. Planned Tertiary Hospital (n = 4,123) Blood loss > 1,000 mL Home: 19 (1.0%), aRR 0.93, 95% CI 0.49 to 1.74, p = 0.97 Primary Unit: 32 (1.1%), Reference	NR	NR

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
	Secondary Hospital: 96 (1.3%), aRR 1.07, 95% CI 0.68 to 1.69, p = 0.45 Tertiary Hospital: 67 (1.6%), aRR 1.10, 95% CI 0.67 to 1.79, p = 0.23 Adjusted for smoking, maternal age, parity, ethnicity, augmentation, length of labor, mode of birth, episiotomy, perineal trauma, newborn birthweight > 4,000 g, mode of third stage management		
Davies-Tuck et al., 2018 Australia Victorian Perinatal Data Collection 2000 to 2015 Poor quality	Low risk, Planned Home (n = 3,202) vs. Planned Hospital (n = 701,058) Postpartum hemorrhage: 291 (9.1%) vs. 90,603 (12.9%), p < 0.001 Mother admitted to HDU/ICU: 6 (0.2%) vs. 4,217 (0.6%), p = 0.002 3rd/4th degree tear, 31 (1.0%) vs. 14,000 (2.0%), p < 0.001	NR	NR
de Jonge, et al., 2013 The Netherlands LEMMoN study merged with Netherlands Perinatal Registry August 2004 to August 2006 Fair quality	Planned Home (n = 92,333) vs. Planned Hospital (n = 54, 419) Severe acute maternal morbidity: 141 (1.5%) vs. 147 (2.7%) Admission to intensive care unit: 32 (0.3%) vs. 38 (0.7%) Blood transfusion ≥4 packed cells: 134 (1.5%) vs. 122 (2.2%) Postpartum hemorrhage (>1,000 mL): 2,699 (29.2%) vs. 2172 (39.9%)	Planned Home (n = 38,728) vs. Planned Hospital (n = 26,499) Severe acute maternal morbidity: 89 (0.23%) vs. 82 (0.31%), aOR 0.77, 95% CI 0.56 to 1.06, RRR 25.7%, 95% CI −0.1% to 53.5% Blood transfusion ≥4 packed cells: 85 (0.22%) vs. 68 (0.26%), aOR 0.90, 95% CI 0.65 to 1.27, RRR 14.5%, 95% CI −14.7% to 45.8%	Planned Home (n = 53,602) vs. Planned Hospital (n = 27,919) Severe acute maternal morbidity: 52 (0.10%) vs. 65 (0.23%), aOR 0.43, 95% CI 0.29 to 0.63, RRR 58.3%, 95% CI 33.2% to 87.5% Blood transfusion ≥4 packed cells: 49 (0.09%) vs. 54 (0.19%), aOR 0.45, 0.30 to 0.68, RRR 52.7, 95% CI 24.9 to 85.3 Postpartum hemorrhage: 1,044 (1.96%) vs. 1,038 (3.76%), aOR 0.50,

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
	Manual removal of placenta: 1,550 (16.8%) vs. 1315 (24.2%) No statistical analysis reported.	Postpartum hemorrhage: 1,655 (4.31%) 1,134 (4.33%), aOR 0.92, 95% CI 0.85 to 1.00, RRR 0.5%, 95% CI −6.8% to 7.9% Manual removal of placenta: 1,099 (2.90%) vs. 773 (2.98%), aOR 0.91, 95% CI 0.83 to 1.00, RRR 2.8%, 95% CI −6.1% to 11.8% Severe acute maternal morbidity includes admission to ICU, eclampsia/HELLP, blood transfusion of 4 or more packed calls, or other serious event Adjusted for parity, gestational age, maternal age, ethnicity, socioeconomic position	95% CI 0.46 to 0.55, RRR 47.9%, 95% CI 41.2% to 54.7% Manual removal of placenta: 451 (0.85%) vs. 542 (1.96%), aOR 0.41, 95% CI 0.36 to 0.47, RRR 56.9%, 95% CI 47.9% to 66.3% Severe acute maternal morbidity includes admission to ICU, eclampsia, blood transfusion of 4 or more packed cells, or other serious event Adjusted for parity, gestational age, maternal age, ethnicity, socioeconomic position
Grigg et al., 2017 New Zealand Maternity and Midwifery Provider Organization data 2010 to 2011 Poor quality	Planned Birthing Center (n = 407) vs. Planned Hospital (n = 285) Postpartum hemorrhage >1,000 ml: 24 (5.9%) vs. 13 (4.6%), aOR 1.74, 95% CI 0.85 to 3.59, p > 0.05 Perineal trauma Third/fourth: 9 (2.2%) vs. 5 (1.8%), aOR 1.43, 95% CI 0.46 to 4.42, p > 0.05 Adjusted for maternal age, smoking status, parity, term, augmentation, induction	NR	NR

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
Halfdansdottir et al., 2018 Iceland Maternity notes review 2005 to 2009 Poor quality	No home birth contraindication Planned Home (n = 278) vs. Planned Hospital (n = 851) Postpartum hemorrhage ≥1,000 mL: 6 (2.2%) vs. 31 (3.7%) OASI: 7 (2.5%) vs. 26 (3.1%) Home birth contraindication present Planned Home (n = 29) vs. Planned Hospital (n = 70) Postpartum hemorrhage ≥1,000 mL: 3 (10.7%) vs. 3 (4.3%) OASI: 1 (3.4%) vs. 2 (2.9%)	NR	NR
Halfdansdottir et al., 2015 Iceland Review of midwives' and doctors' original hand-written maternity notes 2005 to 2009 Poor quality	Planned Home (n = 307) vs. Planned Hospital or Midwifery Alongside Unit (n = 921) Maternal blood transfusion: 1 (0.3) vs. 19 (2.1%), aOR 0.91, 95% Ci 0.41 to 2.05 OASI: 8 (2.6%) vs. 28 (3.0%), aOR 0.97, 95% CI 0.41 to 2.27 Adjusted for maternal age, gestational age, presentation, water birth, birth weight, gender	Planned Home (n = 64) vs. Planned Hospital or Midwifery Alongside Unit (n = 192) Postpartum hemorrhage ≥1,000 mL: 4 (6.3%) vs. 19 (2.6%); aOR 0.71, 95% CI 0.20 to 2.58 OASI: 4 (6.3%) vs. 12 (6.3%), aOR 1.37, 95% CI 0.40 to 4.63	Planned Home (n = 243) vs. Planned Hospital or Midwifery Alongside Unit (n = 729) Postpartum hemorrhage ≥1,000 mL: 5 (2.1%) vs. 19 (2.6%), aOR 1.02, 95% CI 0.34 to 3.02 OASI: 4 (1.6%) vs. 16 (2.2%), aOR 0.73, 95% CI 0.20 to 2.59
Hutton et al., 2016 Ontario, Canada Chart review March 2016 to April 2009 Poor quality	Planned Home (n = 11,493) vs. Planned Hospital (n = 11,493) 3rd or 4th degree perineal laceration: 151 (1.3%) vs. 266 (2.3%), RR 0.57, 95% CI 0.47 to 0.69	Planned Home (n = 4,027) vs. Planned Hospital (n = 4,027) 3rd or 4th degree perineal laceration: 126 (3.1%) vs. 189 (4.7%), RR 0.67, 95% CI 0.53 to 0.83	Planned Home (n = 7,466) vs. Planned Hospital (n = 7,466) 3rd or 4th degree perineal laceration: 25 (0.3%) vs. 77 (1.0%), RR 0.33, 95% CI 0.21 to 0.51

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
	Postpartum hemorrhage: 286 (2.5%) vs. 348 (3.0%), RR 0.82, 95 % CI 0.70 to 0.96	Postpartum hemorrhage: 130 (3.2%) vs. 146 (3.6%), RR 0.89, 95% CI 0.71 to 1.12	Postpartum hemorrhage: 156 (2.1%) vs. 202 (2.7%), RR 0.77, 95% CI 0.63 to 0.95
Hutton et al., 2009 Canada Ontario Ministry of Health database 2003 to 2006 Poor quality	Planned Home (n = 6,692) vs. Planned Hospital-Midwife (n = 6,692) Estimated intrapartum blood loss >1,000 mL: 56 (0.8%) vs. 82 (1.2%), RR 0.68, 95% CI 0.49 to 0.96	Planned Home (n = 2,293) vs. Planned Hospital-Midwife(n = 2,298) Estimated intrapartum blood loss >1,000 mL: 29 (1.3%) vs. 31 (1.3%)	Planned Home (n = 4,393) vs. Planned Hospital-Midwife (n = 4,394) Estimated intrapartum blood loss >1,000 mL: 27 (0.6%) vs. 51 (1.2%)
Janssen et al., 2009 British Columbia, Canada Perinatal Database Registry and vital statistics 2000 to 2004 Poor quality	Planned Home (n = 2,889) vs. Planned Hospital-Midwife (n = 4,752) vs. Matched Sample of Physician-attended Hospital Births (n = 5,331) Prolapsed cord: 2 (0.1%%) vs. 6 (0.1%%) vs. 9 (0.2%) Uterine rupture: 0 (0.0%) vs. 0 (0.0%) vs. 2 (0.04%) Postpartum hemorrhage: 110 (3.8%) vs. 285 (6.0%) vs. 357 (6.7%) Blood transfusion: 2 (0.1%) vs. 10 (0.2%) vs. 15 (0.3%) Obstetric shock: 1 (0.03%) vs. 1 (0.02%) vs. 1 (0.02%) Manual removal of placenta: 28 (1.0%) vs. 85 (1.8%) vs. 90 (1.7%) Uterine prolapse: 1 (0.03%) vs. 1 (0.02%) vs. 2 (0.04%) Puerperal fever: 1 (0.03%) vs. 4 (1.0%) vs. 7 (0.1%)	NR	NR

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
	Third- or fourth-degree perineal tear: 34 (1.2%) vs. 137 (2.9%) vs. 183 (3.4 %) Cervical tear: 2 (0.1%) vs. 5 (0.1%) vs. 4 (0.1%) Third- or fourth-degree perineal tear*: RR 0.43, 95% CI 0.29 to 0.63 Postpartum hemorrhage: RR 0.62, 95% CI 0.49 to 0.77 Infection: RR 0.39, 95% CI 0.13 to 1.14 *Adjusted for parity		
Katoaka et al., 2018 Japan Review of medical records Birth centers: 2001 to 2006, one hospital: 2004 to 2006, other hospital: 2008 Poor quality	Planned Birth Center (n = 5,379) vs. Planned Hospital (n = 4,209) Total blood loss (mL) ≥1,000: 193 (3.6%) vs. 101 (2.4%), aOR 1.77, 95% CI 1.35 to 2.32 Perineal laceration: 2,085 (40.9%) vs. 2,773 (66.1%), aOR 0.38, 95% CI 0.35 to 0.42 Adjusted for age, parity, mode of delivery and gestational weeks	NR	NR
Kennare et al., 2010 Australia Pregnancy Outcome Unit of South Australia Health perinatal data for all births and data on perinatal deaths 1991 to 2006	Planned Home vs. Planned Hospital Third or fourth degree perineal tears: 6/577 (1%) vs. 2,030/112,737 (1.8%), aOR 0.77, 95% CI 0.34 to 1.74, p = 0.53 Postpartum hemorrhage: Planned home births 50/1,136 (4.4%) vs.	NR	NR

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
Poor quality	16,200/292,469 (5.5%), aOR 0.72, 95% CI 0.47 to 1.11, p = 0.14 Adjusted for maternal age, parity, occupational status, smoking, plurality, medical and obstetric complications (e.g., antepartum hemorrhage, diabetes, hypertension), gestational age, small for gestational age, congenital anomalies, city or country hospital, mode of delivery		
Laws et al., 2014 Australia Registry of Births, Deaths, and Marriages, Midwives Data Collection, Admitted Patient Data Collection 2001 to 2009 Poor quality	Planned Birth Center (n = 14,707) vs. Planned Hospital (n = 29,414) Uterine rupture: 4 (0.03%) vs. 24 (0.08%), aOR 0.17, 95% CI 0.04 to 0.73 Third/fourth degree tears: 360 (2.5%) vs. 779 (3.0%), aOR 0.85, 95% CI 0.74 to 0.99 Postpartum hemorrhage: 1,270 (8.6%) vs. 3,128 (10.6%), aOR 0.79, 95% CI 0.73 to 0.86 Postpartum infection: 153 (1.0%) vs. 421 (1.4%), aOR 0.74, 95% CI 0.59 to 0.92 Hysterectomy: 0 (0.0%) vs. 15 (0.1%) Admitted to intensive care: 3 (0.02%) vs. 23 (0.08%), aOR 0.12, 95% CI 0.02 to 0.89	NR	NR

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
	Hospital readmission within 42 days: 691 (4.7%) vs. 1,235 (4.2%), aOR 1.08, 95% CI 0.97 to 1.21 Adjusted for maternal age, Australian/overseas-born, socioeconomic disadvantage, smoking during pregnancy, parity, preexisting medical conditions, admitted patient insurance status, obstetric complications, level of hospital, day of the week, and holidays		
Monk et al., 2014 Australia ObstetriX surveillance system of point-of-care maternity data collection across the antenatal, intrapartum, and immediate postnatal periods 2005 to 2006 Fair quality	Planned Birth Center (n = 494) vs. Planned Tertiary Maternity Unit (n = 3,157) Blood loss (mL) >1,000: 18 (3.6%) vs. 139 (4.4%), aOR 0.88, 95% CI 0.52 to 1.47, p = 0.618 3rd/4th degree tear: 24 (4.9%) vs. 132 (4.2%), aOR 0.90, 95% CI 0.56 to 1.45, p = 0.671 Adjusted for maternal age, smoking status, parity, augmentation, induction, previous cesarean delivery and risk at the onset of labor	NR	NR
Nove et al., 2012 United Kingdom St Mary's Maternity Information System	Planned Home (n = 5,998) vs. Planned Hospital (n = 267,874)	NR	NR

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
1988 to 2000 Fair quality	Postpartum hemorrhage: 23 (0.38%) vs. 2,785 (1.04%), aOR 0.4, 95% CI 0.3 to 0.6, p < 0.001 Adjusted for macrosomia, previous baby with birthweight > 4,500 g, BMI, borderline anemia, parity, mother's age, ethnicity, birthweight, sex of baby, year of delivery, number of ultrasounds, hospital providing care, time of delivery		
Øian et al., 2018 Norway Medical Birth Registry with supplementary data collection January 2008 to December 2010 Poor quality	Births in Midwife-Led Birth Centers, Planned (n = 2,298) vs. Births Planned for a Midwife-led Birth Unit, Took Place Elsewhere (n = 220) vs. Births in Hospital, Low Risk (n = 105,358) Sphincter Injury, Grade 3/4: 13 (.8%) vs. 2 (1.1%) vs. 2,410 (2.3%) Hemorrhage > 500 mL 500 to 1,500 mL: 58 (3.7%) vs. 15 (8.4%) vs. 12,378 (11.7%) > 1,500 mL, Transfusion: 10 (.6%) vs. 5 (2.8%) vs. 1,604 (1.5%) > 500 mL, No Further Details: 15 (1.0%) vs. 5 (2.8%) vs. 264 (.3%)	NR	NR
Schroeder et al., 2017 England Interviews and medical records from Barkantine Birth Centre and Royal	Planned Birth Center (n = 167) vs. Planned Hospital (n = 164) Mean Days in ICU: 0.00 ± 0.0 vs. 1.00 ± 0.0, p = NR	NR	NR

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
London Hospital's obstetric unit in Tower Hamlets, a low-income borough in east London 2008 to 2009 Poor quality			
Wiegerinck et al., 2015 The Netherlands Netherlands Perinatal Register with additionally retrieved data from hospitals and midwife practices 2005 to 2008 Poor quality	Planned Home (n = 26,128) vs. Planned Hospital (n = 21,362) Postpartum hemorrhage: 928 (4%) vs. 1,096 (5%), OR 0.68, 95% CI 0.62 to 0.74, p < 0.001	NR	NR
Non-US, by parity only			
Bailey, 2017 New Zealand Routinely collected maternity outcome data compiled from Counties-Manukau District Health Board (CMDHB) maternity facilities 2003 to 2010 Poor quality	NR	Planned Birthing Center vs. Planned Hospital 2005 to 2010 data Blood transfusion: 24/2,710 (0.9%) vs. 219/9,260 (2.4%), aOR 0.40, 95% CI 0.25 to 0.62 Adjusted for maternal age, ethnicity, deprivation score	Planned Birth Center vs. Planned Hospital 2005 to 2010 data Blood transfusion: 0.4% vs. 1.0%, aOR 0.54, 95% CI 0.35 to 0.83 Adjusted for maternal age, ethnicity, and deprivation score
Bolten et al., 2016 The Netherlands	NR	Planned Home (n = 868) vs. Planned Hospital (n = 717)	Planned Home (n = 1,182) vs. Planned Hospital (n = 728)

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
DELIVER (Data EersteLIjns VERloskunde) Study 2009 to 2010 Poor quality		Anal sphincter damage (third-or fourth degree): 45 (5.3%) vs. 23 (3.2%), aOR 1.75, 95% CI 1.01 to 3.03 Hemorrhage postpartum >1,000 ml: 65 (7.7%) vs. 46 (6.5%), aOR 1.03, 95% CI 0.67 to 1.59 Adjusted for maternal age, gestational age, ethnic background (Dutch/western background/non-western background), BMI, socio-economic position	Anal sphincter damage (third-or fourth degree): 17 (1.4%) vs. 14 (1.9%), aOR 0.73, 95% CI 0.34 to 1.58 Hemorrhage postpartum >1,000 ml: 28 (2.4%) vs. 24 (3.3%), aOR 0.68, 95% CI 0.38 to 1.23 Adjusted for maternal age, gestational age, ethnic background (Dutch/western background/non-western background), BMI, socio-economic position
Christensen & Overgaard, 2017 Denmark Data collected on sociodemographic characteristics, present and previous pregnancies and births, neonatal outcomes and transfers March 2004 to October 2008 Poor quality	NR	Planned Birth Center (n = 215) vs. Planned Obstetric Unit (n = 215) 3rd-4th degree tear: OR 0.9, 95% CI 0.4 to 2.0 Maternal readmission: OR 0.3, 95% CI 0.1 to 0.9	Planned Birth Center (n = 624) vs. Planned Obstetric Unit (n = 624) 3rd-4th degree tear: OR 0.6, 95% CI 0.2 to 1.7 Maternal readmission: OR 0.4, 95% CI 0.1 to 1.3
Hollowell et al., 2017 England Birthplace in England national prospective cohort study April 2008 to April 2010	NR	Planned Birthing Center (n = 5,187) vs. Planned Hospital (n = 8.,350) Third or fourth degree perineal trauma: 4.0% vs. 4.9%, aOR 0.82, 99% CI 0.59 to 1.15, p = 0.13	Planned Birthing Center (n = 6,078) vs. Planned Hospital n = 8,323) Third or fourth degree perineal trauma: 0.9% vs. 1.6%, aOR 0.60, 99% CI 0.36 to 1.00, p = 0.010

Citation, Location, Data Source, Dates	Combined Parity	Nulliparous	Multiparous
Fair quality		Blood transfusion: 0.8% vs. 1.3%, aOR 0.71, 99% CI 0.44 to 1.14, p = 0.063 Maternal admission for higher level care: 0.2% vs. 1.0%, aOR 0.28, 99% CI 0.07 to 1.20, p = 0.025 Adjusted for maternal characteristics and complicating conditions identified at the start of care in labor	Blood transfusion: 0.3% vs. 0.6%, aOR 0.56, 99% CI 0.26 to 1.21, p = 0.052 Maternal admission for higher level care: 0.1% vs. 0.4%, aOR 0.30, 99% CI 0.07 to 1.10, p = 0.016 Adjusted for maternal characteristics and complicating conditions identified at the start of care in labor
van Haaren-ten Haken et al., 2015 The Netherlands Self-reported questionnaires, medical records, and birth registration forms 2007 to 2011 Poor quality	NR	Planned Home (n = 221) vs. Planned Hospital-Midwife (n = 160) vs. Planned Hospital-Obstetrician (n = 176) Postpartum hemorrhage ≥1000: 13 (5.9%) vs. 10 (6.3%) vs. 19 (10.8%), aOR 0.70, 95% CI 0.30 to 1.63 Adjusted for maternal age, method of conception, first pregnancy (previous miscarriage or ectopic pregnancy), gestational age at birth, medical indications pregnancy	Included nulliparous only

Table F5. Outcome Data from Comparative Studies: Breastfeeding

Citation, Location, Data Source, Dates , Quality Assessment	Combined Parity	Nulliparous	Multiparous
U.S. Studies			
MacDorman & Declercq, 2016 United States Birth certificates in 47 states and DC 2004 to 2014 Poor quality	Planned Home (n = 29,021) vs. Planned Birthing Center (n = 18,047) vs. Planned Hospital (n = 3,773,115) Breastfeeding initiation: 97.9% vs. 98.1% vs. 80.8% Excludes births in California and Michigan that did not report breastfeeding	NR	NR
Thornton et al., 2017 U.S. Uniform Data Set from American Association of Birth Centers at 79 US birth centers in 43 states 2006 to 2011 Poor quality	Planned Birth Center (n = 8,776) vs. Planned Hospital (n = 2,527) Breastfeeding at discharge: 8,294 (94.51%) vs. 1,839 (72.77%), aOR 9.12, 95% CI 7.45 to 11.16, p = NR Propensity score adjustment with a covariate considering maternal age, parity, race, payment method, cohabitation status, trimester prenatal care began, gestational age at birth, and newborn weight	NR	NR
Non-U.S. Studies			
de Cock et al., 2015 The Netherlands Survey data, DELIVER study	Planned Home (n = 547) vs. Planned Hospital-Midwife (n = 165)	NR	NR

Citation, Location, Data Source, Dates , Quality Assessment	Combined Parity	Nulliparous	Multiparous
September 2009 to April 2011 Poor quality	Exclusive breastfeeding at median 5 weeks postpartum: 410 (75.0%) vs. 113 (68.5%), aOR 0.79, 95% CI 0.53 to 1.19 Adjusted for parity, age, education level, education level partner, ethnicity, smoking, birth weight aOR 0.80, 95% CI 0.53 to 1.18 Adjusted for characteristics listed above and early opportunity to breastfeed, early skin-to-skin contact, postnatal breastfeeding consult		
Grigg et al., 2017 New Zealand Maternity and Midwifery Provider Organization data 2010 to 2011 Poor quality	Planned Birthing Center (n = 407) vs. Planned Hospital (n = 285) Exclusive or fully at 6 weeks: 328 (80.6%) 224 (78.6%), aOR 1.14, 95% CI 0.76 to 1.70, p > 0.05 Adjusted for maternal age, smoking status, parity, augmentation, induction, term	NR	NR
Hutton et al., 2016 Ontario, Canada Chart review March 2016 to April 2009 Poor quality	Planned Home (n = 11,493) vs. Planned Hospital (n = 11,493) At 10 days: 9,566 (87.8%) vs. 8,459 (78.9%), RR 1.11, 95% CI 1.10 to 1.13	Planned Home (n = 4,027) vs. Planned Hospital (n = 4,027) At 10 days: 3,220 (84.8%) vs. 2,825 (74.9%), RR 1.13, 95% CI 1.11 to 1.16	Planned Home (n = 7,466) vs. Planned Hospital (n = 7,466) At 10 days: 6,346 (89.6%) vs. 5,634 (81.2%), RR 1.10, 95% CI 1.09 to 1.12
Hutton et al., 2009 Canada	Planned Home (n = 6,692) vs. Planned Hospital-Midwife (n = 6,692) Infant feeding at 6 weeks	Planned Home (n = 2,293) vs. Planned Hospital-Midwife (n = 2,298)	Planned Home (n = 4,393) vs. Planned Hospital-Midwife (n = 4,394)

Citation, Location, Data Source, Dates , Quality Assessment	Combined Parity	Nulliparous	Multiparous
Ontario Ministry of Health database 2003 to 2006 Poor quality	Exclusively breastfed: 5,853 (87.5%) vs. 5,140 (76.8%)	Infant feeding at 6 weeks exclusively breastfed: 1,962 (89.1%) vs. 1,680 (76.7%)	Infant feeding at 6 weeks exclusively breastfed: 3,887 (91.1%) vs. 3,460 (82.2%)
Laws et al., 2014 Australia Registry of Births, Deaths, and Marriages, Midwives Data Collection, Admitted Patient Data Collection 2001 to 2009 Poor quality	Planned Birth Center (n = 14,707) vs. Planned Hospital (n = 29,414) Breastfeeding on discharge: 4,951 (93.7%) vs. 9,129 (86.4%), aOR 2.32, 95% CI 2.04 to 2.65 Adjusted for maternal age, Australian/overseas-born, socioeconomic disadvantage, smoking during pregnancy, parity, preexisting medical conditions, admitted patient insurance status, obstetric complications, level of hospital, day of the week, and "holidays."	NR	NR
Monk et al., 2014 Australia ObstetriX surveillance system of point-of-care maternity data collection across the antenatal, intrapartum, and immediate postnatal periods 2005 to 2006 Fair quality	Planned Birth Center (n = 494) vs. Planned Tertiary Maternity Unit (n = 3,157) Exclusive on discharge: 447 (91.22%) vs. 2,586 (82.23%), aOR 1.59, 95% CI 1.14 to 2.24, p = 0.007	NR	NR

Citation, Location, Data Source, Dates , Quality Assessment	Combined Parity	Nulliparous	Multiparous
Quigley et al., 2016 Ireland and United Kingdom Growing Up in Ireland study, 2008 to 2009 United Kingdom Millennium Cohort Study, 2001 to 2002 Fair quality	Ireland Planned Home (n = 157) vs. Planned Hospital (n = 10,447) EBF at 6 months: 35 (22%) vs. 928 (9%), aOR 2.77, 95% CI 1.78 to 4.33, p = 0.007 United Kingdom Planned Home (n = 340) vs. Planned Hospital (n = 17,181) EBF at 6 months: 13 (4%) vs. 213 (1%), aOR 2.24, 95% CI 1.14 to 4.03, p < 0.001	NR	NR

Appendix G. Outcome Data by Subgroups for Comparative Observational Studies

Table G1. Outcome Data by Maternal Age

Cite, Location, Data source, Dates, Quality Assessment	Findings
Grunebaum, McCullough, Arabin et al., 2017 U.S. CDC linked birth-infant death data set 2008 to 2012 Poor quality	Planned home vs. Planned Hospital-Midwife vs. Planned Hospital-Physician Neonatal mortality (birth to 27 days) <35 years 92/74,850 (0.123%) vs. 429/1,216,860 (0.035%) vs. 7,527/12,359,811 (0.061%) Planned home vs. Planned Hospital-Midwife: RR 3.49, 95% CI 2.8 to 4.4 ≥ 35 years 30/20,807 (0.144%) vs. 51/146,339 (0.035%) vs. 1168/2,087,544 (0.056%) Planned home vs. Planned hospital-Midwife: RR 4.1, 95% CI 2.6 to 6.5
Grunebaum, McCullough, Sapra et al., 2017 U.S. CDC linked birth-infant death files 2009 to 2013 Fair quality	Planned Home Birth vs. Hospital-Midwife Neonatal deaths <35: 90/76,703 (0.12%) vs. 302/958,141 (0.03%), SMR 3.72, 95% CI 2.95 to 4.50 ≥ 35: 27/20,106 (0.13%) vs. 32/119,030 (0.03%), SMR 5.11, 95% CI 3.19 to 7.03
Li et al., 2014 United Kingdom Birthplace April 2008 to April 2010 Good quality	Maternal composite outcome per 5- year increase in maternal age Non-Obstetric Unit: aRR 1.21, 95% CI 1.18 to 1.25 Obstetric Unit: aRR 1.12, 95% CI 1.10 to 1.15 Adjusted for ethnic group, understanding of English, marital/partner status, BMI in pregnancy, index of multiple deprivation score quintile, gestation at delivery Intrapartum cesarean section per 5 year increase in maternal age, controlling for birth setting Nulliparous: aRR 1.27, 95% CI 1.23 to 1.32 Multiparous: aRR 1.16, 95% CI 1.06 to 1.28 Instrument delivery by 5 year increase in maternal age, controlling for birth setting Nulliparous: aRR 1.18, 95% CI 1.12 to 1.25

Cite, Location, Data source, Dates, Quality Assessment	Findings
	Multiparous: aRR 1.15, 95% CI 1.05 to 1.27 Third/fourth degree perineal tear, controlling for birth setting Nulliparous: aRR 1.12, 95% CI 1.02 to 1.23 Multiparous: aRR 1.01, 95% CI 0.89 to 1.15 Maternal blood transfusion, controlling for birth setting Nulliparous: aRR 1.13, 95% CI 0.95 to 1.34 Multiparous: aRR 1.24, 95% CI 0.94 to 1.62 Adjusted for ethnic group, understanding of English, marital/partner status, BMI in pregnancy, index of multiple deprivation score quintile, gestation at delivery and planned place of birth (Obstetric Unit vs. Alongside Midwifery Unit vs. Freestanding Midwifery Unit vs. home) Maternal composite outcome by age in nulliparous women, non-Obstetric Unit vs. Obstetric Unit 16 to 19: 252/1553 (17.5%) vs. 480/1239 (39.4%), aRR 0.45, 95% CI 0.38 to 0.54 20 to 24: 886/3679 (24.2%) vs. 1229/2577 (47.9%), aRR 0.51, 95% CI 0.45 to 0.58 25 to 29: 1680/5354 (32.3%) vs. 1670/3003 (55.6%), aRR 0.59, 95% CI 0.54 to 0.65 30 to 34: 1730/4897 (36.6%) vs. 1402/2322 (61.1%), aRR 0.61, 95% CI 0.56 to 0.67 35 to 39: 792/1995 (39.9%) vs. 622/957 (65.5%), aRR 0.62, 95% CI 0.56 to 0.69 40+: 83/196 4(4.8%) vs. 108/148 (71.9%), aRR 0.66, 95% CI 0.51 to 0.87 Adjusted for ethnic group, understanding of English, marital/partner status, BMI in pregnancy, index of multiple deprivation score quintile, gestation at delivery Maternal composite outcome by age in nulliparous women, also adjusted for complicating conditions at start of labor 16 to 19: aRR 0.49, 95% CI 0.42 to 0.58 20 to 24: aRR 0.55, 95% CI 0.49 to 0.62 25 to 29: aRR 0.63, 95% CI 0.57 to 0.70 30 to 34: aRR 0.66, 95% CI 0.60 to 0.73 35 to 39: aRR 0.68, 95% CI 0.61 to 0.76 40+: aRR 0.70, 95% CI 0.53 to 0.93

Cite, Location, Data source, Dates, Quality Assessment	Findings
	Adjusted for ethnic group, understanding of English, marital/partner status, BMI in pregnancy, index of multiple deprivation score quintile, gestation at delivery, complicating conditions identified at the start of care in labor Maternal composite: augmentation, instrument delivery, intrapartum cesarean delivery, general anesthesia, blood transfusion, 3rd or 4th degree tear, or admission to higher level of care Perinatal composite outcome, nulliparous women, controlling for place of birth 40+ vs. 25 to 29 years: aRR 2.29, 95% CI 1.28 to 4.09 Perinatal composite outcome, multiparous women, controlling for place of birth 40+ vs. 25 to 29 years: aRR 1.21, 95% CI 0.60 to 2.43 Adjusted for ethnic group, understanding of English, marital/partner status, BMI in pregnancy, index of multiple deprivation score quintile, gestation at delivery, and planned place of birth (Obstetric Unit vs. Alongside Midwifery Unit vs. Freestanding Midwifery Unit vs. home) Perinatal composite: stillbirth after start of care in labor, early neonatal death, neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured humerus or clavicle, neonatal unit admission within 48 hours of birth for at least 48 hours

Table G2. Outcome Data by Gestational Age

Cite, Location, Data source, Dates, Quality Assessment	Findings
Grunebaum, McCullough, Arabin et al., 2017 U.S. CDC linked birth-infant death data set 2008 to 2012 Poor quality	Planned home vs. Planned Hospital-Midwife vs. Planned Hospital-Physician Neonatal mortality (birth to 27 days): ≥ 37 to < 41 weeks: 77/67,832 (0.114%) vs. 378/1,083,665 (0.035%) vs. 7,487/12,194,578 (0.061%), Planned home vs. Planned Hospital-Midwife: RR 3.25, 95% CI 2.6 to 4.2 ≥ 41 weeks: 45/27,825 (0.162%) vs. 102/279,534 (0.037%) vs. 1,208/2,252,777 (0.054%), Planned home vs. Planned Hospital-Midwife: RR 4.43, 95% CI 3.1 to 6.3
Grunebaum, McCullough, Sapra et al., 2017 U.S. CDC linked birth-infant death data set 2009 to 2013 Fair quality	Planned home vs. Planned Hospital-Midwife Neonatal mortality (birth to 27 days) ≥ 37 to < 41 weeks 0.0994% vs. 0.0295%, SMR 3.37, 95% CI 2.57 to 4.17 ≥41 weeks 0.1717% vs. 0.0359%, SMR 4.78, 95% CI 3.43 to 6.12

Table G3. Outcome Data by Race/Ethnicity

Cite, Location, Data source, Dates, Quality Assessment	Findings
Grunebaum, McCullough, Arabin et al., 2017 U.S. CDC linked birth-infant death data set 2008 to 2012 Poor quality	Planned home vs. Planned Hospital-Midwife vs. Planned Hospital-Physician Neonatal Mortality (birth to 27 days) White non-Hispanic: 112/84,759 (0.132%) vs. 260/728,918 (0.036%) vs. 4,663/7,779,467 (0.06%), Planned home vs. Planned Hospital-Midwife: RR 3.71, 95% CI 3 to 4.6 Others: 10/10,898 (0.918%) vs. 220/634,281 (0.035%) vs. 4,032/6,667,888 (0.061%), Planned home vs. Planned Hospital-Midwife: RR 2.65, 95% CI 1.4 to 5

Table G4. Outcome Data by Composite Risk Scores

Cite, Location, Data source, Dates, Quality Assessment	Findings
Birthplace in England Collaborative, 2011 United Kingdom Birthplace April 2008 to April 2010 Good quality	Without complicating condition at start of labor Nulliparous women Planned Home (n = 4,063) vs. Planned Hospital (n = 8,018) Birthplace composite: 36 (9.5%) vs. 28 (3.5%), aOR 2.80, 95% CI 1.59 to 4.92 Planned Freestanding Midwifery Unit (n = 4,785) vs. Planned Hospital (n = 8,018) Birthplace composite: 22 (4.5%) vs. 28 (3.5%), aOR 1.40, 95% CI 0.74 to 2.65 Multiparous women Planned Home (n = 11,461) vs. Planned Hospital (7,637) Birthplace composite:26 (2.0%) vs. 20 (2.6%), aOR 0.83, 95% CI 0.44 to 1.58 Planned Freestanding Midwifery Unit (n = 5,772) vs. Planned Hospital (7,637) Birthplace composite: 13 (2.2%) vs. 20 (2.6%), aOR 0.97, 95% CI 0.46 to 2.04 Adjusted for maternal age, ethnic group, understanding of English, marital or partner status, body mass index, deprivation score quintile, previous pregnancies, weeks of gestation Test for statistical interaction between planned place of birth and parity. P values for parity adjusted regression tests of heterogeneity: overall 0.03, pairwise (vs. obstetric unit) for home 0.006, freestanding midwifery unit 0.47, and alongside midwifery unit 0.66. All women without complicating condition at start of labor (n = 55,849) Planned Home (n = 15,675) vs. Planned Hospital (n = 15,689) Normal births: 13,902 (89.0%) vs. 9840 (62.2%), aOR 4.12, 95% CI 3.37 to 5.04 Planned Freestanding Midwifery Unit (n = 10,620) vs. Planned Hospital (n = 15,689) Normal births: 8892 (84.1%) vs. 9849 (62.2%), aOR 3.42, 95% CI 2.74 to 4.27

Cite, Location, Data source, Dates, Quality Assessment	Findings
	Normal birth: birth without induction of labor, epidural or spinal analgesia, general anesthesia, forceps or ventouse delivery, cesarean section, or episiotomy
Davies-Tuck et al., 2018 Australia Victorian Perinatal Data Collection 2000 to 2015 Poor quality	High risk, Planned Home (n = 755) vs. Planned Hospital (n = 131,726) Unplanned cesarean: 66 (8.9%) vs. 41,530 (32.4%) < 0.001 Instrumental delivery: 34 (46%) vs. 18,407 (14.4%) < 0.001 Spontaneous vaginal: 640 (86.1%) vs. 68,219 (53.2%) < 0.001 Admission to special care nursery: 33 (4.4%) vs. 17,995 (13.7%), p < 0.001 NICU admission: 12 (1.6%) vs. 555 (0.4%), p < 0.001 5-minute Apgar < 7: 18 (2.4%) vs. 2,390 (1.8%), p = 0.24 HIE: 1 (0.13%) vs. 42 (0.03%), p = 0.13 Birth trauma: 23 (3.1%) vs. 10,056 (7.6%), p < 0.001 Intrauterine hypoxia: 24 (3.2%) vs. 8,714 (6.6%), p < 0.001 Other perinatal morbidity: 3 (0.4%) vs. 287 (0.2%), p = 0.29 Composite morbidity: 59 (7.8%) vs. 22,223 (16.9%), p < 0.001 Postpartum hemorrhage: 108 (14.5%) vs. 25,079 (19.6%), p < 0.001 Mother admitted to high dependency or intensive care unit: 4 (0.5%) vs. 1,459 (1.1%), p = 0.06 3rd/4th degree tear: 12 (1.6%) vs. 2,443 (1.9%), p = 0.58 High risk defined as any of the following: multiple pregnancy, post-term (> 41 and 6 weeks), non-cephalic presentation in labor, obesity (BMI Class 2 or greater), a prior cesarean, previous uterine surgery, grand multiparity (≥5 previous births), any significant maternal medical condition such as pre-existing diabetes, hypertension, renal, cardiac, liver, respiratory, endocrine, immunological, renal, or gastrointestinal disease as determined by individual ICD-10 codes. Birth trauma: brachial plexus injury, fractured clavicle or humerus Other perinatal morbidity: meconium aspiration syndrome, congenital pneumonia or respiratory distress syndrome
Homer et al., 2014 Australia Perinatal Data Collection, Admitted Patient Data Collection,	Planned Home vs. Planned Birth Center vs. Planned Hospital Women without complications at the start of care in labor Stillbirth during labor and early neonatal death: 0/688 (0%) vs. 8/13,718 (0.058%) vs. 198/221,056 (0.089%)

Cite, Location, Data source, Dates, Quality Assessment	Findings
Register of Congenital Conditions, Registry of Birth Deaths and Marriages, and the Australian Bureau of Statistics 2000 to 2008 Fair quality	Birth center vs. Hospital: aOR 0.63, 95% CI 0.31 to 1.28 Composite morbidity or mortality: 4/695 (0.58%) vs. 66/13,723 (0.48%) vs. 1,221/221,193 (0.552%) Home vs. Hospital: aOR 0.87, 95% CI 0.33 to 2.35 Birth center vs. Hospital: aOR 0.82, 95% CI 0.64 to 1.05 Composite: stillbirth, early neonatal death (<7 days), neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured clavicle, fractured humerus Adjusted for maternal age, gestational age in weeks at delivery, parity
Li et al., 2015 United Kingdom Birthplace national prospective cohort study April 2008 to April 2010 Good quality	Higher risk without complicating factor at start of labor Nulliparous - Planned Home (n = 247) vs. Planned Hospital (n = 1,523) Straightforward vaginal birth: 180 (75.9%) vs. 906 (59.0%), aRR 1.43, 95% CI 1.29 to 1.58 Interventions and adverse maternal outcomes: 85 (31.4%) vs. 841 (56.6%), aRR 0.50, 95% CI 0.40 to 0.63 Nulliparous- Planned Home (n = 248) vs. Planned Hospital (n = 1,528) Adverse perinatal outcomes (main composite): 6 (21.1%) vs. 64 (44.7%), aRR 0.43, 95% CI 0.16 to 1.16 Multiparous- Planned Home (n = 1,065) vs. Planned hospital (n = 3,181) Straightforward vaginal birth: 992. (93.4%) vs. 2,484 (77.7%), aRR 1.17, 95% CI 1.13 to 1.20 Interventions and adverse maternal outcomes: 86 (7.9%) vs. 969 (30.7%), aRR 0.26, 95% CI 0.21 to 0.34 Multiparous- Planned Home (n = 1,062) vs. Planned Hospital (n = 3,183) Adverse perinatal outcomes (main composite): 12 (10.5) vs. 75 (24.6%), aRR 0.41, 95% CI 0.18 to 0.89 Straightforward: birth without intrapartum CS, instrumental delivery, 3rd or 4th degree tear, blood transfusion. Adverse perinatal outcomes (main composite): stillbirth after the start of care in labor, early neonatal death, neonatal encephalopathy, meconium aspiration syndrome, brachial plexus

Cite, Location, Data source, Dates, Quality Assessment	Findings
	injury, fractured humerus or clavicle) or admission to a neonatal unit within 48 hours of birth for more than 48 hours. Adverse maternal outcomes: augmentation, instrumental delivery, intrapartum CS, general anesthesia, maternal blood transfusion, 3rd/4th degree perineal tear, maternal admission for higher level care

Table G5. Outcome Data by TOLAC

Cite, Location, Data source, Dates, Quality Assessment	Findings
Grunebaum, McCullough, Sapra et al., 2017 U.S. CDC linked birth-infant death files 2009 to 2013 Fair quality	Planned Home Birth vs. Hospital-Midwife Previous cesarean delivery No: SMR 3.72, 95% CI 3.01 to 4.43 Yes: SMR 8.33, 95% CI 2.59 to 14.07
Rowe et al., 2016 England Birthplace in England national prospective cohort study April 2008 to April 2010 Good quality	Planned Home vs. Planned Hospital Study inclusion criteria of prior cesarean delivery Any vaginal birth: 182/209 (87.6%) vs. 853/1227 (69.1%), aRR 1.15, 95% CI 1.06 to 1.24 Any vaginal birth includes, spontaneous vertex birth, spontaneous breech birth, assisted by vacuum or forceps. Adjusted for maternal age, ethnic group, understanding of English, marital/partner status, BMI in pregnancy, index of multiple deprivation score quintile, gestation at delivery, parity where appropriate, complicating conditions identified at the start of care in labor Unadjusted analyses Stillbirth OR Apgar < 7 at 5 minutes: 4/206 (1.87%) vs. 20/1225 (1.57%), RR 1.19, 95% CI 0.41 to 3.44 Neonatal unit admission: 8/205 (3.71%) vs. 40/1223 (3.04%), RR 1.22, 95% CI 0.57 to 2.59 Maternal blood transfusion or maternal admission for higher level care: 7/209 (2.99%) vs. 36/1218 (2.85%), RR 1.05, 95% CI 0.49 to 2.26
Tilden et al., 2017 U.S. Birth and death certificates 2007 to 2010 Fair quality	TOLAC: Planned Home and Freestanding Birth Center (n = 3,147) vs. Planned Hospital (n = 106,823) Neonatal death: 4 (0.13%) vs. 84 (0.08%), aOR 2.10, 95% CI 0.73 to 6.05, p > 0.05 Apgar score < 7: 139 (4.42%) vs. 2859 (2.68%), aOR 1.62, 95% CI 1.35 to 1.96, p < 0.001 Apgar score < 4: 23 (0.73%) vs. 431 (0.40%), aOR 1.77, 95% CI 1.12 to 2.79, p = 0.016 Neonatal seizures: 6 (0.19%) vs. 23 (0.02%), aOR 8.53, 95% CI 2.87 to 25.4, p = 0.003

Cite, Location, Data source, Dates, Quality Assessment	Findings
	Ventilator support: 12 (0.38%) vs. 309 (0.29%), aOR 1.36, 95% CI 0.75 to 2.46, p = 0.31 NICU: 35 (1.11%) vs. 3,292 (3.10%), aOR 0.40, 95% CI 0.29 to 0.57, p < 0.001 Birth injury: 1 (0.03%) vs. 109 (0.10%), aOR 0.78, 95% CI 0.58 to 1.04, p = 0.089 Adjusted for maternal race, maternal age, maternal education (high school education as referent), Kotelchuck Index (adequate plus as referent), parity, number of previous Cesarean deliveries, maternal weight gain 40 pounds

Table G6. Outcome Data by Breech

Cite, Location, Data source, Dates, Quality Assessment	Findings
Grunebaum, McCullough, Sapra et al., 2017 U.S. CDC linked birth-infant death files 2009 to 2013 Fair quality	Planned Home Birth vs. Hospital-Midwife Cephalic: SMR 3.61, 95% CI 2.92 to 4.31 Breech: SMR 8.14, 95% CI 2.17 to 14.11

Table G7. Outcome Data by Other Factors

Cite, Location, Data source, Dates, Quality Assessment	Findings
Grunebaum, McCullough, Sapra et al., 2017 U.S. CDC linked birth-infant death files 2009 to 2013 Fair quality	Planned Home Birth (n = NR) vs. Planned Hospital-Midwife (n = NR) Nulliparous & ≥35 Y: 0.523% vs. 0.042%, SMR 12.41, 95% CI 4.33 to 20.49 Nulliparous & ≥41 weeks: 0.403% vs. 0.041%, SMR 9.57, 95% CI 5.84 to 13.30 Nulliparous <35 Y: 0.197% vs. 0.036%, SMR 5.35, 95% CI 3.61 to 7.09 ≥41 weeks & ≥35 Y: 0.199% vs. 0.041%, SMR 4.87, 95% CI 2.00 to 7.73 37 to 40 weeks & ≥35 Y: 0.112% vs. 0.024%, SMR 4.71, 95% CI 2.41 to 7.01

Cite, Location, Data source, Dates, Quality Assessment	Findings
	≥41 weeks & <35 Y: 0.165% vs. 0.035%, SMR 4.66, 95% CI 3.16 to 6.15 Nulliparous & 37 to 40 weeks: 0.145% vs. 0.036%, SMR 4.07, 95% CI 2.29 to 5.84 ≥41 Weeks & Parous: 0.106% vs. 0.031%, SMR 3.45, 95% CI 2.04 to 4.85 Parous & 35 Y: 0.099% vs. 0.023%, SMR 4.30, 95% CI 2.32 to 6.28 37 to 40 weeks & <35 Y: 0.096% vs. 0.030%, SMR 3.18, 95% CI 2.31 to 4.04 Parous & <35 Y: 0.091% vs. 0.027%, SMR 3.34, 95% CI 2.43 to 4.24 37 to 40 weeks & Parous: 0.088% vs. 0.026%, SMR 3.41, 95% CI 2.44 to 4.38
Halfdansdottir et al., 2018 Iceland Maternity notes review 2005 to 2009 Poor quality	Within Planned Home Births Contraindication present (n = 29) vs. no home birth contraindication present (n = 274) Maternal Operative birth: OR 5.42, 95% CI 0.60 to 48.99 Postpartum hemorrhage ≥500 mL: OR 3.14, 95% CI 1.05 to 9.37 Postpartum hemorrhage ≥800 mL: OR 7.96, 95% CI 1.70 to 37.36 Postpartum hemorrhage ≥1000 mL: OR 7.29, 95% CI 1.16 to 45.88 OASI: OR 0.44, 95% CI 0.02 to 11.97 Maternal morbidity, 7 days: OR 2.50, 95% CI 0.74 to 8.49 Neonatal NICU admission: OR 1.88, 95% CI 0.41 to 8.64 5-minute Apgar < 7: OR 8.37, 95% CI 0.37 to 189.36 Neonatal resuscitation: OR 1.89, 95% CI 0.14 to 9.68 Neonatal morbidity, 7 days: OR 1.16, 95% CI 0.65 to 5.51
Li et al., 2015 United Kingdom Birthplace national prospective cohort study April 2008 to April 2010 Good quality	All Planned Home Births Nulliparous - Higher risk planned home (n = 283) vs. Low risk planned home (n = 4,399) Adverse perinatal outcomes (main composite): 9 (27.7%) vs. 84 (19.3%), aRR 1.82, 95% CI 0.89 to 3.72 Multiparous - Higher risk planned home (n = 1,186) vs. Low risk planned home (n = 11,910) Adverse perinatal outcomes (main composite): 16 (12.3%) vs. 93 (7.5%), aRR 1.92, 95% CI 1.02 to 3.64 Planned home, without complicating condition at start of labor

Cite, Location, Data source, Dates, Quality Assessment	Findings
	Nulliparous - Higher risk planned home (n = 248) vs. Low risk planned home (n = 3,983) Adverse perinatal outcomes (main composite): 6 (21.1%) vs. 69 (17.8%), aRR 1.69, 95% CI 0.73 to 3.89 Multiparous - Higher risk planned home (n = 1,062) vs. Low risk planned home (n = 11,335) Adverse perinatal outcomes (main composite): 12 (10.5%) vs. 82 (7.1%), aRR 1.69, 95% CI 0.79 to 3.6 Low risk planned home birth from original birthplace cohort Adverse perinatal outcomes (main composite): stillbirth after the start of care in labor, early neonatal death, neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured humerus or clavicle) or admission to a neonatal unit within 48 hours of birth for more than 48 hours

Appendix H. Characteristics of Noncomparative Observational Studies

Citation, Location, Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
Bachilova et al., 2018 U.S. Period Linked Birth/Infant Death databases from the National Center for Health Statistics at the Centers for Disease Control and Prevention (CDC) 2011 to 2013 Poor quality	N = 71,704	Inclusion criteria: Planned home births Exclusion criteria: Births occurring in hospitals, freestanding birth centers, doctors' offices, clinics, other locations, or at an unknown location, home births that were accidental or not planned, planned home births that occurred ≤ 34 weeks gestation, infants born with congenital or chromosomal anomalies including anencephaly, Down syndrome, congenital diaphragmatic hernia, congenital heart disease, omphalocele, gastroschisis, cleft lip and/or palate, and limb defects.	Home Birth (N = 71,704) Maternal race White: 64,323 (89.7%) Black: 1,436 (2.0%) Hispanic: 3,327 (4.6%) Other: 1,190 (1.7) Maternal education < 12 Grades: 18,896 (26.4%) High School: 21,612 (30.1%) University: 30,381 (42.4%) Unknown: 815 (1.1%) Maternal age < 25 Years: 11,092 (15.5%) 25 to 34 Years: 45,621 (63.6%) ≥ 35 Years: 14,991 (20.9%) Parity Nulliparous: 12,103 (17.3%) Multiparous: 57,864 (82.7%) Unknown: 1,737 (2.4%) Fetal presentation Vertex: 47,158 (65.8%) Non-Vertex: 652 (.9%) Unknown: 23,894 (33.3%) Previous cesarean delivery: 3,140 (4.4%) Plurality Single: 71,145 (99.2%) Twins or greater: 559 (.8%)
Blix et al., 2015 Norway, Denmark, Sweden, Iceland Midwives attending planned home births	N = 3,068 Norway n = 482 Sweden n = 445	Inclusion criteria: Planned home births in Norway, Denmark, Sweden, and Iceland between 2008 and 2013	Home Birth (N = 3,068) Age < 20 Years: 10 (.3%) 20 to 24 Years: 201 (6.6%) 25 to 29 Years: 767 (25.0%)

Citation, Location, Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
submitted data through a questionnaire January 2008 to December 2013 Poor quality	Denmark n = 1,843 Iceland n = 298	Exclusion criteria: NR	30 to 34 Years: 1,199 (39.1%) 35 to 39 Years: 736 (24.0%) ≥ 40 Tears: 138 (4.4%) Missing Data: 17 (.6%) Marital status Married/Cohabit: 2,992 (97.5%) Not Married/Cohabit: 48 (1.6%) Missing Data: 28 (.9%) Smokers Yes: 204 (6.7%) No: 2,805 (91.4%) Missing Data: 59 (1.9%) Parity Nulliparous: 572 (18.6%) Multiparous: 2,446 (81.4%) Missing Data: 50 Previous cesarean delivery (Total) No: 2,923 (95.3%) Yes: 144 (4.7%) Missing Data: 1 (0.0%) Previous cesarean (multiparous women) No: 2,301 (94.1%) Yes: 144 (5.9%) Missing Data: 1 (0.0%) Gestational age < 37 Weeks: 8 (0.3%) 37 to 42 Weeks: 2,956 (96.3%) > 42 Weeks: 22 (0.7%) Missing Data: 82 (2.7%) Fetal presentation Occipito-Anterior: 2,887 (94.1%) Abnormal Cephalic: 126 (4.1%) Breech: 7 (.2%) Missing Data: 48 (1.6%)

Citation, Location, Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			BMI < 18.5: 103 (3.4%) 18.5 to 24.9: 1,994 (65.0%) 25.0 to 29.9: 535 (17.4%) > 30: 199 (6.5%) Missing: 237 (7.7%)
Bovbjerg et al., 2017 U.S. Midwives Alliance of North America Statistics Project (MANA Stats) 2.0 and 4.0 2004 to 2009, 2012 to 2014 Poor quality	N = 47,394 MANA Stats 2.0 (2004 to 2009) n = 20,887 MANA Stats 4.0 (2012 to 2014) n = 26,507	Inclusion criteria: Planned home or birth center births, primiparous, multiparous without a history of cesarean delivery, multiparous with a history of cesarean delivery and also a history of vaginal birth, or multiparous with a history of cesarean delivery but without a history of vaginal birth Exclusion criteria: NR	Planned Out-of-Hospital Birth (N = 47,394) Maternal Race/Ethnicity White, non-Hispanic: 41,626 (88.3%) Other: 5,513 (11.7) Expected Source of Payment Medicaid: 5,344 (11.3%) Not Medicaid: 42,042 (88.7%) Obstetric History Primiparous: 14,591 (30.8%) Multiparous, No History of Cesarean: 30,107 (63.6%) Multiparous, History of Both Cesarean and Vaginal Birth: 1,571 (3.3%) Multiparous, History of Cesarean Only: 1,086 (2.3%) BMI < 25: 30,578 (70.1%) 25 ≤ 30: 8,480 (19.4%) 30 ≤ 35: 2,954 (6.8%) 35+: 1,613 (3.7%) Maternal Age 35 Years or Older: 8,805 (18.8%) Maternal Education (fewer than 4 years of college): 20,988 (46.5%) Twin Pregnancy: 138 (0.3%)

Citation, Location, Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			Postterm Pregnancy (more than 42 completed weeks): 3,160 (6.7%) Pregnancy Complications Gestational Diabetes: 516 (1.1%) Preeclampsia: 63 (0.1%) Breech Presentation at Birth: 539 (1.2%)
Catling-Paull et al., 2013 Australia 12 publicly funded home birth programs 2005 to 2010 Poor quality	N = 1,807	Inclusion criteria: Planned to have a home birth at the onset of labor Exclusion criteria: Women who had planned a homebirth but were transferred to hospital-based care during pregnancy (i.e., before the onset of labor)	Home Birth (N = 1,807) Maternal Age (n = 1,805) ≤ 25 Years: 219 (12.1%) 26 to 35 Years: 1,210 (67.0%) 36 to 40 Years: 337 (18.6%) > 40 Years: 39 (2.2%) Gestational Age at Birth (n = 1,807) < 37 Weeks: 19 (1.1%) 37 to 42 Weeks: 1,754 (97.1%) > 42 Weeks: 34 (1.9%) Parity (n = 1,807) Nulliparous: 575 (31.8%) Multiparous: 1,232 (68.2%) Place of Birth (n = 1,807) Home: 1,521 (84.2%) Birth Center:26 (1.4%) Hospital Labor Ward: 163 (9.0%) Operating Theater: 97 (5.4%)
Cheyney et al., 2014 U.S. Midwives Alliance of North America Statistics Project (MANA Stats) 2.0 dataset 2004 to 2009 Poor quality	N = 16,924	Inclusion criteria: Planned home births Exclusion criteria: Women transferred care to another provider prior to the onset of labor, women who at the onset of labor had a planned birth location other than home, women who did not live in the U.S.	Planned Out-of-Hospital Birth (N = 16,924) Race/Ethnicity White: 15,614 (92.3%) Black: 361 (2.1%) Latina: 714 (4.2%) Asian/Pacific Islander: 760 (4.5%) Native American: 163 (1.0%) Other 145 (.9%)

Citation, Location, Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			Belongs to Amish, Mennonite, or Other Plain Church: 1,098 (6.5%) Age at First Prenatal Visit, Mean Years: 30.3 ± 5.3 Education High School Graduate: 15,283 (92.4%) Completed ≥ 4 Years of College: 8,300 (58.0%) Marital Status Married: 14,961 (88.4%) Unmarried With a Partner: 1,579 (9.3%) Single (Includes Separated, Divorced): 331 (2.0%) Other: 51 (.3%) MANA Region of Residence New England: 873 (5.2%) North Atlantic: 1,992 (11.8%) Southeast: 2,054 (12.2%) Midwest: 2,646 (15.6%) West: 3,949 (23.4%) Pacific: 5,364 (31.8) Method of Payment Self-Pay: 10,888 (64.4%) Private Insurance: 4,092 (24.2%) Government Insurance (Includes Medicaid, CHAMPUS): 1,361 (8.0%) Other: 576 (3.4%) Parity Nulliparous: 3,773 (22.3%) Multiparous: 13,150 (77.7%) Grand Multiparous (≥ 5 Pregnancies): 1,150 (9.2%) TOLAC: 1,052 (8.0%) BMI

Citation, Location, Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			Normal BMI Prepregnancy (18.5 to 25 kg/m^2): 11,144 (66.9%) Mother's Pregravid BMI (kg/m^2), Median: 22.5 (IQR, 20.6 to 25.7) Complications/Comorbid Conditions Affecting This Pregnancy Chronic Hypertension: 59 (.3%) Pregnancy-Induced Hypertension: 243 (1.4%) Preeclampsia: 29 (.2%) Eclampsia: 10 (.1%) Gestational Diabetes: 132 (.8%) Persistent Anemia: 146 (.9%) Rh Sensitization: 41 (.2%) Multiple Gestation: 60 (.4%) Breech Presentation: 222 (1.3%) Gestational Age of Neonate Preterm: 423 (2.5%) Postterm: 862 (5.1%)
Cox et al., 2015 U.S. Midwives Alliance of North America Statistics (MANA Stats) Project 2.0 2004 to 2009 Poor quality	N = 13,144 TOLAC n = 1,052 Comparison Group: 12,092	Inclusion criteria: Multiparous women without a history of cesarean delivery Exclusion criteria: Care transferred to another provider prior to the onset of labor, planned birth location other than home prior to the onset of labor, did not live in the U.S., Primiparous women, previous cesarean status unknown	Planned Out-of-Hospital Birth (N = 13,144) TOLAC (n = 1,052) vs. Comparison Group (n = 12,092) Median maternal age at first prenatal visit: 32 (IQR, 28 to 36) vs. 31 (IQR, 27 to 34), p ≤ 0.001 Median maternal pregravid BMI: 24.0 (IQR, 21.3 to 28.0) vs. 22.7 (IQR, 20.6 to 25.8), p ≤ 0.001 Race/ethnicity White: 970 (92.2%) vs. 11,172 (92.4%) Black: 21 (2.0%) vs. 253 (2.1%) Latina: 42 (4.0%) vs. 474 (4.0%) Asian: 46 (4.4%) vs. 487 (4.0%) Native American: 7 (.7%) vs. 120 (1.0%)

Citation, Location, Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			Other: 11 (1.0%) vs. 237 (2.0%), p ≤ 0.05 Amish/Mennonite: 54 (5.1%) vs. 875 (7.2%), p ≤ 0.01 <u>Education</u> High School Graduate: 966 (91.8%) vs. 10,843 (89.7%), p ≤ 0.05 4 or More Years of College: 531 (50.5%) vs. 5,694 (47.1%) <u>Partner status</u> Married: 986 (93.7) vs. 10.923 (90.3%), p ≤ 0.001 Partnered: 49 (4.7%) vs. 942 (7.8%), p ≤ 0.001 Separated/Divorced, Single, or Other: 17 (1.6%) vs. 227 (1.9%), p ≤ 0.001 <u>MANA region of residence</u> New England: 54 (5.2%) vs. 614 (5.1%) North Atlantic: 131 (12.5%) vs. 1,384 (11.5%) Southeast: 187 (17.9%) vs. 1,456 (12.1%), p ≤ 0.001 Midwest: 182 (17.4%) vs. 1,940 (16.1%) West: 214 (20.4%) vs. 2,935 (24.3%), p ≤ 0.01 Pacific: 279 (26.6%) vs. 3,738 (31.0%), p ≤ 0.01 <u>Previous pregnancies</u> 1: 275 (26.1%) vs. 3,971 (32.8%), p ≤ 0.001 2: 247 (23.5%) vs. 3,002 (24.8%), p ≤ 0.001

Citation, Location, Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			3 or 4: 287 (27.3%) vs. 3,145 (26.0%), p ≤ 0.001 Previous cesarean deliveries (TOLAC group only) 1: 943 (89.6%), p ≤ 0.001 2: 91 (8.7%), p ≤ 0.001 3 or More: 18 (1.7%), p ≤ 0.001 Previous vaginal births (TOLAC group only): 721 (68.7%), p ≤ 0.001 Previous VBAC (TOLAC group only): 454 (43.3%), p ≤ 0.001 Comorbid conditions Gestational diabetes: 17 (1.6%) vs. 93 (.8%), p ≤ 0.01 Pregnancy-induced hypertension: 20 (1.9%) vs. 140 (1.2%), p ≤ 0.05 Chronic hypertension: 8 (.8%) vs. 40 (.3%), p ≤ 0.05 Twin pregnancy: 5 (.5%) vs. 49 (.4%), p ≤ 0.05
Edqvist et al., 2016 Norway, Denmark, Sweden, Iceland Midwives attending planned home births submitted data through a questionnaire 2008 to 2012 Poor quality	N = 2,992 (subpopulation of Blix et al., 2015) Norway n = 468 Sweden n = 438 Denmark n = 1,799 Iceland n = 287	Inclusion criteria: NR Exclusion criteria: women who had a cesarean delivery or instrumental delivery after transfer to hospital	Home Birth (N = 2,992) Age Groups < 25 Years: 202 (6.8%) 25 to 34 Years: 1,923 (64.3%) > 35 years: 850 (28.4%) Missing Data: 17 (.6%) Marital Status Married/Cohabit: 2,918 (97.5%) Not Married/Cohabit: 51 (1.7%) Missing Data: 23 (.8%) Tobacco Use Yes: 198 (6.6%) No: 2,735 (91.4%)

Citation, Location, Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			Missing Data: 59 (2.0%) Number of Children* First Baby: 524 (17.5%) 1 Previous Child: 1,257 (42.0%) 2 Previous Children: 828 (27.7%) 3 or More Previous Children: 322 (10.8%) Missing Data: 61 (2.0%) * 141 women had 1 previous cesarean, 3 women had 2 previous cesareans BMI < 18.5: 101 (3.3%) 18.5 to 24.9: 1,943 (64.9%) 25.0 to 29.9: 516 (17.2%) > 30: 196 (6.6%) Missing Data: 236 (7.9%)
Eto et al., 2017 Japan Birth records from 9 Tokyo midwifery centers January 2001 to August 2006 Poor quality	N = 4,051	Inclusion criteria: Delivery at one of 9 birth centers during January 2001 to August 2006 Exclusion criteria: Need for medical treatment related to breach delivery, preterm premature rupture of membrane, weak contractions, weaker fetal heartbeat, or returning to parents' home for delivery, high risk situations (e.g., primary hemorrhage, placenta accrete, hematoma formation)	Planned Birth Center (N = 4,051) Mean maternal age (n = 4,033): 31.7 ± 4.2 Parity Nulliparous: 1,157 (28.6%) Multiparous: 2,893 (71.4%) Mean Gestational Period (n = 4,040): 39.9 ± 1.1 weeks
Johnson & Daviss, 2005 North America (U.S. and Canada) North American Registry of Midwives (planned home birth data), birth	N = 5,418	Inclusion criteria: Women who engaged the services of a certified professional midwife in Canada or the U.S. as their primary caregiver for a birth	Home Birth (N = 5,418) Maternal Age ≤ 19 Years: 130 (2.4%) 20 to 24 Years: 930 (17.2%) 25 to 29 Years: 1,554 (28.7%)

Citation, Location, Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
certificate data from the National Center for Health Statistics (used as proxy for a comparable low risk hospital group) 2000 Poor quality		with the expected date of delivery in 2000 Exclusion criteria: Individuals who left care because of social reasons (e.g., chose hospital birth, moved, changed midwife) or medical reasons (e.g., referred for pregnancy complications, miscarried, preterm labor, stillbirths before labor, set of twins)	30 to 34 Years: 1,423 (26.3%) 35 to 39 Years: 969 (17.9%) ≥ 40 Years: 327 (6.0%) Parity 0: 1,690 (31.2%) 1: 1,295 (23.9%) ≥ 2: 2,415 (44.6%) Mother's Formal Education High School or Less: 2,152 (39.2%) Any College: 1,272 (23.2%) College Graduate: 1,169 (21.3%) Postgraduate: 692 (12.7%) Partner Status at Time of Birth Has Partner: 5,169 (95.4%) No Partner: 164 (3.1%) Ethnicity White: 4,846 (89.4%) Hispanic: 216 (4.0%) African-American: 70 (1.3%) Other: 140 (2.6%) Other Special Groups Amish: 467 (8.7%) Mennonite: 194 (3.6%) Socioeconomic Status Low: 1,256 (23.2%) Middle: 3,244 (59.9%) Upper: 664 (12.3%) Location City: 1,891 (34.9%) Small Town: 1,506 (27.9%) Rural: 1,734 (32.0%) Time (Trimester) Prenatal Care Began 1st: 2,483 (45.8%) 2nd: 2,975 (38.2%)

Citation, Location, Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			3rd: 803 (14.8%) Smoked During Pregnancy No: 5,099 (94.1%) Yes, 1 to 9 Cigarettes/Day: 164 (3.0%) Yes, ≥ 10 Cigarettes/Day: 78 (1.4%) Unknown or Not Stated: 155 (2.9%(Alcohol Intake (Drinks/Week) During Pregnancy Non: 5,162 (95.3%) Yes, Total: 136 (2.5%) Yes, < 2: 136 (2.5%) Yes, ≥ 2: 23 (.4%) Unknown or Not Stated: 120 (2.2%) Gestational Age < 37 Weeks: 77 (1.4%) 37 to 41 Weeks: 4,834 (89.2%) ≥ 42 Weeks: 361 (6.7%)
Nethery et al., 2017 U.S. Midwives Alliance of North America Statistics Project (MANA Stats) 2.0 dataset 2004 to 2009 Poor quality	N = 18,724 Rural n = 3,373 Nonrural n = 14,986	Inclusion criteria: Planned community births (home or birth center), in midwife care at time of delivery Exclusion criteria: Multi-fetal pregnancies, breech, congenital anomalies, pre-existing maternal conditions (e.g., chronic anemia not resolved, chronic hypertension, eclampsia, preeclampsia, Rh sensitization, gestational diabetes), prior cesarean delivery	Planned Out-of-Hospital Birth (N = 18,724) Rural (n = 3,737) vs. Nonrural (n = 14,986) Race/Ethnicity (p ≤ 0.001) African or Caribbean: 18 (.5%) vs. 140 (.9%) Asian: 9 (.2%) vs. 133 (.9%) Caucasian: 3,422 (91.6%) vs. 13,266 (88.5%) Hispanic or Latina: 67 (1.8%) vs. 248 (1.7%) Native American: 18 (.5%) vs. 20 (.1%) Other: 25 (.7%) vs. 124 (.8%) More than 1 race indicated: 167 (4.5%) vs. 914 (6.1%)

Citation, Location, Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			Education (p ≤ 0.001) Any High School or Completed: 1,832 (49.0%) vs. 3,868 (25.8%) Any Postsecondary up to 4 Years: 1,429 (38.2) vs. 7,607 (50.8%) More Than 4 Years of Postsecondary: 417 (11.2%) vs. 3,187 (21.3%) Belongs to Amish, Mennonite, or other Plain Church: 777 (20.8%) vs. 258 (1.7%0) (p ≤ 0.001) Any Medicaid, Primary or Secondary: 499 (13.4%) vs. 1,635 (10.9%) (p ≤ 0.001) Any Other Insurance (Non-Medicaid), Primary or Secondary: 745 (19.9%) vs. 6,408 (42.8%) (p ≤ 0.001) Marital Status: Married, Partnered, or Common-Law: 3,643 (97.5%) vs. 14,558 (97.1%) Age, in Years: 29 (IQR, 25 to 33) vs. 30 (IQR, 26 to 33) (p ≤ 0.001) BMI at Beginning of Pregnancy: 22.8 (IQR, 21 to 26) vs. 22.5 (IQR, 21 to 25) (p ≤ 0.001) Nulliparous: 1,182 (49.7%) vs. 5,801 (38.7%) (p ≤ 0.001) Grand Multiparity (> 4 Prior Vaginal Deliveries): 446 (11.9%) vs. 611 (4.1%) (p ≤ 0.001) History of Home or Birth Center Birth: 1,858 (49.7%) vs. 5,596 (39.8%) (p ≤ 0.001)

Citation, Location, Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			Planned Birth Location at Onset of Labor (p ≤ 0.001): Freestanding Birth Center: 620 (16.6%) vs. 2,910 (19.4%) Home: 3,117 (83.4%) vs. 12,076 (80.6%) Number of Prenatal Care Visits With This Midwife: 10 (IQR, 7 to 12) vs. 11 (IQR, 9 to 12) (p ≤ 0.001) Weeks (From Last Menstrual Period) That Any Prenatal Care Began: 12 (IQR, 9 to 16) vs. 11 (IQR, 8 to 13) (p ≤ 0.001) Birth Location (Actual) (p ≤ 0.001) Freestanding Birth Center: 520 (13.9%) vs. 2,394 (16.0%) Home: 2,881 (77.1%) vs. 10,819 (72.2%) Hospital: 327 (8.8%) vs. 1,751 (11.7%) Other: 9 (.2%) vs. 21 (.1%)
Schuit et al., 2016 The Netherlands Netherlands Perinatal Registry 2000 to 2007 Poor quality	N = 746,642 No Referral to Secondary Care n = 505,047 (68%) Referral to Secondary Care n = 241,595 (32%)	Inclusion criteria: Singleton pregnancy, gestational age between 37 and 42 weeks, started labor in primary care Exclusion criteria: Women with prolonged rupture of membranes without contractions	Planned Out-of-Hospital Birth (N = 746,642) Maternal Age > 25 Years: 96,060 (13%) 25 to 35 Years: 563,724 (76%) > 35 Years: 86,858 (12%) Ethnicity Caucasian: 613,898 (82%) Creole: 15,079 (2%) Hindu: 7,050 (1%) Other Non-Western: 110,615 (15%) Degree of Urbanization Low: 148,462 (20%)

Citation, Location, Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			Average: 457,988 (61%) High: 140,192 (19%) <u>Social Economic Status</u> Low: 221,039 (30%) Average: 345,612 (46%) High: 179,991 (24%) <u>Birth History</u> Nulliparous: 332,854 (45%) Multiparous, Without Previous Instrumental Vaginal Delivery: 374,350 (50%) Multiparous, With Previous Instrumental Vaginal Delivery: 39,438 (5%) <u>Intended Place of Delivery</u> Home n = 466,662 (63%) Midwife-Led Birth Center n = 5,367 (1%) Hospital n = 274,613 (37%) <u>Gestational Age</u> 37+0 to 37+6 Weeks: 31,070 (4%) 38+0 to 40+6 Weeks: 549,026 (74%) ≥ 41+0 Weeks: 166,546 (22%)
Stapleton et al., 2013 U.S. American Association of Birth Centers Uniform Data Set (online data registry) 2007 to 2010 Poor quality	N = 15,574	<u>Inclusion criteria</u>: Planned home center birth; estimated dates of birth during 2007 through 2010; singleton, full-term gestation in vertex presentation with no medical or obstetric risk factors precluding a normal vaginal birth or necessitating interventions such as continuous electronic fetal monitoring or induction of labor <u>Exclusion criteria</u>:	Birth Center (N = 15,574) <u>Maternal Age</u> < 18 Years: 171 (1.1%) 18 to 34 Years: 13,218 (85.4%) ≥ 35 Years: 2,093 (13.5%) <u>Race</u> Non-Hispanic White: 11,810 (77.4%) Hispanic: 1,711 (11.2%) Black: 840 (5.5%) Asian or Pacific Islander: 349 (2.3%)

Citation, Location, Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
		NR	Native American or Native Alaskan: 101 (.7%) Unknown or Other: 440 (2.9%) Marital Status Married: 12,109 (80.1%) Unmarried: 3,015 (19.9%) Parity Nulliparous: 7,355 (47.2%) Multiparous: 8,219 (52.8%) Payment Method Private Insurance: 8,325 (53.5%) Medicaid: 3,701 (23.8%) Self-Pay: 2,261 (14.5%) Military Coverage: 411 (2.6%) Other Insurance/Grants: 406 (2.6%) Medicare: 374 (2.4%) Unknown: 96 (.6%) Education < 12 Years: 1,184 (8.7%) 12 Years: 2,669 (19.6%) 13 to 15 Years: 2,727 (20.0%) ≥ 16 Years: 7,067 (51.8%)
Stephenson-Famy et al., 2017 U.S. Washington State birth certificate data 2004 to 2011 Poor quality	N = 7,118	Inclusion criteria: Planned to give birth in a birth center who delivered a singleton, vertex, live born infant at ≥ 37 weeks gestation Exclusion criteria: Preterm birth, previous cesarean delivery, nonvertex presentation, multiple gestations, or fetal death	Planned Birth Center Birth (N = 7,118) Actual Birth Center Birth (n = 6,617) vs. Actual Hospital Birth (n = 501) Maternal Age (p < 0.001) < 20 Years: 166 (2.5%) vs. 21 (4.2%) 20 to 29 Years: 3,565 (53.9%) vs. 247 (49.4%) 30 to 34 Years: 1,931 (29.3%) vs. 142 (28.4%) 35 to 40 Years: 780 (11.8%) vs. 61 (12.2%)

Citation, Location, Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			> 40 Years: 169 (2.6%) vs. 29 (5.8%) Race White: 6,139 (93.8%) vs. 446 (92.3%) African American: 114 (1.7%) vs. 10 (2.1%) American Indian/Alaska Native: 56 (.9%) vs. 6 (1.2%) Asian: 239 (3.6%) vs. 21 (4.4%) Ethnicity (p < 0.05) Non-Hispanic: 6,330 (96.1%) vs. 462 (94.1%) Hispanic: 261 (3.9%) vs. 29 (5.9%) Marital Status (p < 0.001) Married: 5,518 (83.6%) vs. 361 (72.2%) Not Married: 1,085 (16.4%) vs. 139 (27.8%) Maternal Education (p < 0.05) Less Than High School: 256 (3.9%) vs. 26 (5.2%) High School Graduate: 1,141 (17.3%) vs. 78 (15.7%) Some College: 2,311 (35.1%) vs. 151 (30.4%) College Graduate: 2,041 (31.0%) vs. 151 (30.4%) Graduate Level: 838 (12.7%) vs. 91 (18.3%) BMI (p < 0.001) < 18.5: 223 (3.5%) vs. 221 (52.6%) 18.5 to 25.9: 4,062 (64.2%) vs. 9 (2.1%) 25.0 to 29.9: 1,306 (20.6%) vs. 114 (27.1%) ≥ 30: 736 (11.6%) vs. 76 (18.1%)

Citation, Location, Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			Residence Urban: 5,777 (87.9%) vs. 450 (90.4%) Rural: 793 (12.1%) vs. 48 (9.6%) Insurance Status (p < 0.001) Self-Pay: 265 (4.0%) vs. 19 (3.0%) Medicaid: 1,958 (29.7%) vs. 115 (23.8%) Private Insurance: 4,316 (65.6%) vs. 322 (66.7%) Government Insurance: 49 (.7%) vs. 27 (5.6%) Prenatal Smoking No: 6,390 (96.6%) vs. 473 (95.0%) Yes: 227 (3.4%) vs. 25 (5.0%) Parity (p < 0.001) 0: 2,738 (42.3%) vs. 417 (83.7%) 1: 3,729 (57.7%) vs. 81 (16.3%) (p < 0.001) Gestational Age (p < 0.001) 37 Weeks: 266 (4.0%) vs. 30 (6.0%) 38 Weeks: 744 (11.2%) vs. 42 (8.6%) 39 Weeks: 1,368 (20.7%) vs. 104 (20.6) 40 Weeks: 3,085 (46.7%) vs. 162 (32.3%) 41 Weeks: 1,027 (15.5%) vs. 124 (24.9%) ≥ 42 Weeks: 127 (1.9%) vs. 38 (7.6%) Adequacy of Prenatal Care (Kotelchuck Index) (p < 0.001) Inadequate: 637 (9.9%) vs. 134 (28.9%)

Citation, Location, Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
			Intermediate: 561 (8.7%) vs. 75 (16.2%) Adequate: 4,480 (69.7%) vs. 199 (42.8%) Adequate Plus: 753 (11.7%) vs. 56 (12.1%) <u>Prior Preterm Birth</u> No: 6,544 (98.9%) vs. 496 (99.4%) Yes: 71 (1.1%) vs. 3 (.6%) <u>Maternal Diabetes</u> No: 6,538 (98.8%) vs. 496 (98.2%) Yes: 77 (1.2%) vs. 3 (.6%) Includes preexisting and gestation diabetes <u>Maternal Hypertension (p < 0.001)</u> No: 6,576 (99.4%) vs. 457 (91.6%) Yes: 39 (.6%) vs. 42 (8.4%) Includes chronic hypertension, gestational hypertension, preeclampsia, and eclampsia Group B Streptococcus Positive No: 5,156 (77.9%) vs. 393 (78.8%) Yes: 1,459 (22.1%) vs. 106 (21.2%)
Suto et al., 2015 Japan Data collected from 3 midwife-led birth centers in Tokyo January 2008 to June 2011 Poor quality	N = 1,521 Nulliparous n = 422 Multiparous n = 1,099	<u>Inclusion criteria:</u> Pregnant women who receive initial antenatal care at 1 of 3 birth centers between January 1, 2008 and June 30, 2011 <u>Exclusion criteria</u>: Women who changed childbirth facilities during pregnancy for personal reasons, referral to hospital	Birth Center (N = 1,521) Nulliparous (n = 422) vs. Multiparous (n = 1,099) <u>Maternal Age (Years)</u>: 31 ± 4.4 vs. 33.6 ± 3.9 <u>BMI</u> 16.00 to 16.99: 0 (0%) vs. 1 (.1%) 17.00 to 18.49: 2 (.5%) vs. 3 (.3%)

Citation, Location, Data Source, Dates, Quality Assessment	N	Inclusion and Exclusion Criteria	Population Characteristics
		during pregnancy for pregnancy-related complications, transfer to hospital from the onset of the end of the third stage of labor, gave birth at home unexpectedly, preterm birth, no record of perineal laceration status after birth	18.50 to 22.99: 180 (44.0%) vs. 316 (30.4%) 23.00 to 24.99: 116 (28.4%) vs. 364 (35.0%) 25.00 to 29.99: 111 (27.1%) vs. 356 (34.2%) Living With Partner: 421 (99.8%) vs. 1,099 (100%)

Appendix I. Risk Criteria Matrix: Maternal/Fetal

3	2	1	NA	--
High-risk condition requiring planned hospital birth or transfer to hospital	Consultation required	Eligible for planned out-of-hospital birth provided no other complicating conditions are present	Not applicable or superseded by a separate recommendation	No recommendation identified

Condition	Sub-condition	HERC 2015 CG	Other	2020 Oregon DEM final rule	2020 HERC CG proposed	Footnotes	Description of EbGS change from 2015
Amniotic membrane rupture	**Pre-labor rupture of membranes > 24 hours**	3	NICE 3 WA (2)	--	2		Revised existing criterion
	Rupture before 36 weeks	NA*	CMBC 2^	3	--	*superseded by gestational age recommendation	No change
	Rupture before 37 weeks 0 days	NA*	WA 3	--	3	^34 + 0 to 36 and 6 weeks	Added new criterion
Anemia	**Hemoglobin < 10 g/dL, unresponsive to treatment**	2*	CMBC 2 WA 2	2	2^	*10.5 ^10	Clarified existing criterion
	Hemoglobin < 9 g/dL unresponsive to treatment	--	--	3	--		No change
	Hemoglobin < 8.5 g/ dL (current pregnancy)	3	NICE 3*	--	3	*at onset of labor	No change
Cancer	**Cancer affecting site of delivery**	--	WA 3	3	3*	*Active gynecologic cancer	Added new criterion
Cardiovascular	**Cardiovascular disease causing functional impairment**	--	ACNM 3* CMBC 3^	2~	3%	^disease with failure ~cardiac condition	Added new criterion

Condition	Sub-condition	HERC 2015 CG	Other	2020 Oregon DEM final rule	2020 HERC CG proposed	Footnotes	Description of EbGS change from 2015
			NICE 3			%cardiovascular disease with functional impairment	
			WA 3				
Cervical conditions	**Insufficiency or cerclage**	2*	CMBC 2*	--	--	*history of	Removed existing criterion
Collagen-vascular diseases		--	WA 3	--	2	No specific disease listed	Added new criterion
Congenital or hereditary anomaly	**Prior child with congenital or hereditary disorder**	2	--	--	--		Removed existing criterion
	Known fetal anomalies or conditions affected by site of birth	--	WA 3	2*	--	*that may require medical attention	No change (see below)
	Evidence of congenital anomalies requiring immediate assessment and/or management by a neonatal specialists	--	ACNM 3	--	2		Clarified existing criterion
	Suspected or diagnosed fetal anomaly that may require physician management during or immediately after delivery	--	CMBC 2	--	--		No change

Condition	Sub-condition	HERC 2015 CG	Other	2020 Oregon DEM final rule	2020 HERC CG proposed	Footnotes	Description of EbGS change from 2015
	Life-threatening congenital anomalies (unless non-resuscitation planned)	2	--	--	--		Removed existing criterion
Delivery history	**Less than 12 months from last delivery to present due date**	--	CMBC 2	--	--		No change
	1 Prior cesarean delivery	3	ACNM 3 NICE 3 ACOG 3 WA 3 CMBC 2	1	3		No change
	2 Prior cesarean deliveries	3	ACNM 3 NICE 3 ACOG 3 WA 3 CMBC 2	1	3		No change
	3 Prior cesarean deliveries with a previous successful vaginal birth	3	ACNM 3 ACOG 3 NICE 3 WA 3	1	3		No change
	3 Prior cesarean deliveries without a prior successful vaginal birth	3	ACNM 3 NICE 3 ACOG 3 WA 3	3	3		No change
	4 or more cesarean deliveries	3	ACNM 3 ACOG 3 NICE 3 WA 3	3	3		No change
Diabetes	**Type 1**	3	WA 3 NICE 3	--	3		No change

Condition	Sub-condition	HERC 2015 CG	Other	2020 Oregon DEM final rule	2020 HERC CG proposed	Footnotes	Description of EbGS change from 2015
	Type 2	3	WA 3 NICE 3	2*	3	*blood glucose dysregulation well-controlled with diet and exercise	No change
	Gestational – diet controlled	2	NICE 3	2	--		Remove existing criterion
	Gestational – on medication or uncontrolled	3	CMBC 2* NICE 3 WA 3	--	3	*insulin treated	No change
Endocrine conditions other than diabetes	**Hyperthyroidism**	--	--	2	2^	^listed as an example of a significant endocrine disorder *significant endocrine conditions other than diabetes (e.g. hyperthyroidism)	Added new criterion
	Significant endocrine disorders	--	WA 3	--	2*		
Fetal demise or stillbirth	**Fetal demise (current pregnancy)**	2	CMBC 2 WA 2*	--	--	*after 12 completed weeks gestation	Removed existing criterion
	Prior unexplained stillbirth/neonatal death or death unrelated to intrapartum difficulty	2	CMBC 2	--	2		No change
	History of unexplained stillbirth/neonatal death or previous death related to intrapartum difficulty	3	CMBC 2	--	2		See above

Condition	Sub-condition	HERC 2015 CG	Other	2020 Oregon DEM final rule	2020 HERC CG proposed	Footnotes	Description of EbGS change from 2015
Fetal monitoring or movement	Repetitive or persistent abnormal fetal heart rate pattern during labor	3	WA 3 ACNM 3	3	3		No change
	Abnormal fetal heart rate, Doppler, or surveillance studies	3	CMBC 3 NICE 3 --	2* 3^ --	3	*abnormal fetal cardiac rate or rhythm ^abnormal fetal surveillance testing	No change
	Rate below 110 or above 160 beat/minute, deceleration auscultated	--	NICE 3	--	--		No change
	Inability to adequately follow an intermittent auscultation protocol	--	--	3	--		No change
	Abnormally decreased fetal movement antepartum	--		2	--		No change
	Abnormally decreased fetal movement at onset of labor		NICE 3*		--		No change
Fetal presentation	Breech or non-cephalic presentation	3	AABC 3 ACNM 3 ACOG 3	1~ 2%	3	*consult for breech, transfer for non-cephalic other than breech, greater clarification in guidance ^2 at 37 weeks, 3 if intrapartum ~Frank or complete breech and birth imminent	No change

Condition	Sub-condition	HERC 2015 CG	Other	2020 Oregon DEM final rule	2020 HERC CG proposed	Footnotes	Description of EbGS change from 2015
			CMBC 2/3* NICE 3 WA 2/3^	3[&] Transverse: 3		[%]Frank or complete breech and birth not imminent &Evidence or suspected footling or kneeling breech and birth not imminent	
Gastrointestinal or hepatological	**Excessive vomiting, dehydration, or exhaustion unresponsive to treatment**	--	--	3*	--		No change
	Hepatic disorders including uncontrolled intrahepatic cholestasis of pregnancy and or abnormal liver function tests	--	WA 3 NICE 3	2*	2	*abnormal hepatic test	Added new criterion
General medical conditions	**Actively being treated with prescription medication for any ongoing or chronic medical condition**	--	--	2	--		No change
	Adverse socio-economic conditions	--	CMBC 2	--	--		No change
	Current medical conditions that may affect pregnancy or are exacerbated due to pregnancy	--	CMBC 2	--	--		No change

Condition	Sub-condition	HERC 2015 CG	Other	2020 Oregon DEM final rule	2020 HERC CG proposed	Footnotes	Description of EbGS change from 2015
	Current medical conditions that may affect pregnancy or are exacerbated by pregnancy that require specialized medical care (e.g., cardiac disease, renal disease, pre-existing insulin-dependent diabetes mellitus)	--	CMBC 3	--	3	(this is a modification from prior CMBC)	Clarified existing criterion
	Declining all blood products	--	CMBC 2	--	--	(this is a change from prior CMBC)	No change
	Family history of genetic/heritable disorders that would impact labor, delivery or care of newborn	2	CMBC 2	--	--		Removed existing criterion
	History of trauma or sexual abuse	--	CMBC 2	--	--		No change
	Low-risk uncomplicated pregnancies	1	AABC 1 AAP 1 ACNM 1 ACOG 1 CMBC 1 NICE 1 SOGC 1	1	1		No change

Condition	Sub-condition	HERC 2015 CG	Other	2020 Oregon DEM final rule	2020 HERC CG proposed	Footnotes	Description of EbGS change from 2015
	Medical, obstetric, fetal and/or neonatal condition precluding a safe labor, birth and postpartum period in a birth center	--	AABC 3	--	--		No change
	Medical conditions arising during prenatal care, for example: endocrine disorders, renal disease, suspected or confirmed significant infection including H1N1, hyperemesis unresponsive to pharmacological therapy	--	CMBC 2	--	--		No change
	Pain which persists, worsens, or is unresponsive to therapy within the midwife's scope of practice	--	CMBC 2 NICE 3*	--	--	*differs from pain normally associated with contractions	No change
	Poor nutrition	--	CMBC 2	--	--		No change
	Significant medical illness history	--	CMBC 2	--	--		No change
	Unstable health status	--	ACNM 3	--	--		No change

Condition	Sub-condition	HERC 2015 CG	Other	2020 Oregon DEM final rule	2020 HERC CG proposed	Footnotes	Description of EbGS change from 2015
	Other significant deviations from normal as assessed by the provider	--	WA 2	--	--		No change
	Development of any high risk condition	--	WA 3 NICE 3	--	3		Added new criterion
Gestational age including prior preterm birth	**Uncertain expected date of delivery**	--	CMBC 2	--	2		Added new criterion
	34 weeks or earlier	3	CMBC 3	--	3		No change
	35 weeks, 0 to 6 days	3	CMBC 2*	3	3	*history of	No change
	36 weeks, 0 to 6 days	3	AABC 1 ACNM 3 CMBC 2* WA 3	--	3	*history of or presenting in labor at	No change
	37 weeks 0 days to 41 weeks, 6 days	1	AABC 1 ACNM 1	--	1		No change
	42 weeks, 0 to 6 days	3	ACNM 3 WA 2	--	3*	*(unless already in active labor at 41 weeks 6 days)	Revised existing criterion
	43 weeks or greater	3	CMBC 2	3	3		No change
Group B streptococcus	**Unknown carrier state**	3	--	--	--		Removed existing criterion
	Lack of informed consent on prophylaxis if mother is GBS positive and declines prophylaxis	3	--	--	--		Removed existing criterion
Hematological conditions other than anemia	**Hemoglobinopathies**	--	ACNM 3 CMBC 2 NICE 3	2	2		Added new criterion

Condition	Sub-condition	HERC 2015 CG	Other	2020 Oregon DEM final rule	2020 HERC CG proposed	Footnotes	Description of EbGS change from 2015
	Thrombosis or thromboembolism (or history of)	3	ACNM 3 CMBC 2	2/3*	2/3^	*thromboembolic disease listed under both consult and transfer ^Consult for history of; transfer for current pregnancy	Revised existing criterion
	Thrombophlebitis	--	CMBC 2	2	--		No change
	Suspected embolus	--	CMBC 3	2	3		Added new criterion
	Family history of thrombophilia	--	--	2	--		No change
	Maternal bleeding disorder (or history of)	3	NICE 3	2	2		Revised existing criterion
	Thrombocytopenia (platelets <100,000)	3	NICE 3	2*	3	*platelets < 115,000	No change
Hemorrhage or vaginal bleeding, including history of	**Abnormal bleeding in pregnancy**	3	WA 3 NICE 3*	2	3	*in labor	No change
	Antepartum hemorrhage, recurrent	3	NICE 3 CMBC 2	-- --	3		No change
	Repeated vaginal bleeding other than transient spotting or uncomplicated spontaneous abortion less than 14 weeks	--	CMBC 2	--	--		No change
	Hemorrhage (hypovolemia, shock, need for transfusion,	3	CMBC 3* WA 3	3	3	*unresponsive to therapy, shock	No change

Condition	Sub-condition	HERC 2015 CG	Other	2020 Oregon DEM final rule	2020 HERC CG proposed	Footnotes	Description of EbGS change from 2015
	vital sign instability)						
	History of postpartum hemorrhage or bleeding requiring additional procedures such as Bakri-balloon, dilation and curettage, transfusion, and manual removal of placenta	--	ACNM 3 NICE 3	--	3*	* History of postpartum hemorrhage requiring transfusion or other advanced treatment (e.g. Bakri balloon)	Revised existing criterion
	History of postpartum hemorrhage requiring intervention	2	CMBC 2 WA 3	--	2		No change
Hyperemesis gravidarum		3*	WA 2	--	2*	*refractory	Revised existing criterion
Hypertensive disorders	**Eclampsia (or history of)**	3	CMBC 2/3* NICE 3	3^	3	*consult for history, transfer for current ^current	No change
	HELLP (or history of)	3	CMBC 2/3*	--	3	*consult for history, transfer for current	No change
	History of hypertensive disorders of pregnancy	2*	CMBC 2	--	--	*history of pre-eclampsia not requiring preterm birth.	Remove existing criterion
	Systolic ≥ 140 or diastolic ≥ 90, on 2 occasions 30 minutes apart in pregnancy (e.g. gestational	3	NICE 3* CMBC 2 WA 2/3^	3 (4 hours apart)	3	*any hypertensive disorder ^consult antenatally, transfer intrapartum	No change

Condition	Sub-condition	HERC 2015 CG	Other	2020 Oregon DEM final rule	2020 HERC CG proposed	Footnotes	Description of EbGS change from 2015
	hypertension or pregnancy-induced hypertension)						
	Systolic ≥ 140 or diastolic ≥ 90, on 2 occasions 4 hours apart, and proteinuria (e.g., pre-eclampsia without severe features)	--	CMBC 3 NICE 3*	3	--	*any hypertensive disorder is a 3	No change
	Systolic ≥ 160 or diastolic ≥ 110, on one occasion, or systolic ≥ 140 or Diastolic ≥ 90 with severe features (e.g. pre-eclampsia with severe features)	--	CMBC 3 NICE 3	3	3		Clarified existing criterion
	Pre-eclampsia requiring preterm birth (or history of)	3	NICE 3	3	3		No change
	Pre-existing or chronic hypertension	3	ACNM 3 CMBC 2 NICE 3* WA 3	2	3	*any hypertensive disorder	No change
Infectious Conditions (except for group B streptococcal related)	**HIV/AIDS status**	3	--	3	3		No change
	HIV (unknown or positive)	3	WA 3 CMBC 2	2	3*	*Positive	Revised existing criterion
	Chorioamnionitis	3	ACNM 3	3	3		No change
	Cytomegalovirus	3	--	--	--		Removed existing criterion
		3	CMBC 2	3*	3		

Condition	Sub-condition	HERC 2015 CG	Other	2020 Oregon DEM final rule	2020 HERC CG proposed	Footnotes	Description of EbGS change from 2015
	Maternal temperature ≥ 38.0 C in labor/postpartum		NICE 3 WA 2			*two over 100.4 or one over 102.2	No change
	Genital herpes at time of labor	3	ACNM 3* CMBC 2 WA 2^	3	3	*or at rupture of membranes ^also for primary infection past 1st trimester	No change
	Hepatitis B (unknown or positive)	3	--	--	3*	*Hepatitis B Positive	Revised existing criterion
	Hepatitis B or C with abnormal liver function tests	--	ACNM 3 NICE 3 WA 3	--	--		
	Maternal infection postpartum (e.g., endometritis, sepsis, wound)	3*	WA 2 CMBC 2	2~/3#	3*	*requiring hospital treatment ~Evident or suspected maternal infection unresponsive to treatment #uterine infection	No change
	Rubella	3	ANCM 3	--	3		No change
	Sexually transmitted infection requiring treatment	--	CMBC 2	--	--		No change
	Syphilis (unknown or positive)	3	ACNM 3 WA 3	2	3*	*Positive	Revised existing critierion
	Tuberculosis	--	ACNM 3 NICE 3	--	3*	*other than latent	Added new criterion
	Toxoplasmosis	--	NICE 3*	--	3	*women receiving treatment	Clarified existing criterion

Condition	Sub-condition	HERC 2015 CG	Other	2020 Oregon DEM final rule	2020 HERC CG proposed	Footnotes	Description of EbGS change from 2015
	Urinary tract infection (complicated)	--	CMBC 2	--	--		Added new criterion
	Varicella (active at labor)	3	--	--	3		No change
	Any infection whose treatment is beyond the scope of the provider	--	WA 2	--	--		No change
Intrauterine growth	**IUGR (defined as fetal weight less than fifth percentile using ethnically-appropriate growth tables, or concerning reduced growth velocity on ultrasound)**	3	ACNM 3 NICE 3 WA 3	--	3		No change
	History of IUGR as defined above	2	--	--	--		Removed existing criterion
	Inappropriate uterine growth (size-date discrepancy)	--	CMBC 2 NICE 3* WA 2^	--	2~	*suspected growth restriction ^size/dates discrepancies ~an ultrasound read by a qualified physician constitutes a consultation	Added new criterion
	Prior small for gestational age infant	2	CMBC 2	--	--		Removed existing criterion
	Uteroplacental insufficiency	3	NICE 3	--	3		No change

Condition	Sub-condition	HERC 2015 CG	Other	2020 Oregon DEM final rule	2020 HERC CG proposed	Footnotes	Description of EbGS change from 2015
Isoimmunization	Blood group incompatibility and/or Rh sensitization in current pregnancy	3	ACNM 3 CMBC 2 WA 3 NICE 3	2	3		No change
	Blood group incompatibility and/or Rh sensitization in a prior pregnancy	2	WA 3	2	2		No change
Labor management	Induction	3	NICE 3 ACNM 3	--	3		No change
	Augmentation	--	CMBC 2	--	--		No change
	Desire for pain management	--	WA 3	--			No change
	Failure to progress/failure of head to engage in active labor	3	CMBC 2 WA 3* NICE 3*	--	3	*nullipara	No change
	Lack of adequate progress in 2nd stage with cephalic presentation	3	--	3*	3	*no descent after 3 hours of pushing where the mother is fully dilated and has ruptured membranes; and active pushing	No change
	Lack of adequate progress in 2nd stage with breech presentation	--	--	2*	--	*no descent after 1 hour active pushing	No change
Macrosomia	Prior baby > 4.5 kg or 9 lbs 14 oz.	2	CMBC 2	--	--		Removed existing criterion

Condition	Sub-condition	HERC 2015 CG	Other	2020 Oregon DEM final rule	2020 HERC CG proposed	Footnotes	Description of EbGS change from 2015
	Suspected (estimated weight >4.5 kg or 9lbs 14 oz.)	2	NICE 3	--	--		Removed existing criterion
Maternal Age	**<17 or > 40 years**	--	CMBC 2	--	--		No change
Miscarriage/nonviable pregnancy	**Ectopic**	--	--	3	--		Out of report scope
	Incomplete miscarriage	--	--	3	--		Out of report scope
	Molar	3	CMBC 3 WA 3	--	3		No change
	3 or more 1st trimester spontaneous miscarriages	2	CMBC 2	--	--		Removed existing criterion
	1 or more 2nd trimester spontaneous miscarriage	2	CMBC 2	--	--		Removed existing criterion
Meconium	**Thick meconium staining of amniotic fluid**	3	CMBC 2 any NICE 3 WA 3 AABC 3 ACNM 3 ACOG 3 CMBC 2/3*	3*	--	*birth not imminent	Remove existing criterion
Multiple gestations		3	NICE 3 WA 3	3~/2^	3	*consult for twins, transfer for others with additional guidance in document ~Higher-order multiples (triplets or more) or monochorionic, monoamniotic twins, twin-to-twin transfusion or presenting twin transverse	No change

Condition	Sub-condition	HERC 2015 CG	Other	2020 Oregon DEM final rule	2020 HERC CG proposed	Footnotes	Description of EbGS change from 2015
						^dichorionic, diamniotic twins, monochorionic, diamniotic twins	
Neonatal encephalopathy in prior pregnancy		3	NICE 3	--	2		Revised existing criterion
Neurological	**Significant maternal confusion or disorientation**	--	WA 2*	--	--		No change
	Maternal seizure disorder (excluding eclampsia) (History of)	2	--	--	--		Removed existing criterion
	Neurological disorders or active seizure disorders that would impact maternal or neonatal health	--	ACNM 3*	--	3~	*epilepsy	Added new criterion
			NICE 3^			^epilepsy, myasthenia gravis, previous cerebrovascular accident	
			WA 3			~e.g. epilepsy, myasthenia gravis, previous cerebrovascular accident	
Obesity or overweight (pre-pregnancy)	**Low or high BMI**	--	CMBC 2*	--	--	*specifics not provided BMI At first prenatal visit	No change
	BMI 25 to 29.9	--	--	--	--		

Condition	Sub-condition	HERC 2015 CG	Other	2020 Oregon DEM final rule	2020 HERC CG proposed	Footnotes	Description of EbGS change from 2015
	Class 1: BMI 30 to 34.9	--	--	--	--		
	Class 2 or 3: ≥ 35.0	2	NICE 3	--	--		Removed existing criterion
Oligohydramnios or polyhydramnios		3	ACNM 3 CMBC 2 NICE 3* WA 2	2	3	*oligohydramnios with additional complicating factors, transfer if suspected in labor	No change
Parity	**Grand multipara (5 or more previous births)**	--	CMBC 2	--	--		No change
	Nulliparity		HERC draft Evidence Review		--		No change
Perineal laceration or obstetric anal sphincter injury	**3rd degree prior pregnancy**	2	CMBC 2	--	--		Removed existing criterion
	4th degree prior pregnancy	2*/3	CMBC 2	3	--	*with satisfactory functional recovery	
	3rd degree current pregnancy	2*/3	CMBC 2	--	3^	*not requiring hospital repair ^requiring hospital repair	
	4th degree current pregnancy	3	CMBC 2 WA 3	3	3		
	History of obstetrical anal sphincter injury without satisfactory functional recovery	3	--	--	3		No change

Condition	Sub-condition	HERC 2015 CG	Other	2020 Oregon DEM final rule	2020 HERC CG proposed	Footnotes	Description of EbGS change from 2015
	Laceration requiring hospital repair or beyond expertise of attendant	3	ACNM 3 WA 3	3	3		No change
	Bladder or Rectal dysfunction	3	CMBC 2	--	--		Removed existing criterion
	Enlarging Hematoma	3	--	3	3		No change
Placental conditions	**Low lying placenta within 2 cm or less of cervical os at 36 weeks or later**	3	--	3	3*	*38 weeks or later	Revised existing criterion
	Placenta previa	3	ACNM 3 CMBC 2/3* NICE 3 WA 3	3	3	*consult at third trimester if asymptomatic, transfer if symptomatic	No change
	Vasa previa	3	CMBC 2	--	3		No change
	Evidence of or suspected placenta accreta	--	--	3	--		No change
	Abruption with adverse outcome			2	--		No change
	Abruption	3	CMBC 3* NICE 3 WA 3^	3/2^	3	*if only suspected, consult ^past the first trimester	No change
	Retained placenta	--	ACNM 2 CMBC 2 WA 3	3	--		No change

Condition	Sub-condition	HERC 2015 CG	Other	2020 Oregon DEM final rule	2020 HERC CG proposed	Footnotes	Description of EbGS change from 2015
	Retained placenta > 60 minutes	3	--	--	3		No change
	History of retained placenta requiring surgical removal	3	ACNM 3	--	3		No change
	History of retained placenta requiring manual removal	NA	ACNM 3	--	--		No change
Prenatal care	**No prenatal care until 3rd trimester**	--	CMBC 2 WA 2	--	--		No change
	Inadequate prenatal care*	2*	--	--	--	*< 5 visits or care began in 3rd trimester	Removed existing criterion
	Noncompliance with the plan of care (e.g., frequent missed prenatal visits)	--	WA 3	--	--		No change
Preterm birth (history of)	**History of >1 preterm birth**	2	CMBC 2	--	--		Removed existing criterion
	History of preterm birth (before 34 weeks)	2	CMBC 2	--	--		
Psychiatric disease	**Severe psychiatric illness**	--	WA 3	--	--		No change

Condition	Sub-condition	HERC 2015 CG	Other	2020 Oregon DEM final rule	2020 HERC CG proposed	Footnotes	Description of EbGS change from 2015
	Maternal mental illness requiring inpatient care	3*	--	--	--	*history of	No change
	Mental health concerns presenting or worsening during pregnancy	--	CMBC 2	--	--		No change
	Postpartum psychosis	--	CMBC 3	--	--		No change
	Maternal mental illness under outpatient psychiatric care with suspicion for psychosis or potential harm to self or infant	2	--	--	2^*	*maternal mental illness requiring psychological or psychiatric intervention or psychotropic medications ^history of postpartum mood disorder with high risk to the infant; schizophrenia, other psychotic disorders, bipolar I disorder or schizotypal disorder	Clarified existing criterion
	Psychiatric condition that may affect intrapartum care management or maternal or neonatal transition following birth	--	ACNM 3	--	--		No change

Condition	Sub-condition	HERC 2015 CG	Other	2020 Oregon DEM final rule	2020 HERC CG proposed	Footnotes	Description of EbGS change from 2015
	Postpartum depression or (postpartum) mood disorder with suspicion of possible endangerment to self or others	--	--	3	--		No change
	History of serious psychological problems	--	CMBC 2	--	--		No change
	Psychiatric disorders with concern for maternal and fetal safety	--	--	2	--		No change
Pulmonary	**Active respiratory distress**	--	WA 3*	--	--	*postpartum	No change
	Pulmonary disease	--	WA 3 NICE 3*	--	2^	*asthma requiring an increase in treatment of hospital treatment, cystic fibrosis ^2 for history of chronic pulmonary disease	Added new criterion
Renal	**Acute pyelonephritis**	--	WA 2	--	2		Added new criterion
	Renal disease	--	CMBC 3* NICE 3^ WA 3	2~	3%	*with failure ^abnormal renal function, renal disease requiring supervision by a renal specialist" ~abnormal renal function (consultation)	Added new criterion

Condition	Sub-condition	HERC 2015 CG	Other	2020 Oregon DEM final rule	2020 HERC CG proposed	Footnotes	Description of EbGS change from 2015
						%renal failure or requiring a specialist	
Rheumatological	Systemic lupus erythematosus	--	NICE 3	--	2		Added new criterion
	Scleroderma	--	NICE 3	--	2		Added new criterion
Shoulder dystocia	History of, with or without fetal clavicular fracture	2	NICE 2 ACNM 3	--	2		Clarified existing criterion
Substance use	Drug or alcohol use with high-risk for adverse effects to fetal or maternal health	3	--	--	3*	*drug or alcohol misuse with high-risk for adverse effects to fetal or maternal health	Clarified existing criterion
	Substance use disorder	--	--	2	--		No change
	Cigarette and/or cannabis use	--	CMBC 2	--	--		No change
	Significant use of drugs, alcohol or other toxic substances	--	CMBC 2	--	--		No change
	Substance abuse/dependence	--	ACNM 3	--	--		No change
	Substance misuse, alcohol dependency requiring assessment or treatment	--	NICE 3	--	--		No change
	Active substance abuse	--	--	3	--		No change

Condition	Sub-condition	HERC 2015 CG	Other	2020 Oregon DEM final rule	2020 HERC CG proposed	Footnotes	Description of EbGS change from 2015
Surgical	**Laparotomy during pregnancy**	2	--	--	--		Removed existing criterion
Umbilical cord	**Prolapse**	3	CMBC 3 WA 3	3	3		No change
Uterine condition	**Anatomic anomaly (e.g. bicornuate, large fibroid impacting delivery)**	--	WA 2 CMBC 2	2	2		Added new criterion
	Prior hysterotomy	3	CMBC 2 NICE 3	--	3		No change
	Prior myomectomy	--	CMBC 2 NICE 3	2	2		Added new criterion
	Uterine rupture, inversion or prolapse	3	CMBC 2/3* NICE 3 WA 3%	3^	2*/3	*Uterine prolapse is a consultation criterion; rupture and inversion require transfer ^Rupture only %postpartum uterine prolapse or inversion only.	Revised existing criterion

Appendix J. Risk Criteria Matrix: Newborn

3	2	1	NA	--
High-risk condition requiring planned hospital birth or transfer to hospital	Consultation required	Eligible for planned out-of-hospital birth provided no other complicating conditions are present	Not applicable or superseded by a separate recommendation	No recommendation identified

Condition	Sub-condition	2015 HERC CG	Other	2020 Oregon DEM final rule	2020 HERC CG proposed	Footnotes	Description of EbGS change from 2015
Anatomic anomaly	**Evidence of or suspected major congenital anomaly or abnormality**	3	CMBC 2	3	--	*unless no resuscitation planned	Removed existing criterion
	Fewer than 3 vessels in umbilical cord	--	CMBC 2	--	--		No change
	Unexpected significant or life-threatening	3	--	--	--		Removed existing criterion
	Major apparent abnormalities	--	WA 3	--	--		No change
	Significant congenital anomaly requiring immediate medical intervention, for example omphalocele, myelomeningocele	--	CMBC 3	--	--		No change
	Any other abnormal findings on physical exam	--	CMBC 2	--	--		No change
Apgar score	**< 5 at 5 minutes**	3	--	--	--		Removed existing criterion
	< 7 at 10 minutes	3	CMBC 3	3	--		Removed existing criterion
Appearance	**Excessive ruddiness**	--	--	2	--		No change
	Not clinically well appearing	--	AAP 3	--			No change

Condition	Sub-condition	2015 HERC CG	Other	2020 Oregon DEM final rule	2020 HERC CG proposed	Footnotes	Description of EbGS change from 2015
	Persistent poor suck, poor feeding, lethargy, hypotonia or abnormal cry	--	CMBC 2	2	--		No change
Blood sugar	**Hyperglycemia/hypoglycemia unresponsive to treatment**	3	AAP 3	--	--		Removed existing criterion
	Prolonged glycemic instability	--	WA 3	--	--		No change
Dermatological	**Abrasions, unusual pigmentation and/or lesions**	--	CMBC 2	--	--	*severe abrasions	No change
	Any generalized rash at birth	--	--	2	--		No change
Gastrointestinal	**Significant distended abdomen**	--	--	3	--		No change
	Evident or suspected abnormally elevated bilirubin.	--	--	2	--		No change
	Vomiting, diarrhea	3	CMBC 2	--	--		Removed existing criterion
	Persistent projectile or bilious vomiting or emesis of fresh blood	--	--	3	--		No change
	Jaundice prior to 24 hours	--	CMBC 2 WA 3	--	--		No change
	Failure to pass stool within 48 hours after birth	--	--	2	--		No change
General medical	**In utero exposure to significant drugs, alcohol, or other substances with known or suspected teratogenicity**	--	CMBC 2	--	--		No change
Gestational age	**34 + 0 to 36 + 6 weeks**	--	CMBC 2	2*	--	*less than 36 weeks and 0 days	No change
	Clinical evidence of prematurity (age < 35 weeks)	--	WA 3	--	--	*e.g. Ballard	No change
	< 37 weeks	--	AAP 3	--	--	*obstetrically determined	No change

Condition	Sub-condition	2015 HERC CG	Other	2020 Oregon DEM final rule	2020 HERC CG proposed	Footnotes	Description of EbGS change from 2015
Infectious disease/HIV	Infant born to an HIV positive mother	--	--	2*	--	*consult must be with a pediatrician	No change
	Evident or suspected infection			3	--		No change
	Infection of umbilical stump site	--	CMBC 2	--	--		No change
	Maternal chorioamnionitis	--	AAP 3	--	--		No change
Musculoskeletal	Excessive bruising, enlarging cephalohematoma, significant birth trauma	3	CMBC 2	--	--		Removed existing criterion
	Birth injury such as facial or brachial plexy, suspected fracture or severe bruising	--	CMBC 2*	2	--	*birth injury requiring investigation	No change
	Birth injury requiring medical attention	--	WA 3	--	--		No change
Neurological	Hypotonia, tremors, seizures, hyperirritability	3	CMBC 3	--	--	--	Removed existing criterion
	Seizures	3	CMBC 3 WA 3	3	--		Removed existing criterion
	Evidence or suspected neonatal opioid withdrawal syndrome	--	--	2	--		No change
Temperature	Instability, fever, suspected infection or dehydration	3	CMBC 2	3	--		Removed existing criterion
	Persistent inability to maintain temperature between 97 to 100 degree Fahrenheit	--	CMBC 2	3	--		No change
	Prolonged temperature instability when intervention has failed	--	WA 3	--	--		No change
Respiratory or cardiac	Irregularities, cyanosis, pallor	3	CMBC 2 WA 3	--	--		Removed existing criterion

Condition	Sub-condition	2015 HERC CG	Other	2020 Oregon DEM final rule	2020 HERC CG proposed	Footnotes	Description of EbGS change from 2015
	Prolonged positive pressure ventilation or significant resuscitation	--	CMBC 3	--	--		No change
	Abnormal heart rate pattern or persistent/symptomatic murmur	--	CMBC 3	2	--		No change
	Respiratory rate > 100 within 2 hours of birth and > 80 lasting more than 1 hours without improvement	--	--	2	--		No change
	Heart rate less than 80 or greater than 160 (at rest) without improvement	--	--	2	--		No change
	Pulse oximeter reading of less than 90 percent on right hand at greater than 24 hours	--	--	2	--		No change
	Apnea, central cyanosis, unresolved pallor at birth	--	CMBC 2	3	--		No change
Urinary	**Failure to urinate within 24 hours after birth**	--	CMBC 2*	2	--	*36 hours of life	No change
Weight	**< 5th percentile for gestational age**	3	CMBC 2	--	--		Removed existing criterion
	<2000 grams	--	WA 3	--	--		Removed existing criterion
	<2,270 grams (5 lbs)	--	--	3	--		Removed existing criterion
	< 2500 grams	--	CMBC 2	--	--		Removed existing criterion
	Loss > 10% of birth weight/ failure to thrive	--	CMBC 2 WA 3	--	--		No change

Condition	Sub-condition	2015 HERC CG	Other	2020 Oregon DEM final rule	2020 HERC CG proposed	Footnotes	Description of EbGS change from 2015
	Weight loss in excess of 10% of birth weight that does not respond to treatment	--	CMBC 2	2	--		No change

† Rules as of January, 2020

HERC Coverage Guidance: Planned Out-of-Hospital Birth
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Discussion Table

Discussion Item ID	Comment IDs/ #s	Summary of Issue	Subcommittee Response
1	C2, D1, D3, E1, F1, G1, I1, J1, K1, L1, O1, S1, U1, V1, Y1, AB1	Several commenters said the draft goes into much more detail than most coverage recommendations (including other HERC coverage guidance). Some said risk conditions result in uncertain or variable risk, and others requested a much shorter list of birth risk criteria. Some said the draft coverage guidance is (or has criteria more appropriate for) a practice guideline or licensing rule, and/or encroaches on the role of licensing boards. Most commenters highlighted several reasons the level of detail is problematic:	*According to the rationale for the recommendation, these criteria are more detailed than most HERC criteria because planned out-of-hospital birth is associated with a higher infant mortality rate in the United States. These recommendations aim to reduce the potential harms by clearly identifying the low-risk population for which coverage is recommended.* *In Oregon, out-of-hospital births are not universally well-integrated into the health care system, potentially resulting in delays and poor coordination of care at critical times during pregnancy, labor, and delivery, which can further exacerbate potential harms.*

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Discussion Item ID	Comment IDs/ #s	Summary of Issue	Subcommittee Response
		• Some commenters said that the detailed criteria interfere with a woman's reproductive choice. • The detailed transfer and consultation criteria create an administrative burden, which may limit access to services for planned out-of-hospital birth. Limiting access discriminates against low-income women and others who are disadvantaged. • Recommendations should not cover risks which arise during labor or postpartum care as these are not relevant to selecting a planned birth location. • Uncertainty or undesired changes in planned birth location, or undesired consultations causes stress, panic or trauma for women. • Extensive limits on coverage for planned out-of-hospital birth will drive women to give birth out-of-hospital and unattended, putting out-of-hospital birth attendants in a bind.	*Standards of care and educational requirements for birth attendants are also highly variable in Oregon.* *EbGS recommendations often cover factors relating to variable or uncertain risks. See high-risk condition response table for discussion of specific factors.* *These criteria are not intended as practice standards or licensing rules (though they may be of interest to those developing such standards) but as criteria for coverage of planned out-of-hospital birth.* *To address the comments about the list of criteria being too extensive and limiting access to out-of-hospital birth for low-risk pregnancies, EbGS decided to eliminate a number of consultation and transfer criteria which appeared in the draft posted for comment. While many of the risk factors the subcommittee removed create concerning risk for labor and delivery, using them to define coverage may result in substantial clinical and implementation burden. To balance these concerns, EbGS has removed all of the criteria originating from the Board of Direct Entry Midwifery licensing rules as well as numerous criteria that were recommended only by the College of Midwives of British Columbia, otherwise had*

Discussion Item ID	Comment IDs/ #s	Summary of Issue	Subcommittee Response
		• Some consultation criteria pose an excessive burden, because potential consulting providers are too busy, refuse to consult or never recommend out-of-hospital birth. Many consultation criteria are unnecessary and wasteful and interfere with care. One commenter congratulates HERC for the exhaustive list of risks, and said the approach is similar to guidelines established in high-income countries for planned home birth.	*limited alignment across other health systems/guidelines or were based on subjective criteria that would be difficult to interpret. In addition, EbGS removed all neonatal/postpartum transfer and consultation criteria.*
2	I17	This commenter said international studies are not relevant because different standards are in place in other countries. Basing a recommendation on outcomes from places with different systems of care and regulatory standards is inappropriate. 1. The studies were mostly done in countries where there are strict guidelines for planned home births (e.g., no twins, no prior cesarean, no older women).	*EbGS acknowledges the external validity concerns for international studies, but explicitly decided to include these studies in the evidence search since they demonstrate that good outcomes are possible in the out-of-hospital setting. The factors you identified are mentioned in the draft coverage guidance.* *To mitigate the risk present in the U.S. context, this draft coverage guidance box language recommends against coverage for women with certain high-risk conditions.*

Discussion Item ID	Comment IDs/ #s	Summary of Issue	Subcommittee Response
		2. The midwives doing planned home births in non-U.S. studies are well trained and often have hospital privileges. The midwives in these non-U.S. countries are well integrated in their health systems.	*Regulation of training and systems integration are not within the EbGS's scope to change, but these considerations influenced the EbGS decision to include certain risk factors as a way to minimize risks in an environment with variable integration and training standards.*
3	C2, D1, D3, E1, L1, S1, U1, U14	Many commenters said that the draft coverage guidance is not evidence-based. An evidence-based guidance would only include risk criteria clearly identified based on evidence. Instead, some criteria are based on expert or Subcommittee opinion or external standards. Commenters said the evidence selected for this review is not appropriate to guide these recommendations. Research about hospital birth does not tell us what happens in planned out-of-hospital birth. Research specific to risks in planned, midwife-attended out-of-hospital birth is the evidence that is actually relevant to this guidance.	*Evidence was not available on all the specific risk criteria. In cases where there is little or no evidence, HERC often relies on guidelines, expert opinion and standards from other systems or payers to guide its recommendations. For this draft coverage guidance, the subcommittee based its recommendations on risk factors identified in evidence, factors that served as exclusion criteria of low-risk out-of-hospital births in available studies, and guidelines and practice standards of various bodies that regulate or make recommendations for the practice of out-of-hospital births in settings with excellent out-of-hospital birth outcomes.* *Comparative evidence sources are imperative to address the effectiveness and safety of any intervention. The HERC Coverage Guidance focused on evidence that*

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		Several commenters supported a shorter list of evidence-based exclusions in the coverage guidance.	*compared planned out-of-hospital birth outcomes to planned hospital birth outcomes. This is the most relevant evidence to understand the relative benefits and harms between the two intended birth settings.* *While the available comparative studies within the U.S. contain methodological drawbacks due to limitations of available data sources (e.g., vital statistics) and unresolved confounding or effect modification, they provide relevant evidence for this report.* *It is unclear what specific additional evidence the commenters wish to have added to the coverage guidance. The draft coverage guidance does include limited noncomparative data about out-of-hospital births for identification of certain risks associated with bad outcomes. Many of these studies excluded high-risk populations. See Appendix H.*
4	See *high-risk condition response table*	Multiple comments express concern for the addition, deletion, or modification of specific risk factors.	*See high-risk condition response table for responses to concerns about specific risk factors.*

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Commenters

Identification	Stakeholder
A	Clorissa Hecky, Stay-at-Home Mom/Doula [*Submitted December 19, 2019*]
B	Leonardo Pereira, MD, MCR, Associate Professor, Division Director Maternal Fetal Medicine, Oregon Health & Science University [*Submitted December 19, 2019*]
C	Silke Akerson, CPM, LDM, Oregon Midwifery Council [*Submitted December 31, 2019*]
D	Celeste Kersey, CPM, LDM, President, Oregon Midwifery Council [*Submitted December 31, 2019*]
E	Sarah McClure, CPM, LDM, LM, Hearth and Home Midwifery [*Submitted December 31, 2019*]
F	Whitney Wolfe, CPM, LDM, Harbor Midwifery [*Submitted January 1, 2020*]
G	Mark Lakeman, Founder, Communitecture [*Submitted January 2, 2020*]
H	Jennifer Justice Gallardo, President, Oregon Association of Birth Centers [*Submitted January 2, 2020*]
I	Amos Grunebaum, MD, Professor, Zucker Medical School, Director of Perinatal Research [*Submitted January 3, 2020*]
J	Monica Acre, CNM, Virginia Garcia Memorial Health Center [*Submitted January 5, 2020*]
K	Jessica Ruediger, LDM, CPM, Moonstone Midwifery, LLC [*Submitted January 6, 2020*]
L	Eleanor Hawkins, CPM, LDM, IBCLC, Wallowa Mountain Midwifery [*Submitted January 6, 2020*]
M	Miya Tischler [*Submitted January 7, 2020*]
N	London Lunoux [*Submitted January 7, 2020*]
O	Stephanie Dorr [*Submitted January 7, 2020*]
P	Vanessa Lyon, NP, Canyon Medical Center [*Submitted January 7, 2020*]
Q	Catherine Bailey, CPM, LDM, Member of the Oregon Midwifery Council [*Submitted January 7, 2020*]
R	Holly Nickerson, MBA, BSN, RN, CPHQ, CPPS, Asante Director of Quality, Asante Health Systems [*Submitted January 8, 2020*]
S	Nicole Bendotoff, CPM, LDM, Flourish Women's Wellness and Midwifery [*Submitted January 8, 2020*]
T	Carrie Saum [*Submitted January 8, 2020*]
U	Vileka Fisher, Naturopathic Medicine Program, Class of 2021, National University of Natural Medicine [*Submitted January 8, 2020*]
V	Karen Deon, Birth Center Manager, Canyon Medical Center [*Submitted January 8, 2020*]
W	Aimee Morrisey [*Submitted January 8, 2020*]
X	Jessica Morton, Software Validation Test Engineer [*Submitted January 8, 2020*]

Y	Sarah Dinger, Student Midwife [*Submitted January 8, 2020*]
Z	Jennifer Jensen [*Submitted January 8, 2020*]
AA	Sharron Fuchs, DC [*Submitted January 8, 2020*]
AB	Karen DeWitt, ND, Owner of Canyon Medical Center [*Submitted January 8, 2020*]

Public Comments

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A1	I'm here commenting on the Coverage Guidance for Planned Out of Hospital Birth to tell you my birth story in a Birthing Center and a Hospital. I have had two pregnancies, both with no complications and very healthy babies. My firstborn was brought into the world in a Birth Center in Oregon. Being a survivor of sexual assault, I knew I needed to have care where what I said was genuinely accounted for, have little to no interference, and was surrounded by women. All three of these things happened. Everything I said that I wanted in my birth happened. The pain I experienced was next to nothing while being submerged in water and knowing that I was surrounded by people who truly had my and my babies best interest in their hearts. My birth experience at the Birthing Center has been something that I treasured and revered because for once I was respected and honored. I left feeling absolutely empowered. During postpartum, my child never ever left my side..... but it truly would not have been possible without OHP. With OHP the Birth Center was able to give me a discount which made the birth affordable. At the time I left an abusive relationship, and was a single mother without a job. OHP gave me the birth that I needed to become a better person, and an even better mom. When I left the birthing center with my child tucked under my arm, I knew that giving birth at the Birthing Center was the best decision that I had ever made. Thanks to OHP and the out of hospital midwives.	*Thank you for sharing your experience. The Values and Preferences section of the draft report acknowledges the strong preferences women have for planning the location of birth.* *See response to Discussion Table item 3.* *Regarding cost, though the lower cost of out-of-hospital birth would potentially be offset by other factors including transfers and some avoidable complications, the subcommittee expects the net cost to be lower for planned out-of-hospital birth. That said, HERC uses resource allocation as only one factor in decision-making and the coverage recommendation reflects the*

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	My second born was born into a Hospital. There I was bombarded with questions, people and fingers. The pain I felt was terrible because I was overwhelmed by everyone in the room asking me questions and wanting to do internal exams. When I was literally pushing out my child, the nurses jerked back my legs (which caused a birth injury that I needed physical therapy for) and yanked out my child. In postpartum, they kept taking away my child for everything from tests to diaper changes. My newborn would cry and cry and cry. It took several months for my child to be okay with diaper changes from that experience. Also, whatever decision I made for my son was judged and ridiculed by staff..... I left that hospital with severe PTSD, flashbacks to my sexual assault, physically injured and with a child who scared to be away from his mother. It has me questioning if I'll ever be able to have another child again. Those are my birth stories. Now a few years later, I am a Doula. I know the facts and studies to an in hospital birth to an out of hospital birth..... and my in hospital birth was technically pretty good compared to what most women have had. Over regulating who gets to see a midwife is wrong because the stats and figures show that it's safer and more humane for moms and children to give birth with a midwife. Midwives are meant for ALL moms who are low risk, and actually there are very few conditions as to why a mom should go to a hospital for birth. Just look at the statistics of a birth center or midwife, they're a lot better looking the obstetricians. From a political standpoint, it's actually a lot more inexpensive to use out of hospital midwives! A 3,000 per birth cost instead of a 30,000-50,000 birth cost is a lot easier on taxpayers pockets.	*importance of maternal choice of intended birth location for low-risk pregnancies.*

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	The effects on future generations are going to be widely positive too. Think of how a drugged up baby will be 5 years down the road, or a child who hasn't had their lungs fully emptied from a cesarean birth, or the mother who had an episiotomy. Think of how much more money you could put towards cancer patients than unnecessary hospital births. Supporting the out of hospital midwives is the right answer! P.S. I did grow up out in Oregon. I'm currently living in Ohio with my husband who is from here.	
B1	I have been delivering babies in Oregon for the last 15 years and have performed over 1000 deliveries. I am proud of the collaboration that members of Oregon Health & Science University, Oregon Health Authority, and the Oregon homebirth midwife community have demonstrated in working together to maximize birth experiences and safety for Oregon pregnant patients. In addition to a familiar environment and autonomy over their birth process, Oregon's home birth consumers deserve accurate information about safety and outcomes of delivery under special circumstances. As much as we try to avoid risk in childbirth, it is impossible to eliminate risk entirely, but some factors such as breech, prematurity, prior cesarean section (VBAC or TOLAC), twins and triplets have a high rate of preventable adverse outcome which is directly tied to not only attempting delivery in a hospital, but more importantly a hospital with in house anesthesia and neonatal care unit capabilities. In Oregon, community hospitals and birth centers automatically refer these patients to more specialized OB hospital programs for care, the community of home birth providers should at	*Thank you for your comments in support of inclusion of these risk factors as transfer criteria and alignment with the community hospitals' perspective on risk.*

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	the very least follow the same safety guidelines and recommend delivery at a specialized OB hospital program to the families they care for who are planning high risk deliveries. Thanks for considering my perspective.	
C1	Public comment during HERC meetings has been limited to only a few minutes and HERC staff have repeatedly stated that we could communicate at length about the many concerns we could not express in the meetings during the public comment period yet we have now been told that we must limit our public comment to1000 words. This draft guidance is many pages long, covers a large number of new risk criteria, and has massive effects on birthing people and our profession and there is no way to respond in less than 1000 words. This limit serves to restrict public comment. Our organization is sending our letter in three sections from the executive director, president, and vice president in response to this restriction.	*Thank you for your comments. The 1,000-word limit for individual public comments is standard across all HERC Coverage Guidances and has been in place since 2012.*
C2	I am writing on behalf of the Oregon Midwifery Council to express the concerns of birthing families and midwives about the overreach of the HERC in its current draft coverage guidance on planned out-of-hospital birth. The HERC has overstepped its purpose in this document, which is not the evidence-based coverage guidance it was directed to create, but a sprawling document that encompasses everything from solid evidence to members' personal opinions about what midwives should or shouldn't do and who should or shouldn't have a planned out-of-hospital birth. The HERC must reassess its approach to this coverage guidance and come back to the scope that is appropriate to this body. Recently I have been told by HERC staff and members that the HERC is only doing what it was instructed to do by OHA, but the scope and content of the current draft document are absolutely not consistent with what OHA has actually communicated nor with the stated	*The current draft coverage guidance was developed at request of the Health Evidence Review Commission after stakeholders with diverse views requested an updated version based on evidence.* *While HERC's process is evidence-based, there are many coverage-related questions which are not adequately addressed by evidence. In that context, coverage decisions are frequently informed by expert opinion and standards from other payers,*

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	purpose of the HERC. I was a member of the 2014 LDM Staff Advisory Workgroup that directed the HERC to create coverage guidance on planned out-of-hospital birth (though I was the dissenting member on this recommendation because I feared bias against midwives and ignorance about community birth would cause the HERC to act irrationally) and I remember clearly that we simply requested that the HERC create coverage guidance on planned home birth. The primary motivation for our 2014 request was to provide an evidence review by this respected body that could help CCOs understand that covering planned out-of-hospital birth is evidence-based. We asked that the HERC review the evidence on appropriate candidates for home birth and safety criteria and assumed that the HERC would create coverage guidance, consistent with its previous work, that briefly and simply stated a recommendation for coverage and gave the short list of evidence-based risk criteria that would not be covered for planned out-of-hospital birth by OHP. In that 2014 work group we pre-identified six evidence-based risk criteria that would be excluded before the HERC process and we imagined that the HERC would add a limited number of other evidence-based exclusion criteria based on the research on planned out-of-hospital birth. Instead the HERC has created lengthy practice standards, many of which are not based in the evidence on planned-out-of-hospital birth at all but on the personal or professional opinions of HERC members, none of whom are experts in out-of-hospital birth. At this point the guidance is so comprehensive that it overrides our scope of practice, statute, and rules in many areas, and functions as regulation of the practice of midwifery in out-of-hospital settings for any midwife who is a Medicaid provider.	*professional societies and experts. In this case we have considered these factors as well as practice standards from health systems in other countries where outcomes are good for planned out-of-hospital birth. The subcommittee considered standards from the sources listed in Table 3 of the draft coverage guidance, including several midwife-led groups.* *EbGS deliberations are informed by the expert opinion of four ad hoc experts, including two midwives who have attended or continue to attend out-of-hospital births.* *The HERC Coverage Guidance is a recommendation to Oregon payers, including Oregon Medicaid which is responsible to implement coverage criteria reflected on the Prioritized List of Health Services. This report is not intended to serve as practice standards for any group of licensed providers, though it reflects risk criteria which may be of interest to some licensing bodies.*

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	It is unclear to me how things have come to this point. Was there some direction from OHA that is not part of the public record? Is the opinion of an out-of-state anti-midwife researcher so powerful that it can change the course of this body? Is there some information about decision-making in this process that we, as members of the public, have not had access to? It is hard to know who is directing this process or the OHA's internal work on the prior authorization process at this point. When asked, the HERC points to OHA as the decider and OHA points to the HERC, each body saying that the current state is out of their control and created by the other. In the end, what matters is that there is recognition that, while we all agree that standards of practice for midwifery and out-of-hospital birth are important, it is absolutely not within the purview of the HERC to create professional standards of practice. I want to be clear that we do support an evidence-based HERC coverage guidance on planned-out-of-hospital birth. However, I cannot emphasize enough how far this process has strayed from that intent. A comparative example of HERC coverage guidance that is both evidence-based and appropriate in its scope is the HERC coverage guidance on Indications for Planned Cesarean Delivery. Planned cesarean delivery has significant risks for the mother in the current pregnancy and even more serious risks for both mother and baby in subsequent pregnancies. The relevant HERC guidance restricts itself to the evidence available on this topic and, in one page, recommends coverage for planned cesarean section for 6 indications and does not recommend coverage for 6 indications. It goes on to state, "For prior cesarean delivery and other conditions for which there is insufficient evidence of clear benefit over harms, coverage may be based on an individualized treatment plan." In contrast to this clear, concise, and evidence-based guideline on Planned Cesarean, I am able to find no other HERC	*See Discussion Table items 1 and 3 for EbGS's decision to significantly reduce the number of listed risk criteria, and comment E1 below.*

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	guidance that even approaches the overreach present in the Planned Out-of-Hospital Birth guidance. Please see our continued comments in the letter from Celeste Kersey, Oregon Midwifery Council President. Thank you for your consideration,	
D1	In continuation of our concerns expressed in Silke Akerson's 12/31/19 letter: We are deeply concerned about overreach in the current HERC draft guidance on planned out-of-hospital birth. If the HERC were to assess planned out-of-hospital birth and midwifery using the standard found in other guidance such as the Indications for Planned Cesarean Delivery, the outcome would be a short coverage guidance that recommends coverage of planned out-of-hospital birth for low-risk pregnancies and names the limited number of risk factors for which there is clear evidence of increased risk in the out-of-hospital setting such as uncontrolled gestational diabetes, preeclampsia, breeches, twins, pre-term births, etc. It would not seek to cover every possible risk that midwives should assess, it would not seek to cover risks factors in labor or postpartum which are not relevant to guidance about prenatal planning for place of birth, nor would it seek to dictate the consultation relationship between midwives and receiving hospital providers. We applaud the rigorous evidence review on planned out-of-hospital birth that the HERC has undertaken which is a useful resource for us all. We implore you to step back from drafting professional practice standards, which is not your scope, and use that evidence, including observational studies, to name those limited risk exclusion criteria for which there is clear evidence from the research on out-of-hospital birth. If this does not happen and the HERC continues to create professional practice standards, of	*See responses to comment C2 above, Discussion Table items 1 and 3, and comment E1 below.*

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	the kind that are used by midwifery professional organizations in the US, Canada, the UK and the Netherlands, then you must acknowledge what you are doing, name this as something other than coverage guidance, and include Licensed Direct-Entry Midwife, Certified Nurse-Midwife, and Naturopathic Physician Midwife experts who are Medicaid providers directly in the process. Each of you who are health care providers know how absurd it would be for me to write practice standards for your profession without your input and the current process is equally absurd. Knowing that you may proceed with this process even though it is outside the scope of the HERC, [Name redacted] will also submit the public with some specific concerns about individual risk criteria included in the current draft in a separate letter. As you know, planned midwife-attended birth in the home or birth center setting is not the same as hospital birth. This is not only true in some of the ways that you have noted, such as access to a cesarean section, but also in the innumerable ways that the physiologic processes of pregnancy, birth, and postpartum are impacted by the differences in care, environment, and resources in a planned home birth. Research about hospital birth does not tell us what happens in planned out-of-hospital birth. Research specific to risks in planned, midwife-attended out-of-hospital birth is the evidence that is actually relevant to this guidance.	
D2	There are many examples that show how different outcome can be in the different settings: the rate of infection (chorioamnionitis) is lower in planned out-of-hospital birth than it is in hospital birth; the risk of 3rd and 4th degree tears is much lower for low-risk people giving birth at home than it is in the hospital; the risk of hemorrhage is lower in planned out-of-hospital birth even when risk factors are controlled for.	*As summarized in the evidence review, for several maternal outcomes the risk is similar or lower in the out-of-hospital setting compared to the hospital setting, supporting the recommendation for*

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		coverage of planned out-of-hospital birth for low-risk pregnancies.
D3	You cannot simply apply hospital-based research to an out-of-hospital setting. As you look over the numerous risk criteria in the draft HERC coverage guidance on planned out-of-hospital birth please ask yourself, "what evidence do we have about the outcomes for this risk factor in the out-of-hospital setting?" If the answer is no evidence or mixed evidence, it does not belong in this evidence-based guidance. If there is a risk factor that does not have strong evidence that you think should be in midwifery professional standards that is not already, please communicate that with the appropriate professional organizations. Thank you for your consideration,	*See response to Discussion Table item 3, and comment E1 below.*
E1	I am writing to express my concern regarding the draft of the Coverage Guidance document for Planned Out of Hospital Birth. As a Certified Professional Midwife licensed in both Oregon and Washington, I am intimately familiar with the practice of community midwifery and the risk assessment necessary to optimize safe outcomes for birthing people and newborns. My interest in maternal and neonatal safety underlines my enthusiasm for reasonable and evidence-based recommendations by professional organizations; however, the document in review by HERC is meant to be a coverage guideline and not a professional practice standards draft. It is my assessment that the document created by HERC is far too wide in its scope and attempts to enter into discussions that are meant for professional organizations. The intended purpose of this document was to create evidence-based coverage guidelines, and yet there are a number of limitations listed for transfer and consult in the guideline that are not evidence-based. They have been enumerated in other correspondences and do not	*Thank you for your comments.* *See response to Discussion Table items 1 and 3.* *These criteria are not intended as practice standards or licensing rules (though they may be of interest to those developing such standards) but as criteria for coverage of planned out-of-hospital birth. EbGS has reduced the number of consultation and transfer criteria in response to this and other similar comments.*

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	need repeating here. It is the professional obligation of midwives to perform risk assessment and that the guidelines attempt to shift the burden of risk assessments from the professionals (i.e. midwives) to the HERC organization. Home birth midwives are the specialists in assessing who is appropriate for community birth and already have professional organizations to guide us. The document fails in two key ways: a) it does not offer the guidelines it was designed to offer and b) it does not draw on relevant evidence to arrive at conclusions. The evidence that goes into drafting an out-of-hospital guideline must be primarily based on out-of-hospital research, if such research is available. The members of the committee will be familiar with the differences between planned community and planned hospital births, and relevant research must be the focal point of literature review if the guidelines are to be useful and promote safety. Please consider the numerous voices urging you to review the original intent of the document you have created and to read the document with an attuned eye for bias, over-simplification, and digression from the scope. I look forward to reading a draft in the future that meets the stated objective of creating an evidence-based coverage guideline.	
F1	As a licensed Midwife, I am governed by rules and laws that have been carefully reviewed and voted on by our board of midwifery and have been based in evidence. The HERC guidelines have overstepped our governing body and have placed rules not based in evidence, but in fear. All pregnant people deserve the chance to make informed choices for their pregnancy based on evidence. These HERC rules suggest that low income pregnant people have less of a right to make informed choices about their pregnancy that someone with the ability to pay out of pocket. Ex: A healthy active women, one Caesarian, with one subsequent healthy delivery, with no other increased risk factors, history of healthy pregnancies, and on OHP	*See response to Discussion Table item 3, and to comment E1 above.* *The draft coverage guidance is developed as a resource for all Oregon payers, not just the Oregon Health Plan. The EbGS takes into account women's values and preferences, including values around intended birth location as reflected in the GRADE table.*

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	would have the choice of home birth taken away from her. But another women with the same history, and is fortunate enough to make enough money to pay out of pocket, is able to make the choice to birth at home. This rule does not take into account the risk of hospital birth further increasing the risk of having another Caesarian, which is currently 30-50% in hospitals, which dramatically increases morbidity and mortality and other complication, at a higher rate than home birth. HERC is overstepping our Midwifery board, is discriminatory against low income pregnant people and is not based in evidence. higher risk in the out-of-hospital setting?	*The EbGS also recognizes variation in judgments related to risk. The coverage recommendations in this report balance these with concerns about fetal and infant safety, and are intended to influence coverage decisions.* *Planned out-of-hospital birth is recommended for coverage when provided according to the listed criteria, which have been reduced from the version you commented on.* *Having clear coverage rules encourages high-quality care that results in good outcomes for low-income pregnant women and infants.* *Disparities based on ability to pay for services not covered under health plans exist in Oregon, not exclusive to Medicaid.* *Oregon's legislature has designated HERC to review evidence regarding health services and disseminate evidence-based health care guidelines for use by providers, consumers*

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		and purchasers of health care in Oregon (ORS 414.698). *See high-risk condition response table for discussion of vaginal birth after cesarean.*
F2	Delivery history. The evidence I am aware of is that the outcomes are good for mothers and babies for vaginal birth after cesarean for those who have had a previous vaginal birth.	*See separate high-risk condition response table.*
F3	Fetal demise or stillbirth. What evidence is there that a history of a previous unexplained stillbirth/neonatal death is associated with increased risk in the out-of-hospital setting? What evidence is there that a previous stillbirth/neonatal death related to the difficulties of a twin or breech birth is associated with increased risks for a current non-twin, non-breech pregnancy regardless of setting?	*See separate high-risk condition response table, and response to Discussion Table item 3.*
F4	Hematologic disorders. What evidence is there that anemia with hemoglobin below 8.5 in a prior pregnancy is associated with higher risk in the out-of-hospital setting in future pregnancies? What do you mean by "history of postpartum hemorrhage requiring intervention."? What evidence is there that midwives are unable to assess a history of hemorrhage and identify those cases that need consultation or further assessment?	*See separate high-risk condition response table and response to Discussion Table item 3.*
F5	Infections diseases. What evidence is there that out-of-hospital birth is high risk for people who are HIV positive barring other risks? Is there evidence that midwives are not capable of providing co-care with physicians to make an appropriate plan depending on the individual case?	*See separate high-risk condition response table and response to Discussion Table item 3.*

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F6	Fetal growth. What evidence is there that midwives are not capable of assessing a history of IUGR or SGA and deciding when it makes sense to consult with another provider?	*See separate high-risk condition response table and response to Discussion Table item 3.*
F7	Obesity or overweight. What evidence is there that shows that having midwives consult for BMI over 35 impacts outcomes? What value or safety is added by requiring this consult?	*See separate high-risk condition response table and response to Discussion Table item 3.*
F8	Perineal lacerations or obstetric anal sphincter injury. What evidence is there that midwives are unable to properly assess the pelvic floor in someone who had a previous 3rd degree or 4th degree tear with functional recovery?	*See separate high-risk condition response table and response to Discussion Table item 3.*
F9	Psychiatric conditions. What evidence is there that a person with a history of postpartum psychosis (or even some of the other conditions listed here) is not an appropriate candidate for an out-of-hospital birth if their mental health is currently well-managed? Many of us have seen pregnant people with significant mental health history specifically choose home birth as a way to have control over their environment, ability to sleep without interruption or other factors as a way to reduce the chance of postpartum mental health deterioration. Midwives are perfectly capable of working with a pregnant person's mental health provider(s) to come up with an appropriate safety plan. Additionally, whether a person gives birth in a hospital, home, or birth center is fairly irrelevant when it comes to postpartum psychosis as the onset is generally from 2 days to 4 weeks postpartum. All maternity care providers, including midwives, know how to assess and refer should symptoms of postpartum psychosis occur. There is no advantage to hospital birth in this situation.	*See separate high-risk condition response table and response to Discussion Table item 3.*

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F10	Age. What evidence is there that a midwife is not capable of assessing the potential risk of a pregnant person who is 16 or 41? What value or safety is added by requiring a consult with another provider in these cases?	*See separate high-risk condition response table and response to Discussion Table item 3.*
F11	Congenital or hereditary anomaly of the fetus. Who decides what congenital anomalies "require immediate assessment and/or management" and what happens if the parents disagree?	*See separate high-risk condition response table.*
F12	Fetal demise or stillbirth. What evidence is there that a midwife is not capable of assessing risk to the mother and developing a plan for a fetal demise after 12 weeks gestation? How is safety improved or value added by requiring a midwife to consult when a client has a 14-week miscarriage for example?	*See separate high-risk condition response table and response to Discussion Table item 3.*
F13	Infectious conditions. What evidence is there that a person who chooses not to test for Group B strep carrier status is at an elevated risk in the out-of-hospital birth setting over the hospital setting? What evidence is there to justify infringing on the pregnant person's right to informed choice and informed refusal regarding prenatal testing and screening?	*See separate high-risk condition response table and response to Discussion Table item 3.*
F14	Fetal growth. What evidence is there that a midwife is not capable of assessing the risk involved if there is an estimated fetal weight greater than 4.5 kg? What value or safety is added by requiring a consult in this situation especially for pregnant people with a history of a previous birth of a baby greater than 4.5 kg without complication?	*See separate high-risk condition response table and response to Discussion Table item 3.*
F15	Meconium. What does the planned out-of-hospital birth research show about outcomes for births with meconium staining?	*See separate high-risk condition response table and response to Discussion Table item 3.*

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F16	Parity. What evidence is there that midwives are not able to assess risk for pregnant people who have 5 or more previous births? What value or safety is added through this consultation requirement?	*See separate high-risk condition response table and response to Discussion Table item 3.*
F17	Perineal laceration or obstetric anal sphincter injury. (Comment truncated).	*See separate high-risk condition response table and response to Discussion Table item 3.*
G1	As a recent recipient of excellent midwifery care, and now an enthusiastic supporter of this approach to birth support, I am writing to express my concerns related to HERC's current draft coverage guidance on planned out-of-hospital birth. It seems that the document is overbroad, and is not actually fulfilling the clear directives that the guidance was supposed to create. It appears to be configured to appease its members lack of familiarity with planned out of hospital birth, which may not be based in direct experience with it. Please adjust the scope of this guidance to be commensurate with the directives that it was supposed to actually serve. Please also ensure that the guidance and recommendations that are actually adopted are, in the end, actually evidence based. Thank you for your work and concern for safe and healthy families.	*Thank you for your comments. See response to Discussion Table, items 1 and 3.*
H1	Oregon Association of Birth Centers would like to formally request that you extend the public comment period to February 8, 2020 for the Health Evidence Review Commission's Planned Out-of-Hospital Birth Coverage guidance. As I am sure you know, the December holidays are the busiest season of the year, and a time when many people are trying to focus on their family's needs. Children are out of school, and many families are out of town visiting extended family.	*The length of the public comment period is determined according to administrative rule and cannot be changed without a rulemaking process. There is no provision for lengthening a comment period to accommodate holidays. Nonetheless,*

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	The birth centers and midwives are concerned that the time period for public comment on the HERC rule change was set by OHA over the holidays. The deadline over the holidays has made it impossible for many of our clients to review the materials in order to make their feedback. Oregon birth centers and providers need time to notify the public about OHA's proposed changes. Birth center clients have asked to be alerted on this issue, and would like to exercise their right to provide the state with feedback during the public comment period. Please support the public comment process by extending the public comment period to allow the families served by Oregon birth center to provide feedback and input on the rule changes that will affect them in the future.	*comments submitted outside the formal comment period will be sent to subcommittee and Commission members according to HERC policy.*
I1	I congratulate HERC for having done much work to determine risk conditions for planned home birth and to attempt an exhaustive list of conditions precluding coverage, and for determining whether a condition is a contraindication and requires transfer to the hospital or consultation. This approach is similar to guidelines established in high-income countries for planned home birth. I have met many mothers over the last years who have lost a baby at a planned home birth, so I have a very clear insight into this issue.	*Thank you for your comments. HERC adopted the original list of risk criteria based on a combination of factors including guidelines from other countries which have excellent out-of-hospital birth outcomes.* *Based on other comments, EbGS has now reduced the number of consultation and transfer criteria. See discussion table items 1 and 3.*
I2	**Recommendations to include additional coverage guidance to planned home birth** • Studies have repeatedly shown that women over the age of 34 have increased pregnancy complications and increased maternal mortality. Therefore, the cutoff of a woman's age should be red for >=40, and yellow for 35-39.	*See separate high-risk condition response table.*

HERC Coverage Guidance: Planned Out-of-Hospital Birth
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I3	• Studies have repeatedly shown that women with their first pregnancy have an up to 45% transfer rate and significantly higher neonatal mortality. Therefore, nulliparity should be red and be excluded from planned home births.	*See separate high-risk condition response table.*
I4	• Twins have significantly higher neonatal morbidity and mortality at home births. Therefore, twins should be in red and be excluded from planned home births	*Multiple gestations are a high-risk criterion. See separate high-risk condition response table (multiple gestations)*
I5	• All fetal malformations should be red. Eg fewer than 3 vessels in the umbilical cord is a fetal malformation and has a higher neonatal morbidity and mortality.	*See separate high-risk condition response table.*
I6	• Coombs direct is now yellow. However, Rh disease is detected with an indirect Coomb's test (antibodies). The positive indirect Coomb's test should be a red flag but is not mentioned.	*A direct antibody test (i.e., Coombs) is performed on the newborn's blood. This condition is in the newborn conditions table. Maternal Rh disease appears under isoimmunization.* *This criterion has been removed, since it only appeared in the LDM final rule, and removed from this draft coverage guidance along with other criteria which only appear in that source.*
I7	• The term "cancer affecting site of delivery" is unclear and requires a more scientific explanation	*See separate high-risk condition response table.*

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I8	• "Cardiovascular disease causing functional impairment" is too limited as there are cardiac diseases that do not necessarily cause functional impairment (whatever that definition is) but which are a contraindication to planned home birth.	*See separate high-risk condition response table.*
I9	• Maternal seizure disorder should be red and not be permitted to be delivered at home	*See separate high-risk condition response table.*
I10	• IUGR in present pregnancy should be delivered in the hospital	*Thank you for bringing this to our attention, we have corrected the recommendation to make IUGR a transfer criterion.* *See separate high-risk condition response table.*
I11	• According to CDC guidelines Group Strep requires IV medication (https://www.cdc.gov/mmwr/pdf/rr/rr5910.pdf) which cannot be administered at home and therefore GBS positive women and those with prior GBS newborns should be delivered in the hospital to provide adequate prophylaxis.	*In Oregon, birth attendants can provide IV antibiotic prophylaxis in the out-of-hospital setting.*
I12	• Any meconium staining is of concern and should be delivered in the hospital, not only "thick" meconium (which is difficult to assert in any case and a subjective assessment)	*See separate high-risk condition response table.*
I13	• Pregnancies after 41 weeks (not after 42 weeks only) should be in red because of their increased risks. This is consistent with other countries' guidelines.	*See separate high-risk condition response table.*
I14	• An Apgar at 5-minutes below 7 requires neonatal intensive observation and should require transfer	*See separate high-risk condition response table.*

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I15	• "Abnormal fetal heart rate" is in red but it's unclear how it's being defined and what are "persistent abnormal fetal heart rate patterns during labor"?	*See separate high-risk condition response table.*
I16	• Any decreased fetal movements are of concern and should be in the hospital for more intensive monitoring, not just "abnormally decreased fetal movements"	*See separate high-risk condition response table.*
I17	**International studies do not reflect US facts** Most studies you mention as "good" studies with "good" outcomes are from high income countries (eg UK/England, Netherlands, Australia, New Zealand, Canada, Japan, Iceland). They should be excluded as a source: 1. The studies were mostly done in countries where there are strict guidelines for planned home births (eg no twins, no prior cesarean, no older women). 2. The midwives doing planned home births in non-US studies are well trained and often have hospital privileges 3. The midwives in these non US countries are well integrated in their health systems. This is similar to saying that driving a car is safe and quoting studies from countries where seat belts have been used, but then using that as an argument where seats belts are not being used. If you don't wear seat belts, you cannot argue it's safe by quoting studies where seat belts have been used. If you perform planned home births without guidelines of excluding high risk pregnancies, you cannot claim it's safe by quoting studies where high risk pregnancies were excluded. To say that "low risk patients have good outcomes at planned home births" and to then cite these other studies is mendacious and ignores that in the US there are no midwife guidelines to determine what constitutes a low risk pregnancy for a planned home birth, and which high	*See discussion guide, item 2.* *Regarding the 2019 study, upon review this is a non-comparative study looking at characteristics of intended home births in the United States.*

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	risk pregnancies should be excluded. Our studies show that planned home birth midwives in the US (contrary to other countries) deliver women who not low risk (Amos Grünebaum, Laurence B. McCullough, Francis A. Chervenak. Publication stage: In Press Journal Pre-Proof. American Journal of Obstetrics & Gynecology Published online: November 9, 2019).	
I18	**Your decision that certain studies are "poor quality"** Masking a determination of "poor quality" for peer-reviewed studies such as our own studies (and most others' eg Bachilova 2018) US studies (just because they usually used CDC data) is beyond the boundary of scientific evidence. It is inappropriate to subjectively label evidence-based peer-reviewed publications from the major ObGyn journal with a "poor quality" label. Evidence based determinations are essential, rather than to dissemble the evidence. Most well designed scientific publications show that US planned home births are associated with an unacceptably increased risk of neonatal mortality and morbidity. Adverse outcomes in US planned home births will continue as long as untrained lay midwives who are not connected to the hospital systems are allowed to perform planned home births without having guidelines to exclude risk pregnancies. Even though our and others' studies showed increased neonatal mortality at planned home births, these numbers are an underestimate of actual outcomes because adverse outcomes of planned home births transferred to the hospital (up to 45% of first pregnancies) are falsely attributed to the hospital when they should have been attributed to the planned home birth. Ignoring evidence-based home births studies that show adverse outcomes and labeling them "poor quality" and trying to dismiss them is not so different from demonizing the hundreds of	*The Methods section and Appendix B describe the assessment of methodological risk of bias. Briefly, researchers at the Center for Evidence-based Policy utilize adapted tools to assess cohort studies based on guidelines from the National Institute for Health and Care Excellence (U.K.), Scottish Intercollegiate Guidelines Network, and the National Heart, Lung, and Blood Institute (U.S.).* *Comparative cohort studies of good methodological quality have, in addition to other characteristics, a clearly defined process for the identification of confounding variables and adjustment for said confounders in their analyses.* *The concern about potential misattribution of the neonatal mortality to hospital births*

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	studies which show clear evidence that climate change is a true problem ("climate deniers: https://insideclimatenews.org/topics/climate-denial).	*rather than planned out-of-hospital births has been discussed at EbGS.*
J1	I was part of two panels that helped guide home birth rules and regulations for the state, as well as work groups that were put together by the Oregon Health Authority to guide coverage for patients planning home birth, and carrying Medicaid insurance. The work group I belonged to consistent of several types of out of hospital birth providers- CNMs, DEMs and NDs, physicians and multiple other experts in the topic. We made several recommendations that would help to improve the environment for out of hospital birth providers and moms and babies in Oregon, and asked that the state make it a priority to ensure that low-income families had the option to access home birth if they were appropriately screened for home birth and had established with a home birth provider that would accept Medicaid. This issue had become one of social justice, there were so many barriers to having Medicaid cover home birth, that the only families able to access home birth were those that could pay for the services out of pocket. Instead of opening the doors to a perfectly safe option for moms and babies in Oregon, this proposed coverage guidance has done the opposite, provide more barriers and reasons to exclude families from the services they should be getting. The most recent draft released by the HERC to guide coverage for home birth deliveries has gone way beyond the intended goals of the work group put together by OHA to inform this issue. There are multiple exclusions for families in the draft recommendations from the HERC. The document being proposed appears to be a very exhaustive list of what is and what is not in the scope of practice of a home birth provider, which is not really the intended goal. There are already many national organizations that guide the scope of practice of home birth	*See response to Discussion Table item 1. See also responses to comments C2, E1, F1, J1, K1 and Y1.* *HERC considered the available national recommendations regarding standards for planned out-of-hospital birth and included these in Table 3.* *Patients have the right to refuse health care, even when doing so places them and their fetus or infant at risk.* *Payment rates and methodologies are outside the HERC's purview.*

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	midwives and it seems like the state of Oregon is trying to re-write this scope of practice for the state of Oregon. This was not the goal of the HERCs effort. We should be looking at the HERC findings as a way to support for coverage of the services provided by home birth midwives providers and allow this service to be accessed by families of all incomes. We need to streamline the process for home birth midwives to start getting reimbursed for their services as quickly as they are being provided, so that home birth practitioners don't have to subsidize their own living and income to survive. The way home birth providers work at this time, they provide services and continue to see families throughout their pregnancy, without the assurance that those services will be covered by their Medicaid plan. Not only are home birth midwives highly qualified and guarantee fantastic outcomes compared to hospitals, they have a lot less clients and get very little reimbursement for their services, so are low income themselves. At this time, the barriers to reimbursement for home birth services have forced most home birth providers to stop accepting Medicaid. We need to provide for avenues in which the home birth provider can be reimbursed for their initial visits, in which they assess the risk factors of families and identify the needs for consults etc. They should continue to receive reimbursement for services when they are co-managed with an in hospital provider, as home birth services provide many benefits to families that are not done by traditional OB providers. They should continue to get reimbursed for home visits postpartum so that families that end up in the care of a hospital, can continue to get the benefits of the one on one personalized, timely care home birth practitioners provide families. Home birth midwives should be able to bill for newborn services both immediately after the birth and up to a month of age. The reimbursement model for home birth services	

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	should reflect that these are providers that should be intimately enmeshed and supported by allopathic and hospital services. The model of care being paid for should never exclude the other, as a way to encourage collaboration and integration of services. Please reconsider the entire goal of this effort- and instead of providing more barriers, help us ensure that families of all income levels access these services, encourage collaboration and integration into the current health care system, and stop putting barriers to this group of health care providers that have consistently shown incredible health outcomes while at the same time protecting patient autonomy and respect. I don't believe the HERC should be defining in such detail what health care conditions should or should not be managed by home birth providers, especially when the review of the evidence does not get into such specific detail for such specific conditions. We should be focusing on the issue at hand- provide an avenue to cover those services so that this delivery method is available for all patients. Patients that risk out of home birth practice will be managed by those home birth providers as they always have, by having their home birth practitioner recommend that the family access care via another avenue, while continuing to have support from their home birth practice. That home birth practice will have to document very clearly when a family declines going to another service avenue to get care despite their recommendations. This is unfortunately a common situation that puts home birth practitioners in a true bind. When this happens, home birth practitioners should not be punished for this situation, but instead supported as best we can by our system. Thank you for your time in reading my response to this coverage guidance. Please don't hesitate to call me, email me for further questions.	

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K1	My name is Jessica Ruediger, and I am a Licensed Direct Entry Midwife and a Certified Professional Midwife providing home birth services in the Southern Oregon area. I am deeply concerned about the new HERC guidelines limiting access by low-income women to the full scope of care provided by LDMs in our state. Our licensing board already sets community birth standards. I used to be an OHP provider, but I found the restrictive guidelines set by HERC to be unfair, unclear and burdensome to both myself, as a licensed practitioner practicing within my legal scope, and to my lower income clients. Now HERC is proposing to further restrict the scope of care. This is not justified. HERC does not have the authority to re-write the midwifery licensing regulations; only our board can do that. This situation leads to licensed practitioners having to enforce a different set of protocols for poor women, which is not ethical. I am not in support of any HERC guidelines that restrict community birth standards beyond our evidence-based licensing laws. In my area, almost all of the midwives used to offer OHP. Now there are only a few community birth providers who will accept it. And if these regulations pass, even more midwives will have to discontinue as OHP providers. This is effectively eliminating low income women's access to a legal and regulated service that is a vital and important option in maternity care. Community birth is cheaper, costing the state and Oregon citizens less than hospital birth. Community birth is safe, when LDMs practice within the scope of our care. Birthing women tend to be more satisfied with midwifery care, and there is no justification for eliminating who can access this maternity care alternative in it's full scope based on economic status. Please record my dissent regarding further HERC restrictions to covering community birth. Make it simple, make it cheaper for the OHP system, and make it ethical, by allowing Oregon's low-income women access to the full scope of midwifery care.	*See response to Discussion Table item 1, and responses to comments E1, F1 and K1.* *It is not the intent of EbGS that implementation of these recommendations discourage safe, effective provision of services related to planned out-of-hospital birth. In fact, EbGS recommends coverage for low-risk births, defined according to the criteria included in the recommendation based on outcomes that show benefits to the mother and while minimizing risk to the fetus or infant. EbGS has removed a number of transfer and consultation from the coverage guidance, in response to this and other similar comments.*

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L1	I am writing in regards to the guidelines you have proposed for coverage for community birth. I have read the proposed Coverage Guidance and appreciate the work that went into the various considerations and suggestions. Many of the HERC guidelines make sense and I do not take issue with them. There are however some that seem to defy evidence and moral reality, I am not sure how they could have been included with true evidence review. I serve a rural area in Northeastern Oregon, Wallowa and Union counties, most of the people that contact me are on OHP. The unsubstantiated limitations caused by these recommendations on families of lower socioeconomic status is egregious and has created a massive barrier to access and choice for many families. The HERC claims that "Recommendations for coverage are based on the balance of benefit and harms, resource allocation, values and preferences and other considerations" did you consider rural Oregon and the impact your recommendations would have there? These guidelines seriously impact safe, evidence-based choice in most of Oregon. The cost of being licensed means that my fees are higher than the lay midwives in my area. Subsequently these guidelines have completely removed Northeastern Oregon OHP family's choice to have licensed community birth unless they are able to shoulder the cost personally. This document serves to discriminate and burden Oregonians. I remember when the first HERC guidelines were commissioned and implemented. HERC was asked to review evidence to help define prenatal assessment and risk criteria for planned home birth. I remember well the fear that this body would use the simple OHA request for guidance and instead create a president to police and overreach the objective and moral boundaries of the task at hand, this is what has happened. I grant your intention is probably good but the outcome is inappropriate and harmful. I recall when the 2015 guidelines caused	*See response to Discussion Table items 1 and 3, and responses to comments K1 and Y1.* *EbGS recognizes that access to health services, including out-of-hospital birth or higher-acuity hospital care, can be difficult to access in rural Oregon.* *Now that many criteria have been removed in response to this and other comments, the current draft has fewer consultation and transfer criteria than the 2015 coverage guidance.* *In addition, the current draft also significantly modifies the definition of consultation, now requiring the consultation to be with the appropriate provider (e.g., a hematologist for a hematologic question, a maternal fetal medicine doctor for a potential high-risk condition) rather than only a maternity provider with hospital privileges. Consultation with another LDM*

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	great disparity of access for birthing families and caused most Oregon LDMs to discontinue taking OHP. Because of your selection criteria many of the studies you have used have no bearing on homebirth or true statistics clearly provided by trained and licensed midwives. The guidance you were asked to create was not whole practice guidelines and insurance coverage does not change by actions in labor or immediate postpartum, these sections should be removed. Our OARs rightfully dictate our scope, when we transfer and when we consult. It is NOT the job of HERC to override LDMs appointed statutes, laws, scope and training. A note about consultation: Many doctors are too busy or simply refuse to consult. I happily consult when needed but consulting on many of the matters you outline is redundant to our training. Midwives are trained and can have more education and up to date continuing education regarding maternal care than many general MDs. How does consulting with people with less experience or education in some matters help anyone? Midwives are well informed to identify and manage the majority of the risks you outline. Consulting on things like these will only serve to annoy and stress relationships between LDMs and MDs. It will also serve to discredit the knowledge LDMs do have. This is especially true in rural settings. Consultation should be allowed with other LDMs as well, as defined in ourDEM OARs. Upon becoming licensed 2016 I did not even consider signing on to take OHP because I knew it was following poor evidence-based criteria and personal opinions and it had taken safe choice out of the hands of many families in Oregon. As a medical provider I can not align with the lack of ethics or evidence HERC has caused and I choose not to be involved. I would like to be able to accept OHP. As stated before I support many of the findings but the following are not items I am not willing to force on families.	*would not meet the prior nor newly-proposed consultation requirements.*

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	I believe that the HERC should adjust these in the final document: What evidence is there for the following items as outside LDM education, legal scope or as precluding homebirth? These situations are in my licensed scope of practice, I am trained to perform these types of births. It is not the place of HERC to limit DEM scope and directly alienate and discriminate Oregonians from access to licensed care.	
L2	Mandatory consults: • pregnant people >40. This is a normal age for many multiparous women. • multipara -/>5. • previous pregnancy with fetal demise after 12wks.	*See separate high-risk condition response table.*
L3	Transfer: • Breech. Frank and complete are in my scope of practice, • Multiples. In DEM scope. • VBAC. In DEM scope. There are many reviews and studies that indicate VBAC is safer and preferred to repeat c-sec, which is the only choice for rural Oregon for in hospital birth! • 36-36+6 and 42-42+6 births. In DEM scope. • GBS. It is a pregnant person's right to informed choice and informed refusal regarding prenatal testing, intervention, and treatment.	*See separate high-risk condition response table.*
L4	The following items I find noteworthy and believe they should be changed and researched further. I would not refuse to participate if they are not changed however: Transfer: • Placental delivery >60minutes. What evidence is there for this not to be a consult? Transfer seems poorly supported at this point.	*See separate high-risk condition response table.*

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	• Unknown status for various infections (HIV, Hep B, Syphilis). Many families are in monogamous relationships and have been tested in previous pregnancies for these conditions. Forcing them to do so when some have moral objections is not ethical or evidence-based but rather is overreaching and inappropriate for the scope of what the HERC was originally designed to do.	
L5	I hope that with combined effort on this document your final recommendations will allow the birthing families of Oregon to once again have access to safe and true evidence-based care. Thank you for your consideration,	*Thank you for your comments.*
M1	I have recently been made aware that midwifery care in Oregon is under threat. I think creating barriers to midwifery does a grave disservice to the women of this state who deserve the quality of prenatal and birthing care that is simply not possible in an over-medicalized obstetrical model. The safety, cost-effectiveness, and efficacy of midwifery care is undeniable and developed countries with robust citizen care models favor midwifery as a first line of care for women. Taking the freedom to choose away from the women of Oregon is wrong, and is an effort to medicalize birth and create profit. As an Oregon voter I strongly oppose this action and urge you to reconsider the motivations for such disempowering legislation and your complicity in it.	*See response to comment F1 above.* *Thank you for your comments.*
N1	I would like to comment that your current treatment of midwife care and birthing centers and the rules you place upon them is unacceptable. We the public know good and well that this is about control and putting them out of business and protecting hospital profits and not about the health and well being of women and new borns. What you are doing is a gross overreach and abuse of power. As a woman if I am pregnant it is my body and my choice to choose my	*See Discussion Table 1 above.* *See response to comment E1 above. Many criteria have been removed in response to this and other similar comments.*

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	provider and place of birth. Even women with other health issues, or previous c sections should have the right to make an informed choice without a big hassle to go through. You have put birthing centers out of business and midwives out of jobs. Stop this abuse and control of birthing people and allow them access to the birth and provider of their choice.	*Thank you for your comments.*
O1	You are not in the business of dictating health but in the business of helping people get the care they choose. You do not have authority over their decision. Your authority is how the taxpayer funds it. Individual choice and informed choice should be your number one priority. Stop mandating and dictating medical decisions for poor people.	*See response to comment F1 above.*
P1	I am writing to comment on several proposed changes to the OOH risk criteria. There are several items on this list, requiring careful evaluation and discussion between patient and care provider, but ultimately represent a theoretical or small increased risk in the pregnancy that does not translate to increased risk with choosing a midwife. By taking these choices away from women that are within the scope of out-of-hospital providers, we are unnecessarily discriminating against these women and influencing care. I would love to participate in a separate discussion about how this is implemented.	*See response to Discussion Table items 1 and 3, and response to comment F1.* *Thank you for your comments.*
P2	Collagen Vascular disease: exclusion criteria RA is a collagen vascular disease. While there is increased risk of adverse pregnancy outcomes with RA consultation would suffice. 1. Severity of RA varies. While some women do well with concervative treatment and medication, others need to work with a high-risk provider. 2. Increased risk of adverse outcomes (low birth weight, SGA, pre-eclampsia and cesarean section) are low and can be managed by skilled provider, who knows when to transfer.	*See separate high-risk condition response table.*

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	We can and should provide increased surveillance of these patients, while still providing access to midwifery care, unless complications arise . 3. Research supports midwifery care improves outcomes related to LBW, SGA and CS. Women with RA may have better outcomes when receiving care from midwives. 4. There is no evidence that patients with RA have increased adverse events when delivering out of hospital, unless additional risk factors develop to exclude them, which would require a transfer of care anyway.	
P3	Previous CS: exclusion criteria. Remove this as exclusion criteria. 1. Midwives in Oregon have high VBAC success rates OOH. Women with previous CS should be encouraged to birth with a skilled midwife, close to back up facilities if that is their preference. (Additional data on this available via OABC, please email.) 2. The risk of VBAC and TOLAC are well studied and understood. Because of protective factors of being in midwifery care it is a disservice to birthing people to take that choice away from them. See AABC clinical bulletin resource 1. 3. There is significant benefits to maternal health and neonatal health in avoiding repeat CS. Risk of accreta after 2 or more cesereans increases significantly. Repeat CS is significantly more likely if TOLAC occurs in a hospital. 1 in 14 mothers with accreta die. 1 in 17 babies with accreta die. There is insufficient data showing OOH VBAC has enough increased risk to outweigh the benefits to mom and baby of avoiding repeat cesarean.	*See separate high-risk condition response table.*
P4	4. Significant Endocrine conditions other then diabetes 5. Additional clarification is needed. If hypothyroidism. If patient is seeing a CNM or ND that is trained to manage hypothyroidism in pregnancy, additional consultation is not	*Thank you for alerting us to this error in the draft coverage guidance. Hyperthyroidism*

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	necessary if patient is well managed. Requiring this consult increases cost of care and is inconvenient for the patient.	*(not hypothyroidism) was intended as a consultation criterion.* *See separate high-risk condition response table for proposed resolution.*
P5	History of unexplained stillbirth / neonatal death or previous death related to intrapartum difficulty. Proposed change: Include as consultation criteria only. unless additional risk factors develop to exclude them. Unless there is a genetic link to the loss or an anatomical variation, there is no research showing that delivering in a hospital, after a previous stillbirth, decreases risk of subsequent stillbirth/neonatal loss to remove. This simply removed choice from a patient who already traumatized.	*See separate high-risk condition response table.*
P6	History of pre-eclampsia requiring pre-term birth and HELLP as exclusion criteria. This should be consult criteria only. Midwives in Oregon are able to identify signs and symptoms of pre-eclampsia in adequate time for transfer of care as indicated, if they arise. In some rural areas, having access to a midwife increases the likelihood a patient with warning signs of pre-eclampsia will be promptly referred to the appropriate provider and facility. At this time there is insufficient evidence that women with a history of pre-eclampsia requiring pre-term birth, have poor outcomes when receiving prenatal care from a midwife in a subsequent pregnancy. While there is research showing that their outcomes may be improved when they received care from a midwife.	*See separate high-risk condition response table.*

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P7	BMI ≥ 35 consult The information women receive at these consults is typically generic and no more insightful than an informed consent. It inflicts further emotional trauma and makes them less likely to seek care from providers in the future when they feel stigmatized by their weight. Intent of this could be achieved via a signed informed consent for women that decline consult.	*See separate high-risk condition response table.*
P8	Psychiatric conditions: Schizophrenia, other psychotic disorders etc This inappropriately discriminates against women with these types of mental illness. Women with significant mental illness may choose midwifery care and home / birth center delivery. There isn't data to show this as being unsafe. In many cases this may be just the type of personal one on care these patients need. Choice in provider and the personalized care offered in this model has so much benefit, especially when they are co-managed by the appropriate psychiatric provider.	*See separate high-risk condition response table.*
P9	History of postpartum mood disorder with high risk to infant Most midwives complete a minimum of 2 home visits over the first week of life, and ongoing postpartum care with a close relationship with their provider. This allows them to closely monitor patients that are at risk for severe PPD. There is not significant evidence to show that this is a risk for these people, and therefore restricting access to this care is discriminatory.	*See separate high-risk condition response table.*
P10	Amniotic membrane rupture greater then 24 hrs. There is insufficient data to show that expectant manage of ROM > 24 hrs has enough increased risk to mom or baby that this choice should be taken away from women. As long as	*See separate high-risk condition response table.*

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	there is appropriate follow up by the provider and client, risk of infection and adverse outcomes is low.	
P11	Diabetes, gestational managed by medication. Gestational diabetes managed by metformin is within the scope of NDs. There is no data showing that these patients have worse outcomes when cared for in hospital, vs cared for by ND.	*See separate high-risk condition response table.*
P12	Thrombocytopenia Recommend 75,000 as cut off.	*See separate high-risk condition response table.*
P13	Group B strep unknown Women have the right to decline testing in pregnancy. There is sufficient data from countries that do not routinely test for GBS but used risk based protocols that not testing is a reasonable choice for an informed person and provider to make. I proprose require risk based management for women that decline GBS testing or transfer if additional risk factors develop.	*See separate high-risk condition response table.*
P14	Uterine condition: Prolapse Does not require transfer if it immediately reduces	*See separate high-risk condition response table.*
Q1	1000 words is not enough to adequately express my concerns about this exhaustive draft. This draft is too long, too detailed, and more than what the scope of coverage guidance should be. Please cut this down to basic guidelines. I have been a licensed direct-entry midwife for 6 years and have been a Medicaid Provider for most of that time and most of my	*See responses to Discussion Table item 1, and to comments C1 and K1 above.* *Thank you for your comments.*

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	clients are on OHP. This coverage guidance greatly affects my ability to give the best care to my clients and my ability to get paid for my work and I hope that you consider my feedback.	
Q2	Intro: 1) Consultation with an LDM should be one of the options for consulting provider. LDMs are capable of determining when a hospital provider needs to be the person we consult with.	*See response to comment L1 for discussion of consultation by one licensed direct-entry midwife with another.*
Q3	Medical or OB History: 1) Prior Cesarean Section - Although Prior Cesarean section has increased risks I believe that there should be coverage for all people who've had a prior c-section and a prior vaginal birth and also for all people who've had one prior c-section, with a low, transverse incision, who fully understand the risks and sign a detailed informed consent document.	*See separate high-risk condition response table.*
Q4	2) History of unexplained stillbirth/neonatal death or previous death related to intrapartum difficulty - What does intrapartum difficulty mean here? Assuming a death related to an intrapartum breech entrapment is an 'intrapartum difficulty' why would someone need to have a hospital birth if they are planning a vertex birth? This should be removed entirely as an exclusion for coverage and the consult item should be clarified.	*This language was clarified to the following consultation criteria:* • Prior stillbirth/neonatal death
Q5	3) Under 'Fetal Growth' these items should all be removed. Midwives are capable of determining when they need to consult for prior IUGR, SGA and LGA babies.	*See separate high-risk condition response table.*
Q6	4) Hematologic Disorders - Midwives are capable of determining when they need to consult for all of the listed conditions - remove these items.	*See separate high-risk condition response table.*
Q7	5) Miscarriage - Remove these consult requirements. How is this evidence based?	*See separate high-risk condition response table.*

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Q8	6) Encephalopathy - what is the evidence that a prior baby with encephalopathy poses higher risks in a current pregnancy in the out of hospital setting?	*See separate high-risk condition response table.*
Q9	7) BMI>35 consult - How will this consult affect outcomes for these clients? Midwives know when they need to consult about a particular client. I have done many of these consults for my OHP clients with little to no benefit for me or the client.	*See separate high-risk condition response table.*
Q10	8) How would a consult about prior 3rd or 4th degree lacerations improve outcomes for clients in a subsequent pregnancy?	*See separate high-risk condition response table.*
Q11	9) Psychiatric Conditions - these should be removed from coverage exclusion. Midwives are particularly suited to these clients. We are capable of consulting when needed, referring for extra services, and are present much more in the postpartum period when most postpartum mood disorders arrive. I have taken care of many of these clients with great success and they have reported feeling well taken care of.	*See separate high-risk condition response table.*
Q12	Conditions of Current Pregnancy: 1) Age - Midwives can determine when they need to consult for a client <17 or > 41 years old. This should be removed.	*See separate high-risk condition response table.*
Q13	2) Pre-labor ROM >24 hours should be a consult not a requirement to transfer. While of course the risk goes up with these clients, with appropriate management and avoidance of vaginal exams, this can end in successful, healthy home vaginal births most of the time. This should be replaced with s/s of infection post-rupture.	*See separate high-risk condition response table.*
Q14	3) Consult for fetal demise after 12 weeks - There are many straightforward miscarriages after 12 weeks - midwives should determine if they need to consult for this condition.	*See separate high-risk condition response table.*

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Q15	4) Fetal Growth - midwives can determine when they need to consult for these clients - this list should be removed. For example, someone may measure size < dates for their whole pregnancy but have consistent growth and not need a consult or ultrasound. Or, someone may measure small one month and on track the next. This should be determined on a case by case basis.	*See separate high-risk condition response table.*
Q16	5) Gestational Age > or = to 42 weeks 0 days - Remove. So many clients, when given the opportunity to not be induced, ride this line of 42 weeks. Perhaps it could change to 42 weeks 3 days, or, include 'without family history of post-dates delivery.' I have many clients with family history of going post-dates go post-dates themselves with no issue.	*See separate high-risk condition response table.*
Q17	6) Group B Strep Unknown - Clients should be able to have coverage and refuse screening tests with informed consent.	*See separate high-risk condition response table.*
Q18	7) 'Genital Herpes at time of labor' - change to: 'Genital Herpes Outbreak that is uncoverable at time of labor.'	*See separate high-risk condition response table.*
Q19	8) Thick meconium staining of amniotic fluid transport requirement - Remove. What is the evidence that this is safer in the hospital? If there are ALSO abnormal fetal heart tones, this is a different story.	*See separate high-risk condition response table.*
Q20	9) 'Significant maternal confusion or disorientation' should be a consult not a transfer. This can occur when someone is feeling triggered about past abuse history in labor and it can come and go without significant safety risk to the mom or baby. What is the evidence that this would be safer in the hospital?	*See separate high-risk condition response table.*

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Q21	10) Consult for grand multiparty - how would this improve outcomes? Remove.	*See separate high-risk condition response table.*
Q22	11) Low lying placenta within 2cm of os at 36 weeks or later - should be changed to 'at last documented ultrasound before onset of labor' because someone could get an ultrasound at 38 weeks that shows it has moved.	*See separate high-risk condition response table.*
Q23	12) <5 prenatal care visits or prenatal care beginning in the third trimester should be removed as a consult requirement. Midwives can assess when they need to consult for a particular client and these are often not necessary. Evidence based?	*See separate high-risk condition response table.*
Q24	13) Psychiatric Conditions - midwives can determine when they need to consult for these clients. Remove.	*See separate high-risk condition response table.*
Q25	Neonatal Conditions: 1) Appearance - should be removed - midwives know when to consult for newborn behavior, appearance, and feeding issues.	*See separate high-risk condition response table.*
Q26	2) Weight less than 5th% for GA with no other complications or issues should be removed as a transfer requirement Thank you for your consideration..	*See separate high-risk condition response table.*
R1	In response and review of the Health Evidence Review Commission (HERC) 12/10/2019 draft for coverage guidance regarding planned out-of-hospital birth, Asante Health System would like to note the following: • There is limited to no existing regulation of training/credentials for providers assisting with deliveries outside of the acute care center.	*EbGS recognizes the value of high-quality neonatal care being critical to improving neonatal outcomes.*

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	• There is an increased risk of neonatal mortality for planned out-of-hospital births. • Neonatal resuscitation program states that "every birth should be attended by at least 1 qualified individual, skilled in the initial steps of newborn care and positive pressure ventilation (PPV), whose only responsibility is management of the newly born baby." "A qualified team with full resuscitation skills, including endotracheal intubation, chest compressions, emergency vascular access and medication administration, should be identified and immediately available for every resuscitation". A newborn with apnea, gasping, or a HR less than 100 needs PPV within 30-60sec of birth. 4-10% of births require PPV. We are unable to reliably predict prenatally which newborns will require resuscitation. Births outside of the hospital are unable to meet these immediate, lifesaving needs of a distressed newborn. Asante is committed to continuous improvement efforts related to the safe delivery inside the hospital setting and cannot recommend, with current practices and regulatory structure, any acceptable home birth. This recommendation comes with a strong care for the safety of mother and infant for the inherent risks of out-of-hospital delivery. It is imperative that the State of Oregon take significant considerations in recommendations and contracts with insurance coverages to support best practice and continue to promote safe care across Oregon.	*Although the Neonatal Resuscitation Program (NRP) is considered the standard protocol for neonatal resuscitation, HERC does not have the authority to specify neonatal resuscitation requirements as a condition for coverage.* *EbGS also does not have the authority to require an additional birth attendant whose only responsibility is management of the newly born baby.* *Thank you for your comments.*
S1	I am a Certified Professional Midwife, Licensed in Oregon. I provide evidence-based care to pregnant people, including those who are insured by the Oregon Health Plan. As a provider I am concerned about the new coverage guidance the HERC is putting out regarding out-of-hospital birth.	*See responses to Discussion Table items 1 and 3, and to comments E1, J1 and K1 above.* *EbGS recognizes the stress and anxiety caused by potential or actual transitions of*

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	My understanding is that the HERC is to create simple evidence-based coverage guidance for out-of-hospital birth; not to provide comprehensive overreaching practice guidelines. I do support an evidence-based HERC coverage guidance on planned out-of-hospital birth. However, the current draft appears to be more akin to the Oregon Administrative Rules, which already outlines safe practice guidelines and provides laws for out-of-hospital birth providers regarding when we must transfer care and consult. As providers, we are thoroughly trained to care for women the antepartum, intrapartum and postpartum. We are able to assess what constitutes a low-risk pregnancy, to decide when a consult or transport is warranted during pregnancy, birth or the postpartum and to ensure our clients are being cared for in a safe, evidence-based manner. As much as you, we do not want high-risk patients giving birth at home. Our goal is to provide birthing families a safe option for low-risk out-of-hospital birth. We work diligently to maintain good outcomes and to improve outcomes. The guidelines and process for out-of-hospital birth approval by OHP are already making it difficult for providers and patients to work together. There is increased stress on patients with the insecurity of not knowing whether their care will be covered. This is detrimental to them. Providers are declining to work with OHP patients due to the instability of the situation as well and the lack of autonomy they have in determining what is right for their patients. No other insurance company tries to define the scope of practice of a provider. They can choose not to cover something, as the HERC guidelines can outline (no twins, breeches, preeclampsia, etc), but do not require continual monitoring and review of the care being provided. My request is that the HERC stay within their scope by creating a simple, evidence-based coverage guide, not a document that will create barriers to safe and appropriate care for	*care, and balances these concerns with concerns about the safety of out-of-hospital birth for pregnant women with certain risk factors.*

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	pregnant and birthing people. I would be happy to provide further details about what this would look like if needed. Out-of-hospital providers are 100% committed to keeping their clients healthy and safe. Please, allow us to do the job we were trained to do. Thank you for your time,	
T1	My name is Carrie and I have given birth to two healthy babies under the care of my midwives, Dr Leslie Hamlett and Karen DeWitt at Canyon Medical Center in Portland, OR. I was given the highest level of care, felt safe and relaxed, and all of my concerned were taken seriously and addressed appropriately. I have attended other births of family members and friends under Canyon's midwifery care, and observed the same attention to detail, safe practices, and gentle methods I experienced. What this comes down to, however, is choice. Regulating where a person can give birth is anti-choice, and removes autonomy from the person giving birth. This predominantly affects binary women, but also affects those who are often discriminated against in traditional medical settings. Black women, transgendered persons, fat women, financially disadvantaged families, and same sex couples will be the ones who will bear the greatest consequences by removing safe, low-cost birth options and personal autonomy. Midwifery is a valid, safe, and wonderful option for birth that should remain available to those who desire it. Please stop trying to regulate women's reproductive choices.	*See response to comment F1 above.*
U1	Several items on the proposed coverage guidance, while they should be addressed by the patient and her provider, should not preclude a patient from experiencing an out of hospital	*See response to Discussion Table item 3.*

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	birth. Many of the risks associated with those conditions are theoretical or extremely small. If anything, these proposed changes would unfairly target poor women, women with larger families, and women in larger bodies. Out of hospital providers have already seen a decrease in home and birth center births due to the current pre-approval system, which is already extremely cumbersome and convoluted. I have a problem with the process by which HERC is selecting criterion. HERC does not provide evidence for some of the conditions listed as exclusion or consultation criteria. If HERC cannot provide compelling evidence, then it should remove those conditions from its list. Those conditions are highlighted in the following chart. ***Exclusion and consultation criteria that should be revised or removed from the proposed guidelines:***	
U2	Previous C-section: CMS data indicates that VBACs are safe and successful in out of hospital settings. Women are more likely to have better VBAC outcomes if they have their babies out of hospital.	*See separate high-risk condition response table.* *It is unclear which CMS data the commenter is referring to.*
U3	Significant Endocrine conditions other than diabetes: Hypothyroidism—consult unnecessary unless not well controlled.	*Hypothyroidism was incorrectly listed in Appendix I, it is not a consult criteria in the updated draft coverage guidance. Thank you for bringing this to our attention.*
U4	History of unexplained stillbirth/neonatal death or previous death related to intrapartum difficulty	*See separate high-risk condition response table.*

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U5	History of pre-eclampsia requiring pre-term birth and HELLP as exclusion criteria: Patients with a past hx of these conditions are not guaranteed to develop them again. They can be managed by a qualified out of hospital provider.	*See separate high-risk condition response table.*
U6	BMI ≥ 35: This is discrimination based on body size and not supported by evidence. Correlation does not equal causation. It's like saying that if you're a certain height you must have a hospital birth. Plenty of research has broken down any supposed links between health and body size.	*See separate high-risk condition response table.*
U7	Psychiatric conditions: Schizophrenia, other psychotic disorders, taking psychotropic medications, etc.: This is not an evidence-based exclusion criterion.	*See separate high-risk condition response table.*
U8	History of postpartum mood disorder with high risk to infant	*See separate high-risk condition response table.*
U9	Amniotic membrane rupture greater than 24 hrs	*See separate high-risk condition response table.*
U10	Gestational diabetes managed by medication or diet.: If well managed by oral meds or diet, GD patients should not be denied out of hospital births.	*See separate high-risk condition response table.*
U11	Group B strep unknown: Providers can use a risk-based protocol if testing is declined. Providers are trained in monitoring the mother and baby for signs of infection. Furthermore, patients are allowed to exercise autonomy and decline tests after being informed about the risks.	*See separate high-risk condition response table.*
U12	Uterine Prolapse: If immediately reduced, it does not require immediate transfer.	*See separate high-risk condition response table.*

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U13	Prenatal Care, <5 visits in the 3rd trimester: Patients have a right to autonomy, meaning every patient should be able to choose who they see for prenatal care.	*See separate high-risk condition response table.*
U14	It's hard to provide research when it doesn't exist or when only poor research is available. In addition, out of hospital care that is supportive of physiological birth is inherently different than hospital-based birth. It's apples and oranges. The data is too heterogeneous. Ignoring available evidence or making biased inferences from available evidence and ignoring the clinical expertise of out of hospital birth providers will not improve current guidelines. Moreover, much of the proposed guidelines disregard reproductive rights. We can trust pregnant women to make the best decisions for themselves, and if a woman wants to have an out of hospital birth with a qualified provider, then she should have that opportunity.	*See responses to Discussion Table item 3, and to comment F1 above.*
V1	I have been in Oregon for almost two years, finishing up my midwifery training, I came here to do so because people still had choices for out of hospital births. I am getting ready to sit for NARM. Currently I am the Birth Center Manager at Canyon Medical Center. There are several items on this list, that while they require careful evaluation and discussion between the patient and care provider, represent a theoretical or small increased risk in the pregnancy that does not translate to increased risk with choosing a midwife. By taking these choices away from women that are within the scope of out-of-hospital providers, we are unnecessarily discriminating against pregnant people. The actual enforcement of this PA process has lead to a significant decrease in the number of out of hospital births, because midwives are not paid for PN care when a client is not approved; the process is cumbersome due to the amount of documentation required.	*See responses to Discussion Table item 1, and to comments F1 and K1 above.*

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	Approval needs to be given at the beginning of pregnancy, and then can be re-evaluated later if needed.	
V2	Topic: Previous CS: exclusion criteria. Remove this as exclusion criteria. 1. Midwives in Oregon have high VBAC success rates OOH. Women with previous CS should be encouraged to birth with a skilled midwife, close to back up facilities if that is their preference. 2. The risk of VBAC and TOLAC are well studied and understood. Because of protective factors of being in midwifery care it is a disservice to birthing people to take that choice away from them. See AABC clinical bulletin resource 1. 3. There is significant benefits to maternal health and neonatal health in avoiding repeat CS. Risk of accreta after 2 or more.	*See separate high-risk condition response table.*
V3	Topic: History of unexplained stillbirth / neonatal death or previous death related to intrapartum difficulty. Women with previous loss are capable of understanding risks and benefits to choosing their provider and place of birth. Restricting access to coverage based on this history is traumatic for women with that history. They may choose out of hospital birth for a variety of reasons. It also may drive patients that are not comfortable in a hospital to birth unassisted at home, increasing the risk to mother and baby. There is insufficient data showing that delivering in a hospital, after a previous stillbirth, decreases risk of subsequent stillbirth/neonatal loss to remove this choice for birthing people.	*See separate high-risk condition response table.*

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V4	Topic: History of preeclampsia requiring pre-term birth and HELLP as exclusion criteria. This should be consult criteria only. Midwives in Oregon are able to identify signs and symptoms of pre-eclampsia in adequate time for transfer of care as indicated, if they arise. In some rural areas, having access to a midwife increases the likelihood a patient with warning signs of preeclampsia will be promptly referred to the appropriate provider and facility. There is no evidence that women with a history of preeclampsia requiring pre-term birth have poor outcomes when receiving prenatal care from a midwife in a subsequent pregnancy, and in fact the opposite may be true.	*See separate high-risk condition response table.*
V5	Topic: BMI ≥ 35 consult Information women receive at a consult is not so nuanced as to need an in-person consult. It does not justify the cost and the emotional expense to these women. They have already educated themselves and there is no added improved outcome by having a consult. It does further stigmatize their weight. Intent of this could be achieved via a signed informed consent for women that decline consult.	*See separate high-risk condition response table.*
V6	Topic: History of postpartum mood disorder with high risk to infant Midwives complete a minimum of 2 home visits over the first week of life, and ongoing postpartum care with a close relationship with their provider, most of the time they don't see an OB for six weeks.	*See separate high-risk condition response table.*
V7	Topic: Group B strep unknown Women have the right to decline testing in pregnancy. There is sufficient data from countries that do not routinely test for GBS but used risk based protocols that not testing is a	*See separate high-risk condition response table.*

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	reasonable choice for an informed person and provider to make. I propose require risk based management for women that decline GBS testing or transfer if additional risk factors develop.	
V8	Topic: Uterine condition: Prolapse Does not require transfer if it immediately reduces.	*See separate high-risk condition response table.*
W1	I was denied coverage for my planned birth center birth in June 2019. The reason for denial was a previous cesarean in 2018. I went on to have a successful vaginal birth after cesarean at a birth center. I was forced to pay out of pocket for my care because OHP denied my chosen delivery method. The care I received at the birth center was by far superior to the care I received at the hospital after my first birth. Every woman who has had a previous cesarean should have every right to make an informed decision about how and where she gives birth. Studies have shown a higher success rate of VBAC in a birth center setting then a hospital setting. There has also been studies showing that a vaginal birth after a cesarean is safer for the woman and baby. Studies have also shown that 80% of women who attempt a vaginal birth after cesarean are successful. Women are being traumatized with lack of evidence based care. The most empowering thing that can be given to pregnant women is a voice.	*Thank you for your comments.* *See separate high-risk condition response table.*
X1	There should be safe and affordable midwives and birthing centers available for all pregnant women. Several birth centers in Oregon have closed because of this policy and Medicaid is covering drastically less out of hospital births because of it. In cases where the medical risk is small, it's important to maintain patient autonomy and I'm gravely concerned that these requirements create discrimination against out of hospital providers and their Medicaid recipients that seek an out of hospital birth. If a provider is already contracted with OHA, why	*Thank you for your comments.*

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	are we requiring such lengthy, involved process for them to be approved to birth with their chosen provider. Pregnancy and birth are normal events in a woman's life, not unique conditions. I suggest a single page document, with patient's demographics and a signature from their midwife that says they don't have certain high-risk conditions. This should be adequate to approve out of hospital delivery, and approval be offered as early as the first trimester so there is not an obstacle to them having complete prenatal care with their chosen provider.	
Y1	I am writing in regard to the proposed coverage guidance for planned out of hospital birth. I am deeply concerned and frustrated by the extensive and detailed list of indications for consult and transfer of care. I find myself wondering whether it is possible that the HERC is unaware that LDMs in Oregon already practice according to a detailed set of rules? I do not disagree with many of the indications listed, but because these rules already exist, much of the proposed draft is, in fact, redundant. Additionally, the proposed draft lists indications for consult that should be left to a midwife's discretion. Whether an LDM needs to consult depends on the specifics of the situation, and on that person's experience with similar situations. For example, as required for OHP coverage, I recently consulted for a history of macrosomic babies. The client had two truly uncomplicated home births with large babies and a negative test for gestational diabetes. The CNM with whom I consulted seemed confused by what I was asking; she replied that "obviously" this person is an appropriate candidate for home birth. This was obvious to me as well. The required consult in these situations is a waste of time for the LDM, for the CNM, and even for the person who is reviewing the chart to determine OHP coverage eligibility. At the same time, consult and sharing of information is an important part of midwifery practice among LDMs. Every midwife	*See response to Discussion Table items 1 and 3.* *EbGS has selected its consultation criteria based on evidence and on criteria used to guide care in various settings. The consultation criteria differ from the 2015 coverage guidance in that consultation can be with a specialist not credentialed to deliver babies at a hospital.* *See separate high-risk condition response table.*

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	I have met is deeply committed to providing excellent care to their clients. As such, if a midwife does not have experience with a situation or condition, they will consult with one or more practitioners who can provide recommendations. It is condescending for the HERC to enumerate every specific case in which consult is required. This same reasoning applies to indications for transfer of care in the proposed draft for coverage guidance. Midwives are trained and licensed professionals AND are already practicing according to a detailed set of practice standards created by the Oregon board of direct entry midwifery. I am currently a student midwife nearing the end of my training, and feel strongly that it is important to accept clients who have OHP coverage. However, it is discouraging to be faced with the additional restrictions and requirements detailed in the proposed draft. These not only dictate how a midwife can practice, but also necessitate extra work and time. I know that many midwives do not accept OHP clients because they are not comfortable with letting the coverage guideline dictate their care and infringe upon their ability to provide true informed choice to clients. A simplified and evidence-based coverage guideline could go a long way toward increasing the number of midwives willing to accept OHP clients. I strongly request that the HERC create a concise list of evidence-based recommendations for coverage guidance, rather than attempting to create a midwifery practice standard.	
Z1	In November of 2018, when I was 36 weeks pregnant, I was forced to undergo an OHP Prior Authorization ultrasound. It was supposedly because I had 3rd degree lacerations with my first pregnancy, which was 18 years ago. After the ultrasound, which lasted a full hour, the doctor who came to speak to me was rude, abrupt, and didn't listen to anything I said. She told me that I was going to be forced to	*Thank you for sharing your experience.* *See responses to comments S1 and Y1 above.*

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	change providers, at 36 weeks, and that I was "taking (my) baby's life in my hands" and that a vaginal birth, let alone a birth center birth, was out of the question. I was actually able to transfer care (unheard of at that late stage) and gave birth, vaginally, unmedicated, and out of hospital just a couple of weeks later. He was a perfectly healthy, beautiful baby boy who is now a year old. While I WAS able to transfer care, it was ONLY because of my fantastic midwife, who I trusted and had developed a relationship with. She was able to pull some strings and get me in to a different place, with some more stringent rules. This is an incredibly important time in a woman's life, and pregnancy. In a time when I SHOULD have been the happiest, secure in my birth team, happily preparing to give birth, I was having severe panic attacks, and sobbing regularly, not knowing who would help deliver my child, where I would give birth, or how it would be paid for. This is a time when blood pressure is important, yet I had panic attacks, induced by this ridiculous, asinine process, which (obviously) caused my blood pressure to rise. That can't be healthy. This process robs the mother to be of her security, making her pregnancy more at risk, and her labor longer. The providers who have known the patient, developed a relationship with her, and helped her plan, know the patient, and her pregnancy, including any extenuating circumstances FAR better than the one off doctor who is supposed to come in and tell them what is going on, without ANY knowledge of the patient. Yet this one off doctor (who was incorrect on all accounts) made my last few weeks of pregnancy hell. A lawsuit was considered but ultimately decided against.	

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	The prior authorization protocol of OHP robs patients of their choice and makes medical induced interventions far more likely with worse outcomes for both mother and child.	
AA1	As an Oregon Doctor of Chiropractic trained in out of hospital births I ask for the following additions to the draft Medicaid Guidance for Planned Out of Hospital Births: Mandatory fetal and infant mortality reporting to Oregon Medicaid for sentinel event review by a multidisciplinary team to include medical physicians (MD). Deidentified data collected from these reports to be organized and made publicly available. Mandatory reporting to Oregon Medicaid the outcomes for all births including but not limited to all injuries , no matter how slight, to birth mother or baby with those injuries attached to both birth mother and baby records . Meaning, an injury to birth mother is noted in the babies Medicaid report records. Deidentified data collected from these reports to be organized and made publicly available. Mandatory reporting to Oregon Medicaid circumstances of all transfers from home or birth center to a hospital. Deidentified data collected from these reports to be organized and made publicly available.	*Mandatory reporting of sentinel events and data collection and analysis by health plans are outside the scope of this report.*
AA2	Advanced maternal age ,greater than 35, as a high/ higher risk factor precluding planned out of hospital birth. (Advanced maternal age is not low risk).	*See separate high-risk condition response table.*
AA3	Post dates, beyond 41 completed weeks, as a high/ higher risk factor precluding planned out of hospital birth. (Post dates is not low risk).	*See separate high-risk condition response table.*
AA4	All births in early labor to be confirmed by ultrasound that fetus is in the cephalic presentation. No payment for 'surprise ' breech.	*See separate high-risk condition response table.*

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AA5	All Medicaid records , including labor and delivery records, to be completed on Oregon Medicaid standardized forms. No 'draft' or rewriting of any record at anytime.	*Documentation requirements are determined by health plans and are outside of the scope of this report.*
AA6	The scope of practice and the standards of care for All planned out of hospital births in Oregon is the same for all professions. Meaning, all planned out of hospital births are to be low risk as defined by the Oregon Health Evidence Review Commission under the Oregon Health Authority. No Oregon licensing board, especially one who is also under the purview of the Oregon Health Authority, can independently decide that a planned out of hospital birth can be anything other than low risk as per the Oregon Health Evidence Review Commissions' definition of low risk. To intentionally practice anything other than low risk care and attend births that are anything other than low risk jeopardizes the health and safety of the patient(s) and is considered unprofessional conduct under Oregon law.	*Licensing standards are outside the scope of this document. They are determined by licensing boards as required by law.*
AA7	The question of maternal choice has come up as a reason for the EBGSs to not fully investigate and define some factors as high / higher risk ie nulliparity. Maternal choice is of significance only as to the 'consideration' of place of birth NOT as to maternal personal choice of what the definition of low risk is and thus demanding a payor conform to their personal choice of definitions. Safety of mother and baby is not a question of choice.	*See response to comment F1 above.*
AB1	There are several items on this list, that while they require careful evaluation and discussion between the patient and care provider, represent a theoretical or small increased risk that does not translate to increased risk with choosing OOH birth.	*See responses to Discussion Table item 1, and as to comments F1, K1, and S1 above.*

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ID/ #	Comment	Disposition
	To take this choice away from women that are within the scope of out-of-hospital providers, unnecessarily discriminates against these women by restricting their access to the provider of their choice. Oregon decided many years ago to provide access to out-of-hospital birth for women on Medicaid, and that right is legally protected. The implementation of these guidelines has drastically reduced the numbers of out-of-hospital births in Oregon. If OHA truly wants to provide access to this care, they need to allow their contracted providers to provide maternity care without a cumbersome and restrictive prior authorization process. In my experience since HERC was implemented the majority of patients that undergo the PA process find it stressful at best and at times traumatic and demoralizing. My clients have stated they feel like they are being discriminated against for being poor, or fat, or having too many miscarriages, etc. I have seen patients make significant sacrifices to pay for their birth out of pocket after OHP denied their PA, when they were in fact low-risk and a candidate for delivery at the birth center.	
AB2	Topic: Collagen Vascular disease: exclusion criteria. Change to consult only. RA is a collagen vascular disease. 1. Severity of RA varies. 2. The increased risk of adverse outcomes (low birth weight, SGA, pre-eclampsia and cesarean section) is minimal. 3. Research supports midwifery care improves outcomes related to LBW, SGA and CS.	*See separate high-risk condition response table.*

ID/ #	Comment	Disposition
AB3	Topic: Previous CS: exclusion criteria. Remove as exclusion criteria. 1. Midwives in Oregon have high VBAC success rates OOH. Women with previous CS should be encouraged to birth with a skilled midwife, close to back up facilities if that is their preference. 2. Risk of VBAC and TOLAC are well studied and understood. Because of protective factors of being in midwifery care; it is a disservice to birthing people to take that choice away from them. See AABC clinical bulletin resource 1. 3. Benefits to maternal health and neonatal health in avoiding repeat CS. Risk of accreta after 2 or more cesereans increases significantly. Repeat CS is significantly more likely if TOLAC occurs in a hospital. 1 in 14 mothers with accreta die. 1 in 17 babies with accreta die. There is insufficient data showing OOH VBAC has increased risk to outweigh the benefits to mom and baby of avoiding repeat cesarean, which midwives excel at.	*See separate high-risk condition response table.*
AB4	Topic: Significant Endocrine conditions other then diabetes Please clarify that if patient is seeing a CNM or ND that is trained to manage hypothyroidism in pregnancy, additional consultation is not necessary if patient is well managed. Requiring this consult increases cost of care and is inconvenient for the patient.	*See separate high-risk condition response table. See hypothyroidism response in comment P4.*
AB5	Topic: History of unexplained stillbirth / neonatal death or previous death related to intrapartum difficulty. Women with previous loss are capable of understanding risks and benefits to choosing their provider and place of birth. Restricting access to coverage based on this history is traumatic for women. They may choose OOH birth for a variety of reasons.	*See separate high-risk condition response table.*

ID/ #	Comment	Disposition
	There is insufficient data showing that delivering in a hospital, after a previous stillbirth, decreases risk of subsequent stillbirth/neonatal loss. Proposed change: Include as consultation criteria only, unless additional risk factors develop.	
AB6	Topic: History of pre-eclampsia requiring pre-term birth and HELLP as exclusion criteria. Consult criteria only. Midwives in Oregon are able to identify signs and symptoms of pre-eclampsia in adequate time for transfer of care as indicated, if they arise. In rural areas, having access to a midwife increases likelihood a patient with early signs of pre-eclampsia will be promptly referred to the appropriate provider and facility. There is not evidence that women with a history of pre-eclampsia requiring pre-term birth have poor outcomes when receiving prenatal care from a midwife in a subsequent pregnancy.	*See separate high-risk condition response table.*
AB7	Topic: BMI ≥ 35 consult Information women receive is not so nuanced as to need an in person consult. It does not justify cost and emotional expense to these women. There is no added improved outcome by having an in person consult. It does further stigmatize their weight. Intent of this could be achieved via a signed informed consent for women that decline consult.	*See separate high-risk condition response table.*
AB8	Topic: Psychiatric conditions: Schizophrenia, other psychotic disorders etc Inappropriately discriminates against women with mental illness. Women with significant mental illness may choose OOH birth. There is not data to show this as being unsafe, and rather having a choice in their provider and the personalized care offered in this model has benefit for these patients when they are being co-managed by the appropriate psychiatric provider.	*See separate high-risk condition response table.*

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HERC Coverage Guidance: Planned Out-of-Hospital Birth
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AB9	Topic: History of postpartum mood disorder with high risk to infant Remove as exclusion criteria. Personalized care and close follow up by midwives including home visits are one of several reasons women with PPD hx may choose a midwife. Also in may be important to choose the same provider in a subsequent pregnancy as they are already familiar with their history.	*See separate high-risk condition response table.*
AB10	Topic: Amniotic membrane rupture greater then 24 hrs. There is insufficient data to show that expectant manage of ROM > 24 hrs has enough increased risk to mom or baby that this choice should be taken away from women.	*See separate high-risk condition response table.*
AB11	Topic: Diabetes, gestational managed by medication. Gestational diabetes managed by metformin is within the scope of NDs. There is no data showing that these patients have worse outcomes when cared for in hospital, vs cared for by ND.	*See separate high-risk condition response table.*
AB12	Topic: Thrombocytopenia Recommend 75,000 as cut off.	*See separate high-risk condition response table.*
AB13	Topic: Group B strep unknown Women have the right to decline testing in pregnancy. Recommend risk based management for women that decline GBS testing or transfer if additional risk factors develop.	*See separate high-risk condition response table.*
AB14	Topic: Uterine condition: Prolapse Does not require transfer if it immediately reduces.	*See separate high-risk condition response table.*

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References Provided by Commenters

ID	References
I	Grunebaum A, McCullough LB, Chervenak FA. Most intended home births in the United States are not low risk: 2016 – 2018 [published online ahead of print November 9, 2019]. *Am J Obstet Gynecol.* doi: 10.1016/j.ajog.2019.11.

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Discussion Table

IDs/#s	Summary of Issue	Draft Subcommittee Response
A1	Absence of neonatal consultation or transfer criteria.	*EbGS removed the neonatal consultation and transfer criteria (from the prior draft) because they are more appropriate as clinical guidance regarding care that would occur after the birth itself than as coverage criteria.*
B2, D2	Request for clarification or modification for history of postpartum hemorrhage requiring intervention (specifically around the scope of intervention).	*Consider changing to:* *History of postpartum hemorrhage requiring intervention* ***(e.g., blood transfusion or other advanced treatment such as ≥ 2 pharmacologic therapies)****.*
B3	Request to change a transfer condition to a consultation: 1. History of preeclampsia requiring preterm birth in the event it was a higher risk condition in the prior pregnancy (e.g., twins) that is not present in the current pregnancy.	*EbGS discussed the issue of preeclampsia requiring preterm birth and concluded that the risk associated with this condition requires a planned hospital birth.*
C2, F1	Request to change a transfer condition to a consultation:	*Prior cesarean delivery is a transfer criterion due to evidence of worse neonatal outcomes. This recommendation is aligns with*

IDs/#s	Summary of Issue	Draft Subcommittee Response
	2. History of prior cesarean delivery.	*recommendations from ACNM (2015), ACOG (2017), NICE (2017), and the WA Billing Guide (2017). It is also consistent with decisions to exclude women with prior cesarean sections from low-risk groups in multiple studies.* *EbGS previously discussed expert testimony indicating TOLAC is safe for women with a prior vaginal birth with a lower threshold for transfer. However, the subcommittee did not recommend coverage because TOLAC is not available at many rural hospitals due to a lack of availability of emergency delivery services (e.g., in-house anesthesia and/or in-house maternity provider) as well as the potential acuity of the need for transfer and potential for harm.*
C3	Request for removal for gestational Age > or = to 42 weeks 0 days.	*Studies report an increased mortality rate at ≥ 41 weeks gestation. There is also alignment with multiple sources for restrictions at ≥ 42 weeks gestation.* *However, for women who go into labor just before 42w0 but are in active labor progressing from 41w6 to 42w0, it may be appropriate to permit coverage?* *EbGS decision: Change to ≥ 42 weeks 0 days (unless already in active labor at 41w6d)*
E1	Scope of coverage guideline for organizations without practice guidelines.	*This coverage guidance is intended to aid in development of insurance coverage policy; it is not intended to be a clinical practice guideline.*

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HERC Coverage Guidance: Planned Out-of-Hospital Birth
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IDs/#s	Summary of Issue	Draft Subcommittee Response
E1	Request to readopt the 2015 Guidance for Planned Out-of-Hospital Birth.	*We are aware of the 2015 guidance and have produced the current guidance in light of additional evidence, extensive deliberation and public testimony.*

Commenters

Identification	Stakeholder
A	T. Allen Merritt, MD, MHA, FAAP, Samaritan Health Services [*Submitted February 16, 2020*]
B	Silke Akerson, CPM, LDM, Oregon Midwifery Council [*Submitted February 24, 2020*]
C	Catherine Akerson Bailey, CPM, LDM [*Submitted March 2, 2020*]
D	Celeste Kersey, CPM, LDM, Oregon Midwifery Council [*Submitted March 3, 2020*]
E	Sharron Fuchs, DC [*Submitted March 3, 2020*]
F	Desirée Ford [*Submitted March 3, 2020*]

Public Comments

ID/#	Comment	Disposition
A1	In the revision forwarded, I do not see any Neonatal guidelines for consultation or transfer of newborns. These are essential.	*See discussion table.*
B1	Thank you so much for the work that you put into the current draft of the Planned Out-of-Hospital Birth Coverage Guidance. It is clear that you took seriously the concerns about overreach of the previous draft expressed in the public comment period and that you put much thought into aligning the guidance with the available evidence. We support the current draft coverage guidance and think that it reflects the best evidence available on low-risk, planned, midwife-attended, out-of-hospital birth.	*Thank you for your comment.*
B2	We have two remaining small concerns. First, the consult requirement for "history of postpartum hemorrhage requiring intervention" remains vague. While we agree that consultation is appropriate in a case where a person has a history of hemorrhage requiring transfusion or other advanced treatment, we are	*Changed to "History of postpartum hemorrhage requiring transfusion or*

ID/#	Comment	Disposition
	concerned that, as currently worded, we may be required to consult for every person who had any intervention for hemorrhage even if it resolved with one minor intervention, such as Pitocin, and without complication.	*other advanced treatment (e.g. Bakri balloon)"*
B3	Second, in the very rare instance that a person had a history of preeclampsia requiring preterm birth in a previous twin pregnancy, we are concerned that the transfer requirement might exclude someone who may not actually be high risk in a current, singleton pregnancy.	*See discussion table.*
B4	We are grateful for the care you have taken in creating this draft guidance. Thank you.	*Thank you for your comment.*
C1	Wow! Thank you so much for listening to the feedback I (and many others) sent in for the last round of public comment. You have made so many positive changes to this document and I am really grateful! You have condensed this list in a way that seems much more in line with its intent. Thank you.	*Thank you for your comment.*
C2	There are a few remaining items that I am concerned about. They include: Medical History or OB History: 1. Cesarean Section - Move to consult requirement. Clients should be able to choose their place of birth whether or not they've had a previous cesarean birth, even though it is more high risk, as long as they have been given adequate informed consent and have had a consult with a hospital provider. Please consider changing this requirement.	*See discussion table.*
C3	Conditions of Current Pregnancy: 2. Gestational Age > or = to 42 weeks 0 days - Remove. So many clients, when given the opportunity to not be induced, ride this line of 42 weeks. Perhaps it could change to 42 weeks 3 days, or, include 'without family history of post-dates delivery' or allow primips to go a few days past 42 weeks, since it's so much more common for them to go late. I have many clients with family history of going post-dates and also many primips, with or without family history, go post-dates themselves with no issue. Of course I understand that the risk of stillbirth increases after 42 weeks, but I do believe that it should be an option for clients to decline induction with informed consent.	*See discussion table.*
C4	Thank you for taking the time to consider my feedback.	*Thank you for your comment.*

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HERC Coverage Guidance: Planned Out-of-Hospital Birth
Disposition of Public Comments

ID/#	Comment	Disposition
D1	I'm so grateful for the work that you put into the current draft of the Planned Out-of-Hospital Birth Coverage Guidance and your openness to considering many of the concerns raised at the December meeting. Thank you for looking closely at what evidence is available and applicable to our rules. We at the Oregon Midwifery Council and myself, as an independent midwife, support the current draft coverage guidance and believe that it does reflect the best evidence available and pertinent to out-of-hospital birth.	*Thank you for your comment.*
D2	While most all the draft is appropriate I want to suggest that the consult requirement for "history of postpartum hemorrhage requiring intervention" be given more clarity. I can see the wisdom in having a consultation for a case where a person has a history of hemorrhage requiring transfusion or other advanced treatment, I am worried that this could mean that we are required to consult when a client has had any intervention for hemorrhage even if it easily resolved.	*See discussion table.*
D3	Again, thank you for the care you have taken in creating this draft guidance and for considering my comments.	*Thank for your comment.*
E1	The draft Coverage Guidance for Planned Out-of-Hospital Birth is wholly inadequate as Guidance or Guidelines for professions that have no written scope of practice or standards of care, including the Chiropractic profession. I ask you to readopt the 2015 Guidance for Planned Out-of-Hospital Birth.	*See discussion table.*
F1	When I was 21 I experienced the birth of my first son. I decided to go with a certified nurse midwife in hospital after researching different birth options and what I thought would be best for my baby. I wanted to have a natural birth with the least amount of interventions as possible. On the day of my estimated due date I was told I needed to have my labor induced, but not really given a reason why. This induction created a snow ball effect of expensive interventions that lead to an unnecessary C-section and the reason why I have had two VBACS since. At the hospital I was induced with cervical gel, my labour was not progressing as fast as the nurse midwife liked so they administered pitocin. My labor came on very fast and was extremely painful after this was administered. I have labored twice since then, and the contractions brought on by pitocin were far more painful in comparison. I was then given pain medication which didn't do much for the pain and made me feel like I was on drugs. At this point I was told an epidural would be helpful, so through the guidance of my midwife, I was told that it was needed. I got the epidural and my labour slowed. I was exhausted, frustrated, confused, overwhelmed and wanting to do what was best for my baby. I was told due to failure to progress	*Thank you for your comment.* *EbGS does not weigh in on individual cases, rather, creates recommendations to HERC for coverage policy.* *The provided citation, Hochler et al. (2019) is a poster abstract investigating in-hospital outcomes for women with 1 one prior cesarean delivery and grandmultiparity (≥ 6 deliveries) undergoing induction or augmentation for trial of labor after*

ID/#	Comment	Disposition
	at eight centimeters I needed a C-section. Before I knew it I was being prepped for surgery and getting ready to do the thing I wanted to avoid. There was no safety risk, I was just taking to long according to the hospital. Before I had the surgery I was laboring for 20 hours. This is not uncommon and is in fact quite an average amount of time for first time births. Fast forward 6 years. I found out I was pregnant again. I started researching my options for my up coming birth. I heard about a VBAC and saw there was a lot of success. I weighed the pro's and con's and felt the pro's far out weighed the cons. I decided this was the direction I was going to go. I had two options I wanted to look into. Hospital VBAC or out of hospital VBAC. First I toured a couple hospitals and asked if they allow VBACs. Some nurses would say they do, but most would say they are required to do a C-section. This was super discouraging, but I just moved a long my search and looked into the birth center. At the birth centers I loved the set up as well as the community that was supportive of natural birth. Unfortunately, my insurance didn't cover the birth center, so my search continued. This is when I met the midwife that would be there for my first vaginal delivery, and completely change my life. The appointments were wonderful, she had so much information about VBACs, nursing, postpartum depression and how to have a successful natural birth. Her support was so amazing during the pregnancy. I felt so empowered and confident about my choices. Quickly the due date came and we were ready to go. I started having the contractions on my own and they were not as bad as the ones brought on by the pitocin. They progressed and got heavier. They were very intense, but it was okay. When my midwife arrived she checked my cervix and I was at nine centimeters. Nine centimeters! In the hospital they claimed I was failure to progress at eight. At this point I knew I could do it. Emotionally, I was elated. Two hours later I delivered a 10lb 21inch healthy baby. I felt so proud of myself and I can say to this day that it was the most empowering experience in my life. I was able to have a successful nursing relationship, produce plenty of milk and bond with my baby in a way I did not experience previously. I had excellent aftercare, physically healed quicker and did not experience postpartum depression symptoms. Over all I felt like I had a fantastically comprehensive foundation for taking care of my new born.	*cesarean, compared to women with 2-5 prior deliveries (including 1 prior cesarean) undergoing TOLAC induction or in spontaneous labor. This study would not meet inclusion criteria for our evidence review (i.e., abstract, in-hospital setting).* *See discussion table.*

ID/#	Comment	Disposition
	What I would like for you to consider after reading this letter is just how much of a positive impact this birth experience had on my family and myself. Not only was I able to birth my child with no interventions what so ever, I also know that having two vaginal births has reduced the danger of my risk status. Even DMAP has seen this in their studies and is quoted in saying ”DMAP also argues that petitioner's case is not justiciable because certain relevant circumstances may change in the future. For one, DMAP argues that, due to petitioner's successful VBAC at the birth center, she may no longer be considered “high risk” for a future VBAC and therefore would not necessarily be denied prior authorization for an out-of-hospital birth”. If this is DMAPS opinion on this case, then why not for mine? Vaginal birth is so much more affordable, it just does not make economic sense to cover a much more expensive procedure that is unnecessary .The issue I am facing with a hospital birth is many have protocol in place that require me to have a C-section just because I have had a C-section in the past. The data attached will show that I no longer qualify as “high risk” I had a successful VBAC back twice and it was covered by Oregon Health Plan before. I feel like it should continue to be covered now and in the future as well. Thank you for taking the time to consider my letter.	

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References Provided by Commenters

ID	References
F1	Blevins v. Division of Medical Assistance Programs, Court of Appeals of Oregon (decided 2018). https://caselaw.findlaw.com/or-court-of-appeals/1895602.html Hochler, H., et al. (2019). Uterine rupture risk in a trial of labor after cesarean section with previous vaginal birth. *American Journal of Obstetrics & Gynecology, 220*(1), S508-S509. https://www.ajog.org/article/S0002-9378(18)31822-2/fulltext Margulis, J. (2016, February 27). "Denied: Vaginal birth after Cesarean." *Jefferson Public Radio.* https://www.ijpr.org/post/denied-vaginal-birth-after-cesarean#stream/0

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HERC Coverage Guidance: Planned Out-of-Hospital Birth

High-Risk Condition Response Table (Updated with EbGS February and June 2020 Decisions)

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Table 1. Medical History or Obstetric History

Risk Factor (Medical or Obstetric History)	Comment ID/ Summary	Evidence/ Guidelines/ Standards	Options considered for EbGS February 2020 meeting	EbGS February 2020 Decision (June 2020 Revisions *Italicized*)
Cancer • Cancer affecting site of delivery	I7 Proposed modification – clarification, commenter says criterion is unclear.	This phrasing arises from the WA Billing Guide (2017). Available studies do not mention cancer in exclusion criteria. LDEM proposed (2019) uses "active cancer" phrasing.	Consider modification: Active gynecologic cancer	Change to: • Active gynecologic cancer
Cardiovascular disease • Cardiovascular disease causing functional impairment	I8 Proposed modification – expansion, commenter says functional	Birthplace (2011) excludes confirmed cardiac disease. Language regarding severity of cardiac disease varies by guideline. The phrasing here is from WA Billing Guide (2017). NICE (2017) has individual planning when cardiac disease will not have	Consider modification: Significant cardiovascular disease (e.g., functional impairment).	No change.

	impairment too restrictive, functional impairment unclear as well.	intrapartum implications. ACNM (2015) states "substantial medical conditions that have required acute medical supervisions during the pregnancy and could impact the birth such as cardiac disease."		
Collagen vascular disease • Any	P2, AB2 Proposed modification – allow for consultation for rheumatoid arthritis based on variable disease severity.	This phrasing arises from the WA Billing Guide (2017) in which it is a transfer criterion. Birthplace (2011) excludes women with systemic lupus erythematosus, scleroderma but does not specifically address rheumatoid arthritis.	No change or consider changing collagen vascular disease from a transfer (3) to a consult criterion (2). (Note: Meeting materials correct a comment in Appendix I that incorrectly listed this as a consultation criterion.)	Change to consult criteria and combine with connective tissue disorders – Rename Connective Tissue Disorders. • Systemic lupus erythematous • Scleroderma • Rheumatoid arthritis • Any collagen-vascular disease
Delivery history • Prior cesarean section	F1, F2, L3, P3, Q3, U2, V2 W1, AB3 Conflicting comments, delete entire category based on good VBAC outcomes for OOHB, modify to coverage	While a successful VBAC is an optimal outcome, this issue at hand regards outcomes for all women attempting a TOLAC. The exclusion of prior cesarean section is in keeping with findings from a comparative U.S. study (Grunebaum, McCullough, Spara et	Make no change. This is based on evidence of worse neonatal outcomes and in keeping with ACNM (2015), ACOG (2017), NICE (2017), and the WA Billing	No change.

	when there is a prior vaginal delivery as well (F2, Q3). Commenters cite unspecified data, or from the Oregon Association of Birth Centers, American Association of Birth Centers or CMS showing good outcomes for women with prior cesarean and prior vaginal deliveries. Some suggest coverage with informed consent in this population.	al., 2017) that found an 8-fold increase in neonatal mortality. A separate U.S. study (Tilden et al., 2017) observed a non-statistically significant increase in neonatal death for women completing a vaginal birth after cesarean in home or birth center settings compared to hospitals. Findings from non-comparative studies (Bachilova et al., 2018; Cox et al., 2015) also observe rare but higher rates of neonatal harm or death in women undergoing TOLAC. Cheney et al., 2014 observed higher rates of intrapartum neonatal death but the results were not statistically significantly different. The question of outcomes for women attempting a TOLAC with a prior vaginal delivery are not addressed by comparative studies. For neonates, TOLAC increased odds of low 5-minute Apgars, hospitalization and NICU admission (Bovjberg et al., 2017). This exclusion condition is also aligned with guidelines from AABC	Guide (2017) and exclusion of prior cesarean section as low risk in multiple studies. EbGS previously discussed expert testimony indicating TOLAC is safe for women with a prior vaginal birth with a lower threshold for transfer. However, the subcommittee did not recommend coverage because TOLAC is not even available at many rural hospitals because of a lack of availability of emergency delivery services (lack of in-house anesthesia and/or in-house maternity provider).	

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		(2017), ACNM (2015), ACOG (2017), NICE (2017), and the WA Billing Guide (2017). In many rural parts of Oregon, TOLAC is unavailable in hospitals because of a requirement that the hospital have an anesthesiologist available at all times.		
Endocrine conditions • Significant endocrine conditions other than diabetes (e.g., hyperthyroidism)	P4, U3, AB4 Proposed modification – clarification for CNM or ND (e.g., hypothyroidism).	Washington has "Significant endocrine disorders" as a transfer criteria (3). LDM Board has hyperthyroidism as a consultation criteria (2).	Make no change to the current recommendation for consultation for significant endocrine conditions other than diabetes (e.g., hyperthyroidism). Fix the error in Appendix I to omit an incorrect reference to hypothyroidism which may have resulted in confusion.	No change.
Fetal demise or stillbirth • History of unexplained fetal demise or stillbirth or	F3, P5, Q4, U4, V3, AB5	This phrasing arises from Birthplace (2011), continues to be a high-risk condition in NICE (2017). NICE (2017) allows for individual planning when a	Consider changing to: • Prior unexplained fetal demise, ~~or~~	Simplify to the following consult criteria:

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previous death related to intrapartum difficulty	F3 Questions evidence for both transfer and consult. P5 and AB5 suggest changing transfer requirement to a consultation. Q4 asks for clarification of intrapartum difficulty and removal of transfer requirement (e.g., death related to intrapartum breech is not a risk for future pregnancies). U4 requests removal of transfer requirement. V3 proposes dropping transfer criteria based on informed decision of patient.	history of stillbirth/neonatal death from a non-recurrent cause. CMBC (2018) has consultation for previous neonatal mortality or stillbirth (no specific comment regarding intrapartum difficulty).	stillbirth, or previous death related to intrapartum difficulty	• Prior stillbirth/neonatal death

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High-Risk Condition Response Table (Updated with EbGS February and June 2020 Decisions)

Fetal demise or stillbirth • Prior unexplained stillbirth/neonatal death or death unrelated to intrapartum difficulty (consult)	F3 Questions evidence for transfer and consult.	See line above for response.	• Prior unexplained stillbirth, neonatal death, or death unrelated to intrapartum difficulty (consult) • Prior explained fetal demise, stillbirth, or previous death with potential for recurrence (consult)	Simplify to the following consult criteria: • Prior stillbirth/neonatal death
Fetal growth • History of intrauterine growth restriction (IUGR) • Prior small for gestational age infant • Prior baby > 4.5 kg or 9 lbs 14 oz	F6, F14, Q5 Proposed deletion all three consult criteria based on lack of evidence.	Phrasing arises from prior CG (2015) and CMBC (2018).	Consider deletion.	Delete category.
Hematologic disorders • History of thrombosis or thromboembolism	Q6 Proposed deletion of this category.	Birthplace (2011) excluded women with hemoglobinopathies, thromboembolic or bleeding	No change. Or consider:	Change to consultation criteria

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• Maternal bleeding disorder	Commenter reports provider medical judgment should suffice.	disorders, platelet disorders given their higher risk for adverse events in pregnancy. Guidelines concur with these consultation and exclusion criteria ACNM (2015), NICE (2017), LDEM proposed (2019).	• History of unprovoked thrombosis or thromboembolism • Maternal bleeding disorder	• History of thrombosis or thromboembolism Maternal bleeding disorder remains a transfer criterion.
Hematologic disorders • Anemia with hemoglobin < 8.5 in prior pregnancy • Hemoglobinopathies • History of postpartum hemorrhage requiring intervention	F4 Proposed deletion- anemia with hemoglobin < 8.5 in prior pregnancy. Proposed modification – clarification on intent of history of postpartum hemorrhage requiring interventions.	Phrasing for history of postpartum hemorrhage requiring intervention arises from WA billing guide (2017) and is consistent with ACNM (2015), NICE (2017). Postpartum hemorrhage requiring interventions includes but not limited to Bakri balloon, blood transfusion, uterine aspiration or curettage, manual removal of placenta.	Thank you for bringing this to our attention. This was an error in the coverage guidance as posted for comment; the error has now been corrected by removing this criterion and the erroneous row in Appendix I.	Delete • Anemia with hemoglobin < 8.5 in prior pregnancy
Hypertensive disorders • Eclampsia • Pre-eclampsia requiring preterm birth	P6, U5, V4, AB6 P6, V4, AB6 - Proposed modification of the	Birthplace (2011) excluded women a history of pre-eclampsia requiring pre-term birth as high risk of adverse outcomes. Unable to identify unspecified evidence referenced by P6 on	No change.	No change.

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• HELLP syndrome (hemolysis, elevated liver enzymes, low platelets) • Pre-existing or chronic hypertension	category to consult only. Proposed deletion (U5) of the history of pre-eclampsia requiring pre-term birth and HELLP components as these conditions not guaranteed to return in future pregnancies	improvement of outcomes for women with this history in the care of midwives. Guidelines concur with this exclusion condition NICE (2017).		
Infectious diseases • HIV positive	F5 Proposed deletion of this component based on provider capability to assess risk and lack of evidence.	Women with HIV are excluded from comparative studies (Birthplace, 2011; Hutton et al., 2016.) given their higher than average risk. Viral load influences delivery planning for mother and management of the neonate for post-exposure prophylaxis. Guidelines concur with this exclusion condition ACNM (2015), NICE (2017), WA Billing Guide (2017).	Make no change. This was discussed during EbGS and was agreed to require hospital level care. ACOG recommends cesarean section at 38 weeks for elevated viral load. Infant requires immediate antiretroviral therapy. Some recommend intrapartum antiretrovirals.	No change.

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Miscarriage/nonviable pregnancy • 3 or more 1st trimester spontaneous miscarriages • 1 or more 2nd trimester spontaneous miscarriages	Q7 Proposed deletion of this category based on lack of evidence.	Phrasing from CMBC (2018) only and no mention of this condition across included studies.	Consider deletion.	Delete category.
Neonatal encephalopathy in prior pregnancy	Q8 Proposed deletion of this category based on lack of evidence.	Birthplace (2011) excluded women with a previous child with neonatal encephalopathy. NICE (2017) has this as an exclusion for planned out-of-hospital birth.	No change.	Change to consult criteria.
Neurological disorders • History of maternal seizure disorder	I9 Proposed modification that any maternal seizure disorder should be a transfer.		No change. EbGS previously discussed that active seizure disorders would be a transfer criteria and history of maternal seizure disorder that was not active (e.g., no seizure in 20 years) was	Delete history of maternal seizure disorder. Neurological disorders or active seizure disorders that would impact maternal or neonatal health (e.g. epilepsy, myasthenia gravis, previous cerebrovascular

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			appropriate for consult.	accident) remains a transfer criterion.
Obesity or overweight (pre-pregnancy) • Class 2 or 3: BMI ≥ 35.0	F7, P7, Q9, U6, V5, AB7 Proposed deletion of this category – Evidence for consult lacking (F7, Q9). Lack of value in consult (F7, P7, Q9, V5, AB7). Discrimination and lack of evidence of harm for this population (U6). Request for informed refusal form (V5, AB7).	Absence of evidence on women from comparative studies as Birthplace (2011) women with BMI over 35 at booking excluded. Also excluded in the Dutch Perinatal Registry analysis (van der Kooy et al., 2017). Other comparative international studies of higher risk individuals did not isolate outcomes for this specific risk factor (Davis-Tuck et al., 2018; Li et al., 2015). Non-comparative U.S. studies observed increased neonatal harms with pre-pregnancy obesity (BMI ≥ 35 compared to < 25) (Bovbjerg et al., 2017). OHA review of neonatal deaths (2013) observed morbid obesity (BMI > 40) as one of several high-risk factors present.	Consider whether to make no change or delete. Evidence suggests increased harms, aligns with CMBC.	Delete category.
Perineal lacerations or obstetric anal sphincter injury	F8, Q10 Proposed deletion of these components	No included studies address prior perineal lacerations or obstetric anal sphincter injuries.	Consider deletion. Erroneous classifications in	Delete category.

• 4th degree prior pregnancy without satisfactory functional recovery • 3rd degree prior pregnancy • 4th degree prior pregnancy with satisfactory functional recovery	based on provider ability to determine.	Current phrasing consistent with prior CG (2015), CMBC (2018).	Appendix I for WA and LDEM (should be for current pregnancy, not historical).	
Psychiatric conditions • History of postpartum mood disorder with high risk to the infant (e.g., psychosis) • Schizophrenia, other psychotic disorders, bipolar I disorder or schizotypal disorders	F9, P8, P9, Q11, U7, U8, V6, AB8, AB9 Proposed deletion of this category based several concerns by commenters: Postpartum psychosis history, when well-supported and controlled in current pregnancy shouldn't impact place of birth (F9, P9). OOHB allows for greater control, closer follow-up, and	Birthplace excluded women requiring current inpatient care, consistent in NICE (2017). No additional evidence from comparative or non-comparative studies for this category. WA Billing Guide (2017) lists current severe psychiatric illness as a high-risk exclusion criteria. ACNM – psychiatric conditions that may affect intrapartum care management or maternal or neonatal transition following birth. CMBC – "history of serious psychological problems," requires consult.	Discuss whether to make no change or change to consult. Extensive EbGS discussion about this and variable recommendations from others on transfer versus consult.	Change to consult criteria. • History of postpartum mood disorder with high risk to the infant (e.g. psychosis) • Schizophrenia, other psychotic disorders, bipolar I disorder or schizotypal disorders

	may improve outcomes (F9, P8, Q11. V6, AB8, AB9). Absence of evidence (P8, U7, U8, AB8).	LDEM board – consult recommended for psychiatric disorders with concern for maternal and fetal safety, current treatment with prescription medication for any ongoing or chronic medical conditions." Extensive committee discussion weighing risks and benefits of the language for this condition and discussed concerns regarding involuntary transfers and potential for hospitals to exacerbation psychiatric conditions.		

Table 2. Conditions of Current Pregnancy

Risk Factor (Conditions of Current Pregnancy)	**Comment ID/ Summary**	**Evidence/ Guidelines/ Standards**	**Options for consideration at EbGS February 2020 meeting**	**EbGS February 2020 Decision (June 2020 Revisions *Italicized*)**
Age • < 17 years • > 40 years	F10, I2, L2, Q12, AA5 Proposed deletion of this category (F10, Q12) or the > 40 years component (L2).	Comparative studies of fetal or neonatal mortality from U.S. settings report greater risk for women over 35 years of life but did not adjust for other potential confounders or	Discuss options: 1) Make no change 2) Delete it altogether	Delete category.

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	Proposed addition with language for consult if maternal age 35 to 39 years, and transfer for maternal age ≥ 40 years (I2). Proposed addition with language for transfer if maternal age > 35 years (AA5).	identify effect modifiers in older women (e.g., obesity, medical comorbidities). Comparative studies from non-U.S. settings that attempt to adjust for confounding observed the greatest risk of neonatal harm for nulliparous women over 40 (Li et al., 2014). NICE (2017) has age over 35 as indicating individual assessment. CMBC (2018) recommends consultation for young (< 17) or older (> 40) year old women.	3) Make more restrictive	
Amniotic membrane rupture • Pre-labor rupture > 24 hours	Q13, P10, U9, AB10 Proposed modification (Q13) – change to consult for pre-labor rupture of membranes (ROM) > 24 hours and transfer for ROM > 24 hours with signs or symptoms of infection. Request for deletion.	Included studies do not address this condition. Current phrasing arise from NICE (2017) and WA Billing Guide (2017).	Discuss whether to make no change or consider change to consult for pre-labor ROM > 24 hours and transfer for ROM > 24 hours with risk factors (e.g., GBS positive or unknown) or signs or symptoms of infection.	Change to consult criteria. Rupture before 37 weeks 0 days remains a transfer criterion.

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Congenital or hereditary anomaly of the fetus • (Evidence of congenital anomalies requiring immediate assessment and/or management by a neonatal specialist)	F11 Proposed modification – requests clarification of who decides and right to refusal.		The decision would likely be based on a high-risk OB/Gyn consultant and/or pediatric consult. For coverage to occur, the transfer and consult criteria must be followed.	Change to consult criteria.
Congenital or hereditary anomaly of the fetus • Evidence of congenital anomalies requiring immediate assessment and/or management by a neonatal specialist	I5 Proposed addition with language requiring transfer for all fetal malformations based on increased risk. Specifically mentions *including < 3 vessel cord*.	Congenital anomalies constituted 29.5% of neonatal deaths among midwife-assisted home births (Grunebaum, McCullough, Arabin, et al., 2017). Many comparative studies specifically exclude known congenital anomalies from estimates (de Cock et al., 2015; Grunebaum, McCullough, Sapra, et al., 2017; Hutton et al., 2016; Snowden et al., 2015)	Discuss whether to make no change or consider whether < 3 vessel cord should be included as a transfer criterion. EbGS had an extensive discussion about the intent to enable coverage in the case of non-resuscitation, but otherwise any major congenital anomaly	Change to consult criteria. Do not mention 3 vessel cord.

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		Phrasing arises from the ACNM (2015). Guideline language varies "affected by site of birth" (WA).	would likely require hospital delivery.	
Diabetes, gestational • Requiring medication or uncontrolled • Diet controlled	Proposed deletion for ND providers as medications within their scope of practice.		No change. Pregnant women who require pharmacotherapy for diabetes require more intensive monitoring and early induction of labor and increased infant monitoring. NICE and WA both consider pharmacotherapy for diabetes a transfer criterion.	No change to diabetes requiring medications or uncontrolled diabetes. Delete: Diet-controlled.
Diabetes, gestational • Requiring medication or uncontrolled • Diet controlled	U10 Proposed deletion of this category.	Birthplace (2011) excludes women with gestational diabetes. Phrasing aligns with ACNM (2015), NICE (2017) and WA (2017).	No change. Consultation for diet-controlled diabetes could be with a pregnancy dietician.	No change to diabetes requiring medications or uncontrolled diabetes. Delete: Diet-controlled.

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Fetal demise or stillbirth • Fetal demise (after 12 weeks gestation)	F12, Q14 Proposed deletion of this category based on lack of evidence, unclear impact on safety or value.	Included studies do not address this condition. Phrasing arises from the WA billing guide (2017).	Discuss whether to make no change or consider deletion.	Delete category.
Fetal growth • IUGR (defined as fetal weight less than 5th percentile using ethnically-appropriate growth tables, or concerning reduced growth velocity on ultrasound)	I10 Proposed modification with language to require transfer for IUGR in current pregnancy.		This was an error, IUGR should have been red, not yellow, thank you for bringing this to our attention.	Clarified error. Keep as transfer criteria.
Fetal growth • Uteroplacental insufficiency • IUGR (defined as fetal weight less than 5th percentile using ethnically-	F14, Q15 Proposed deletion of the component suspected macrosomia (estimated weight > 4.5 kg or 9 lbs 14 oz) (F14) or category (Q15) as commenters request medical	Included studies do not address this condition. NICE (2017) recommend transfer for suspected growth restriction or macrosomia.	Discuss whether to make no change versus consider deletion of "suspected (estimated weight > 4.5 kg or 9 lbs, 14 oz)."	Delete: Suspected (estimated weight > 4.5 kg or 9 lbs, 14 oz)

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appropriate growth tables, or concerning reduced growth velocity on ultrasound). • Inappropriate uterine growth (size-date discrepancy). (An ultrasound read by a qualified physician constitutes a consultation). • Suspected (estimated weight > 4.5 kg or 9 lbs, 14 oz)	judgment of individual case should suffice.			
Fetal monitoring • Abnormal fetal heart rate pattern	I15 Proposed modification – clarify definition as unclear.	Included studies do not address this condition. Topic of discussion by committee ultimately settled on current phrasing based on variety of language used by ACNM (2015), CMBC (2018), NICE (2017), proposed LDEM	No change. EbGS had an extensive discussion about this and was in favor of more broad compared to more detailed language.	Delete category.

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		rules (2019) and WA billing guide (2017).		
Fetal monitoring or movement • Abnormally decreased fetal movement antepartum	I16 Proposed modification- to require transfer with any decreased fetal movements.	Included studies do no address this condition. Phrasing arises from NICE (2017). Topic of discussion by committee ultimately settled on current phrasing.	No change. EbGS had an extensive discussion about this and settled on this language.	Delete category.
Fetal presentation • Breech or noncephalic presentation	L3, AA8 Proposed modification to require transfer for only non-frank, non-complete breech presentations.	Included studies observed increased risk of neonatal death in non-cephalic presentations (Grunebaum, McCullough, Sapra et al., 2017). Phrasing aligns with AABC (2017), ACNM (2015), ACOG (2017), NICE (2017) and WA Billing Guide (2017).	No change.	No change.
Gestational age • < 37 weeks 0 days • ≥ 42 weeks 0 days	L3 Proposed modification to require transfer for gestational age < 36 weeks and 6 days and for > 42 weeks and 6 days based on scope of practice.	Included comparative studies on outcomes by gestational age reported increased risk of neonatal mortality ≥ 41 weeks (Grunebaum, McCullough, Sapra et al., 2017; Grunebaum, McCullough, Arabin et al., 2017). The included studies but	No change based on increased death rate at ≥ 41 weeks gestation. There is alignment with multiple sources ≥ 42. EbGS also discussed that planned OOHB	Change to "≥ 42 weeks 0 days (unless already in active labor at 41 weeks 6 days)."

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		did not adjust for other potential confounders or identify effect modifiers (e.g., obesity, medical comorbidities, hypertensive disorders). Phrasing aligns with AABC (2017), ACNM (2015), NICE (2017).	may be more likely to be assigned to a later gestational age based on dating methodologies.	
	Q16 Proposed modification with language to require transfer for gestational age ≥ 42 weeks and 3 days or consideration of family history of post-dates births.	*See response above.* Family history consideration not addressed by included evidence nor guidelines.	No change. See above.	No change.
	I13, AA6 Proposed modification with language to require transfer for gestational age ≥ 41 weeks based on increased risk.	*See response above.* NICE (2017) covers women from 37 and 0 to 41 weeks and 6 days gestation.	Discuss whether to leave it at ≥ 42 weeks or change it to ≥ 41 weeks. Death rates increase at ≥ 41 weeks gestation. There is alignment with multiple sources ≥ 42.	No change.

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Hematologic conditions • Thrombocytopenia (platelets < 100,000)	P12, AB12 Proposed modification with requesting language to require transfer for thrombocytopenia (< 75,000).	Birthplace (2011) excluded women with history of thrombocytopenia < 100,000. Phrasing aligns with NICE (2017)	No change given lack of alignment with the new proposed platelet number.	No change.
Infectious conditions • Group B strep unknown	F13, L3, P13, Q17, U11, V7, AB13 Proposed deletion of this component based on patient right for informed refusal and lack of evidence.	Included studies and guidelines do not address this condition. OHA (2013) identified unknown or untreated group B streptococcal infection as a factor in neonatal deaths in the out of hospital birth setting.	Discuss whether to make no change or consider deletion.	Delete.
Infectious conditions • HIV, Hepatitis B or syphilis status unknown or positive	L4 Proposed modification for Unknown status for infections (i.e., HIV, Hep B, syphilis) – specific comment on low-risk individuals previously screened, necessity of repeating in current pregnancy and patient right to refuse unnecessary medical care.	Evidence nor guidelines comment on this issue.	Discuss whether to make no change or consider deletion of "unknown status."	Delete unknown status. Change to: • HIV, Hepatitis B or syphilis positive

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Infectious disease • Genital herpes at time of labor	Q18 Proposed modification to change language to require transfer for genital herpes that is uncoverable [sic] at time of delivery.	Included studies do not address this suggested approach to managing active genital herpes. Included guidelines align with current phrasing ACNM (2017), NICE (2017), WA Billing Guide (2017).	No change.	No change.
Meconium	Proposed deletion of this category based on lack of evidence (F15) or when only risk factor should not require transfer (Q19). Proposed modification with language to change language to require transfer for any meconium staining (I12) based on increased risk.	Studies vary in their handling of meconium-stained fluids and consider meconium staining a complicating condition at the start of labor (e.g., Birthplace, 2011). Phrasing aligns with NICE (2017) and WA Billing guide (2017).	No change. Conflicting requests and currently aligns with others.	Delete category.
Multiple gestations	L3 Proposed deletion of this category based on scope of practice. I4 Affirmed that multiple gestations represent high risk	All included comparative studies report outcomes for singleton pregnancies and exclude multiple gestations. Findings from noncomparative studies (Bovbjerg et al., 2017) observed increased odd of maternal (cesarean delivery) and neonatal harms (low 5-	No change.	No change.

	of neonatal morbidity and mortality.	minute Apgar, NICU admission) for twin pregnancies. This condition also aligns with AABC (2017), ACNM (2015), ACOG (2017), CMBC (2018), NICE (2017), and WA Billing Guide (2017).		
Neurological disorders • Significant maternal confusion or disorientation	Q20 Proposed modification to change to consult based on a specific clinical example.	Phrasing arises from WA Billing Guide (2017).	Discuss whether to make no change or consider deletion.	Delete.
Parity • Grand multipara (5 or more previous births)	F16, L2, Q21 Proposed deletion of this category based on absence of evidence and lack of utility (F16), within scope (L2), unclear impact on outcomes (Q21).	Included studies do not address this condition. Phrasing arises from CMBC (2018).	Consider deletion.	Delete grand multipara.
	I3 Proposed addition of requiring transfer for nulliparity based on higher	Included comparative studies of neonatal mortality for nulliparous women observed increase risk (Grunebaum, McCullough, Sapra et al., 2017; Grunebaum, McCullough,	No change.	Do not add nulliparity to transfer criteria.

	neonatal mortality and high transfer rate.	Arabin et al., 2017). In studies with composite outcomes, neonatal harms are increased (Birthplace, 2011) or no different (Li et al., 2015) across settings for nulliparous women. Included guidelines do not address this suggestion addition. This was a topic of extensive discussion by the committee who ultimately prioritized the value women place on choice of birth setting for this category.		
Placental conditions • Low lying placenta within 2 cm or less of cervical os at 36 weeks or later	Q22 Proposed language clarification-low-lying placenta within 2 cm of OS at last documented ultrasound before onset of labor. Proposes if resolved on a 38 weeks scan, women should be eligible for OOHB.	The current phrasing arose from the proposed LDEM rules and 2015 coverage guidance. Evidence does not address this proposed clarification.	Discuss no change versus modifying to: Low lying placenta within 2 cm or less of cervical os at last documented ultrasound before the onset of labor ~~36 weeks or later~~.	Modify to: • Low lying placenta within 2 cm or less of cervical os at 38 weeks 0 days or later
Placental conditions	L4	Included studies do not address this condition.	No change.	No change.

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• Placental delivery > 60 minutes	Proposed modification to a consult.	Included guidelines align with this condition ACNM 2015, NICE (2017), WA Billing guide (2017).	Others aligned with this.	
Prenatal care • Inadequate prenatal care defined as < 5 visits or care began in 3rd trimester	Q23, U13 Proposed deletion of this category citing patient autonomy (U13) and provider judgment (Q23).	Included studies do not address this condition. Phrasing varies from exclusion to consultation in WA Billing Guide (2017), CMBC (2018), and the 2015 CG depending on the timing of initiation, language around number of visits or compliance with the care plan.	Discuss no change or deletion.	Delete category.
Psychiatric conditions • Maternal mental illness requiring psychological or psychiatric intervention • Patient currently taking psychotropic medications	Q24 Request for deletion based on provider medical judgment should determine need for consult.	Included studies do not provide evidence on this specific condition. Included studies excluded individuals with maternal mental illness requiring inpatient admission (Birthplace, 2011). Included guidelines use a variety of language to address this condition (Appendix I) that broadly include wording regarding risk for potential harm to self or infant (ACNM,	No change. The language states the patient needs psychological or psychiatric intervention, therefore a consultation is necessary. The new consultation definition would clarify that a psychologist or psychiatrist would serve as the consultant.	No change.

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		2015; CMBC, 2018; NICE, 2017; WA, 2017).		
Uterine condition • Uterine rupture, inversion or prolapse	P14, U12, V8, AB14 Proposed modification with addition of clarifying language: unless immediately reduces.	CMBC (2018), NICE (2017) and WA (2017) and DEM all have this as a transfer criterion. Included studies nor guidelines do not address this proposed modification.	No change. There is consistency across many sources that this should be a transfer requirement.	Change uterine prolapse to a consultation criterion; rupture and inversion remain transfer criteria.

Table 3. Neonatal Conditions

Risk Factor (Neonatal Conditions)	Comment ID/ Summary	Evidence/ Guidelines/ Standards	Options presented for consideration at February EbGS meeting	EbGS February 2020 Decision
Apgar score • < 5 at 5 minutes • < 7 at 10 minutes	I14 Proposed modification with language to require transfer if Apgar < 7 at 5 minutes based on increased risk.	Phrasing arises from CMBC (2018).	Discuss no change or change to Apgar < 7 at 5 minutes. Apgar Score • < ~~5~~7 at 5 minutes • < 7 at 10 minutes	Delete entire category of neonatal conditions.
Neonatal appearance • Persistent poor suck, poor feeding,	Q25 Proposed deletion of this criteria as clinical judgment should suffice.	Phrasing arises from CMBC (2018).	Consider deletion.	Delete entire category of neonatal conditions.

Risk Factor (Neonatal Conditions)	Comment ID/ Summary	Evidence/ Guidelines/ Standards	Options presented for consideration at February EbGS meeting	EbGS February 2020 Decision
lethargy, hypotonia or abnormal cry				
Neonatal weight • < 5th % for GA	Q26 Proposed deletion of this criteria unless other complications or issues.	Phrasing arises from the 2015 CG, proposed LDEM rules and CMBC (2018).	Discuss whether to make no change versus deletion.	Delete entire category of neonatal conditions.

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