Health Evidence Review Commission's Evidence-based Guideline Subcommittee

February 5, 2015

2:00 PM

Meridian Park Community Health Education Center
Room 117B&C
Tualatin, OR 97062

Section 1.0

Call to Order

AGENDA

EVIDENCE-BASED GUIDELINES SUBCOMMITTEE (EbGS)
February 5, 2015
2:00pm - 5:00pm
Meridian Park Hospital
Community Health Education Center Room 117B&C

(All agenda items are subject to change and times listed are approximate)

#	Time	Item	Presenter
1	2:00 PM	Call to Order	Steve Marks
2	2:05 PM	Review of November minutes	Steve Marks
3	2:10 PM	Staff report	Cat Livingston
4	2:15 PM	Inferior Vena Cava Filters for Prevention of Pulmonary Embolism • Review public comment for coverage guidance	Valerie King Cat Livingston
5	2:35 PM	Coronary artery revascularization for stable angina • Continued review of initial draft coverage guidance	Cat Livingston
6	3:30 PM	Home Birth • Review public comment for coverage guidance	Cat Livingston Valerie King
7	4:55 PM	Confirmation of next meeting April 2, 2015	Steve Marks
8	5:00 PM	Adjournment	Steve Marks

Note: Public comment will be taken on each topic per HERC policy at the time at which that topic is discussed.

MINUTES

Evidence-based Guidelines Subcommittee
Meridian Park Community Health Education Center, Room 117B&C
19300 SW 65th Avenue, Tualatin, OR
November 6, 2014
2:00-5:00pm

Members Present: Wiley Chan, MD, Chair; Vern Saboe, DC; Beth Westbrook, PsyD; Leda Garside, RN, MBA (via phone); Bob Joondeph, JD

Members Absent: Steve Marks, MD, Vice-Chair; Eric Stecker, MD, MPH; Som Saha, MD, MPH

Staff Present: Darren Coffman; Cat Livingston, MD, MPH; Jason Gingerich.

Also Attending: Alison Little, MD (CEbP) ; Duncan Neilson, MD (Legacy Health); Melissa Cheyney, PhD, CPM, LDM; Leigh Hess (OHSU); Wayne Powell and Arthur Lee, MD (Society for Cardiovascular Angiography and Interventions); Ed Toggart, MD; John Rudoff; Carole LeVanda; Sharron Fuchs.

---

1. CALL TO ORDER

Wiley Chan called the meeting of the Evidence-based Guidelines Subcommittee (EbGS) to order at 2:04 pm.

---

2. MINUTES REVIEW

There was a correction made to the September 4, 2014 minutes, Beth was not in attendance. **Minutes approved with correction 5-0.**

---

3. REVIEW PREVIOUSLY DISCUSSED COVERAGE GUIDANCE

A) HOME BIRTH

Livingston reviewed the interim changes to the Home Birth Draft Coverage Guidance document and answered clarifying questions. There was an extensive discussion about the level of evidence that was appropriate given the absence of RCTs, the reliance on large cohort studies, and the risk of internal biases which lead to an initial “low quality” assessment. Because of the further external validity concerns this was downgraded to “very low.” It was further decided that the consistency of evidence could not upgrade the level based on GRADE methodology, which does not permit upgrading of an observational study that has been downgraded for any reason.

Dr. Neilson and Dr. Cheyney provided expert input stating that there is significant recent US data that may obviate the external validity issue. Dr. Cheyney also shared that a

new Dutch study was published in October that discredited the Wax study. It reportedly included more years of data and extended mortality up to 28 days (Wax apparently had only gone out to 7 days). She explained the mortality rate is likely due to intrapartum transfer delays, and is also deeply regulated by client selection. They stated these studies may change the concerns about external validity, given that one uses a large US database, which may result in a strengthening of the quality of evidence.

Subcommitee members discussed the impact of costs (with home birth being much less expensive than hospital birth) as well as the strong preference of some members of the public to have a home birth. The final recommendation for coverage of home birth in low risk women places a high value on decreased bad outcomes, and also recognizes that patient preferences and resource considerations support this. The final algorithm pathway for low risk women is II A1b.

There was a discussion about the utility of including infant emergencies and obstetric emergencies that would require transfer. The group felt it was useful to include as a reference.

Experts and members expressed concerns that the list of high risk conditions may not be exhaustive. They decided to add the language "including, but not limited to". In the discussion of safety systems and training, they thought this should be attributed to the evidence base.

Actions:

1) Approved draft with the following changes:
    - GRADE table modifications for low risk women
        - Expand details in the values and preferences section
        - Downgrade quality of evidence to Very Low – due to external validity concerns
        - Final recommendations: weak recommendation for low risk women, strong against among unselected pregnancies
    - Modifications to language around high risk conditions to qualify that the list is not exhaustive
    - Attribute language around safety to underlying evidence base

Motion to accept as edited. Motion approved 5-0.

---

4. REVIEW OF NEW DRAFT COVERAGE GUIDANCES

A) INFERIOR VENA CAVA FILTERS FOR PREVENTION OF PULMONARY EMBOLISM

The appointed expert was introduced: Dr. Andy Felcher, hospitalist at Kaiser Sunnyside, served as head of the Kaiser anticoagulation clinic for 8 years. He shared his experience is with filters involving medical patients and that Kaiser has a registry for IVC filter patients. No conflicts were declared.

Little reviewed the evidence. Livingston reviewed the draft GRADE table and proposed algorithm pathways. Discussion of IVC filters in trauma patients ensued. There was a discussion about the endpoints of pulmonary embolism (PE) versus mortality and the risks of increasing deep vein thrombosis (DVT). Clarifying questions were asked of the expert about when IVC filters are placed. Dr. Felcher stated that in medical patients with contraindication to anticoagulation; if they have had a recent clot, generally they do put in a filter, and when anticoagulation is feasable again, retrieve the filter and restart anticoagulation. He shared that nationally only a third of patients get their IVC filters removed and stated that removal is definitely indicated due to the risk of DVT. Trauma patients in particular may have less follow up. Locally, two health systems apparently have conflicting standards with OHSU putting them in none of their trauma patients and Legacy putting them in all. Members were quite interested in this divergence in practice and requested staff to request information about protocols and rationale from the trauma surgery departments at each institution.

For IVC filters in hospitalized trauma patients, the algorithm would lead to a strong recommendation for coverage (1A1b). This was downgraded to a weak recommendation because of harms (DVT), issues of retrievability, and a lack of benefit on mortality.

For IVC filters in bariatric surgery patients, the group agreed that sufficient evidence demonstrates higher mortality and no benefit from IVC filters and thus made a strong recommendation against.

For IVC filters in populations with proximal DVT who are candidates for anticoagulation, there is insufficient evidence of effectiveness, but more risk than not using IVC filters. The group made a strong recommendation against.

For IVC filters in those with proximal DVT or PE and contraindication to anticoagulation a strong recommendation for was made. This was based on insufficient evidence, recognizing the unlikelihood of a study ever being conducted given many patients would choose this procedure to be protected against fatal PE. It follows the coverage guidance development framework pathway IIb1a2 and is upgraded from a weak to a strong recommendation based on preferences and the low likelihood of additional evidence.

There was a discussion about the statement about retrieving filters. Dr.Felcher stated that it is strongly recommended to remove IVC filters (within a limited window of time) whenever possible because of the long-term known risk of DVT.

Actions:

1. GRADE table was modified as discussed
2. Staff to follow up with trauma surgeons at Legacy and OHSU to ask what are their policies and the rationale supporting them
3. Staff to obtain estimates of cost related to IVC filters

A motion was made to approve the draft coverage guidance as edited and post it for public comment. **Motion approved 5-0.**

B) CORONARY ARTERY REVASCULARIZATION FOR STABLE ANGINA

Little reviewed the evidence. Livingston reviewed the draft GRADE tables and algorithm pathways. The appointed expert, Dr. Ed Toggart , interventional cardiologist, was introduced. There was an extensive discussion as to whether the studies included in the evidence review were examining optimal medical therapy (OMT) in contrast to PCI alone or PCI plus OMT. The evidence appears to be a mixture of these two, while Dr. Toggart stated that guideline-directed medical therapy is preferable for patients with stable ischemic heart disease, compared to initial treatment with PCI. He addressed the complexity of the topic and discussed the guideline endorsed by three specialties that has 879 references. He disagreed about the quality assessment of this guideline. Little clarified the reason why it did not receive a higher quality rating is because there is no description of quality assessment of the studies, which is a required standard for higher quality guidelines. Toggart also raised the concern that risk assessments would guide different types of therapy.

After extensive discussion, the GRADE table was modified to state the comparator is PCI plus OMT vs. OMT in patients with non-acute coronary heart disease. Dr. Toggert proposed to add coverage for high risk cases that failed medical therapy. There was a lack of clarity on what the definition of failed therapy would be.

There were questions asked about COURAGE trial results as well as the rationale for rating the evidence very low for several indications that had 1-2 RCTs. Dr. Little said she will re-review these RCTs and gain further details on the quality assessment.

A proposal was put forth to change the indications to revascularization as a group, rather than treatment with PCI or with CABG. There were concerns raised that the literature does not demonstrate equivalency. There was significant concern about the >75 years of age designation and clarification that evidence was better for that group than in <75, but the recommendation against seemed inappropriate. They gave illustrative examples that simply because there isn't data in African Americans a recommendation should not be made against a treatments use in that population. The group decided to remove this recommendation.

Action:

1. This topic will be addressed further at the February EbGS meeting.

---

5. PUBLIC COMMENT

Prior to ending discussion of the draft coverage guidance for Revascularization for Chronic Stable Angina, the subcommittee received the following public testimony.

Dr. Arthur Lee, representing the Oregon Chapter of the American College of Cardiology (ACC) and Society for Cardiovascular Angiography and Interventions (SCIA), provided public comment and declared no conflicts of interest. He discussed a problem with the literature reviewed in that most of the studies looked at bare metal stents while contemporary studies with drug-eluting stents show better outcomes. He also provided

written testimony that recommended guideline-directed medical therapy be tried and revascularization reserved for those who fail. He stated that there are robust studies demonstrating improvement in quality of life and this is a key outcome. He also took issue with the quality rating of the specialty guideline, raised concerns about the >75 years of age statement, and recommended the inclusion of a PCI guideline. He also provided a NICE guidance reference and raised concerns about poor candidates for CABG who may be good PCI candidates.

---

6. ADJOURNMENT

The meeting was adjourned at 4:59 pm. The next meeting is scheduled for February 5, 2015 from 2:00-5:00pm in Room 117B of the Meridian Park Hospital Community Health Education Center in Tualatin.

Section 2.0

IVC filters for prevention of pulmonary embolism

COVERAGE GUIDANCE: INFERIOR VENA CAVA FILTERS FOR PREVENTION OF PULMONARY EMBOLI

DRAFT for EbGS meeting materials February 5, 2015

HERC Coverage Guidance

IVC filters are recommended for coverage in:

- Hospitalized patients with trauma* (*weak recommendation*)
- Patients with active DVT/PE for which anticoagulation is contraindicated (*strong recommendation*)

Whenever possible, the IVC filter should be retrieved if the benefits of removal outweigh harms *(weak recommendation)*.

IVC filters are not recommended for coverage for patients with DVT who are candidates for anticoagulation *(strong recommendation)*

*Examples of trauma for which IVC filters may be indicated include patients with severe trauma and prolonged hospitalization.

Note: Definitions for strength of recommendation are provided in Appendix A. GRADE Element Description

RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
- Represents high costs, significant economic impact
- Topic is of high public interest

Coverage guidance development follows to translate the evidence review to a policy decision. Coverage guidance may be based on an evidence-based guideline developed by the Evidence-based Guideline Subcommittee or a health technology assessment developed by the Heath Technology Assessment Subcommittee. In addition, coverage guidance may utilize an existing evidence report produced by one of HERC's trusted sources, generally within the last three years.

EVIDENCE SOURCES

Trusted sources

Scottish Intercollegiate Guidelines Network. (SIGN). (2010). *Prevention and management of venous thromboembolism*. Edinburgh: SIGN. Retrieved on October 2, 2014, from http://sign.ac.uk/pdf/sign122.pdf

Singh, S., Haut, E.R., Brotman, D.J., Sharma, R., Chelladurai, Y., Shermock, K.M., et al. (2013). *Pharmacologic and mechanical prophylaxis of venous thromboembolism among special populations*. Rockville, MD: Agency for Healthcare Research and Quality (AHRQ). Retrieved on October 2, 2014, from http://effectivehealthcare.ahrq.gov/ehc/products/341/1501/venous-thromboembolism-special-populations-130607.pdf

Sobieraj, D.M., Coleman, C.I., Tongbram, V., Lee, S., Colby, J., Chen, W.T., et al. (2012). *Venous thromboembolism in orthopedic surgery*. Rockville, MD: AHRQ. Retrieved on October 2, 2014, from http://effectivehealthcare.ahrq.gov/ehc/products/186/992/CER-49_VTE_20120313.pdf

Young, T., Tang, H., & Hughes, R. (2010). Vena caval filters for the prevention of pulmonary embolism. *Cochrane Database Syst Rev*, *2*(2). DOI: 10.1002/14651858.CD006212.pub4

Additional sources

Decousus, H., Leizorovicz, A., Parent, F., Page, Y., Tardy, B., Girard, P., et al. (1998). A clinical trial of vena caval filters in the prevention of pulmonary embolism in patients with proximal deep-vein thrombosis. *New England Journal of Medicine*, *338*(7), 409-416. Retrieved October 15, 2014, from http://www.nejm.org/doi/pdf/10.1056/NEJM199802123380701

Decousus, H., Barral, F., Buch-muller, A., Charbonnier, B., Girard, P., Lamer, C., et al. (2005). Eight-year follow-up of patients with permanent vena cava filters in the prevention of pulmonary embolism. The PREPIC (Prévention du Risque d'Embolie Pulmonaire par Interruption Cave) Randomized Study. *Circulation, 112(3),* 416-422. Retrieved October 15, 2014, from http://circ.ahajournals.org/content/112/3/416.full.pdf+html

Fullen, W. D., Miller, E. H., Steele, W. F., & McDonough, J. J. (1973). Prophylactic vena caval interruption in hip fractures. *Journal of Trauma-Injury, Infection, and Critical Care*, *13*(5), 403-410.

Guyatt, G.H., Cook, D.J., Jaeschke, R., Pauker, S.G., & Schunemann, H.J. (2008). Grades of recommendation for antithrombotic agents: ACCP evidence-based clinical practice guidelines (8th Edition). *Chest, 133*(6), 123S–131S.

Kearon, C., Kahn, S. R., Agnelli, G., Goldhaber, S. Z., Raskob, G., Comerota, A. J., & American College of Chest Physicians. (2008). Antithrombotic therapy for venous thromboembolic disease: ACCP evidence-based clinical practice guidelines. *Chest*, *133*(6), 454S-545S.

The summary of evidence in this document is derived directly from these evidence sources, and portions are extracted verbatim.

EVIDENCE OVERVIEW

Clinical background

Blood clots or deep venous thrombosis (DVT) form in the lower extremities and can occur under a number of different circumstances. Temporary circumstances are prolonged immobility, recent surgery, trauma, pregnancy, or estrogen therapy. Longer term situations include people who have cancer, or people who have an inherited hypercoagulable tendency.

Deep vein thromboses can fragment and travel through the venous system to the lungs causing pulmonary embolism (PE). The major conduit of venous drainage from the lower half of the body is the inferior vena cava. Deep vein thromboses that extend into the thigh or pelvis are more likely to embolise than those that do not extend beyond the calf. Case series data indicate a rate between 27% to 60% for the risk of embolism if the clot is situated either within the inferior vena cava, the thigh, or pelvic veins.

The current treatment for pulmonary embolism is anticoagulation (heparin and vitamin K antagonists (warfarin, coumadin)). Infrequently, recurrent pulmonary emboli can occur despite therapeutic levels of anticoagulation; one suggested a rate is 3.8%.

Indications

Filters are recommended for individuals who have a proximal DVT or pulmonary embolism, or both, where it is too dangerous for them to receive anticoagulation. There is controversy in the literature about whether other groups of people may potentially benefit from having a vena caval filter inserted.

Technology description

Vena caval filters may be placed in the inferior or superior vena cava to mechanically trap emboli, interrupting their course before reaching the heart and lungs. These devices most commonly resemble an umbrella in appearance, are made from metal alloys, and can be inserted percutaneously. Once deployed, permanent filters are left in situ; they become endothelialised and are eventually incorporated within the blood vessel wall. Temporary or retrievable filters can be removed within a certain time interval (specified by the manufacturer) if their use is no longer required (up to approximately 12 weeks). There are currently approximately 12 filter designs, several of which are retrievable. Retrievable filters have potential advantages over the permanent filters; one is the opportunity for subsequent removal if no longer needed, thus avoiding longer term sequelae of DVT. Despite being called "retrievable", these filters can become permanent implants if their subsequent removal becomes

complicated due to endothelialisation, or if there is a significant amount of trapped thrombus within the filter such that the filter cannot be retracted back into its sheath.

Evidence review

Trusted sources

Cochrane 2010

Two trials met inclusion criteria for this systematic review. The PREPIC study was a randomized controlled trial of 400 participants with documented proximal DVT or PE who were also receiving vitamin K antagonists; this trial was followed for up to eight years. Four different permanent filter designs were employed. At two year follow-up, there was no significant difference in the incidence of symptomatic PE (OR = 0.50, 95% CI 0.19 to 1.33); however, the study lacked statistical power to detect a difference (power calculation required 800 participants to detect an expected 4% decrease in PE).

At eight years follow up, the PREPIC study demonstrated the efficacy of caval filters in preventing pulmonary embolism (hazard ratio 0.37, 95% CI 0.17 to 0.79 in favor of a filter). However, there was a significant increase in the rate of DVT in the filter group (hazard ratio 1.52, 95% CI 1.02 to 2.27). Post-thrombotic syndrome was a common complication (defined as the appearance or worsening of edema, varicose veins, trophic disorders, or ulcers) in both groups, affecting 68% to 70% of people in each study group. There also continued to be no significant difference between groups in mortality (HR = 0.97, 95% CI 0.74 to 1.28, p = 0.83). No data were collected on filter-related complications.

Fullen (1973) was a quasi-randomized trial of 129 participants with a traumatic hip fracture who were followed approximately 33 days; neither group was anticoagulated. It demonstrated that caval filters were effective in reducing PE but not mortality. Mortality was 4/41 in the filter group and 14/59 in the control group (RR 0.41, 95%CI 0.15 to 1.16). Rate of pulmonary embolism in the filter group was 4/41, and 19/59 in the control group (RR 0.3, 95% CI 0.11 to 0.82). The incidence of short-term complications were reported to be similar in both groups, with the exception of PE, with both groups having similar incidences of infectious complications and phlebitis, although no statistical testing was done. No details about long term complication rates were given.

No recommendations can be drawn from the two studies. One study showed a reduction in PE rates but not mortality, but was subject to significant biases. The other study lacked statistical power to detect a reduction in PE in clinically significant time periods, and demonstrated that permanent IVC filters were associated with an increased risk of long term lower limb DVT.

There is a paucity of IVC filter outcome evidence when used within currently approved indications and a lack of trials on retrievable filters.

AHRQ 2013

Singh et al evaluated the efficacy and harms of IVC filters in patients with trauma, traumatic brain injury, burns, or liver disease; patients on antiplatelet therapy; and those undergoing obesity surgery.

Trauma

The strength of evidence (SOE) is low that prophylactic IVC filter placement when compared with no filter use is associated with a lower incidence of PE and fatal PE in hospitalized patients with trauma, based on one RCT and 7 cohort studies (3 prospective, 1 retrospective, 3 using historical controls). Most of these included at least some patients who received anticoagulation. Two studies reported using venous compression devices alone, however both of these were excluded from the meta-analyses because the authors considered them to have fatal flaws. The RCT was a pilot study to determine feasibility of a larger trial, and reported one PE in the control group (n=16) and one DVT in the IVC filter group (n=18). No statistical testing was reported. Over 85% of participants were receiving pharmacologic prophylaxis on enrollment.

Meta-analysis of six studies showed a precise and consistent evidence of reduction in PE with IVC filters compared with no IVC filters without any evidence of statistical heterogeneity (RR:0.20, 95% CI:0.06-0.70; I^2=0%). Meta-analysis of four studies showed precise and consistent evidence of reduction in fatal PE with IVC filters compared with no IVC filters, without any evidence of statistical heterogeneity (RR, 0.09,95% CI 0.01 to 0.81; I^2=0%) However, there was no statistically significant difference in mortality [three studies, RR 0.70 (0.40 to 1.23; I^2=6.7%), insufficient SOE].

There is insufficient evidence that prophylactic IVC filter placement is associated with an increased incidence of DVT in hospitalized patients with trauma when compared with no use of filters, based on three studies. Meta-analysis resulted in a RR of 1.76 (95% CI = 0.49 to 6.18: p=0.38), and there was substantial statistical heterogeneity, with an I^2=56.8%. The evidence was also insufficient to evaluate the comparative effectiveness and safety of various filter subtypes, or to evaluate the rates of other filter complications.

Bariatric Surgery

There is a low SOE to support that IVC filters do not reduce the risk of PE in patients undergoing bariatric surgery, based on four cohort studies (RR = 0.91, 95% CI = 0.32 to 2.57;p=0.858 ; 1^2=16.3%)). The evidence is insufficient to comment on the effectiveness of IVC filters for reducing fatal PE or VTE (one study each), or to support that IVC filters increase the incidence of DVTs, based on four cohort studies (RR = 2.77, 95% CI=0.87 to 8.85; p=0.086 ;1^2=62.6%). There is low grade evidence to support that IVCFs are associated with increased mortality in patients undergoing bariatric surgery, based on 4 cohort studies (RR =3.63, 95% CI=1.99 to 6.61;p <0.05; 1^2=0.0%).

Complications of filter placement occasionally occur, some of which may be fatal (five cohort studies, two case reports). These include filter migration to the heart, nonfatal IVC thrombosis, fatal IVC thrombosis, errant placement of the filter into the common iliac vein, wrong positioning

of the filter, pneumothorax, hemopericardium, and the inability to perform a transvenous ablation of a cardiac accessory pathway due to the filter. A subset of studies reported that physicians ultimately removed more than two thirds of the retrievable filters placed.

Other Populations

The evidence is insufficient to evaluate the use of IVC filters in patients with traumatic brain injury, burns, liver disease, or patients taking antiplatelet therapy.

AHRQ 2012

Sobieraj et al attempted to evaluate the efficacy and safety of prophylactic use of IVC filters in orthopedic surgery, but found no studies that met their inclusion criteria.

Scottish Intercollegiate Guidelines Network 2010

The SIGN group developed a guideline on the prevention and management of venous thromboembolism. They recommend the following:

> "Good Practice Point (expert opinion only): If a device is used, retrievable IVC filters should be used although successful retrieval cannot be guaranteed.
>
> Grade D Recommendation (based on case reports, case series or expert opinion): Where IVC filters have been fitted because of an existing contraindication to anticoagulants at the time of presentation, anticoagulation may be introduced when the contraindication is resolved."

The guideline provides the following rationale:

> "Use of inferior vena cava (IVC) filters is rarely appropriate. No evidence was identified to support the routine placement of an IVC filter when a patient is able to be anticoagulated. If anticoagulation therapy is not possible for patients with acute deep vein thrombosis then placement of an IVC filter can lead to reduction in radiologically diagnosed PE but no difference in symptomatic PE and no overall mortality benefit. Once any contraindication to anticoagulation has passed, it should be reinstituted. Whenever possible the filter should be retrieved. Filter insertion is not without complications and frequently filters cannot be retrieved." (Based on expert opinion)
>
> "There is no evidence to support or refute long term anticoagulation merely to prevent IVC filter thrombosis."
>
> "IVC filters significantly reduce the number of PEs suffered by patients who present with proximal DVT (1.1% v 4.8%, OR 0.22, 95% CI 0.05 to 0.90) but they are associated with an increase in the development of recurrent DVT (20.8% v 11.6%, OR 1.87, 95% CI 1.10 to 3.20) at two years follow up. This is the major complication of IVC filter insertion in

patients with proximal DVT." (Based on expert opinion and meta-analyses, systematic reviews, or RCTs with a high risk of bias)

Other complications are shown in the table below:

Table 1. Complications of IVC Filter Insertion

Immediate	
Misplacement	1.3%
Hematoma	0.6%
Pneumothorax	0.02%
Air embolism	0.2%
Carotid artery puncture	0.04%
Atrioventricular fistula	0.02%
Early	
Insertion site thrombosis	8.5%
Infection	Rare but documented
Late	
DVT	21%
IVC thrombosis	2-10%
Post-thrombotic syndrome	15-40%
IVC penetration	0.3%
Filter migration	0.3%
Entrapment of guidewires	Rare but documented
Filter tilting	Rare but documented
Fracture	Rare but documented

EVIDENCE SUMMARY

There is a general consensus that IVC filters are indicated for patients who have proximal DVT or PE and cannot be anticoagulated. However, the evidence is insufficient to reach conclusions about the efficacy of IVC filters in this population, and there is evidence that IVC filters increase the risk of DVT (low SOE).

In hospitalized patients with trauma, the strength of evidence is low that IVC filter placement is associated with a lower incidence of pulmonary embolism and fatal pulmonary embolism compared with no IVC filter placement. However, there is no statistically significant impact on overall mortality.

In patients undergoing bariatric surgery, IVC filters are associated with increased mortality and do not decrease the risk of pulmonary embolism (low SOE).

GRADE-Informed Framework

The HERC develops recommendations by using the concepts of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. GRADE is a transparent and structured process for developing and presenting evidence and for carrying out the steps involved in developing recommendations. There are four elements that determine the strength of a recommendation, as listed in the table below. The HERC reviews the evidence and makes an assessment of each element, which in turn is used to develop the recommendations presented in the coverage guidance box. Balance between desirable and undesirable effects, and quality of evidence, are derived from the evidence presented in this document, while estimated relative costs, values and preferences are assessments of the HERC members.

Indication/ Intervention	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Variability in values and preferences	Coverage recommendation	Rationale
IVC filter in hospitalized trauma patients	Decreased incidence of all PE and fatal PE, but no difference in overall mortality	Low	Moderate	High	IVC filters in hospitalized trauma patients are recommended for coverage *(weak recommendation).*	Evidence of less PE and fatal PE but no difference in mortality. High variability in preferences leads to weak recommendation for coverage.
IVC filter in bariatric surgery patients	No decrease in PE, increase in mortality	Low	Moderate	Low	IVC filters are not recommended for coverage in bariatric surgery patients *(strong recommendation)*	Sufficient evidence demonstrates higher mortality and no benefit from IVC filters in bariatric surgery patients.
IVC filter for populations with proximal DVT who	Possible decrease in PE, increase in DVT	Very low	Moderate	Low	IVC filters are not recommended for coverage for	Insufficient evidence of effectiveness but more risk than no IVC

Indication/ Intervention	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Variability in values and preferences	Coverage recommendation	Rationale
are candidates for anticoagulation					patients with DVT who are candidates for anticoagulation *(strong recommendation)*	filters.
IVC filter in those with proximal DVT or PE and contraindication to anticoagulation	Unknown	Very low	Moderate	Low – many patients would be uncomfortable with a "time bomb" of a DVT which could cause fatal PE. There is unlikely to be a study given lack of equipose	IVC filters are recommended for coverage *(strong recommendation)* Whenever possible, the filter should be retrieved (based on expert opinion).	While there is insufficient evidence, it is very unlikely a study would be conducted, many patients would choose to have this procedure to protect against fata PE. It follows the coverage guidance development framework pathway IIb1a2 and is upgraded from a weak to a strong recommendation based on preferences and the low likelihood of additional evidence.

*The Quality of Evidence rating was assigned by the primary evidence source, not the HERC Subcommittee

Note: GRADE framework elements are described in Appendix A

POLICY LANDSCAPE

Quality measures

No quality measures were identified when searching the National Quality Measures Clearinghouse.

Clinical practice guidelines

Because a primary evidence source for this document referenced a practice guideline in their background section, pertinent portions of the updated version of that guideline are extracted and presented here:

Antithrombotic therapy for venous thromboembolic disease: American College of Chest Physicians Evidence-based Clinical Practice Guidelines (8th Edition)[1]

Vena Caval Filters for the Initial Treatment of DVT

> 1.13.1. For patients with DVT, we recommend against the routine use of a vena cava filter in addition to anticoagulants (Grade 1A).
>
> 1.13.2. For patients with acute proximal DVT, if anticoagulant therapy is not possible because of the risk of bleeding, we recommend placement of an inferior vena cava (IVC) filter (Grade 1C).
>
> 1.13.3. For patients with acute DVT who have an IVC filter inserted as an alternative to anticoagulation, we recommend that they should subsequently receive a conventional course of anticoagulant therapy if their risk of bleeding resolves (Grade 1C).

Inferior vena caval (and rarely superior vena caval [SVC]) filters can be used instead of initial anticoagulation (eg, unacceptable risk of bleeding), or as an adjunct to anticoagulation, in patients with acute DVT. No randomized trial or prospective cohort study have evaluated IVC filters as sole therapy in patients with DVT (ie, without concurrent anticoagulation). Permanent IVC filter insertion as an adjunct to anticoagulant therapy has been evaluated in a single, large RCT of patients with acute DVT who were considered to be at high risk for PE (PREPIC study). The findings of that study, which were reported after 2 years and 8 years of follow-up, provide the strongest evidence to guide use of IVC filters in patients with acute VTE, and can be summarized as follows. First, routine insertion of filters in patients who are also anticoagulated does not alter the frequency of recurrent VTE (RR, 1.34 at 2 years; and RR, 1.03 at 8 years) or

[1] Evidence grading used by the ACCP in this document is as follows:

- Grade 1A: strong recommendation, high-quality evidence
- Grade 1B: strong recommendation, moderate-quality evidence
- Grade 1C: strong recommendation, low or very low-quality evidence
- Grade 2A: weak recommendation, high-quality evidence
- Grade 2B: weak recommendation, high-quality evidence
- Grade 2C: weak recommendation, high-quality evidence

total mortality (RR, 1.08 at 2 years; and RR, 0.95 at 8 years). Second, filters reduce PE at 12 days (RR, 0.4; this estimate includes asymptomatic PE detected by routine lung scanning), 2 years (RR, 0.54), and at 8 years (RR, 0.41). Third, filters increase DVT at 2 years (RR, 1.8) and at 8 years (RR, 1.3; hazard ratio, 1.5; 95% CI, 1.02 to 2.3 in the original report). Fourth, despite more frequent DVT during follow-up and frequent evidence of thrombosis at the filter site in those with recurrent VTE (43% of cases), filters were not associated with a higher frequency of post-thrombotic syndrome (PTS; defined as presence of at least one of edema, varicose veins, trophic disorders or ulcers) [hazard ratio, 0.87; 95% CI, 0.66 to 1.13]. Fifth, 2.5% (five patients) of the non-filter group and 1.0% (two patients) of the filter group died of PE during eight years of follow-up. Sixth, other complications of filter placement are rare (none were reported).

A comprehensive review of mostly retrospective case series of vena caval filter insertions (a total of 6,500 patients in 89 reports who had filters inserted for many different reasons) suggests that venous thrombosis at the site of filter insertion sites is common (e.g., approximately 10% of patients), that filters can be placed above the renal veins if necessary, and that it is feasible to place filters in the SVC. Epidemiologic data suggest that IVC filters are not associated with an increased risk of recurrent VTE in patients who present with DVT. If an IVC filter is being inserted in a patient with acute DVT or PE because anticoagulant therapy is temporarily contraindicated (e.g., active bleeding), there is the option of inserting a retrievable filter and removing the filter when it is safe to start anticoagulant therapy. However, the risks and benefits of using a retrievable filter compared with a permanent filter in this setting are uncertain.

Vena Caval Filters for the Initial Treatment of PE

> 4.6.1. For most patients with PE, we recommend against the routine use of a vena caval filter in addition to anticoagulants (Grade 1A).
>
> 4.6.2. In patients with acute PE, if anticoagulant therapy is not possible because of risk of bleeding, we recommend placement of an IVC filter (Grade 1C).
>
> 4.6.3. For patients with acute PE who have an IVC filter inserted as an alternative to anticoagulation, we recommend that they should subsequently receive a conventional course of anticoagulant therapy if their risk of bleeding resolves (Grade 1C).

As previously noted, vena caval filters can be used instead of initial anticoagulant therapy (e.g., unacceptable risk of bleeding) or as an adjunct to anticoagulation in patients with acute VTE. As for acute DVT, no randomized trials or prospective cohort studies have evaluated IVC filters as sole therapy for acute PE (i.e., without concurrent anticoagulation). The PREPIC study, which evaluated IVC filters as an adjunct to anticoagulation in 400 high-risk patients with proximal DVT, showed that filters reduced PE, increased DVT, and did not change overall frequency of VTE (DVT and/or PE combined). The PREPIC study included 145 patients (36% of total) with symptomatic PE and 52 patients (13% of total) with asymptomatic PE at enrollment in addition to proximal DVT. Multivariable analyses did not find an association between the presence of PE at entry and the frequency of PE at 2 years; however, such an association was present after eight years of follow-up.

There is uncertainty about the risk and benefits of inserting an IVC filter as an adjunct to anticoagulant and thrombolytic therapy in patients with massive PE. Among patients with hemodynamic compromise in the International Cooperative Pulmonary Embolism Registry, insertion of an IVC filter was associated with a reduction of early recurrent PE and death. Epidemiologic data suggest that insertion of an IVC filter in patients who present with PE (with or without symptomatic DVT) is associated with about a doubling of the frequency of VTE during follow-up; most of this increase is due to a higher frequency of DVT (approximately 2.6-fold increase) rather than PE (approximately 1.3-fold increase).

Pulmonary Thromboendarterectomy, Vitamin K Antagonists (VKA), and Vena Cava Filter for the Treatment of Chronic Thromboembolic Pulmonary Hypertension (CTPH)

6.1.1. In selected patients with CTPH, such as those with central disease under the care of an experienced surgical/medical team, we recommend pulmonary thromboendarterectomy (Grade 1C).

6.1.2. For all patients with CTPH, we recommend life-long treatment with a VKA targeted to an INR of 2.0 to 3.0 (Grade 1C).

6.1.3. For patients with CTPH undergoing pulmonary thromboendarterectomy, we suggest the placement of a permanent vena caval filter before or at the time of the procedure (Grade 2C).

Primary therapy for CTPH is pulmonary thromboendarterectomy, which, if successful, can reduce and sometimes cure pulmonary hypertension. The operation requires a median sternotomy, institution of cardiopulmonary bypass, deep hypothermia with circulatory arrest periods, and exploration of both pulmonary arteries. Pulmonary thromboendarterectomy removes organized thrombus by establishing an endarterectomy plane in all involved vessels. At the most experienced centers, the mortality rate is < 5%. The most common postoperative problem is reperfusion pulmonary edema, generally managed with supportive care that requires several days of mechanical ventilation. When pulmonary thromboendarterectomy is successful, patients can usually resume normal daily activities and experience a greatly improved quality of life. Management usually includes insertion of a permanent vena cava filter before or during pulmonary endarterectomy and indefinite anticoagulant therapy with a target INR of 2.5.319 No randomized trials of CTPH therapy have been undertaken. Patients with CTPH who are not candidates for pulmonary endarterectomy because of comorbid disease or surgically inaccessible lesions may be candidates for pulmonary artery angioplasty.

Coverage guidance is prepared by the Health Evidence Review Commission (HERC), HERC staff, and subcommittee members. The evidence summary is prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center). This document is intended to guide public and private purchasers in Oregon in making informed decisions about health care services.

The Center is not engaged in rendering any clinical, legal, business or other professional advice. The statements in this document do not represent official policy positions of the Center. Researchers involved in preparing this document have no affiliations or financial involvement that conflict with material presented in this document.

APPENDIX A. GRADE ELEMENT DESCRIPTIONS

Element	Description
Balance between desirable and undesirable effects	The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. The narrower the gradient, the higher the likelihood that a weak recommendation is warranted
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—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

Strong recommendation

In Favor: The subcommittee is confident that the desirable effects of adherence to a recommendation outweigh the undesirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences.
Against: The subcommittee is confident that the undesirable effects of adherence to a recommendation outweigh the desirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences.

Weak recommendation

In Favor: The subcommittee concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences, but is not confident.
Against: The subcommittee concludes that the undesirable effects of adherence to a recommendation probably outweigh the desirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences, but is not confident.

Quality or strength of evidence rating across studies for the treatment/outcome[2]

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 effect estimate: 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 effect estimate 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 effect estimate: 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.

[2] Includes risk of bias, precision, directness, consistency and publication bias

APPENDIX B. APPLICABLE CODES

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
451.11	Phlebitis and thrombophlebitis of femoral vein (Deep) (Superficial)
451.19	Phlebitis and thrombophlebitis of other
451.81	Phlebitis and thrombophlebitis of iliac vein
453.2	Other venous embolism and thrombosis of inferior vena cava
453.3	Embolism and thrombosis of renal vein
453.40	Acute venous embolism and thrombosis of unspecified deep vessels of lower extremity
453.41	Acute venous embolism and thrombosis of deep vessels of proximal lower extremity
453.42	Acute venous embolism and thrombosis of deep vessels of distal lower extremity
453.50	Chronic venous embolism and thrombosis of unspecified deep vessels of lower extremity
453.51	Chronic venous embolism and thrombosis of deep vessels of proximal lower extremity
453.52	Chronic venous embolism and thrombosis of deep vessels of distal lower extremity
ICD-10 Diagnosis Codes	
I80.10	Phlebitis and thrombophlebitis of unspecified femoral vein
I80.209	Phlebitis and thrombophlebitis of unspecified deep vessels of unspecified lower extremity
I80.219	Phlebitis and thrombophlebitis of unspecified iliac vein
I82.220	Acute embolism and thrombosis of inferior vena cava
I82.221	Chronic embolism and thrombosis of inferior vena cava
I82.3	Embolism and thrombosis of renal vein
I82.409	Acute embolism and thrombosis of unspecified deep veins of unspecified lower extremity
I82.419	Acute embolism and thrombosis of unspecified femoral vein
I82.429	Acute embolism and thrombosis of unspecified iliac vein
I82.439	Acute embolism and thrombosis of unspecified popliteal vein
I82.4Y9	Acute embolism and thrombosis of unspecified deep veins of unspecified proximal lower
I82.449	Acute embolism and thrombosis of unspecified tibial vein
I82.499	Acute embolism and thrombosis of other specified deep vein of unspecified lower extremity
I82.4Z9	Acute embolism and thrombosis of unspecified deep veins of unspecified distal lower
I82.509	Chronic embolism and thrombosis of unspecified deep veins of unspecified lower extremity
I82.599	Chronic embolism and thrombosis of other specified deep vein of unspecified lower extremity
I82.519	Chronic embolism and thrombosis of unspecified femoral vein
I82.529	Chronic embolism and thrombosis of unspecified iliac vein
I82.539	Chronic embolism and thrombosis of unspecified popliteal vein
I82.5Y9	Chronic embolism and thrombosis of unspecified deep veins of unspecified proximal lower extremity
82.549	Chronic embolism and thrombosis of unspecified tibial vein
I82.5Z9	Chronic embolism and thrombosis of unspecified deep veins of unspecified distal lower extremity
ICD-9 Volume 3 (Procedure Codes)	
	None
CPT Codes	
37191	Insertion of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy, when preformed.
37192	Repositioning of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy, when preformed.
37193	Retrieval (removal) of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation,

	intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy, when preformed.
HCPCS Level II Codes	
C1880	Vena cava filter

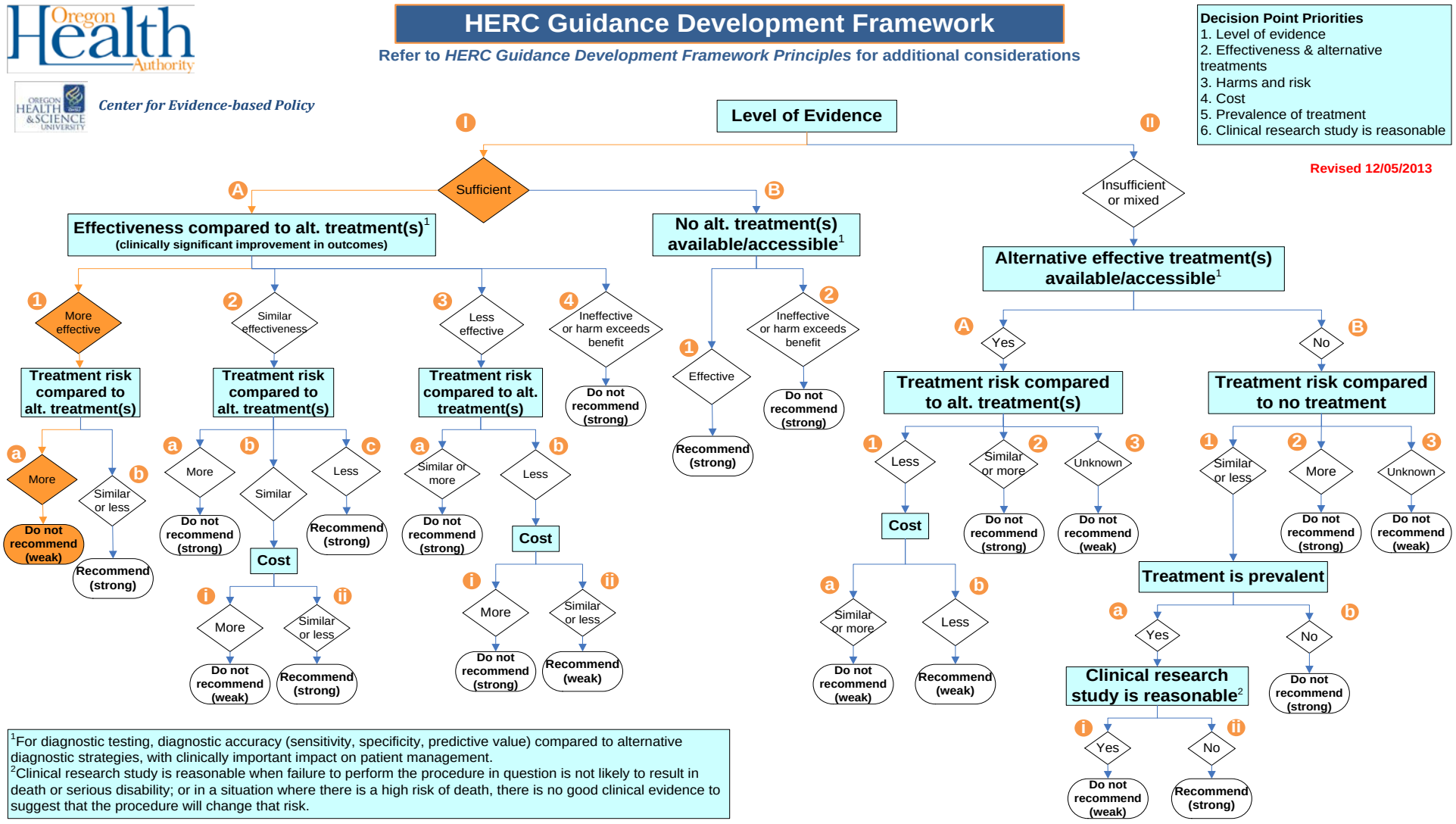
Note: Inclusion on this list does not guarantee coverage

APPENDIX C. HERC GUIDANCE DEVELOPMENT FRAMEWORK

HERC Guidance Development Framework Principles

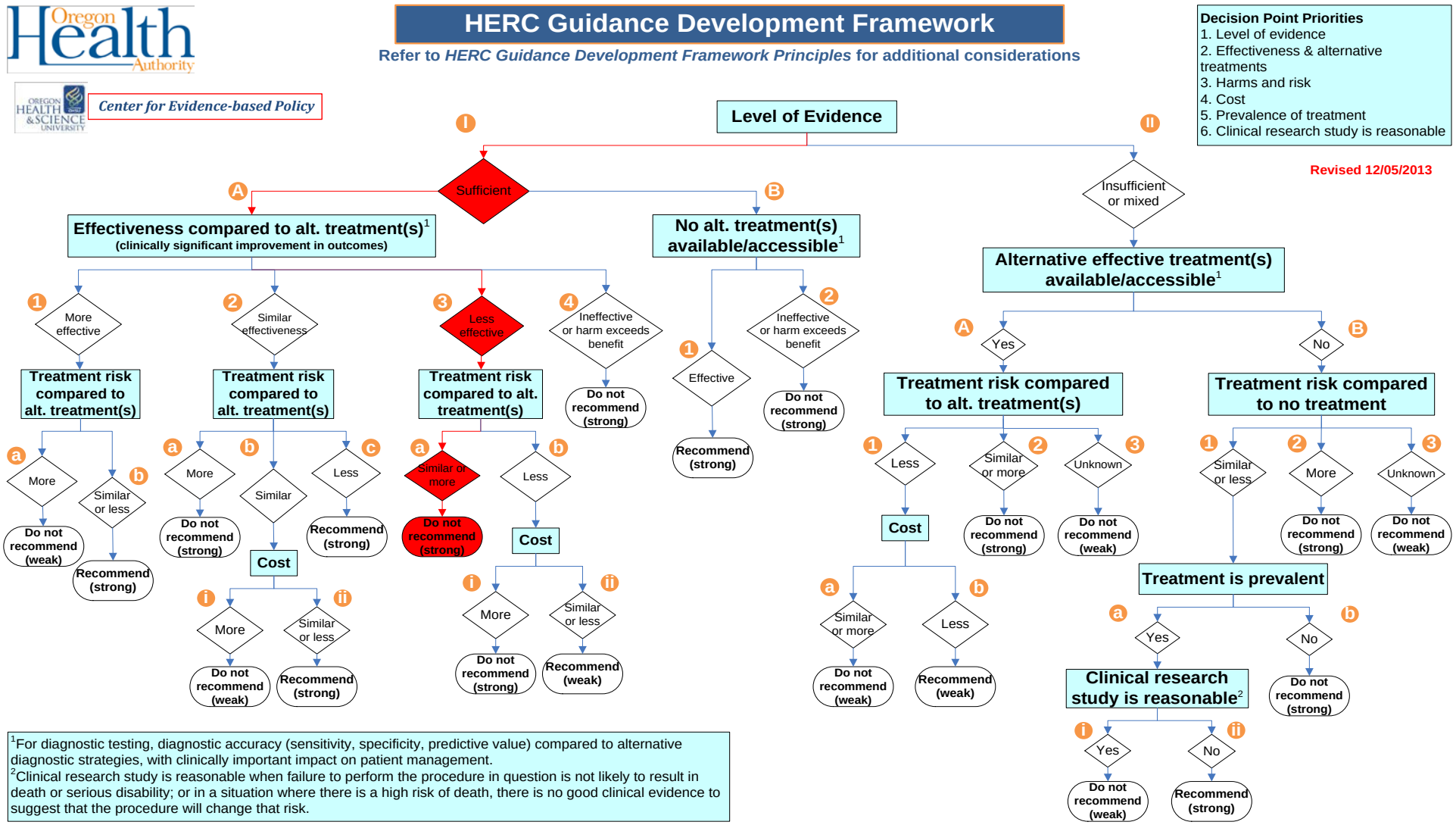
This framework was developed to assist with the decision making process for the Oregon policy-making body, the HERC and its subcommittees. It is a general guide, and must be used in the context of clinical judgment. It is not possible to include all possible scenarios and factors that may influence a policy decision in a graphic format. While this framework provides a general structure, factors that may influence decisions that are not captured on the framework include but are not limited to the following:

- Estimate of the level of risk associated with the treatment, or any alternatives;
- Which alternatives the treatment should most appropriately be compared to;
- Whether there is a discrete and clear diagnosis;
- The definition of clinical significance for a particular treatment, and the expected margin of benefit compared to alternatives;
- The relative balance of benefit compared to harm;
- The degree of benefit compared to cost; e.g., if the benefit is small and the cost is large, the committee may make a decision different than the algorithm suggests;
- Specific indications and contraindications that may determine appropriateness;
- Expected values and preferences of patients.



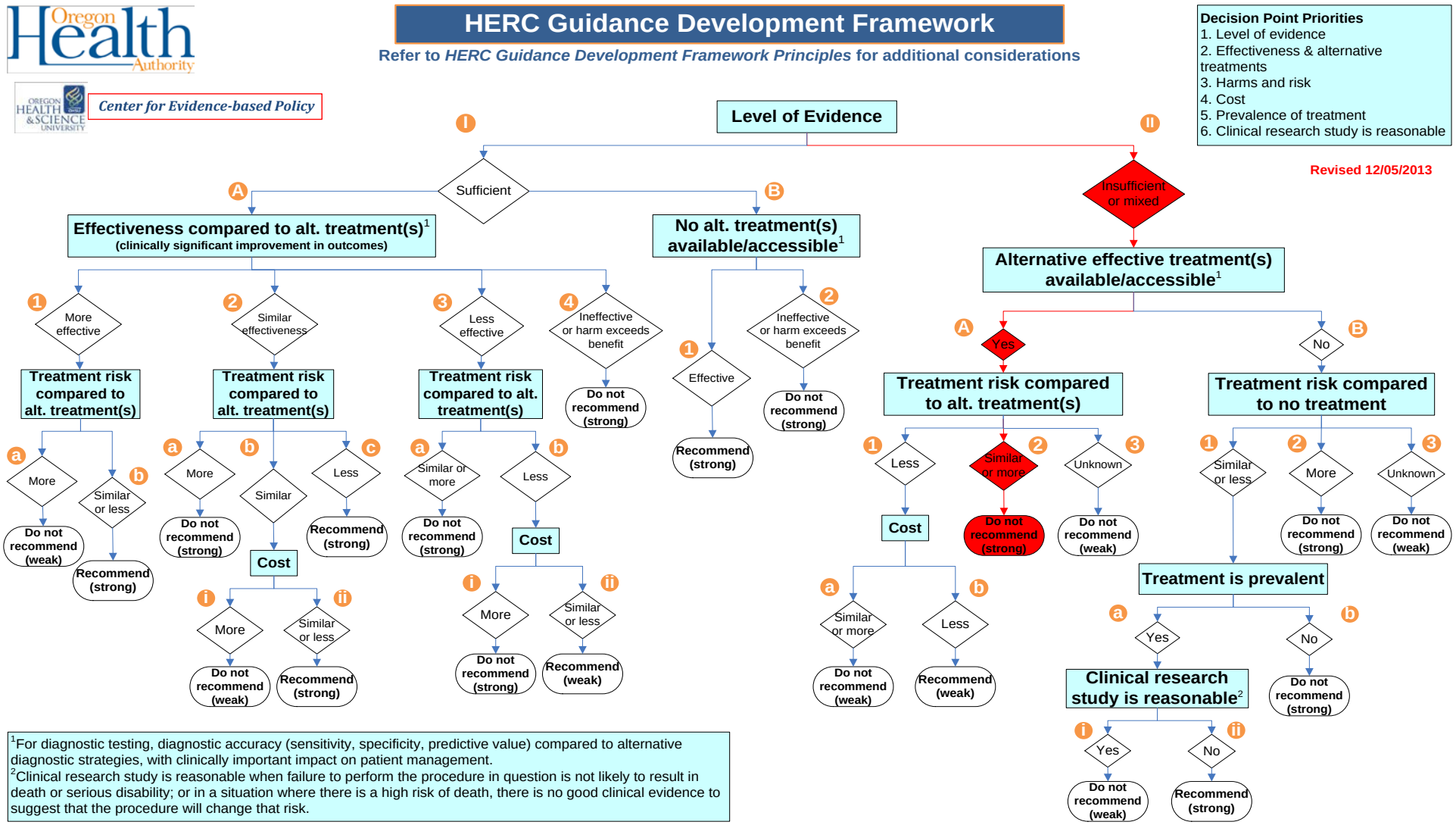
[1]For diagnostic testing, diagnostic accuracy (sensitivity, specificity, predictive value) compared to alternative diagnostic strategies, with clinically important impact on patient management.
[2]Clinical research study is reasonable when failure to perform the procedure in question is not likely to result in death or serious disability; or in a situation where there is a high risk of death, there is no good clinical evidence to suggest that the procedure will change that risk.

IVC filter in bariatric surgery patients



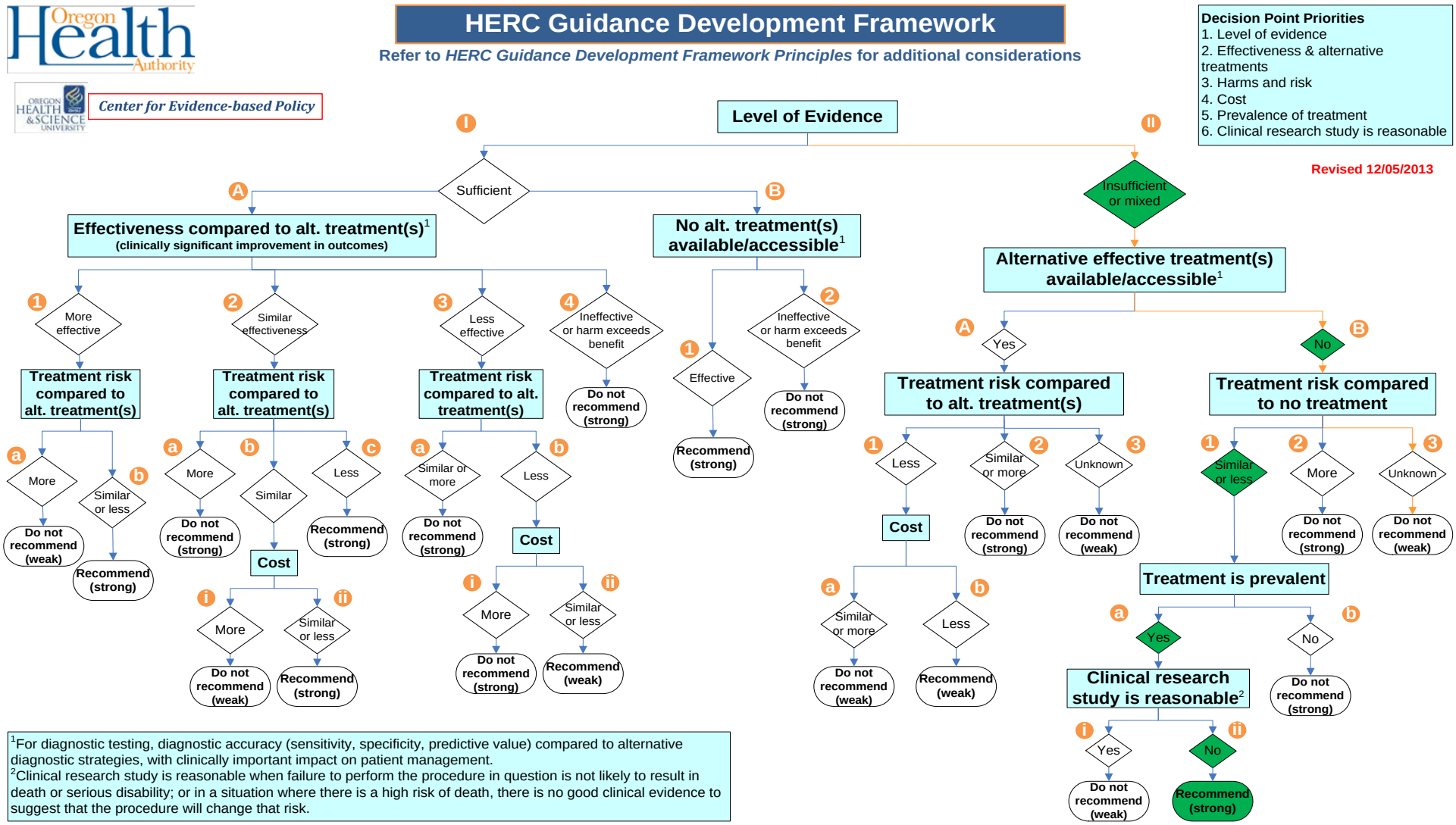
[1]For diagnostic testing, diagnostic accuracy (sensitivity, specificity, predictive value) compared to alternative diagnostic strategies, with clinically important impact on patient management.
[2]Clinical research study is reasonable when failure to perform the procedure in question is not likely to result in death or serious disability; or in a situation where there is a high risk of death, there is no good clinical evidence to suggest that the procedure will change that risk.

IVC filter in patients with proximal DVT who are candidates for anticoagulation



[1]For diagnostic testing, diagnostic accuracy (sensitivity, specificity, predictive value) compared to alternative diagnostic strategies, with clinically important impact on patient management.
[2]Clinical research study is reasonable when failure to perform the procedure in question is not likely to result in death or serious disability; or in a situation where there is a high risk of death, there is no good clinical evidence to suggest that the procedure will change that risk.

IVC filter in those with proximal DVT or PE and contraindication to anticoagulation



[1]For diagnostic testing, diagnostic accuracy (sensitivity, specificity, predictive value) compared to alternative diagnostic strategies, with clinically important impact on patient management.
[2]Clinical research study is reasonable when failure to perform the procedure in question is not likely to result in death or serious disability; or in a situation where there is a high risk of death, there is no good clinical evidence to suggest that the procedure will change that risk.

HERC Coverage Guidance –
Disposition of Public Comments

Table of Contents

Commenters

Identification	Stakeholder
A	Society of Interventional Radiology, Faifax, VA [*Submitted December 10, 2014*]

Public Comments

Ident.	#	Comment	Disposition
A	1	The Society of Interventional Radiology (SIR) is a professional medical association that represents approximately 5,400 members who are practicing in the specialty of vascular and interventional radiology. The society and its membership are dedicated to improving public health through pioneering advances in minimally invasive, image-guided therapy. Our members are at the forefront of innovative and minimally invasive therapies to treat an array of diseases and conditions without surgery. Interventional radiology treatments have become first-line care for many conditions, including inferior vena cava (IVC) filter placements (and retrieval) for patients at risk of pulmonary embolisms.	Thank you for taking the time to comment.
	2	SIR has been at the forefront of advancing the science around IVC filters, even prior to the U.S. Food and Drug Administration's (FDA's) August 2010 safety communication. We realized several years ago that a rigorous research trial would be the only way to come to any conclusions about IVC filter procedures. Accordingly, SIR and the Society for Vascular Surgery, in partnership, have launched a national large-scale, multispecialty prospective clinical research trial to evaluate the use of IVC filters (IVCFs) and related follow-up treatment in the United States. This collaboration between SIR and the SVS is set to enroll the first patient in spring 2015, with participation from seven IVCF manufacturers. The Predicting the Safety and Effectiveness of Inferior Vena Cava Filters (PRESERVE) trial will directly address the August 2010 FDA medical alert detailing the possibility that retrievable IVC filters could move or fracture, potentially causing significant health risks for patients. SIR and the SVS collaboratively formed the IVC Filter Study Group Foundation, a 501(c)(3) not-for-profit entity that sponsors and will oversee the PRESERVE trial. The study will have the goal of obtaining a real-world view of the safety and efficacy of most filters placed in the United States.	Thank you for Informing EbGS about the PRESERVE trial.
	3	With respect to the draft Oregon report, we offer several overall comments and suggestions that the commission may want to consider: The draft report's recommendations and reasons for those recommendations are clear and, in general, well-supported. Overall, relative to the primary question raised in the report, SIR asserts that the medical community is in concurrence that **IVC filters prevent pulmonary emboli (PE).** It is clear from all available literature that IVCFs reduce PE rates (see the 1998 randomized, prospective, PREPIC study by Decousus et al., which demonstrated a clear reduction in PE incidence in the IVCF group).	Thank you for your comment.
	4	SIR agrees with the draft's recommendation that IVCFs are not appropriate in people who can be anticoagulated but are appropriate for people who cannot be.	Thank you for your comment.
	5	The draft makes a "weak recommendation" for use of IVCFs for trauma patients . Filters are not indicated for the vast majority of patients with trauma, but the draft fails to note that in its recommendation, implying that the decision about whether or not to place an IVCF in a trauma patient is up to the treating physician. SIR agrees with that implication but suggests that the authors consider providing more specifics about which trauma patients may benefit from placement of an IVCF—e.g., pelvic trauma, trauma with venous injury, expected prolonged immobilization or mechanical ventilation, and injuries that will obviate use of anticoagulation. However, since the precise patient populations that will 100 percent benefit from an IVCF is uncertain, SIR asserts that patients will benefit the most when that decision is left to the treatment team when all factors can be used in the medical decision process.	Additional box language has been added to address this concern. *For EbGS discussion*

Ident.	#	Comment	Disposition
	6	SIR is uncertain about the draft's recommendation that IVCFs are not appropriate for patients who are to undergo bariatric surgery. In general, this recommendation is true. However, there are several studies (admittedly small and/or retrospective) that suggest that patients with a body-mass index (BMI) > 60 or a history of venous thromboembolic (VTE) disease might benefit from the use of an IVCF. The SIR is concerned that the draft's recommendation against IVCFs for all bariatric surgery patients might result in payment policies that deny reimbursement for use of an IVCF in a patient with a BMI > 60 or a history of VTE disease. Preventing a fatal PE is paramount, and SIR asserts that each patient's situation needs to be carefully evaluated and that a blanket statement may be problematic.	No citations provided. The evidence source identified no RCTs in this population; conclusions were based on 2 prospective cohort studies, 8 retrospective cohort studies and 2 case reports. BMI ranged from 45 to 74 kg/m^2. *For EbGS discussion*
	7	Furthermore, developers of the draft may want to delve further into other potential scenarios in which an IVCF might be appropriately placed. For example, what if an IVCF is requested for a patient who is undergoing resection of a large pelvic tumor with thrombus likely present in the iliac veins inferior to the tumor?	If high risk, pharmacologic anticoagulation may be indicated. *For EbGS discussion*
	8	SIR would advise caution on using language in the draft that states "whenever possible, the IVC filter should be retrieved." Retrievable filters are approved for permanent use and many are used with the intention that they will be permanent. As stated in the draft policy (without a listed strength of recommendation), those filters should be removed without consideration of the clinical scenario. We encourage the HERC to closely follow the latest FDA guidance. In its May 2014 Update, the FDA stated: *"The FDA encourages all physicians involved in the treatment and follow-up of patients receiving IVC filters to consider the risks and benefits of filter removal for each patient. A patient should be referred for IVC filter removal when the risk/benefit profile favors removal and the procedure is feasible given the patient's health status."* SIR suggests a change in wording of the draft report to be more consistent with the FDA statement: "The implanting physicians and clinicians responsible for the ongoing care of patients with retrievable IVC filters should consider removing the filter as soon as protection from PE by the IVC filter is no longer needed."	Box language has been modified, and a weak recommendation (expert opinion) added. *For EbGS discussion*
	9	Thank you for the opportunity to submit these comments. If we can provide any additional information or if the Health Evidence Commission wishes further discussion on this topic with SIR members who frequently perform IVC filter procedures, please do not hesitate to contact Susan E. Sedory Holzer, MA, CAE, SIR's executive director, at (703) 691-1805, or sholzer@sirweb.org.	Thank you providing this information.

References Provided by Commenters

Commenter	References
A2	Decousus H, Leizorovicz A, Parent F, Page Y, Tardy B, Girard P, et al. A clinical trial of vena caval filters in the prevention of pulmonary embolism in patients with proximal deep-vein thrombosis. N Engl J Med 1998;338(7):409-15.

PACIFIC SURGICAL P.C.

501 N. Graham Street, Suite 580
Portland, OR 97227
P (503) 528-0704
F (503) 528-0708

01/09/2015

Cat Livingston MD MPH

Associate Medical Director

Health Evidence Review Commission

Oregon Health Authority

1225 Ferry Street, Suite C

Salem, OR 97301

RE: Guidelines for IVC Filters

Dear Dr. Livingston:

Please forgive me for being so slow to respond to your earlier request. This has actually been (albeit intermittently) an issue of great interest to me personally and the group as a whole. I enclose our 2012 guidelines, for the trauma patient, and you will see historically we have used a score (RAP in this iteration) to group patients into risk categories. Now with EPIC the hospital automatically sets risk criteria. Our guidelines for IVC filters prophylactically are all relative, and we try not to place them. We have a liberal threshold for US screening, although the literature does not support this across multiple centers. Probably our most common indication is a patient at high risk or with an infra popliteal dvt who has to undergo many operations resulting in breaks in prophylaxis. For patients with documented dvt we follow standard guidelines (i.e. if you cannot be therapeutically anticoagulated, you get a filter if upper extremity sources are not the cause or if a patient has a PE while on therapeutic anticoagulation).

This sounds like a cool group! Have you bent your mind around guidelines for prophylactic anticoagulation in the head injured group?

Sincerely

Riyad Karmy-Jones MD, FACS, FRCSC,FAHA,FCCP

LEGACY HEALTH SYSTEM

Practice Guideline: LTS.910.5034
Effective Date: 6/99
Last Revision Date: 12/04
NextRevision Date: 1/07

SECTION: CLINICAL

SUBJECT: DVT PROPHYLAXIS AND THERAPEUTIC INTERVENTION

PURPOSE: To prevent and treat venous thromboembolism in trauma patients who are at high risk for deep vein thrombosis (DVT) and pulmonary embolism (PE) for patients 13 years of age and older.

RESPONSIBLE PARTIES: Trauma Surgeon (TS)
Trauma Residents (TR)
Trauma Physician Assistant (PA)
Trauma Resuscitation Nurses (TRN)
Trauma Nurse Coordinators (TNC)
Trauma Radiologists
Nursing Staff
Pharmacists

INSTRUCTIONS:

I. Identify Risk Factors for DVT/PE
   A. Obtain risk assessment profile (RAP) score (see attachment #1)
      1. RAP score less than or equal to 5 = low risk
      2. RAP score 6 to 14 = moderate risk
      3. RAP score greater than or equal to 15 = high risk
   B. Other factors to consider
      1. number of days on bedrest or immobile
      2. patient use of birth control pills or estrogen replacement therapy

II. **LOW RISK PATIENTS**: diagnostic exam and prophylaxis
   A. Duplex ultrasound of lower extremities only per trauma surgeon order
   B. Prophylactic treatment
      1. SCD (Sequential Compression Device) – calf length
      2. plantar pulse devices
      3. Mobilization as soon as appropriate (OT/PT evaluation if needed)

III. **MODERATE RISK PATIENTS**: diagnostic exam, prophylaxis and treatment

A. Prophylaxis treatment
   1. SCD or plantar pulse devices
   2. Start Enoxaparin 30 mg SC BID per pharmacy protocol unless contraindicated (see below)

B. Diagnostic exam
   1. Duplex ultrasound of lower extremities every 7 days.
   2. Duplex ultrasound before discharge for patients hospitalized 4 – 7 days.

C. Treatment for new DVT – (see DVT treatment below.)

IV. **HIGH RISK PATIENTS** (RAP score>15): Diagnostic exam, prophylaxis, and treatment (severely restricted mobility during acute illness)

A. Prophylaxis treatment
   1. SCD or plantar pulse device if possible.
   2. If not contraindicted, begin Enoxaparin 30 mg SC every 12 hours per pharmacy protocol. (see below)
   3. Enoxaparin Xa levels (heparin assay) will be measured per pharmacy protocol in obese patients and patients with renal impairment.
   4. Consider IVC filter placement (see relative indications below)
   5. Special considerations for patients with:
      a. coagulopathy
      b. long term or preexisting need for anticoagulation (ie: DVT/PE, Atrial Fibrillation, Prosthetic heart valve)
      c. morbid obesity or renal failure
      d. planned surgery or procedures at risk for bleeding within 24 hours

***KEY POINT**: Hold Enoxaprain (Lovenox) for 24 hours pre and/or post-op to minimize bleeding.*

B. Enoxaparin contraindications/ relative contraindications:
   1. Active bleeding
   2. Recent intracerebral bleed (clear with neurosurgery).
   3. Recent intracerebral or intraocular surgery (clear with surgeon).
   4. Spinal or epidural anesthesia within 12 hours (clear with anesthesia).
   5. Coagulopathy
   6. History of heparin-induced thrombocytopenia

C. Diagnostic exam
   1. Duplex ultrasound of lower extremities 3 days after admission.
   2. Follow-up ultrasounds every 3 days

V. Theurapeutic intervention for new DVT
   A. Treatment of new proximal DVT – above the knee
      1. Begin Enoxaparin (Lovenox) - 1mg/kg every 12 hours SC per pharmacy protocol. Dose will be adjusted per protocol in obese patients and patients with renal impairment.
      2. Start warfarin per pharmacy protocol when appropriate (ie: no further surgery planned and patient is stable)
      3. Monitor daily PT/INR after warfarin is initiated. (goal = INR of 2.0 – 3.0)
      4. Continue Enoxaparin until a therapeutic INR has been achieved (minimum: 5 days overlap with warfarin)
      5. Duplex ultrasound in 3 days to monitor DVT
         a. If DVT progresses
            i. obtain enoxaparin Xa level (heparin assay).
            ii. adjust dose to achieve peak enoxaparin Xa level of 0.8 – 1.2 when drawn 4 hours after dose.
         b. Consider IVC filter placement and/or hematologic consult.
   B. Treatment of distal DVT – below the knee
      1. Initiate or continue prophylactic dose of enoxaprin (30mg sc q12h per pharmacy protocol).
      2. Repeat duplex ultrasound in 3 days. If DVT progresses above the knee, treat as proximal DVT above.
   C. Adequate follow-up must be arranged prior to the patient's discharged/transfer from the hospital. Planning for continued outpatient anticoagulation should begin well before discharge.
      1. If patient is going to be going out of town, arrangements should be made with the patient's primary care provider in their local area. Contact the PCP prior to discharge to assure continuity of care and document this in the patient's chart.
      2. Patients that reside in the Portland metropolitan area should have arrangements made with either their PCP or the Anticoagulation Clinic.
         a. If the patient is to be managaed by their PCP, the PCP should be contacted prior to discharge to assure adequate plans for anticoagulation management are in place and document this contact in the patient's chart.
         b. If the patient is to be managed by the Anticoagulation Clinic, a Leagcy Anticoagulation Clinic Referral Form should be completed at least one day prior to discharge. The form must include the signature of a LIP and must include the name of the LIP that will be responsible for following the patient's anticoagulation therapy.
         c. Patient's should have bilateral lower extremity duplex ultrasound and follow-up visit at the Trauma Clinic at 3 months.
      3. Pharmacy to complete warfarin patient education prior to discharge.

KEY POINT: Anticoagulation for DVT treatment should be continued for a minimum of 3 months. Longer treatment may be required for patients with decreased mobility or other risk factors for DVT recurrance.

VI. Relative Indications for Prophylactic IVC filter placement

A. Quadriplegia – traumatic with other injuries
B. Paraplegia – traumatic with other injuries/illnesses limiting mobility
C. Complex pelvic fractures requiring prolonged bed rest (> 3 weeks)
D. Pelvic fractures and leg long bone fractures
E. Contra-indication to anticoagulation in a patient with known DVT in a major vein (lower IVC, iliacs, femorals, popliteal veins)
F. Progression of DVT despite adequate anticoagulation
G. PE from lumbar veins/IVC, iliac, femoral, popiteal veins despite adequate anticoagulation.
H. RAP score > 15.

Attachments:

Table for DVT prophylaxis and VTE therapy
RAP score

Requests for reprints should be submitted to Director of Trauma Services.

Originator: Dr. Steve Datena and Andrew Michaels

Revisions: 11/04 Dr. Michaels, Carl Heisel, and Nancy Baker

Bibliography:

Cipolle MD, Wojcik R, Seislove E, et.al. The Role of Surveillance Duplex Scanning in Preventing Venous Thromboembolism in Trauma Patients. J of Trauma. 52(3): 453-462. March 2002.

EAST Trauma Practice Guideline. www.east.org , 1998.

Geerts WH, Jay RM, Code KI, et.al. A Comparison of Low Dose Heparin with Low-Molecular-Weight Heparin Against Venous Thromboembolism After Major Trauma. NEJM 335: 1996, 701-707.

Ibrahim EH, Iregui M, Prentice D, et.al. Deep Vein Thrombosis During Prolonged Mechanical Ventilation Despite Prophylaxis. CC Med. 30(4): 771-774, April 2002.

Kim J, Gearhart MM, Zurick A, et.al. Preliminary Report on the Safety of Heparin for Deep Vein Thrombosis Prophylaxis After Severe Head Injury. J of Trauma. 53(1): 38-43, July 2002.

Maxwell RA, Chavarria-Aquilar M, Cockerham WT, et.al. Routine Prophylactic Vena Cava Filtration Is Not Indicated After Acute Spinal Cord Injury. J of Trauma. 30(5): 902-906, May 2002.

Meyer CS, Blebea J, Davis K, et. al. Surveillance Venous Scans for Deep Vein Thrombosis in Multiple Trauma Patients. Annals of Vascular Surgery 9(1): 109-14, 1995

Norwood SH, MaAuley CE, Berne JD, et.al. A Potentially Expanded Role for Enoxaparin in Preventing Venous Thromboembolism in High Risk Blunt Trauma Patients. J of Amer Coll Of Surgeons. 192(2): 161-167, February 2001.

Rogers FB, Cipolle MD, Velmahos G, et.al. Practice Management Guidelines for the Prevention Of Venous Thromboembolism in Trauma Patients: The EAST Practice Management Guidelines Work Group. J of Trauma 53(1): 142-164, July 2002.

Sekharan J, Dennis JW, Miranda FE, et.al. Long Term Followup of Prophylactic Greenfield Filters in Multisystem Trauma patients. J of Trauma, 51(6): 1087-1091, Dec 2001.
Vavilala MS, Nathens AB, Jurkovich GJ, et.al. Risk Factors for Venous Thromboembolism In Pediatric Trauma. J of Trauma. 52(5): 922-927, May 2002.

See Algorithms and RAP score below

DVT Prophylaxis

Determining Level of Risk

Risk Assessment Profile (RAP)	Weight
1. Underlying conditions	
Obesity (>120% Metropolitan Life Table)	2
Malignancy	2
Abnormal coagulation factors at admission	2
History of thromboembolism	3
2. Iatrogenic factors	
Central femoral line > 24 hours	2
Four or more transfusions during 1st 24-hours	2
Surgical procedures > 2 hours	2
Repair or ligation of major vascular injury	3
3. Injury related factors	
AIS > 2 for Chest	2
AIS > 2 for Abdomen	2
Spinal factures	2
AIS > 2 for the Head	3
Coma (GCS <8 for > 4 hours)	3
Complex lower extremity fracture	4
Pelvic fracture	4
Spinal cord injury with para or quadraplegia	4
4. Age	
≥ 40 but < 60	2
≥ 60 but < 75	3
≥ 75	4

AIS >2 Chest

- Penetrating injury or avulsion > 20% blood loss
- Hemo or pneumothorax
- Major vessel injury: intimal tear, laceration, perforation, puncture
- Tracheal or bronchus laceration
- Pulmonary contusion, Pneumo or hemomediastinum
- Major cardiac contusion <25%EF
- Greater than 3 rib fractures or 1st rib fracture with pneumo or hemothorax
- Sternal fracture

AIS >2 Abdomen

- Penetrating injury or avulsion > 20% blood loss
- Major vessel injury: intimal tear, laceration, perforation, puncture
- Injury to organ greater than simple laceration or contusion. Greater than Grade I or II organ injury spleen, liver, ect.

AIS >2 Head

- Scalp laceration or avulsion >20cm, or blood loss 20% or more
- Cerebral, carotid artery, sigmoid, transverse sinues lacerations or thrombosis
- Cerebrum, brain stem, cerebellum contusion, hemorrhage, hematoma. To include EDH, SDH, SAH.DAI
- Skull fractures unless simple, nondisplaced and isolated head injury

Total RAP Score_____

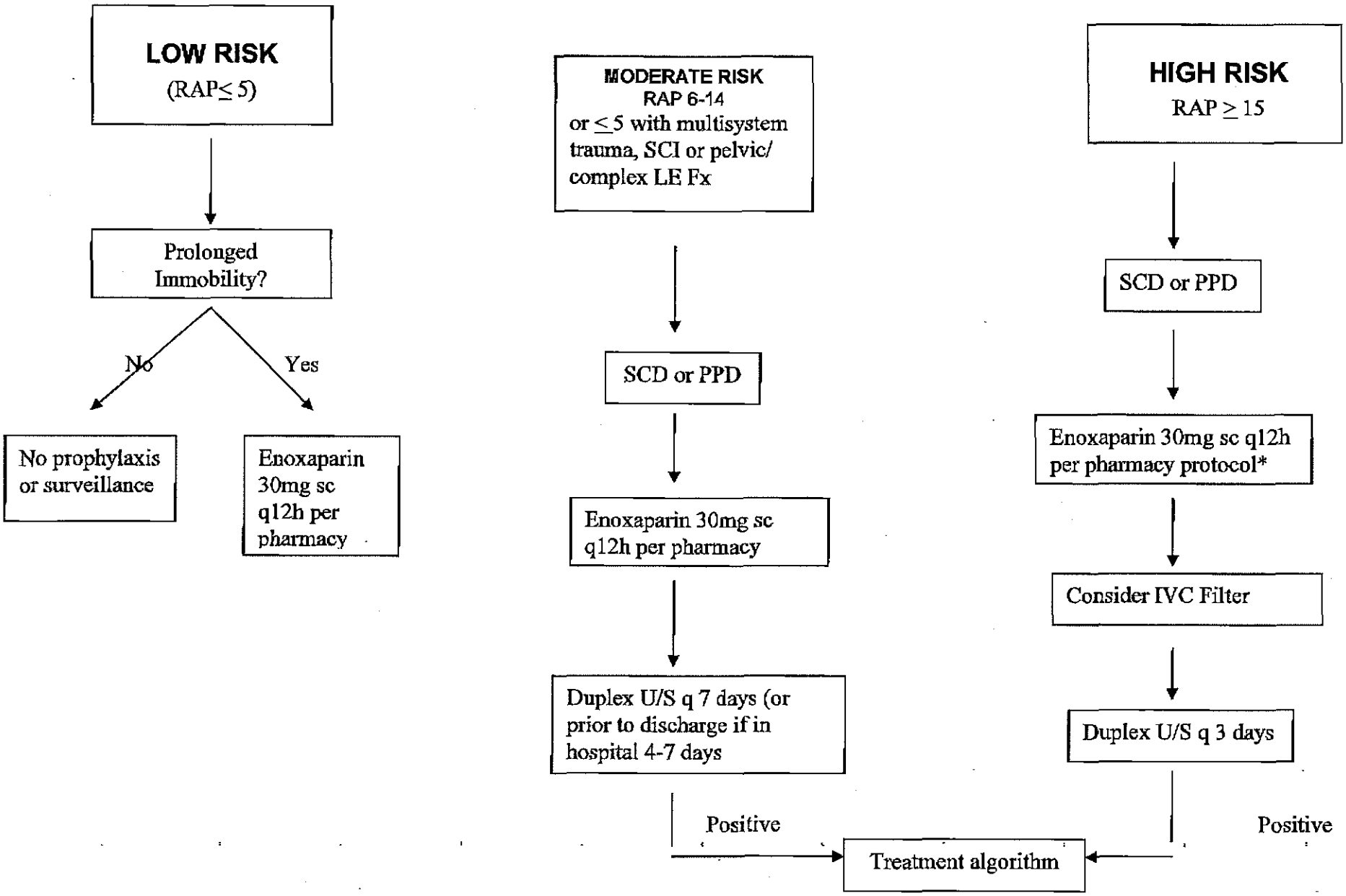
- RAP ≤ 5 is low risk
- RAP 6 -14 is moderate risk
- RAP > 15 High risk

Date: _____Attending MD_____

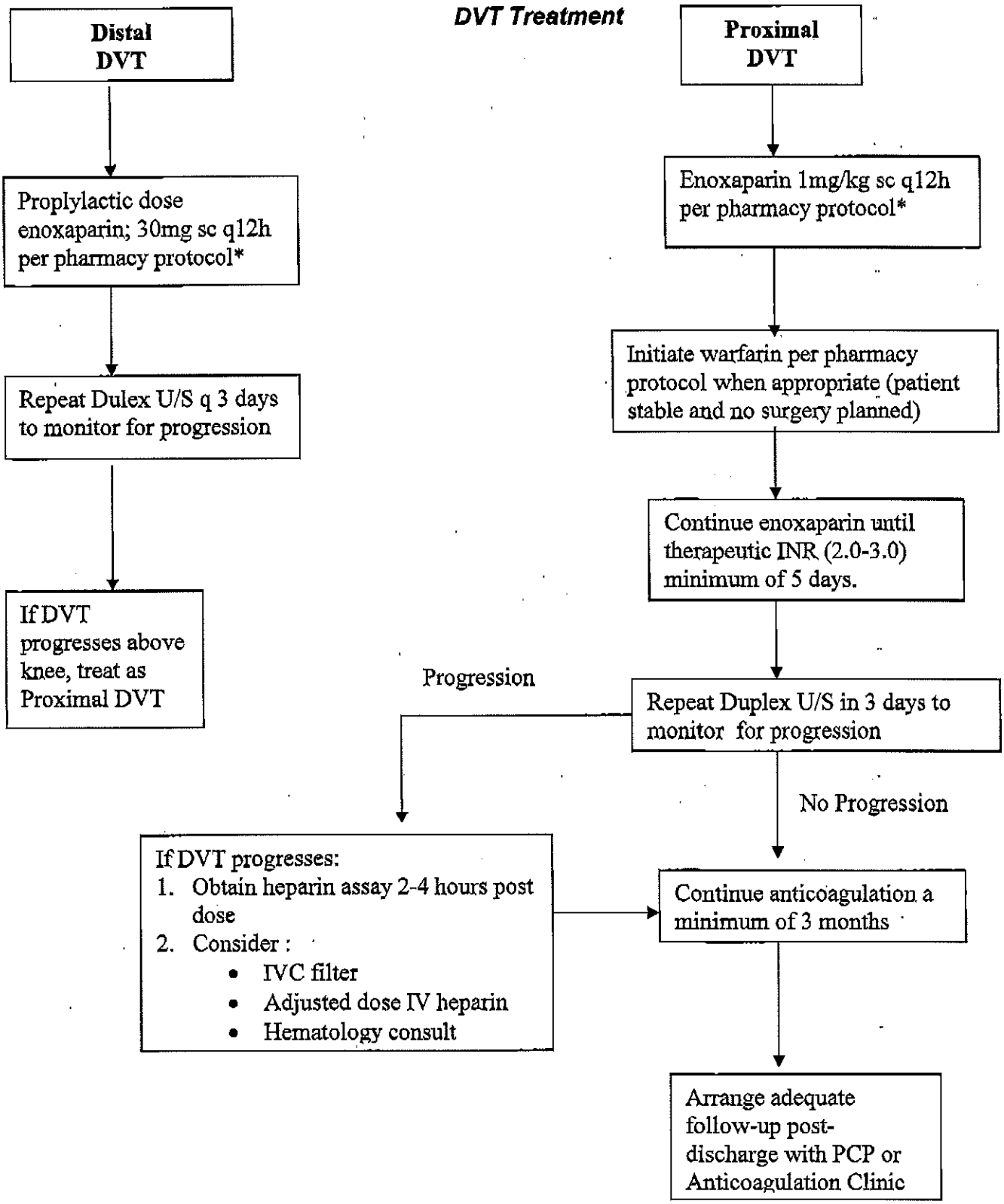
Assessment by_____

Patient Sticker

DVT Prophylaxis



* Enoxaparin contraindicated in: active bleeding, recent Intracerebral bleed (clear with neurosurg), recent Intracerebral or intraocular surgery (clear with surgeon), spinal or epidural anesthesia within 12hrs (clear with anesthesia), coagulopathy, history of HIT



- Enoxaparin contraindicated in: active bleeding, recent Intracerebral bleed (clear with neurosurg), recent Intracerebral or intraocular surgery (clear with surgeon), spinal or epidural anesthesia within 12hrs (clear with anesthesia), coagulopathy, history of HIT.

Body Mass Index Table

	Normal						Overweight					Obese										Extreme O				
BMI	**19**	**20**	**21**	**22**	**23**	**24**	**25**	**26**	**27**	**28**	**29**	**30**	**31**	**32**	**33**	**34**	**35**	**36**	**37**	**38**	**39**	**40**	**41**	**42**	**43**	**44**
Height (inches)	**Body Weight (pounds)**																									
58	91	96	100	105	110	115	119	124	129	134	138	143	148	153	158	162	167	172	177	181	186	191	196	201	205	210
59	94	99	104	109	114	119	124	128	133	138	143	148	153	158	163	168	173	178	183	188	193	198	203	208	212	217
60	97	102	107	112	118	123	128	133	138	143	148	153	158	163	168	174	179	184	189	194	199	204	209	215	220	225
61	100	106	111	116	122	127	132	137	143	148	153	158	164	169	174	180	185	190	195	201	206	211	217	222	227	232
62	104	109	115	120	126	131	136	142	147	153	158	164	169	175	180	186	191	196	202	207	213	218	224	229	235	240
63	107	113	118	124	130	135	141	146	152	158	163	169	175	180	186	191	197	203	208	214	220	225	231	237	242	248
64	110	116	122	128	134	140	145	151	157	163	169	174	180	186	192	197	204	209	215	221	227	232	238	244	250	256
65	114	120	126	132	138	144	150	156	162	168	174	180	186	192	198	204	210	216	222	228	234	240	246	252	258	264
66	118	124	130	136	142	148	155	161	167	173	179	186	192	198	204	210	216	223	229	235	241	247	253	260	266	272
67	121	127	134	140	146	153	159	166	172	178	185	191	198	204	211	217	223	230	236	242	249	255	261	268	274	280
68	125	131	138	144	151	158	164	171	177	184	190	197	203	210	216	223	230	236	243	249	256	262	269	276	282	289
69	128	135	142	149	155	162	169	176	182	189	196	203	209	216	223	230	236	243	250	257	263	270	277	284	291	297
70	132	139	146	153	160	167	174	181	188	195	202	209	216	222	229	236	243	250	257	264	271	278	285	292	299	306
71	136	143	150	157	165	172	179	186	193	200	208	215	222	229	236	243	250	257	265	272	279	286	293	301	308	315
72	140	147	154	162	169	177	184	191	199	206	213	221	228	235	242	250	258	265	272	279	287	294	302	309	316	324
73	144	151	159	166	174	182	189	197	204	212	219	227	235	242	250	257	265	272	280	288	295	302	310	318	325	333
74	148	155	163	171	179	186	194	202	210	218	225	233	241	249	256	264	272	280	287	295	303	311	319	326	334	342
75	152	160	168	176	184	192	200	208	216	224	232	240	248	256	264	272	279	287	295	303	311	319	327	335	343	351
76	156	164	172	180	189	197	205	213	221	230	238	246	254	263	271	279	287	295	304	312	320	328	336	344	353	361

Source: Adapted from *Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults: The Evidence Report.*

From Marty Schreiber, OHSU Trauma Surgery

The OHSU trauma service utilizes IVC filters in patients with deep vein thrombosis who cannot be anti-coagulated and in patients who have suffered pulmonary embolus who continue to do poorly despite therapeutic anticoagulation. The OHSU trauma service does not use IVC filters "prophylactically" due to the absence of data showing a benefit and the data showing potential harm.

Section 3.0

Revascularization and stenting for chronic angina

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE: CORONARY ARTERY REVASCULARIZATION FOR STABLE ANGINA

For EbGS Meeting Materials 2/5/2015

HERC Coverage Guidance

~~In non-acute heart disease, percutaneous interventions (stents and angioplasty) are:~~

~~Recommended for coverage in:~~

- ~~Women *(strong recommendation)*~~
- ~~Patients with recent myocardial infarction *(weak recommendation)*~~

~~Not recommended for coverage for:~~

- ~~Stable angina over optimal medical therapy in men *(strong recommendation)*~~

~~Coronary artery bypass grafting (CABG) is recommended for coverage for:~~
~~Multivessel disease (strong recommendation)~~

Coronary revascularization (with stents, angioplasty or CABG) is recommended for coverage in patients with stable angina whose symptoms are not controlled with optimal medical therapy[1] *(weak recommendation).* [2]

CABG is recommended as the revascularization method of choice for patients with stable angina who have left main coronary artery stenosis or three-vessel coronary artery stenosis, with or without a trial of optimal medical therapy *(strong recommendation).*

---

[1]Optimal medical therapy for angina symptom control prior to PCI is defined as two or more antianginals (with or in addition to standard treatment for coronary artery disease). Antianginals are defined as: beta-blocker, nitrate, calcium channel blocker, or ranolazine.
[2] Evidence suggests PCI improves symptom management, but does not reduce mortality or major cardiovascular event rates; CABG reduces long-term rates of major cardiovascular events and repeat revascularization (although possibly limited to patients with left main or 3-vessel disease), but has higher short-term surgical morbidity.

Note: Definitions for strength of recommendation are provided in Appendix A GRADE Element Description

RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

- Represents a significant burden of disease

- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
- Represents high costs, significant economic impact
- Topic is of high public interest

Coverage guidance development follows to translate the evidence review to a policy decision. Coverage guidance may be based on an evidence-based guideline developed by the Evidence-based Guideline Subcommittee or a health technology assessment developed by the Heath Technology Assessment Subcommittee. In addition, coverage guidance may utilize an existing evidence report produced by one of HERC's trusted sources, generally within the last three years.

EVIDENCE SOURCES

Trusted sources

Dolor, R.J., Melloni, C., Chatterjee, R., Allen LaPointe, N.M., Williams, J.B., Coeytaux, R.R., et al. (2012). *Treatment strategies for women with coronary artery disease*. Rockville, MD: AHRQ. Retrieved on October 2, 2014, from,http://effectivehealthcare.ahrq.gov/ehc/products/218/1227/CER66_Treatment-Coronary-Artery-Disease_FinalReport_20120816.pdf

Greenhalgh, J., Hockenhull, J., Rao, N., Dundar, Y., Dickson, R. C., & Bagust, A. (2010). Drug-eluting stents versus bare metal stents for angina or acute coronary syndromes. *The Cochrane Library.* DOI:10.1002/14651858.CD004587.pub2.

Skinner, J.S., & Cooper, A. (2011). Secondary prevention of ischemic cardiac events. *BMJ Clinical Evidence*, 8, 206.

Other sources

Fihn, S. D., Gardin, J. M., Abrams, J., Berra, K., Blankenship, J. C., Douglas, P. S, et al. (2012). 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS guideline for the diagnosis and management of patients with stable ischemic heart disease: a report of the American College of Cardiology Foundation/American Heart Association task force on practice guidelines, and the American College of Physicians, American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. *Journal of the American College of Cardiology*, *60*(24), e44-e164. DOI:10.1016/j.jacc.2012.07.013. Accessed on October 27, 2014 from, http://content.onlinejacc.org/data/Journals/JAC/926038/07013.pdf

Fihn, S.D., Blankenship, J.C., Alexander, K.P., Bittl, J.A., Byrne, J.G., Fletcher, B.J., et al. (2014). 2014 ACC/AHA/ AATS/PCNA/SCAI/STS Focused Update of the Guideline for the Diagnosis and Management of Patients With Stable Ischemic Heart Disease. *Journal*

of the American College of Cardiology, *64*(18):1929-1949. DOI: 10.1161/CIR.0000000000000095. Accessed on October 27, 2014 from, http://content.onlinejacc.org/article.aspx?articleid=1891717&resultClick=3

The summary of evidence in this document is derived directly from these evidence sources, and portions are extracted verbatim.

EVIDENCE OVERVIEW

Clinical background

Coronary artery disease is the leading cause of mortality in resource-rich countries, and is becoming a major cause of morbidity and mortality in resource-poor countries. There are international, regional, and temporal differences in incidence, prevalence, and death rates. In the USA, the prevalence of coronary artery disease is over 6%, and the annual incidence is over 0.33%.

Most ischemic cardiac events are associated with atheromatous plaques, which may rupture or erode and lead to acute thrombosis and obstruction of coronary arteries. Many of these are preventable. Coronary artery disease is more likely in people who are older, male, or who have risk factors, such as smoking, hypertension, high cholesterol, and diabetes mellitus.

Within 1 year of having a first MI, 25% of men and 38% of women will die. Within 6 years of having a first MI, 18% of men and 35% of women will have another MI, 22% of men and 46% of women will have heart failure, and 7% of men and 6% of women will die suddenly.

Secondary prevention in this context is long-term treatment to prevent recurrent cardiac morbidity and mortality in people who have had either a prior acute myocardial infarction (MI) or acute coronary syndrome[1], or who are at high risk due to severe coronary artery stenoses or prior coronary surgical procedures.

Indications

Treatment options for secondary prevention include medical therapy (antiplatelet agents, statins, blood pressure reduction if indicated, beta-blockers and angiotensin converting enzyme inhibitors), coronary artery bypass grafting (CABG) and a number of less invasive methods, including percutaneous transluminal coronary angioplasty (PTCA), in which a small elongated balloon is inflated at the site of the plaque, effectively compacting the deposited material against the vessel wall. This is often accompanied by a coronary artery stent.

Technology description

Coronary artery stents are expandable devices resembling a tubular wire mesh used to 'scaffold' vessels open during PTCA procedures to relieve coronary obstructions in patients. The first of these were metal and are referred to as bare metal stents (BMS). Restenosis (re-

[1] An umbrella term that includes myocardial infarction and unstable angina

narrowing of the treated vessel), which may require a repeat intervention, is a significant limitation of PTCA with the use of stents; rates of restenosis are recorded as ranging between 20 and 50 per cent, depending on the size, location and complexity of the lesion. In order to improve results and reduce restenosis, developments in stent design have been augmented by new drug-eluting technologies. Drug-eluting stents (DES) release anti-proliferative agents from their surface with the objective of limiting cell growth around the stent using cytotoxic, cytostatic and other agents (sirolimus, paclitaxel, everolimus, tacrolimus). Percutaneous coronary intervention (PCI) is an umbrella term that includes PTCA, with and without the additional use of stents.

This report is limited to individuals with stable angina or non-acute coronary heart disease (CHD); it does not address coronary interventions used in the setting of acute coronary syndrome. It is also limited to a comparison to optimal medical therapy to either PCI or CABG. There is a large body of evidence comparing PCI to CABG that is not included in this report.

Oregon utilization

Data from the Dartmouth Atlas of Health Care demonstrate that in Oregon, utilization of PCI is low compared to the national average and in proportion to utilization of CABG.

Table 1. Percutaneous Coronary Interventions (PCI) versus Inpatient Coronary Artery Bypass Grafting (CABG) Utilization per 1,000 Medicare Enrollees in 2012

	Male		Female		Overall	
	PCI	CABG	PCI	CABG	PCI	CABG
Oregon	5.6	3.9	2.9	1.2	4.1	2.4
Washington	6.9	3.5	3.4	1.3	4.9	2.3
National Average	8.4	4.1	4.5	1.4	6.2	2.6
90th Percentile	10.7	5.4	6.1	2.0	8.1	3.4
10th Percentile	5.8	3.1	3.0	0.9	4.3	1.9

Adapted from The Dartmouth Atlas of Health Care Website, http://www.dartmouthatlas.org/

EVIDENCE REVIEW

Percutaneous coronary intervention vs. optimal medical therapy in stable coronary heart disease

It is unclear whether PTCA with or without stenting is more effective than medical treatment alone at reducing mortality, cardiac death, composite outcomes including mortality and cardiovascular morbidity, non-fatal MI, need for revascularization, or heart failure in people with non-acute CHD (low quality evidence). Populations and interventions (particularly the use of

stents) varied between trials, and results varied by the specific analysis undertaken, outcome assessed, and population included (low-quality evidence).

Four systematic reviews comparing PTCA with or without stenting versus medical treatment alone (Jeremias 2009, Katritsis 2005, Ioannidis 2007, Trikalinos 2009) and three subsequent reports of RCTs included in the reviews (Boden 2009, Malek 2009, Mark 2009) were identified. There was a large overlap in the RCTs meta-analyzed in the systematic reviews. However, each review combined different RCTs in their analysis and therefore all four reviews are reported on here.

The first review (Katrisis 2005, search date 2004, 11 RCTs, 2950 people with angiographically documented coronary stenosis in non-acute coronary artery disease settings) compared PTCA versus medical treatment. People with an acute coronary syndrome within the past week were excluded. However, in two RCTs all people had an MI within the past 3 months, but not in the past week. Most RCTs mainly included people with single-vessel or two-vessel disease, but one included people with multi-vessel disease only. The use of stents in people receiving PTCA varied among RCTs, and no RCT used drug-eluting stents. The review found no significant difference between PTCA and medical treatment in mortality (11 RCTs; 95/1476 [6%] with PTCA v 101/1474 [7%] with medical management; RR 0.94, 95% CI 0.72 to 1.24), non-fatal MI (11 RCTs; 87/1476 [6%] with PTCA v 65/1474 [4%] with medical management; RR 1.28, 95% CI 0.94 to 1.75), cardiac death or MI (11 RCTs; 126/1476 [8%] with PTCA v 109/1474 [7%] with medical management; RR 1.17, 95% CI 0.88 to 1.57), need for CABG (11 RCTs; 109/1476 [7.4%] with PTCA v 106/1474 [7.2%] with medical management; RR 1.03, 95% CI 0.80 to 1.33), or need for PTCA during follow-up (11 RCTs; 219/1476 [15%] with PTCA v 243/1474 [16%] with medical management; RR 1.23, 95% CI 0.80 to 1.90). However, there was considerable heterogeneity among trials.

Pre-specified subgroup analyses found that there was no significant difference in the end points considered in RCTs whether stents were available or not, and in trials with follow-up exceeding 2 years there was no difference in end points between PTCA and medical treatment. However, in RCTs with a mean follow-up <2 years, PTCA was associated with significantly higher rates of the composite outcome of cardiac mortality or MI compared with medical treatment (RR 1.82, 95% CI 1.10 to 2.99; absolute numbers not reported), although the confidence intervals overlapped with those from longer-term trials in which the difference was not significant (RCTs with follow-up exceeding 2 years, cardiac mortality or MI; RR 0.99, 95% CI 0.68 to 1.46). The review found that, in the two RCTs that exclusively included people with a relatively recent MI (more than one week but less than three months), PTCA significantly reduced mortality (RR 0.40, 95% CI 0.17 to 0.95) and need for PTCA during follow-up (RR 0.42, 95% CI 0.20 to 0.91; absolute numbers not reported) compared with medical treatment. The largest RCT (Pocock 2000) identified by the review (1018 people) found that, compared with medical treatment, PTCA improved physical functioning (P <0.001), vitality (P = 0.01), and general health (P = 0.008) at 1 year (proportion of people rating their health "much improved": 33% with PTCA v 22% with medical treatment; P = 0.008), but found no significant difference at 3 years. The improvements were related to breathlessness, angina, and treadmill tolerance. High transfer (27%) to PTCA by people initially randomized to medical treatment may partly explain the lack

of significant difference between groups at 3 years. The review found no significant difference between groups for death or MI (including procedure-related events) at 5 years (9% with PTCA v 8% with medical treatment; ARR +1.8%, 95% CI –1.7% to +5.2%).

The second review (Ioannidis 2007, search date 2007, 6 RCTs and 1 sub study, 2617 people that were stable and had an occluded coronary artery, 1–45 days from the onset of acute MI symptoms [mean 8 days], most RCTs with a mean ejection fraction between 44% and 53%, 1 RCT with a mean ejection fraction of 36%) compared PTCA versus medical treatment. Three RCTs had long-term follow up (mean: range 34–50 months), while the others were limited to 4 to 12 months. Three RCTs used stents in people receiving PTCA. The review found no significant difference between PTCA and medical treatment in mortality (99/1310 with PTCA v 106/1317 with medical management; RR 0.95, 95% CI 0.73 to 1.23; P = 0.69), non-fatal MI (70/1310 with PTCA v 55/1317 with medical management; RR 1.26, 95% CI 0.86 to 1.78; P = 0.19), death or MI (161/1310 with PTCA v 141/1317 with medical management; RR 0.99, 95% CI 0.57 to 1.70; P = 0.96), or heart failure (51/1310 with PTCA v 67/1317 with medical management; RR 0.67, 95% CI 0.36 to 1.22; P = 0.19). The review found no significant heterogeneity among RCTs for any of the summary effects (P >0.10 for all outcomes).

The third review (Jeremias 2009, search date 1997–2008), which included RCTs of coronary revascularization versus medical treatment in people with non-acute coronary artery disease, included a total of 28 RCTs, of which 17 RCTs were confined to PTCA versus medical treatment with a further 2 RCTs randomizing to PTCA, CABG, and medical treatment. In total, 8052 people were included in the trials comparing percutaneous coronary intervention (PCI) versus medical therapy, and the RCTs ranged in follow-up from 1 to 10.2 years. The population in the RCTs included people with stable angina, exercise-induced ischemia, post-thrombolytic therapy for MI, asymptomatic single vessel coronary artery disease, and ischemia post MI, among others. Most RCTs compared balloon angioplasty without stenting versus medical treatment, although in 5 RCTs bare metal stents were implanted in 72% to 100% of cases. The review found that PTCA significantly reduced all-cause mortality compared with medical treatment (OR 0.82, 95% CI 0.68 to 0.99; results presented graphically; absolute numbers not reported).

The fourth review (Trikalinos 2009, search date 2008, people with symptomatic or asymptomatic non-acute coronary artery disease) first compared PTCA without stents versus medical management (7 RCTs, number of people [median] 201, follow-up [median] 60 months, age [mean] 56 years, percentage men [median] 85%, 0% with multivessel disease). The review found no significant difference between PTCA and medical treatment in mortality (7 RCTs, 1991 people; RR 0.82, 95% CI 0.59 to 1.15), non-fatal MI (7 RCTs, 1991 people; RR 1.09, 95% CI 0.59 to 1.99), CABG (5 RCTs, 1646 people; RR 1.10, 95% CI 0.81 to 1.49), and any revascularization (7 RCTs, 1991 people; RR 1.08, 95% CI 0.74 to 1.56; absolute numbers not reported for any outcome). Significant heterogeneity among RCTs was found for the outcomes of non-fatal MI and any revascularization. The review also compared PTCA with bare metal stents versus medical management (4 RCTs, number of people [median] 1134, follow-up [median] 30 months, age [mean] 60 years, percentage men [median] 83%, 60% with multivessel disease). The review found no significant difference between PTCA with bare metal stents and medical treatment in mortality (3 RCTs, 4518 people; RR 0.96, 95% CI 0.79 to 1.18), non-fatal

MI (4 RCTs, 4619 people; RR 1.18, 95% CI 0.97 to 1.43), CABG (2 RCTs, 2267 people; RR 0.97, 95% CI 0.63 to 1.50), and any revascularization (3 RCTs, 4518 people; RR 0.78, 95% CI 0.58 to 1.05; absolute numbers not reported for any outcome). Significant heterogeneity among RCTs was found for the outcome of any revascularization. No RCTs directly compared PTCA with drug-eluting stents versus optimal medical therapy.

The first subsequent report (Boden 2009, 2287 people with initially severe angina [CCS grade 4] stabilized medically and at least 70% stenosis in at least one proximal epicardial coronary artery, and either objective evidence of myocardial ischemia or at least one coronary stenosis of at least 80% and classic angina without provocative testing) reported prespecified tertiary outcomes of one RCT included in a systematic review. The initial report of the RCT (the COURAGE trial) had reported on primary and major secondary end points. This report assessed the impact of PCI when added to optimal medical therapy on major, cause-specific cardiovascular outcomes (i.e., prespecified tertiary end points) during long-term follow-up. PTCA was attempted in 1077 of the 1149 people randomized to PTCA and 94% received at least one stent, the majority being bare metal stents. The RCT found no significant difference between PTCA and medical treatment in cardiac death (39/1149 [3.4%] with PTCA v 44/1138 [3.9%] with medical treatment; HR 0.87, 95% CI 0.56 to 1.33; P = 0.51), the composite outcome of cardiac death and MI (172/1149 [15.0%] with PTCA v 162/1138 [14.2%] with medical treatment; HR 1.07, 95% CI 0.86 to 1.33; P = 0.62), the composite outcome of cardiac death, MI, and acute coronary syndrome (270/1149 [23.5%] with PTCA v 257/1138 [22.6%] with medical treatment; HR 1.07, 95% CI 0.91 to 1.27; P = 0.60), the composite outcome of cardiac death, MI, and stroke (188/1149 [16%] with PTCA v 173/1138 [15%] with medical treatment; HR 1.10, 95% CI 0.89 to 1.35; P = 0.45), and the composite outcome of cardiac death, MI, acute coronary syndrome, and stroke (313/1149 [27.2%] with PTCA v 305/1138 [26.8%] with medical treatment; HR 1.05, 95% CI 0.89 to 1.22; P = 0.51).

The second and third subsequent reports were follow-ups from RCTs included in three systematic reviews (Malek 2009, Mark 2009). Malek 2009 compared PTCA with stenting versus optimal medical therapy in people with total occlusion of the infarct-related artery (793 left anterior descending [LAD group], 1408 left circumflex or right coronary artery [non-LAD group]). On days 3 to 28 (minimum of 24 hours) after MI, people were randomized to PTCA and stenting with optimal medical therapy (1101 people) or to optimal medical therapy alone (1100 people). People with LAD infarct-related artery were significantly older than people with non-LAD infarct-related artery (mean: 59.5 years with LAD v 58.1 years with non-LAD; P = 0.005) and the proportion of men was significantly lower (591/793 [75%] with LAD v 1126/1408 [80%] with non-LAD; P = 0.003). The RCT found that the 5-year cumulative primary composite outcome of first occurrence of MI, admission to hospital for heart failure, or all-cause mortality occurred more frequently in people with LAD infarct-related artery compared with people with non-LAD infarct-related artery (19.5% with LAD v 16.4% with non-LAD; HR 1.34, 99% CI 1.00 to 1.81; P = 0.01). The RCT found that in people with LAD infarct-related artery, PTCA did not significantly reduce the primary outcome compared with medical treatment (22.7% with PTCA v 16.4% with medical treatment; HR 1.35, 99% CI 0.86 to 2.31; P = 0.09). Similarly, it found that in people with non-LAD infarct-related artery, PTCA did not significantly reduce the primary outcome compared with medical treatment (16.9% with PTCA v 15.8% with medical treatment; HR 1.03, 99% CI

0.70 to 1.52; P = 0.83). It also reported that there was no significant difference between people with LAD infarct-related artery and people with non-LAD infarct related artery for the secondary outcomes of death or non-fatal re-infarction, fatal and non-fatal reinfarction, or admission to hospital for heart failure or stroke. It reported that there was no significant difference for PTCA versus medical treatment for these secondary outcomes in either people with LAD infarct-related artery or in people with non-LAD infarct-related artery.

Mark 2009 (a substudy of 951 of 2166 people in original trial enrolled in the quality-of-life assessment, 3–28 days post MI) compared PTCA versus medical treatment for the outcome of quality of life at 4, 12, and 24 months' follow-up. The RCT found that PTCA significantly improved quality of life as assessed on the Duke Activity Status Index at 4 months' follow up compared with medical treatment (P = 0.008), whereas there was no significant difference between groups at 12 months' (P = 0.36) or 24 months' follow-up (P = 0.29). It found that there was no significant difference for PTCA versus medical treatment in quality of life as assessed by the Mental Health Inventory 5 at any follow-up.

Subgroups

Age

One systematic review (Jeremias 2009) which included one RCT (TIME investigators 2001) was identified. The RCT (305 people aged >75 years, 44% female, with chronic refractory angina) compared PTCA versus medical treatment alone. It found that PTCA reduced all adverse cardiac events (death, non-fatal MI, hospital admissions for ACS) and decreased anginal severity compared with medical treatment, but had no significant effect on deaths or non-fatal MI after 6 months (adverse cardiac events, AR: 19% with PTCA v 49% with medical treatment; P <0.0001; change in angina class: –2.0 with PTCA v –1.6 with medical treatment; P <0.0001; deaths, AR: 9% with PTCA v 4% with medical treatment; P = 0.15; non-fatal infarctions, AR: 8% with PTCA v 12% with medical treatment; P = 0.46).

Gender

One SR examined treatment of women with coronary disease (Dolor 2012). For women with stable angina, meta-analysis of three good quality studies (all women less than age 75) showed a reduction in the composite outcome of death/MI/repeat revascularization at 5 years for revascularization with PCI compared to optimal medical therapy (OR 0.64; CI, 0.47 to 0.89; p=0.008, moderate SOE). In one of these trials, patients had multivessel disease.

This information is summarized in the table below.

Table 1. Percutaneous coronary interventions vs. optimal medical therapy

Review or Trial	Outcomes	Sub-group Information
Katrisis 2005 (SR – no DES)	No difference in: • Mortality • Non-fatal MI • Composite of cardiac death or MI	No difference with or without stents Mean F/U < 2 years: higher rates of composite in PTCA Recent (< 3 mos, > 1 week) MI:

	• Need for CABG • Need for PTCA	lower mortality, need for PTCA in PTCA F/U > 5 years: no diff in death or MI
Ioannidis 2007 (SR)	No difference in: • Mortality • Non-fatal MI • Composite of cardiac death or MI • Heart failure	
Jeremias 2009 (SR – no DES)	PTCA reduced all-cause mortality	
Trikalinos 2009 (SR – no DES)	No difference in: • Mortality • Non-fatal MI • Any revascularization • CABG	Same results comparing PTCA without stents and with bare metal stents
Boden 2009 (RCT – most stented, some DES)	No difference in: • Cardiac death • Composite of cardiac death or MI • Composite of cardiac death, MI or ACS • Composite of cardiac death, MI or stroke • Composite of cardiac death, MI, ACS or stroke	
Malek 2009 (RCT – recent MI, most stented)	No difference in: • Composite (5 year F/U) of MI, admit to hospital for heart failure, or all-cause mortality • Death or non-fatal reinfarction • Any reinfarction • Admit to hospital for heart failure or stroke	Same results comparing LAD and non-LAD infarct related arteries
Mark 2009 (RCT – recent MI, most stented)	PTCA improved quality of life at 4 months, but not 12 or 24 months	
TIME Investigators 2001 (RCT)	PTCA reduced all adverse cardiac events and angina severity No difference in deaths or non-fatal MI	Patients > 75
Dolor 2012 (SR)	PCI reduced composite of death, MI or repeat revascularization at 5 year F/U	Women

Summary

In summary, there is no clear advantage of an initial routine strategy of PTCA with or without stenting compared with medical treatment to reduce mortality and MI in patients with stable coronary disease and no recent MI. However, there may be short-term improvement in quality of life, and for women and older individuals, PCI may result in a reduction in angina symptoms and adverse cardiac events.

Coronary artery bypass graft vs. optimal medical therapy

Two systematic reviews comparing CABG versus medical treatment were identified. In the first systematic review (Yusuf 1994, search date not reported, 7 RCTs, 2649 people with CHD, mostly male, aged 41–60 years, 80% with ejection fraction >50%, 60% with prior MI; and 83% with 2–3 vessel disease), people assigned to CABG also received medical treatment, and 37% initially assigned to medical treatment underwent CABG in the following 10 years. It found that, compared with medical treatment, CABG significantly reduced mortality at 5 and 10 years (5 years: RR 0.61, 95% CI 0.48 to 0.77; 10 years: RR 0.83, 95% CI 0.70 to 0.98). Most trials did not collect data on quality of life; neither did they report detailed information about long-term medication use. However, at one year, 66% of the medical treatment group and 20% of the CABG group were treated with beta-blockers, and 19% of the medical treatment group and 26% of the CABG group were treated with antiplatelet agents. The review found that, of the 1240 people who had CABG, 40 (3%) died and 88 (7%) had non-fatal MI within 30 days of the procedure. At 1 year, rates of the combined outcome of mortality or MI were significantly higher with CABG compared with medical treatment (12% with CABG v 8% with medical treatment; RR 1.45, 95% CI 1.18 to 2.03).

The second systematic review (Jeremias 2009, search date 1977–2008) included RCTs of coronary revascularization (CABG/PCI/mixed) versus medical treatment in people with non-acute coronary artery disease. It included 28 RCTs in total, of which 6 RCTs evaluated CABG (largely with saphenous vein grafts) versus medical treatment (all of which were included in the first review) and it included a further two RCTs evaluating PCI or CABG (the majority with internal thoracic artery graft). The 8 RCTs comparing CABG versus medical treatment included 3098 people, who were mostly male, and follow-up in the RCTs was from 1 to 5 years. The 8 RCTs included people with stable angina, disabling angina, mild stable angina, or free of angina post MI, and no symptoms; the year of publication of the RCTs varied from 1977 to 2004. The review found that CABG significantly reduced all-cause mortality compared with medical treatment (8 RCTs; OR 0.62, 95% CI 0.50 to 0.77; results presented graphically; absolute numbers not reported).

No harms were reported in either SR.

Subgroups

Reduced left ventricular function

The Yusuf 1994 systematic review described above found that the relative benefits of CABG were similar in people with normal compared with reduced left ventricular function (death: OR 0.61, 95% CI 0.46 to 0.81, with normal left ventricular function; OR 0.59, 95% CI 0.39 to 0.91, with reduced left ventricular function). The absolute benefit of CABG was greater in people with a reduced left ventricular function because the baseline risk of death was higher.

Multiple vessel disease

Yusuf 1994 found that CABG reduced mortality compared with medical treatment in people with single-vessel, two-vessel, three-vessel, and left main stem disease. ~~However, c~~Change in mortality was not significant for people with single-vessel and two-vessel disease; however, ~~.~~ ~~T~~this may have been because the number of deaths was small. The risk of ~~(~~mortality was~~:~~ 0.54~~,~~ (95% CI 0.22 to 1.33)~~,~~ with single-vessel disease,~~:~~ 0.84~~,~~ (95% CI 0.54 to 1.32)~~,~~ with two-vessel disease,~~:~~ 0.58~~,~~ (95% CI 0.42 to 0.80)~~,~~ with three-vessel disease, and~~;~~ 0.32~~,~~ (95% CI 0.15 to 0.70) with left main stem disease~~)~~.

Asymptomatic individuals

The efficacy of revascularization and medical treatment has been evaluated in people with asymptomatic ischemia in one RCT (Davies 1997). The RCT (558 people with asymptomatic ischemia identified by exercise test or ambulatory ECG) compared three interventions: revascularization (90 selected for CABG, 11 later refused and 1 had the procedure outside the specified time window; 102 selected for PTCA, 8 later refused and 2 had the procedure outside the time window), angina-guided medical treatment, and ischemia-guided medical treatment. In the angina-guided treatment group, drug treatment was sufficient to control angina. In the ischemia-guided group, additional drug therapy was added if ischemia was still present on ambulatory ECG recording. At 2 years, the rate of mortality or MI was lower with revascularization (angina-guided treatment: 12%; ischemia-guided treatment: 9%; revascularization: 5%). The difference between angina-guided treatment and revascularization was significant (P <0.01), but the differences between ischemia-guided treatment and revascularization (P = 0.12) and angina-guided treatment and ischemia-guided treatment (P = 0.3) were not significant. There was a tendency for the benefit of revascularization to be concentrated in those with proximal LAD artery disease, and in those with three-vessel disease compared with one- or two-vessel disease.

Gender

One SR examined treatment of women with coronary disease (Dolor 2012). For women with stable angina, meta-analysis of two good quality studies showed a reduction in the composite outcome of death/ MI/repeat revascularization at 5 years for revascularization with CABG compared to OMT (OR 0.56; CI, 0.32 to 0.96; p=0.04; low SOE). However, patients in these two trials either had multivessel disease or left ventricular dysfunction.

Summary

In summary, CABG plus medical treatment may be more effective than medical treatment alone at reducing mortality in the long run in people (mostly male) aged 41 to 60 years, most with previous MI and two to three-vessel disease and also in people with non-acute coronary artery disease (low quality evidence). However, it may increase the estimated incidence of the composite outcome of death or MI at 1 year. Further analysis in people (mostly male) aged 41 to 60 years, most with previous MI and two- to three-vessel disease, found that CABG may reduce mortality compared with medical treatment both in people with normal left ventricular function or with reduced left ventricular function, and may reduce mortality in people with three-vessel and left main stem disease, although the effect of CABG in those with single- or two-vessel disease are unclear, as the number of deaths in these groups was small (low-quality evidence).

No clinically important results about the effects of CABG in asymptomatic people with coronary artery disease were found. People included in trials may not be easily generalized to current practice; people were generally 65 years or younger, almost all were male, high-risk people were under represented, and some trials did not use current medical regimens.

Limitations of the evidence on coronary artery bypass grafting compared to optimal medical therapy

The results of the systematic reviews may not be easily generalized to current practice. People were generally aged 65 years or younger, but >50% of CABG procedures are now performed on people >65 years of age. In addition, almost all were male, and high-risk people (such as those with severe angina and left main coronary artery stenosis) were under represented. Internal thoracic artery grafts were largely confined to two more recent trials. In the first systematic review lipid lowering agents (particularly statins) and aspirin were used infrequently (aspirin used in 3% of people at enrollment, about 22% at 1 year). Only about 50% of people were taking beta-blockers at baseline. The first systematic review (Yusuf 1994) evaluated the efficacy of an initial strategy of CABG compared with medical treatment, although there was considerable crossover to surgery in those assigned to medical treatment; in the three larger trials, 25% by 5 years, 33% by 7 years, and 41% by 10 years. However, some general observations can be made, and those with more-extensive CHD and impaired left ventricular function are likely to derive the greatest absolute benefit with improved survival from CABG. One RCT (Hueb 2007) included in the second systematic review (Jeremias 2001) in those with preserved left ventricular function and multivessel disease more accurately reflects contemporary clinical practice with the use of more arterial conduits, although the mean age of participants was still only 60 years. The RCT was not powered to detect differences in survival, but CABG reduced the need for additional revascularization procedures and improved angina-free survival at 5 years. People with prior CABG have not been studied in RCTs, although they now represent a growing proportion of those undergoing CABG.

EVIDENCE SUMMARY

Most of the evidence suggests that, compared to optimal medical therapy, PCI does not result in improvement in mortality or most other cardiac outcomes (non-fatal MI, need for revascularization, heart failure, composite outcomes), based on low quality evidence (multiple conflicting SRs). However, most studies utilized only PTCA or bare metal stents, and only a few trials included drug eluting stents. Some subgroups appear to have differential outcomes; PCI may result in short-term benefit in mortality in patients with a recent MI (very low quality evidence, based on three conflicting RCTs), as well as in women (moderate quality evidence, based on one SR). In addition, PCI may improve physical functioning and quality of life in the short-term compared to OMT (very low quality evidence, based on one RCT), and for patients over age 75, may reduce anginal severity (very low quality evidence, based on one RCT).

On the contrary, CABG does appear to result in improved mortality compared to OMT, at least at five years follow up, although short-term risks are higher (low quality evidence). This benefit is present regardless of left ventricular function or gender, but may be limited to patients with multi-vessel or left main stem disease.

There are a number of limitations to the evidence base, including the fact that most trials were limited to patients age 65 or younger, few trials included DE stents and OMT in many trials was suboptimal compared to current standards. In addition, for CABG trials, most did not utilize internal thoracic artery grafts. Lastly, there was considerable cross-over to surgery in those assigned to OMT (up to 41% by 10 years).

GRADE-Informed Framework

The HERC develops recommendations by using the concepts of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. GRADE is a transparent and structured process for developing and presenting evidence and for carrying out the steps involved in developing recommendations. There are four elements that determine the strength of a recommendation, as listed in the table below. The HERC reviews the evidence and makes an assessment of each element, which in turn is used to develop the recommendations presented in the coverage guidance box. Balance between desirable and undesirable effects, and quality of evidence, are derived from the evidence presented in this document, while estimated relative costs, values and preferences are assessments of the HERC members.

Indication/ Intervention	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Variability in values and preferences	Coverage recommendation	Rationale
PCI vs. OMT (patients with non-acute coronary heart disease)	No difference in mortality, MI, MACE	Low based on multiple conflicting SRs*	Moderate	LOW most patients would not want a semi-invasive intervention without some assurance of proven significant benefit	Do not recommend for coverage *(strong recommendation)* based on mortality, MI, MACE	PCI is not recommended for coverage for improvement in MACE or mortality given the lack of evidence of benefit for these outcomes.
	Possible short-term improvement in physical functioning, QOL, angina	Very low based on 1 RCT[#]			*Recommended for coverage with failure of optimal medical therapy for the purposes of symptomatic improvement (weak recommendation).*	While the evidence is weak, it would be appropriate to cover this for symptomatic relief if optimal medical therapy has been tried and is ineffective at

Indication/ Intervention	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Variability in values and preferences	Coverage recommendation	Rationale
						controlling symptoms, and coronary anatomy is appropriate.
~~PCI (patients with recent MI) vs. OMT~~	~~Possible improvement in mortality~~	~~Very Low, based on 2 RCTs#~~	~~Moderate~~	~~LOW~~	~~Recommended for coverage *(weak recommendation)*~~	~~While the evidence is weak, improvement in mortality is a key outcome. This group however, is not with stable CHD but in a different class.~~
PCI (women) vs. OMT	Improvement in composite (death, MI, repeat revascularization)	Moderate based on 1 SR*	Moderate	LOW Most women would choose this based on moderate strength of evidence and important benefits	Recommended for coverage *(strong recommendation)*	Moderate quality evidence suggests improvement in multiple outcomes. Many women would choose this because of proven benefit. This is recommended for coverage.
CABG vs. OMT	Short-term worse mortality, long-term benefit in mortality (possibly limited to multivessel or left main stem disease)	Low based on multiple SRs*	High	MODERATE Long term benefit is appealing but this is a major cardiac surgery and	Recommended for coverage in those with multivessel or left mainstem disease *(strong recommendation)*	There is low quality evidence but with significant improvements in long-term mortality. ~~Additional anatomic~~

Indication/ Intervention	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Variability in values and preferences	Coverage recommendation	Rationale
				increased short-term mortality is concerning		~~lesions were identified through the review of additional sources and added to the box language.~~ CABG is recommended for coverage for those who have failed optimal medical therapy and for those with stable CHD but with appropriate anatomy, regardless of failure of OMT.

*The Quality of Evidence rating was assigned by the primary evidence source, not the HERC Subcommittee

Note: GRADE framework elements are described in Appendix A

POLICY LANDSCAPE

Quality measures

Nine potentially relevant quality measures were identified when searching the National Quality Measures Clearinghouse. Six were measures developed by the Agency for Healthcare Research and Quality, and three were developed by the Canadian Institute for Health Information. Seven of the measures quantified utilization of either PCI or CABG (area rate, volume), while there was one measure for each PCI and CABG documenting the mortality rate associated with the procedure.

Professional society guidelines

The 2012 ACC/AHA/AATS/PCNA/SCAI/STS Guideline for the Diagnosis and Management of Patients With Stable Ischemic Heart Disease addresses diagnosis, risk assessment, treatment and follow up of patients with known or suspected SIHD. While the guideline developers have been meticulous in maintaining and documenting editorial independence, the guideline overall receives a poor rating, primarily because study selection criteria are not specified, and no assessment of study quality is taken into account when developing recommendations.

Treatment is the section of the guideline that pertains to this coverage guidance document. Selected background and recommendations that are pertinent to stable disease from this section are presented below.

Factors That Should Not Influence Treatment Decisions

-The 2 medical indications for revascularization are to prevent death and cardiovascular complications and to improve symptoms and quality of life. Nonetheless, the use of revascularization has risen dramatically in the past 3 decades. Much of this increase appears to be for indications for which benefits in survival or symptoms in comparison with noninvasive therapies are unlikely. National data suggest that about 12% of PCIs could be inappropriate because they lack evident potential to improve either survival or symptoms. Several reasons influence patients and physicians to prefer revascularization when the likelihood of benefit is less than the potential risk of the procedure. An ingrained preference for action (i.e., revascularization) over perceived inaction (i.e., medical therapy alone) likely often influences the decision making of both patients and physicians. Moreover, some healthcare professionals are unduly pessimistic about survival with conservative medical therapy and inaccurately optimistic about the survival benefits of revascularization procedures. As indicated earlier, patients often believe mistakenly that PCI has the potential to prevent AMI and prolong survival. In addition, the attendant expense and risk of combined antiplatelet therapy for an uncertain period of time might not be fully considered. Physicians are professionally obligated to provide accurate estimates of the risks, benefits, and costs of various therapeutic options that are based on the best available scientific data. Other factors can induce physicians to recommend revascularization. These include medicolegal concerns (often exaggerated) and feeling compelled to satisfy the expectations of patients and referring physicians

(which are sometimes misinformed or unrealistic). Additionally, there are well-documented regional variations in the use and appropriateness of cardiac procedures that appear to reflect local practice styles. This might partly reflect a mistaken belief by some physicians that “more care is better care”.

Although successful procedures can be psychologically satisfying to the physician and the patient, this does not justify the attendant economic costs and risk of complications of procedures that offer minimal, if any, genuine benefit. Although rarely discussed explicitly, financial incentives seem to affect the willingness of a minority of physicians and institutions to recommend certain procedures or drug therapies. Strong incentives created by the payment system encourage overutilization. Also, a small number of physicians might have financial relationships with the manufacturers of devices or drugs that might represent apparent conflicts that ought to be disclosed to patients. At a higher level, those responsible for the payment system, the manufacturers of devices and drugs, and physicians making clinical decisions must commit to supporting guideline based interventions. Any and all conflicts of interest must be revealed to patients in the process of informed consent before any invasive or noninvasive procedure.

Revascularization to Improve Survival: Recommendations

Left Main CAD Revascularization

CLASS I Recommendations

1. CABG to improve survival is recommended for patients with significant (≥50% diameter stenosis) left main coronary artery stenosis. (Level of Evidence: B)

CLASS IIa Recommendations

1. PCI to improve survival is reasonable as an alternative to CABG in selected stable patients with significant (≥50% diameter stenosis) unprotected left main CAD with: 1) anatomic conditions associated with a low risk of PCI procedural complications and a high likelihood of good long-term outcome (e.g., a low SYNTAX score [≤22], ostial or trunk left main CAD); and 2) clinical characteristics that predict a significantly increased risk of adverse surgical outcomes (e.g., STS-predicted risk of operative mortality ≥5%). (Level of Evidence: B)

CLASS IIb Recommendations

1. PCI to improve survival may be reasonable as an alternative to CABG in selected stable patients with significant (≥50% diameter stenosis) unprotected left main CAD with: a) anatomic conditions associated with a low to intermediate risk of PCI procedural complications and an intermediate to high likelihood of good long-term outcome (e.g., low–intermediate SYNTAX score of <33, bifurcation left main CAD); and b) clinical characteristics that predict an increased risk of adverse surgical outcomes (e.g., moderate–severe chronic obstructive pulmonary disease, disability from previous stroke,

or previous cardiac surgery; STS-predicted risk of operative mortality >2%). (Level of Evidence: B)

CLASS III Recommendations: Harm

1. PCI to improve survival should not be performed in stable patients with significant (≥50% diameter stenosis) unprotected left main CAD who have unfavorable anatomy for PCI and who are good candidates for CABG. (Level of Evidence: B)

Non–Left Main CAD Revascularization

CLASS I Recommendations

1. CABG to improve survival is beneficial in patients with significant (≥70% diameter) stenoses in 3 major coronary arteries (with or without involvement of the proximal LAD artery) or in the proximal LAD artery plus 1 other major coronary artery. (Level of Evidence: B)

2. CABG or PCI to improve survival is beneficial in survivors of sudden cardiac death with presumed ischemia-mediated ventricular tachycardia caused by significant (≥70% diameter) stenosis in a major coronary artery. (CABG Level of Evidence: B ; PCI Level of Evidence: C)

CLASS IIa Recommendations

1. CABG to improve survival is reasonable in patients with significant (≥70% diameter) stenoses in 2 major coronary arteries with severe or extensive myocardial ischemia (e.g., high-risk criteria on stress testing, abnormal intracoronary hemodynamic evaluation, or >20% perfusion defect by myocardial perfusion stress imaging) or target vessels supplying a large area of viable myocardium. (Level of Evidence: B)

2. CABG to improve survival is reasonable in patients with mild–moderate LV systolic dysfunction (EF 35% to 50%) and significant (≥70% diameter stenosis) multi-vessel CAD or proximal LAD coronary artery stenosis, when viable myocardium is present in the region of intended revascularization. (Level of Evidence: B)

3. CABG with a left internal mammary artery (LIMA) graft to improve survival is reasonable in patients with significant (≥70% diameter) stenosis in the proximal LAD artery and evidence of extensive ischemia. (Level of Evidence: B)

4. It is reasonable to choose CABG over PCI to improve survival in patients with complex 3-vessel CAD (e.g., SYNTAX score >22), with or without involvement of the proximal LAD artery who are good candidates for CABG. (Level of Evidence: B)

5. CABG is probably recommended in preference to PCI to improve survival in patients with multivessel CAD and diabetes mellitus, particularly if a LIMA graft can be anastomosed to the LAD artery. (Level of Evidence: B)

CLASS IIb Recommendations

1. The usefulness of CABG to improve survival is uncertain in patients with significant (70%) diameter stenoses in 2 major coronary arteries not involving the proximal LAD artery and without extensive ischemia. (Level of Evidence: C)

2. The usefulness of PCI to improve survival is uncertain in patients with 2- or 3-vessel CAD (with or without involvement of the proximal LAD artery) or 1-vessel proximal LAD disease. (Level of Evidence: B)

3. CABG might be considered with the primary or sole intent of improving survival in patients with SIHD with severe LV systolic dysfunction (EF<35%) whether or not viable myocardium is present. (Level of Evidence: B)

4. The usefulness of CABG or PCI to improve survival is uncertain in patients with previous CABG and extensive anterior wall ischemia on noninvasive testing. (Level of Evidence: B)

CLASS III Recommendations: Harm

1. CABG or PCI should not be performed with the primary or sole intent to improve survival in patients with SIHD with 1 or more coronary stenoses that are not anatomically or functionally significant (e.g., <70% diameter non–left main coronary artery stenosis, FFR >0.80, no or only mild ischemia on noninvasive testing), involve only the left circumflex or right coronary artery, or subtend only a small area of viable myocardium. (Level of Evidence: B)

Revascularization to improve symptoms

CLASS I Recommendations

1. CABG or PCI to improve symptoms is beneficial in patients with 1 or more significant (≥70% diameter) coronary artery stenoses amenable to revascularization and unacceptable angina despite guideline directed medical therapy (GDMT). (Level of Evidence: A)

CLASS IIa Recommendations

1. CABG or PCI to improve symptoms is reasonable in patients with 1 or more significant (≥70% diameter) coronary artery stenoses and unacceptable angina for whom GDMT cannot be implemented because of medication contraindications, adverse effects, or patient preferences. (Level of Evidence: C)

2. PCI to improve symptoms is reasonable in patients with previous CABG, 1 or more significant (≥70% diameter) coronary artery stenoses associated with ischemia, and unacceptable angina despite GDMT. (Level of Evidence: C)

3. It is reasonable to choose CABG over PCI to improve symptoms in patients with complex 3-vessel CAD (e.g., SYNTAX score >22), with or without involvement of the proximal LAD artery, who are good candidates for CABG. (Level of Evidence: B)

CLASS IIb Recommendations

1. CABG to improve symptoms might be reasonable for patients with previous CABG, 1 or more significant (≥70% diameter) coronary artery stenoses not amenable to PCI, and unacceptable angina despite GDMT. (Level of Evidence: C)

2. Transmyocardial revascularization (TMR) performed as an adjunct to CABG to improve symptoms may be reasonable in patients with viable ischemic myocardium that is perfused by arteries that are not amenable to grafting. (Level of Evidence: B)

CLASS III Recommendations: Harm

1. CABG or PCI to improve symptoms should not be performed in patients who do not meet anatomic (≥50% diameter left main or ≥70% non–left main stenosis diameter) or physiological (e.g., abnormal FFR) criteria for revascularization. (Level of Evidence: C)

The 2014 ACC/AHA/AATS/PCNA/SCAI/STS Focused Update of the Guideline for the Diagnosis and Management of Patients With Stable Ischemic Heart Disease updates the 2012 guideline described above. The areas addressed, where new evidence was found or recommendations were revised, were there following:

- Diagnosis of SIHD
- Treatment: Chelation therapy
- Treatment: Enhanced external counterpulsation
- CAD Revascularization: Revascularization to improve survival

Only the last area pertains to this guidance document, and will be discussed further. The 2012 recommendation was as follows:

Class IIa

CABG is probably recommended in preference to PCI to improve survival in patients with multivessel CAD and diabetes mellitus, particularly if a LIMA graft can be anastomosed to the left anterior descending (LAD) artery. (Level of Evidence: B)

The 2014 focused update makes the following new recommendation:

Class I

1. A Heart Team approach to revascularization is recommended in patients with diabetes mellitus and complex multivessel CAD. (Level of Evidence: C)

2. CABG is generally recommended in preference to PCI to improve survival in patients with diabetes mellitus and multivessel CAD for which revascularization is likely to improve survival (3-vessel CAD or complex 2-vessel CAD involving the proximal LAD), particularly if a LIMA graft can be anastomosed to the LAD artery, provided the patient is a good candidate for surgery. (Level of Evidence: B)

APPENDIX A. GRADE ELEMENT DESCRIPTIONS

Element	Description
Balance between desirable and undesirable effects	The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. The narrower the gradient, the higher the likelihood that a weak recommendation is warranted
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—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

Strong recommendation

In Favor: The subcommittee is confident that the desirable effects of adherence to a recommendation outweigh the undesirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences.

Against: The subcommittee is confident that the undesirable effects of adherence to a recommendation outweigh the desirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences.

Weak recommendation

In Favor: The subcommittee concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences, but is not confident.

Against: The subcommittee concludes that the undesirable effects of adherence to a recommendation probably outweigh the desirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences, but is not confident.

Quality or strength of evidence rating across studies for the treatment/outcome[2]

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 effect estimate: 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 effect estimate 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.

[2] Includes risk of bias, precision, directness, consistency and publication bias

***Very low*:** The subcommittee has very little confidence in the effect estimate: 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.

APPENDIX B. APPLICABLE CODES

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
413.0	Angina decubitus
413.1	Prinzmetal angina
413.9	Other and unspecified angina pectoris
414.0	Coronary atherosclerosis
414.2	Chronic total occlusion of coronary artery
414.8-9	Other specified and unspecified forms of chronic ischemic heart disease
ICD-10 Diagnosis Codes	
I20.1	Angina pectoris with documented spasm
I20.8	Other forms of angina pectoris
I20.9	Angina pectoris, unspecified
I20.10	Atherosclerotic heart disease of native coronary artery without angina pectoris
I25.82	Chronic total occlusion of coronary artery
I25.89	Other forms of chronic ischemic heart disease
I25.9	Chronic ischemic heart disease, unspecified
ICD-9 Volume 3 (Procedure Codes)	
36.0	Removal of coronary obstruction and insertion of stent(s)
36.1	Bypass anastomosis for heart revascularization
CPT Codes	
33510-33516	Coronary artery bypass – venous grafting only
33517-33530	Combined arterial-venous grafting for coronary bypass
33533-33548	Arterial grafting for coronary artery bypass
92920-92944	Percutaneous revascularization procedures
HCPCS Level II Codes	
	None

Note: Inclusion on this list does not guarantee coverage

APPENDIX C. HERC GUIDANCE DEVELOPMENT FRAMEWORK

HERC Guidance Development Framework Principles

This framework was developed to assist with the decision making process for the Oregon policy-making body, the HERC and its subcommittees. It is a general guide, and must be used in the context of clinical judgment. It is not possible to include all possible scenarios and factors that may influence a policy decision in a graphic format. While this framework provides a general structure, factors that may influence decisions that are not captured on the framework include but are not limited to the following:

- Estimate of the level of risk associated with the treatment, or any alternatives;
- Which alternatives the treatment should most appropriately be compared to;
- Whether there is a discrete and clear diagnosis;
- The definition of clinical significance for a particular treatment, and the expected margin of benefit compared to alternatives;
- The relative balance of benefit compared to harm;
- The degree of benefit compared to cost; e.g., if the benefit is small and the cost is large, the committee may make a decision different than the algorithm suggests;
- Specific indications and contraindications that may determine appropriateness;
- Expected values and preferences of patients.

PCI (NON-ACUTE CHD) vs. OMT – BASED ON MORTALITY, MI, MACE

Oregon Health Authority

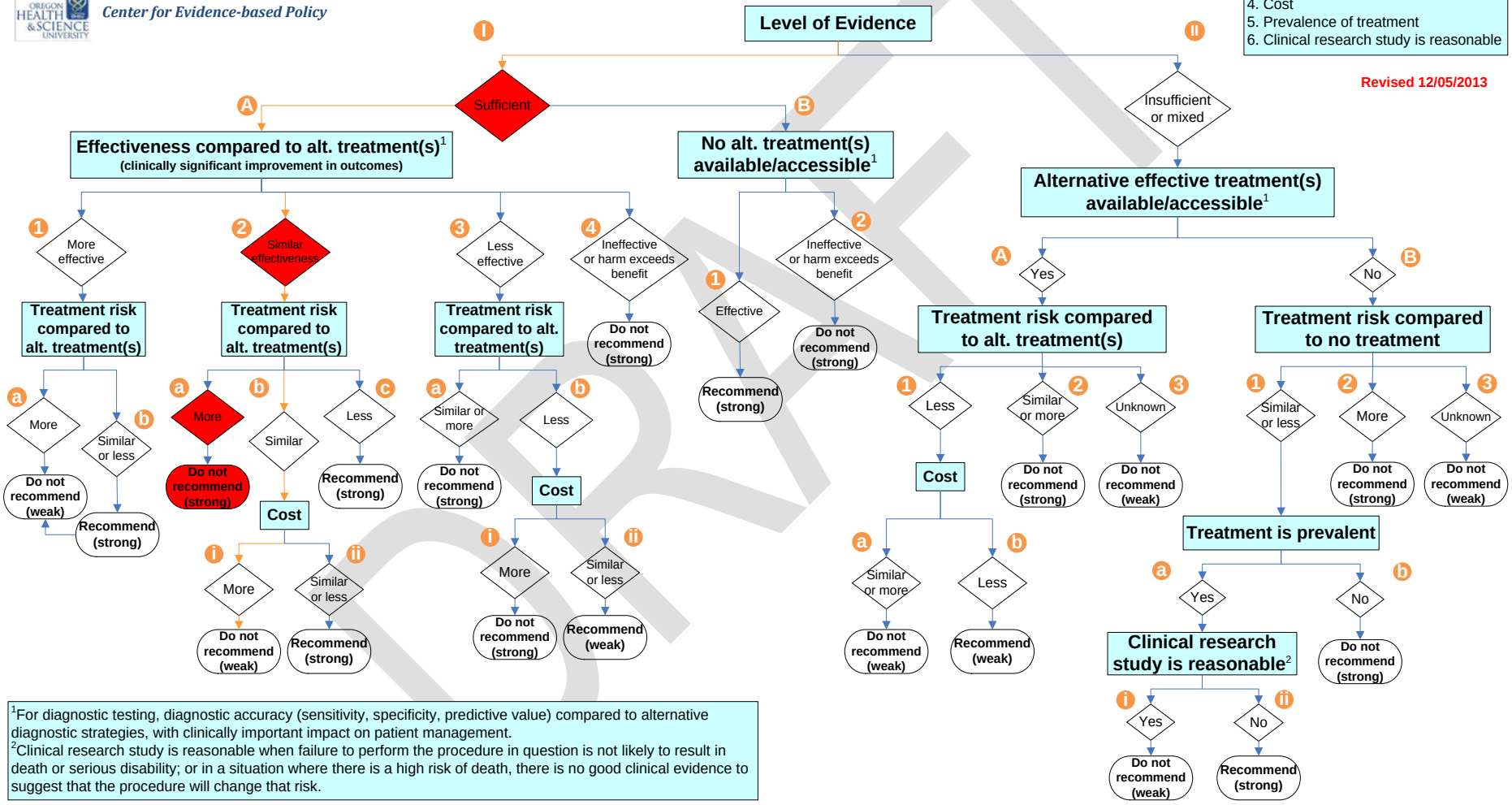
Center for Evidence-based Policy

HERC Guidance Development Framework

Refer to *HERC Guidance Development Framework Principles* for additional considerations

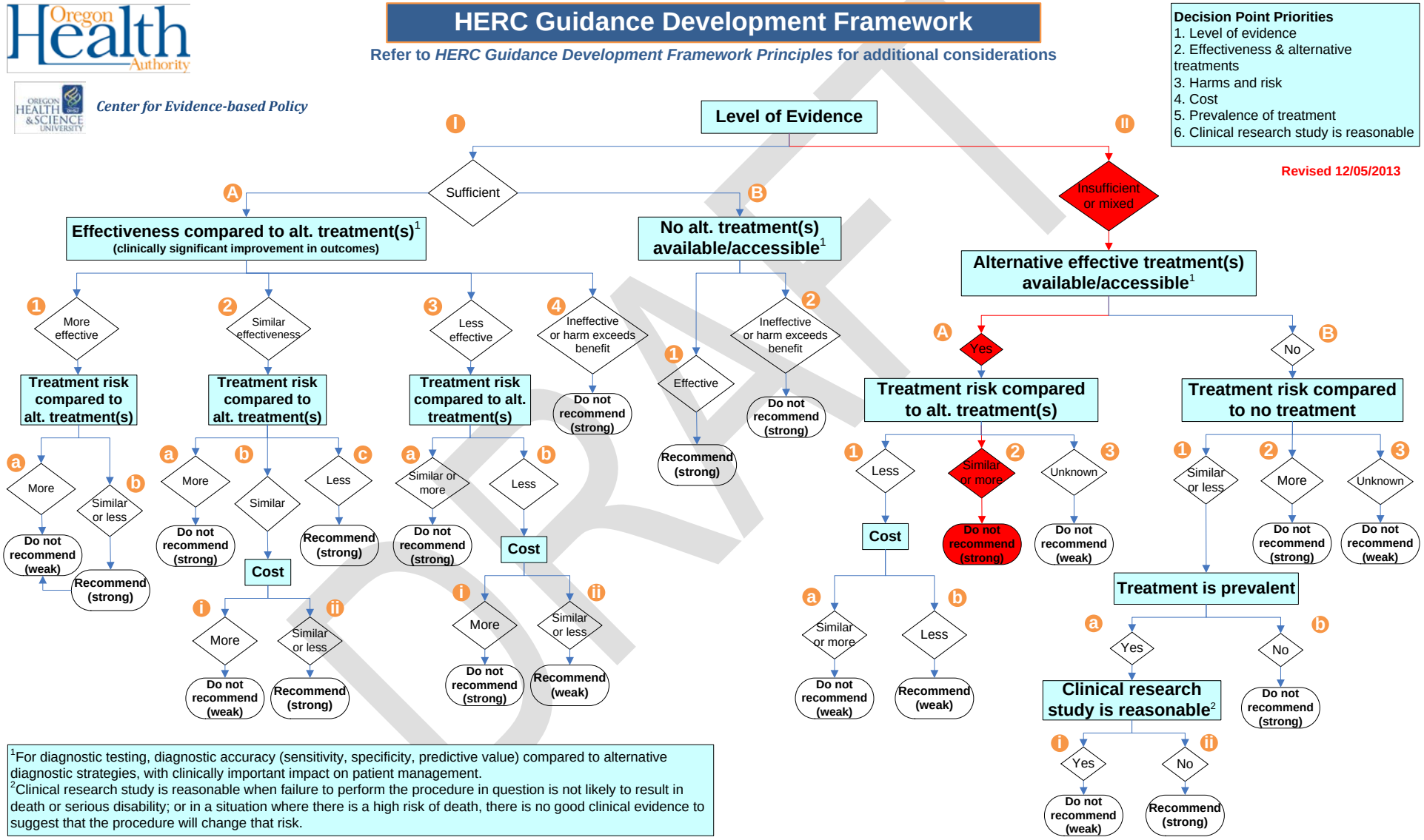
Decision Point Priorities
1. Level of evidence
2. Effectiveness & alternative treatments
3. Harms and risk
4. Cost
5. Prevalence of treatment
6. Clinical research study is reasonable

Revised 12/05/2013



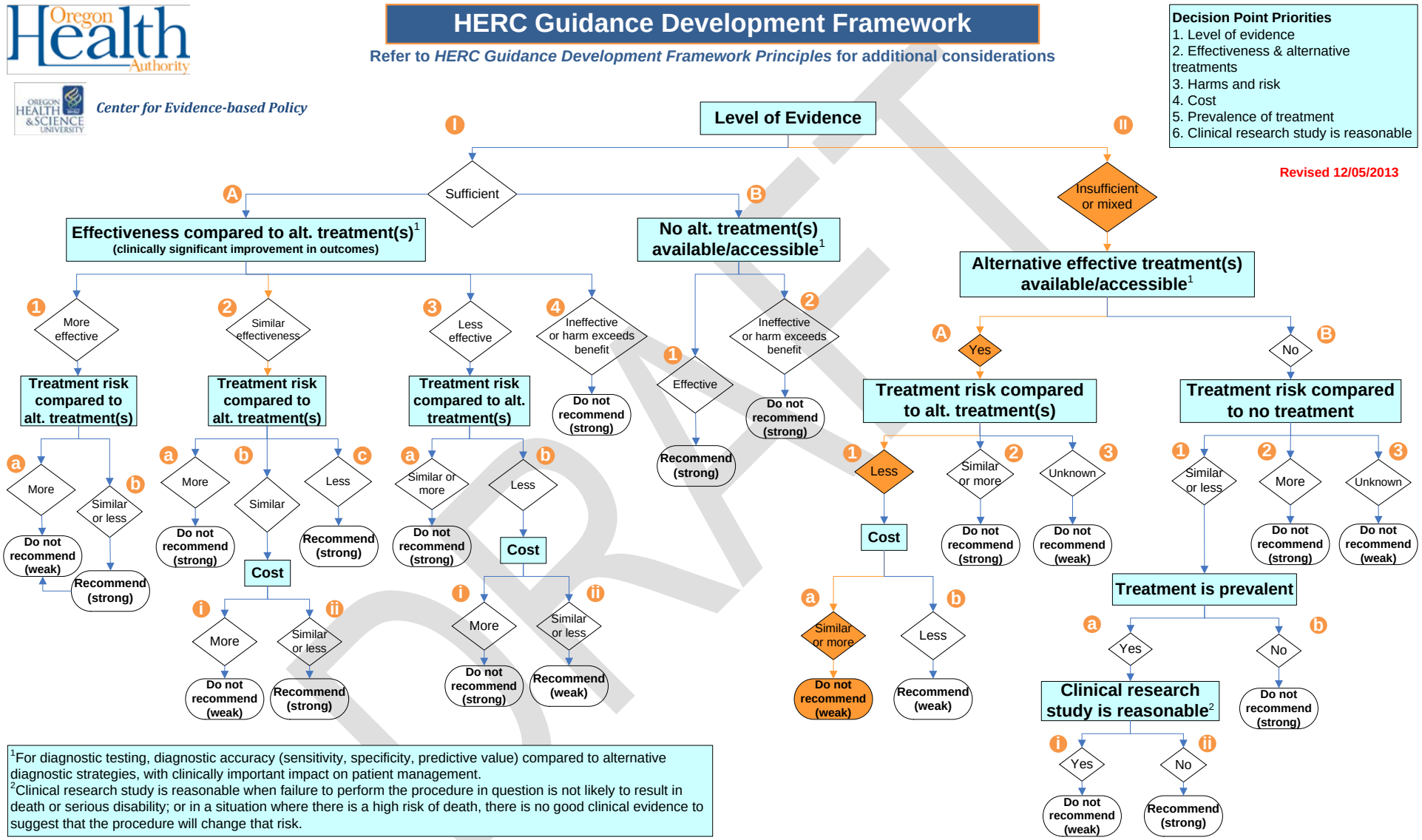
[1]For diagnostic testing, diagnostic accuracy (sensitivity, specificity, predictive value) compared to alternative diagnostic strategies, with clinically important impact on patient management.
[2]Clinical research study is reasonable when failure to perform the procedure in question is not likely to result in death or serious disability; or in a situation where there is a high risk of death, there is no good clinical evidence to suggest that the procedure will change that risk.

PCI (NON-ACUTE CHD) vs. OMT – BASED ON QUALITY OF LIFE



[1]For diagnostic testing, diagnostic accuracy (sensitivity, specificity, predictive value) compared to alternative diagnostic strategies, with clinically important impact on patient management.
[2]Clinical research study is reasonable when failure to perform the procedure in question is not likely to result in death or serious disability; or in a situation where there is a high risk of death, there is no good clinical evidence to suggest that the procedure will change that risk.

PCI (PATIENTS WITH RECENT MI) vs. OMT



[1]For diagnostic testing, diagnostic accuracy (sensitivity, specificity, predictive value) compared to alternative diagnostic strategies, with clinically important impact on patient management.
[2]Clinical research study is reasonable when failure to perform the procedure in question is not likely to result in death or serious disability; or in a situation where there is a high risk of death, there is no good clinical evidence to suggest that the procedure will change that risk.

PCI (PATIENTS > 75) vs. OMT

Oregon Health Authority

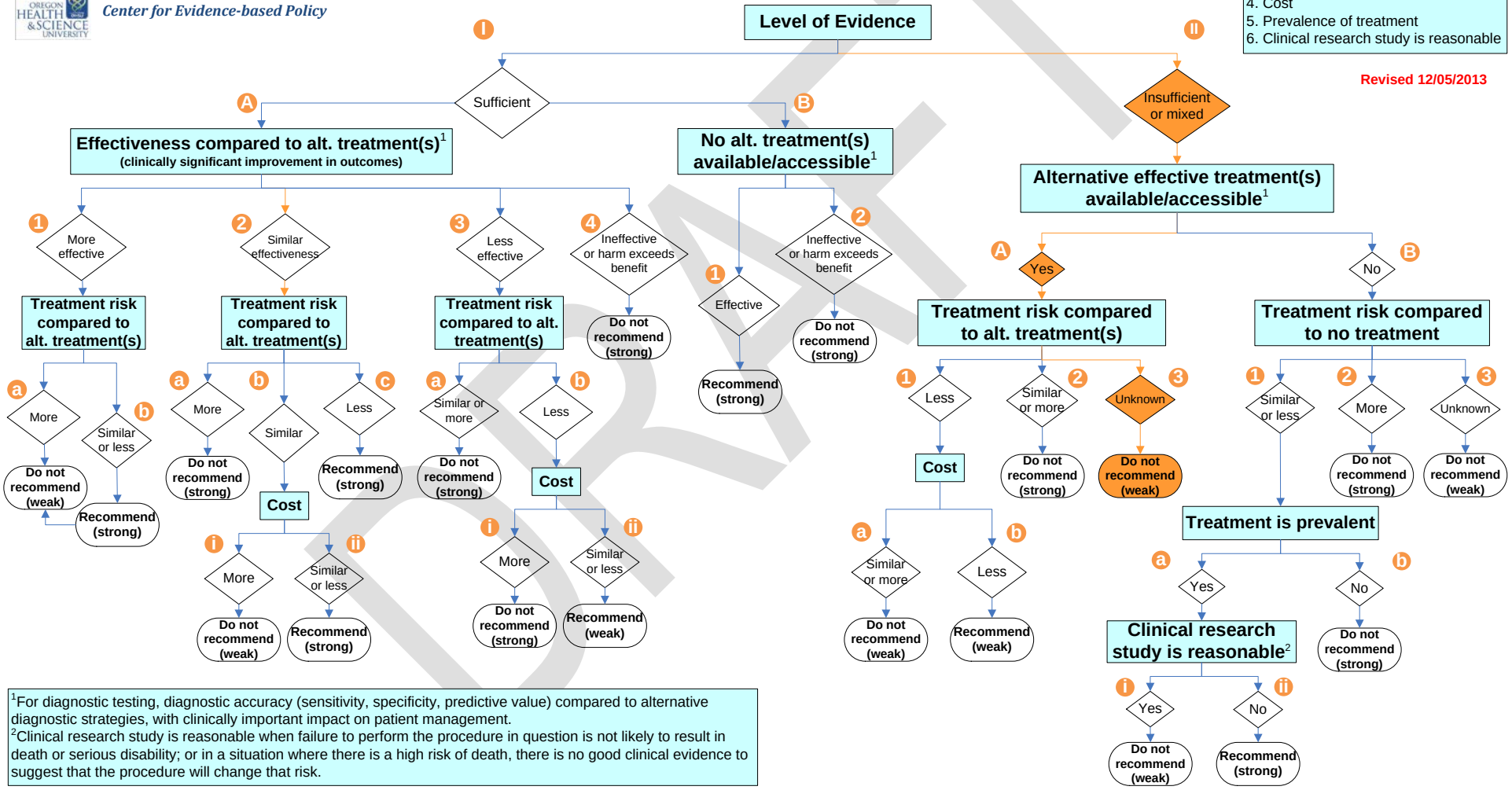
Oregon Health & Science University — *Center for Evidence-based Policy*

HERC Guidance Development Framework

Refer to *HERC Guidance Development Framework Principles* for additional considerations

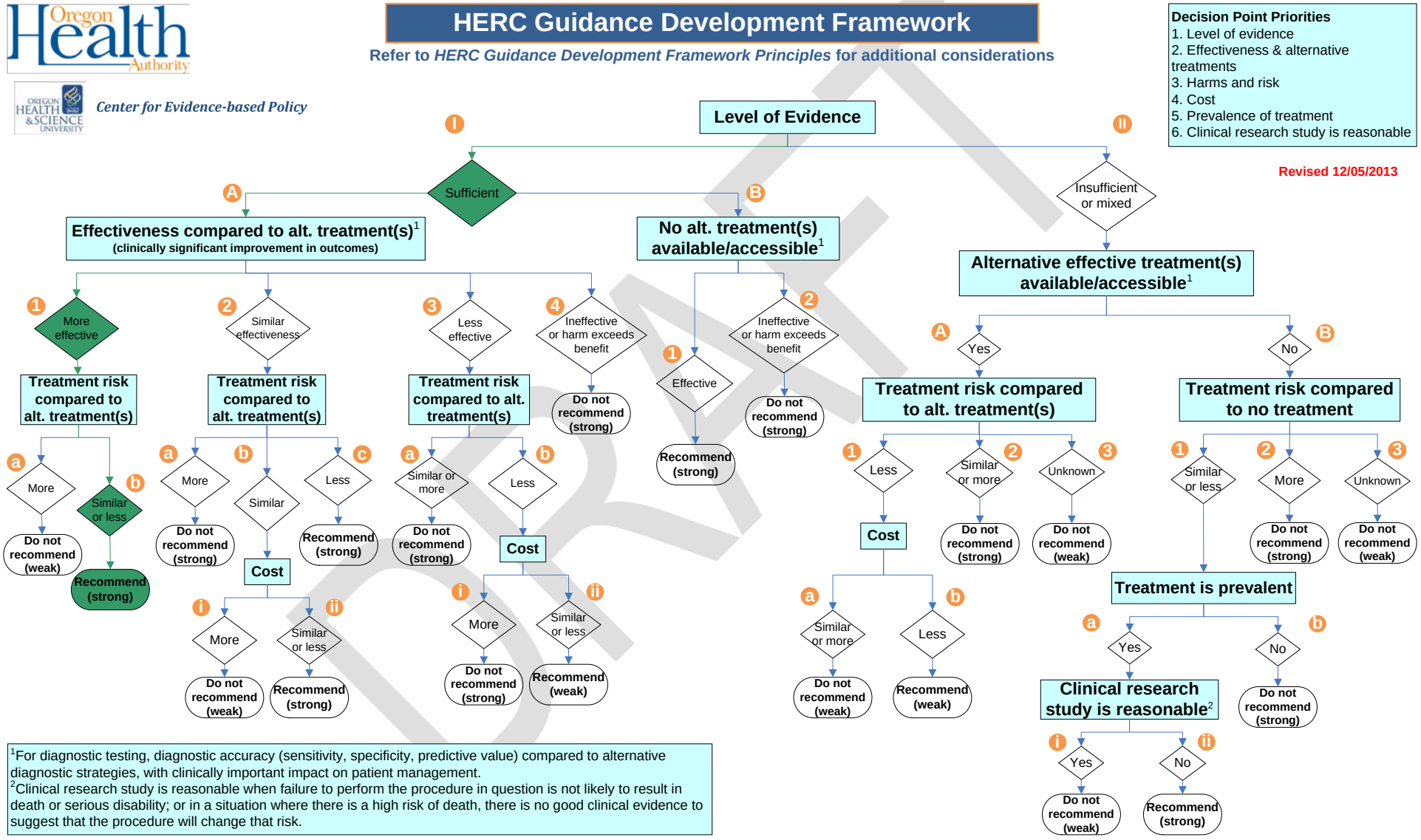
Decision Point Priorities
1. Level of evidence
2. Effectiveness & alternative treatments
3. Harms and risk
4. Cost
5. Prevalence of treatment
6. Clinical research study is reasonable

Revised 12/05/2013



[1]For diagnostic testing, diagnostic accuracy (sensitivity, specificity, predictive value) compared to alternative diagnostic strategies, with clinically important impact on patient management.
[2]Clinical research study is reasonable when failure to perform the procedure in question is not likely to result in death or serious disability; or in a situation where there is a high risk of death, there is no good clinical evidence to suggest that the procedure will change that risk.

PCI (WOMEN) vs. OMT; CABG vs. OMT



[1]For diagnostic testing, diagnostic accuracy (sensitivity, specificity, predictive value) compared to alternative diagnostic strategies, with clinically important impact on patient management.
[2]Clinical research study is reasonable when failure to perform the procedure in question is not likely to result in death or serious disability; or in a situation where there is a high risk of death, there is no good clinical evidence to suggest that the procedure will change that risk.

Section 4.0

Home birth

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE: PLANNED ~~HOME~~ OUT-OF-HOSPITAL BIRTH

DRAFT for 2/5/2015 EbGS meeting materials

HERC Coverage Guidance

Planned out-of-hospital birth for low-risk pregnancies is recommended for coverage when appropriate risk assessment is performed, and consultation and transfer criteria are conducted (weak recommendation). Low risk criteria, high-risk conditions requiring planned hospital delivery, conditions requiring consultation and emergent conditions requiring intrapartum transfer of care are defined per this coverage guidance.

Low-risk patients who are appropriate for planned out-of-hospital birth include those who meet minimum low-risk criteria and who do not develop a high-risk condition requiring planned hospital delivery at the time of delivery (weak recommendation).

Planned out-of-hospital birth is not recommended for coverage in patients who do not meet low risk criteria or who are not managed according to the consultation/transfer criteria (strong recommendation).

Risk assessment should be done initially when planning the location of birth and monitored throughout pregnancy, labor, and delivery to determine if out-of-hospital birth is still appropriate (weak recommendation).

Informed consent of the benefits and risks of-out-hospital birth risks of transfer and delays in emergency care is required (strong recommendation).

Low risk criteria

- Gestational age ≥ 36 and ≤ 41 completed weeks of pregnancy (37 weeks + 0 days thru 41 weeks + 6 days)
- Singleton
- Vertex position
- No prior cesarean section or other hysterotomy

High risk conditions indicating planned hospital birth

High risk conditions indicating planned hospital birth include (but are not limited to) patients with:

Complications in a previous pregnancy

- Unexplained stillbirth/neonatal death or previous death related to intrapartum difficulty
- Previous baby with neonatal encephalopathy
- HELLP syndrome
- Placental abruption with adverse outcome
- Pre-eclampsia requiring preterm birth

- Eclampsia
- Uterine rupture
- Postpartum hemorrhage requiring additional pharmacologic treatment or blood transfusion
- Retained placenta requiring manual and/or surgical removal
- Shoulder dystocia with or without fetal clavicular fracture
- Fourth-degree laceration without satisfactory functional recovery

Complications of current pregnancy

- Low lying placenta within 2 cm or less of cervical os at term; placenta previa, vasa previa
- Eclampsia or pre-eclampsia
- Placental abruption/abnormal bleeding
- Anemia – hemoglobin less than 8.5 g/dl
- Induction of labor
- Substance misuse
- Alcohol dependency requiring assessment or treatment
- Body mass index at first prenatal visit of greater than 35 kg/m2
- Recurrent antepartum hemorrhage
- Small for gestational age fetus (less than fifth percentile using ethnically-appropriate growth tables, or reduced growth velocity on ultrasound)
- Abnormal fetal heart rate/Doppler/surveillance studies
- Oligo or polyhydramnios
- Blood group incompatibility with atypical antibodies (including Rh sensitization)
- Prelabor rupture of membranes > 24 hours
- Life-threatening congenital anomalies
- Inadequate prenatal care (defined as less than five prenatal visits or care began in the third trimester)
- Current active infection of varicella/rubella/genital herpes in the woman or baby
- Refractory hyperemesis gravidarum
- Thrombosis/thromboembolism/ thrombocytopenia (platelets <100,000), or other maternal bleeding disorder
- Uteroplacental insufficiency
- Molar pregnancy
- Maternal mental illness requiring inpatient care
- Diabetes, type I or II, uncontrolled gestational diabetes, or gestational diabetes controlled with medication
- Maternal seizure disorder requiring medication

High risk conditions necessitating consultation

Certain high risk conditions require consultation by a provider of maternity care who is credentialed to admit and manage pregnancies in a hospital. Written documentation is required in the patient record. These complications include (but are not limited to) patients with:

Complications in a previous pregnancy

- More than three first trimester spontaneous abortions, or more than one second

trimester spontaneous abortion
- Blood group incompatibility
- Pre-eclampsia in previous pregnancy, not requiring preterm birth
- History of more than one preterm birth, or preterm birth less than 34 weeks 0 days in most recent pregnancy
- Cervical insufficiency/prior cerclage
- Intrauterine growth restriction
- Fourth-degree laceration with satisfactory functional recovery
- Third-degree laceration
- Perinatal death
- Prior child with congenital and/or hereditary disorder
- Prior baby > 4.5 kg
- History of unexplained stillbirth/neonatal death or previous death unrelated to intrapartum difficulty

Complications of current pregnancy

- Fetal macrosomia (estimated weight >4.5 kg or 9 lbs 14 oz)
- Maternal hypertension, either preexisting or pregnancy-induced
- Family history of genetic/heritable disorders
- Laparotomy during pregnancy
- Cervical dysplasia requiring evaluation
- Gestational diabetes, diet-controlled
- Maternal age < 14 years or > 35 years
- Maternal recreational drug use (occasional use of alcohol or marijuana)
- Maternal mental illness under outpatient psychiatric care
- Maternal anemia with hemoglobin < 10.5
- Confirmed intrauterine death
- History of maternal seizure disorder (excluding eclampsia), not requiring medication

High-risk conditions requiring transfer

If out-of-hospital birth is planned, certain intrapartum and postpartum complications require transfer to a hospital. 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. Indications requiring transfer are:

- Repetitive or persistent abnormal fetal heart rate pattern
- Thick meconium staining of amniotic fluid ~~without reassuring heart tones~~
- Raised diastolic blood pressure over 90 mmHg or raised systolic blood pressure over 140 mmHg on two consecutive readings taken 30 minutes apart.
- Chorioamnionitis or other serious infection (including toxoplasmosis, rubella, CMV, HIV, etc.)
- Failure to progress/failure of head to engage in active labor
- Prolapsed umbilical cord
- Uterine rupture, inversion or prolapse
- Hemorrhage (hypovolemia, shock, need for transfusion)
- Retained placenta > 3 hours
- Laceration requiring hospital repair (e.g., extensive vaginal, cervical or third- or fourth-

degree trauma)
- Enlarging hematoma
- Infection (endometritis, UTI, wound, breast)
- Thrombophlebitis/thromboembolism
- Bladder or rectal dysfunction

If infant is delivered out-of-hospital, the following complications require transfer to a hospital:
- Low Apgar score (< 5 at 5 minutes, < 7 at 10 minutes)
- Temperature instability, fever, suspected infection or dehydration
- Hypotonia, tremors, seizures, hyperirritability
- Respiratory or cardiac irregularities, cyanosis, pallor
- Weight less than 5th percentile for age
- Unexpected significant or life-threatening congenital anomalies
- Excessive bruising, enlarging cephalohematoma, significant birth trauma
- Hyperglycemia/hypoglycemia unresponsive to treatment
- Vomiting/diarrhea

Good outcomes for planned out-of-hospital birth have been demonstrated in several countries. However, these settings have system characteristics that help to maximize safety. Chief among these is a robust system of consultation and referral/transfer that can assure seamless care for the woman and her newborn when transfer is needed. In addition, these systems include thorough education (informed consent) of women and families about the potential need for consultation/referral/transfer and the potential risks associated with having a delay to receipt of emergency obstetric and neonatal care. Another characteristic is written agreements that cover consultation/referral/transfer and a well-defined and practiced system of transfer. Out-of-hospital birth attendants in these systems are appropriately trained and experienced in the identification and management of obstetric and neonatal emergencies, and are also licensed and certified. These providers should be capable of initiating appropriate newborn resuscitation, and be able to provide standard newborn care in addition to the routine postpartum care of women. Certification requirements for the practice of midwifery vary significantly between the US and other countries, with US requirements generally being less rigorous with regard to both years of formal education and experience.

~~**Planned home births for low-risk pregnancies are recommended for coverage *(weak recommendation).***~~
~~To be considered low-risk, pregnancies must meet all of the following characteristics :~~
- ~~Gestational age ≥ 36 weeks and ≤41 completed weeks of pregnancy~~
- ~~Singleton~~
- ~~Vertex position~~
- ~~Absence of preexisting or pregnancy-related maternal disease~~

~~**High risk conditions necessitating consultation or transfer include (but are not limited to) patients with:**~~
~~Complications in a previous pregnancy~~
- ~~Unexplained stillbirth/neonatal death or previous death related to intrapartum difficulty~~
- ~~Previous baby with neonatal encephalopathy~~
- ~~Pre-eclampsia/ HELLP syndrome~~

- ~~Placental abruption with adverse outcome~~
- ~~Eclampsia~~
- ~~Uterine rupture~~
- ~~Postpartum hemorrhage requiring additional treatment or blood transfusion~~
- ~~Retained placenta requiring manual removal~~
- ~~Shoulder dystocia~~
- ~~Cesarean section~~
- ~~Blood group incompatibility~~
- ~~Fetal growth retardation~~
- ~~Preterm birth~~
- ~~Cervical insufficiency/ prior cerclage~~
- ~~Fourth degree laceration~~
- ~~More than three first trimester spontaneous abortions, or more than one second trimester spontaneous abortion~~

~~Complications of current pregnancy~~

- ~~Placenta previa, vasa previa, low lying placenta~~
- ~~Eclampsia, pre-eclampsia or pregnancy-induced hypertension, hypertension (before or after delivery)~~
- ~~Preterm labor or preterm prelabor rupture of membranes~~
- ~~Placental abruption/ abnormal bleeding~~
- ~~Anemia – hemoglobin less than 8.5 g/dl~~
- ~~Confirmed intrauterine death~~
- ~~Induction of labor~~
- ~~Substance misuse~~
- ~~Alcohol dependency requiring assessment or treatment~~
- ~~Body mass index at first prenatal visit of greater than 35 kg/m2~~
- ~~Recurrent antepartum hemorrhage~~
- ~~Small for gestational age fetus~~
- ~~Abnormal fetal heart rate/Doppler/surveillance studies~~
- ~~Oligo- or poly-hydramnios~~
- ~~Blood group incompatibility (including Rh sensitization)~~
- ~~Prelabor rupture of membranes > 24 hours~~
- ~~Life-threatening congenital anomalies~~
- ~~No prenatal care~~
- ~~Genital herpes~~
- ~~Chorioamnionitis or other serious infection (including toxoplasmosis, rubella, CMV, HIV, etc.)~~
- ~~Thick meconium staining of amniotic fluid~~
- ~~Failure to progress/ failure of head to engage in active labor~~
- ~~Prolapsed umbilical cord~~
- ~~Laparotomy during pregnancy~~
- ~~Cervical dysplasia requiring evaluation~~
- ~~Hyperemesis gravidarum~~
- ~~Thrombosis/ thromboembolism/ thrombopenia~~
- ~~Uteroplacental insufficiency~~
- ~~Molar pregnancy~~

- ~~Uterine rupture, inversion or prolapse~~
- ~~Family history of genetic/ heritable disorders~~
- ~~Age < 14~~

~~Transfer to a higher level of care is recommended in the following circumstances:~~

~~Post-partum complications - maternal~~

- ~~Hemorrhage (hypovolemia, shock, need for transfusion)~~
- ~~Retained placenta~~
- ~~Laceration requiring hospital repair~~
- ~~Enlarging hematoma~~
- ~~Third or fourth degree, or periuretheral, laceration~~
- ~~Infection (endometritis, UTI, wound, breast)~~
- ~~Thrombophlebitis/ thromboembolism~~
- ~~Bladder or rectal dysfunction~~

~~Post-partum Complications – Infant~~

- ~~Low Apgar score (< 5 at 5 minutes, < 7 at 10 minutes)~~
- ~~Temperature instability, fever, suspected infection or dehydration~~
- ~~Hypotonia, tremors, seizures, hyperirritability~~
- ~~Life-threatening congenital anomalies~~
- ~~Respiratory or cardiac irregularities, cyanosis, pallor~~
- ~~Failure to pass urine or meconium within 24 to 36 hours, depending on organization~~
- ~~Feeding difficulties/ significant weight loss, failure to regain birth weight by 3 weeks, weight less than 5th percentile for age~~
- ~~Congenital anomalies, less than 3 vessels in umbilical cord~~
- ~~Excessive bruising, enlarging cephalohematoma, significant birth trauma~~
- ~~Hyperglycemia/ hypoglycemia unresponsive to treatment~~
- ~~Vomiting/ diarrhea~~
- ~~Jaundice within the first 24 hours~~
- ~~Prematurity~~

~~Planned home births in unselected pregnancies are not recommended for coverage *(strong recommendation).*~~

~~Studies demonstrating positive outcomes including the following system characteristics: Women planning a home birth were informed of the potential need for transfer and the potential risks associated with having a delay to emergency obstetric and neonatal care. There was a well-defined system of transfer. Attendants of home birth were licensed and certified, and appropriately trained in the identification and management of obstetric and neonatal emergencies.~~

Note: Definitions for strength of recommendation are provided in Appendix B GRADE Element Description

RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
- Represents high costs, significant economic impact
- Topic is of high public interest

Coverage guidance development follows to translate the evidence review to a policy decision. Coverage guidance may be based on an evidence-based guideline developed by the Evidence-based Guideline Subcommittee or a health technology assessment developed by the Heath Technology Assessment Subcommittee. In addition, coverage guidance may utilize an existing evidence report produced by one of HERC's trusted sources, generally within the last three years.

EVIDENCE SOURCES

Trusted sources

Olsen, O., & Clausen, J. A. (2012). Planned hospital birth versus planned home birth. *Cochrane Database of Systematic Reviews, 9*. Accessed August 9, 2014, from http://almenpraksis.ku.dk/nyheder/oleolsen/Hjemmef_dsel.pdf

National Institute for Clinical Excellence (2014). *Intrapartum care: care of healthy women and their babies during childbirth. Clinical Guideline ~~55~~190, ~~Draft for consultation,~~ ~~May~~December* 2014*.* Accessed ~~August 12~~December 15, 2014, from https://www.nice.org.uk/guidance/cg190/resources/guidance-intrapartum-care-care-of-healthy-women-and-their-babies-during-childbirth-pdf~~http://www.nice.org.uk/guidance/gid-cgwaver109/resources/intrapartum-care-update-nice-guideline2~~

Additional sources

Cochrane, A. L. (2000). 1931-1971: A critical review, with particular reference to the medical profession. *Medicines for the year*, 1-11.

College of Midwives of British Columbia. (2014). *Indications for discussion, consultation, and transfer of care*. Accessed August 4, 2014, from http://www.cmbc.bc.ca/pdf.shtml?Registrants-Handbook-12-01-Indications-for-Discussion-Consultation-and-Transfer-of-Care

College of Midwives of Ontario (2015). C*onsultation and transfer of care*. Accessed October 1, 2014, from http://www.cmo.on.ca/?page_id=1026

de Jonge, A., van der Goes, B. Y., Ravelli, A. C., Amelink-Verburg, M. P., Mol, B. W., Nijhuis, J. G., et al. (2009). Perinatal mortality and morbidity in a nationwide cohort of 529, 688 low-risk planned home and hospital births. *BJOG: An International Journal of Obstetrics & Gynaecology, 116*(9), 1177-1184.

Dowswell, T., Thornton, J. G., Hewison, J., Lilford, R. J., Raisler, J., MacFarlane, A., et al. (1996). Should there be a trial of home versus hospital delivery in the United Kingdom? *BMJ: British Medical Journal, 312*(7033), 753.

Hendrix, M., Van Horck, M., Moreta, D., Nieman, F., Nieuwenhuijze, M., Severens, J., et al. (2009). Why women do not accept randomisation for place of birth: feasibility of a RCT in the Netherlands. *BJOG: An International Journal of Obstetrics & Gynaecology, 116*(4), 537-544.

Hodnett E.D., Stremler R., Weston J.A., & Mckeever P. Reconceptualizing the hospital labor room: the Place (Pregnant and Laboring in an Ambient Clinical Environment) pilot trial. (2009). *Birth, 36*(2), 159–66.

Hutton, E. K., Reitsma, A. H., & Kaufman, K. (2009). Outcomes associated with planned home and planned hospital births in low-risk women attended by midwives in Ontario, Canada, 2003–2006: a retrospective cohort study. *Birth, 36*(3), 180-189.

Janssen, P. A., Saxell, L., Page, L. A., Klein, M. C., Liston, R. M., & Lee, S. K. (2009). Outcomes of planned home birth with registered midwife versus planned hospital birth with midwife or physician. *Canadian Medical Association Journal, 181*(6-7), 377-383.

Netherlands Ministry of Health, Welfare, and Sport. (n.d). *Final report of the obstetric working group of the national health insurance board of the Netherlands (abridged version)*. The Hauge, NL: Government of the Netherlands. Accessed August 4, 2014, from http://blog.lib.umn.edu/kuli0015/studygroup/Dutch%20OB%20Indications.doc

Oregon Health Authority. (2013). *Oregon birth outcomes by planned birth place and attendant*. Accessed August 1, 2014, from https://public.health.oregon.gov/BirthDeathCertificates/VitalStatistics/birth/Documents/PlannedBirthPlaceandAttendant.pdf

Wax, J. R., Lucas, F. L., Lamont, M., Pinette, M. G., Cartin, A., & Blackstone, J. (2010). Maternal and newborn outcomes in planned home birth vs planned hospital births: a meta-analysis. *American journal of obstetrics and gynecology, 203*(3), 243-e1.

Zeitlin, J., Mohangoo, A., Alexander, S., Barros, H., Blondel, B., Bouvier-Colle, et al. (n.d). *Health and care of pregnant women and babies in Europe in 2010*. Accessed on August 1, 2014 from http://www.europeristat.com/images/doc/Peristat%202013%20V2.pdf

The summary of evidence in this document is derived directly from this evidence source, and portions are extracted verbatim.

TOPIC BACKGROUND

The Licensed Direct Entry Midwife (LDM) Staff Advisory Workgroup was convened in January 2014 by the Director of the Oregon Health Authority (OHA). The workgroup was established to provide recommendations regarding perinatal services provided to Medicaid enrollees by LDMs. The workgroup was guided by the Triple Aim goals of improving population health, improving the individual's experience of care, and reducing per capita costs. One of the recommendations of the final report of this workgroup to the OHA was to request that the Health Evidence Review Commission develop a Coverage Guidance related to home birth, including evidence regarding:

- The maternal and fetal/neonatal/child health outcomes of home birth compared with birth in other settings
- Appropriate candidates for home birth
- Criteria for optimizing safety with regard to provider training, equipment, standards, consultation, and other systems of care

EVIDENCE OVERVIEW

Clinical background

From Cochrane 2012

Medicalization of childbirth is a central feature in Western societies. The majority of women living in high and middle-income countries have given birth in hospitals since the middle of the 20th century. However, there are regions where home birth is considered part of normal practice. The most cited case is the Netherlands where planned home birth is supported by the official healthcare system. There, planned home birth is considered an appropriate choice for a woman of low risk and approximately 30% of all births take place at home. It is of historical interest to note that the transfer of low-risk births from home to hospital in the 1960s, despite lack of high-quality evidence, was one of the pivotal issues when Archie Cochrane laid out the ideological ground for The Cochrane Collaboration. Cochrane awarded 'the wooden spoon' to obstetrics, because "the specialty missed its first opportunity in the sixties, when it failed to randomize the confinement of low-risk pregnant women at home or hospital. Then, having filled the emptying beds by getting nearly all pregnant women into hospital, the obstetricians started to introduce a whole series of expensive innovations into the routines of pre- and postnatal care and delivery, without any rigorous evaluation. The list is long, but the most important were induction, ultrasound, f~~o~~etal monitoring, and placental function tests" (Cochrane 1979). The relationship between hospitalization, childbirth, and intervention is still an important issue as "Concern about the iatrogenic effects of obstetric intervention in women who do not have a clinical need for it has put 'normal' birth firmly on the agenda for the 21st century." (EURO-PERISTAT 2008).

A range of interventions continue to be used routinely in relation to births at many hospitals despite the fact that for a long time they have been proven to have harmful effects, or only marginal or no beneficial effect (e.g., fetal monitoring, episiotomy and early cord clamping). Even though the use of a few specific interventions have been reduced (e.g., placental function

tests), in general “routine medical interventions have [...] increased steadily over time despite the efforts of the Cochrane Pregnancy and Childbirth Group, its predecessors, and other researchers carrying out systematic reviews” (Hodnett 2009).

The Cochrane review is about healthy pregnant women at term for whom no serious complications have been identified prior to the spontaneous initiation of birth and for which the birth is expected to be medically uncomplicated. Generally, between 70% and 80% of all pregnant women may be considered as low risk at the start of labor.

EVIDENCE REVIEW

Cochrane 2012

The inclusion criteria for the Cochrane 2012 review was limited to randomized controlled trials that compared planned hospital births to planned home births. Authors identified two RCTs; however one was only able to recruit one patient. This study (Hendrix 2009) was conducted in the Netherlands and recruited nulliparous women of low obstetric risk (n = 1). In this trial, 35 midwives in 14 primary care midwifery practices were involved in recruiting pregnant women in different parts of the Netherlands where 30% of all births are home births. However, the study author reported that only one of 116 women was willing to be randomized, the others having all decided where they wanted to deliver before being recruited into the study.

The second trial, Dowswell 1996, was conducted in the United Kingdom and recruited multiparous women judged to be at low obstetric risk by a consultant obstetrician and likely to have suitable home support and home circumstances (n = 71). Recruitment was carried out by one consultant obstetrician in an area where planned home birth was otherwise uncommon (0.5% to 1%). The midwives assisting the home births were community midwives who spent a few days each month in hospital; all UK midwives are trained to do home births, but the ones in the trial were probably not experienced with home birth. The hospital births were standard hospital care with intermittent auscultation at a university hospital with consultant obstetrician on call (but not called routinely) and full neonatal facilities. One midwife served one to two women in single rooms; she used intermittent auscultation and was not continuously present. This study was rated as having high methodologic quality, except for the small size.

The fully assessed trial with reported outcomes was too small to draw reliable conclusions. Only 11 women agreed to randomization. Four of the primary outcomes in this review were available for inclusion: baby not breast fed, assisted vaginal birth, caesarean section, and other (non-epidural) medical pain relief. In addition, three other outcomes were reported and these are also included here: perineal sutures, mother disappointed about allocation, and father did not state that he was relieved. One difference seems statistically significant: the majority of mothers in the hospital group were disappointed about the allocation while none of the mothers in the home birth group were disappointed [(Peto odds ratio 12.18, 95% confidence interval (CI) 1.05 to 141.17; however, the difference is non-significant using a Fisher’s exact test P value = 0.07)]. There were no instances of assisted vaginal birth or cesarean section, and for the other outcomes, there were no statistically significant differences between groups.

The Cochrane authors report that these results dto not "contradict the evidence from the largest observational studies (de Jonge 2009; Hutton 2009; Janssen 2009) identified in the most recent systematic review (Wax 2010)."

Because of the paucity of RCTs addressing this comparison, the systematic review and observational studies listed above are summarized below.

Wax 2010

This systematic review did not limit inclusion criteria by study design. The search was through November 2009, and included MEDLINE, EMBASE and Cochrane Database of Systematic Reviews. Inclusion criteria included performance in developed western countries, English language, peer reviewed and outcomes analyzed by planned delivery location. Twelve studies were included, including the three cohort studies described below and the single RCT described above, with a total of 342,056 planned home and 207,551 planned hospital deliveries.

Meta-analysis of maternal outcomes found that planned home births experienced significantly fewer medical interventions including epidural analgesia, electronic fetal heart rate monitoring, episiotomy, and operative vaginal and cesarean deliveries. Likewise, women intending home deliveries had fewer infections, third degree lacerations, perineal and vaginal lacerations, hemorrhages, and retained placentas. There was no significant difference in the rate of umbilical cord prolapse.

Meta-analysis of neonatal outcomes found that women planning home births were less likely to have preterm deliveries or babies who were low birth weight. Planned home births more often progressed to at least 42 weeks. While there was no overall pooled difference in the rate of assisted ventilation, one large study found more frequent ventilation among planned home births, while two smaller studies noted lower rates in this group. Perinatal mortality was similar by intended delivery location (OR 0.95 95% CI 0.77 to 1.18), as well as just among non-anomalous offspring (OR 0.95, 95% CI 0.76 to 1.18). In contrast, neonatal mortality was almost twice as high in planned home versus planned hospital births (OR 1.98, 95% CI 1.19 to 3.28, absolute number 32 out of 16,500 planned home births [0.20%] compared to 32 out of 33,302 planned hospital births [0.09%]), and almost tripled among non-anomalous neonates (OR 2.87, 95% CI 1.32 to 6.25, absolute number 23 out of 15,633 planned home births [0.15%] compared to 14 out of 31,999 planned hospital births [0.04%]). While the reason for the difference between neonatal and perinatal mortality rates is unclear from this analysis, the authors speculate that it may be due to the lower obstetric risk associated with patients planning home births. If this is the case, planned home births may face a higher perinatal mortality rate than similar risk planned hospital births.

The results of the sensitivity analyses excluding studies that included home births attended by other than certified midwives or certified nurse midwives had findings similar to the original analysis, except that the ORs for neonatal deaths among all (OR, 1.57; 95% CI, 0.62–3.98) and non-anomalous (OR, 3.00; 95% CI, 0.61–14.88) newborns were not statistically significant.

de Jonge 2009

This is a nationwide cohort study conducted in the Netherlands that included a total of 529,-688 low-risk women who were in primary midwife-led care at the onset of labor. In the Netherlands, the indications for referral to an obstetrician have been agreed upon by the professional groups involved and are laid out in the "Obstetric Indication List" (see Appendix A). Of these, 321,-307 (60.7%) intended to give birth at home, 163,-261 (30.8%) planned to give birth in hospital and for 45,-120 (8.5%), the intended place of birth was unknown. Authors adjusted for a number of maternal characteristics (e.g., parity, gestational age, maternal age, ethnic background and socioeconomic status).

No significant differences were found between planned home and planned hospital birth in neonatal outcomes reported. Adjusted relative risks (RR) and 95% CI were as follows: intrapartum death (RR 0.97, 95% CI: 0.69 to 1.37), intrapartum death and neonatal death during the first 24 hours (RR 1.02, 95% CI: 0.77 to 1.36), intrapartum death and neonatal death up to 7 days (RR 1.00, 95% CI: 0.78 to 1.27), admission to neonatal intensive care unit (RR 1.00, 95% CI: 0.86 to 1.16).

Hutton 2009

Midwives in Ontario, Canada, provide care in the home and hospital and are required to submit data for all births to the Ontario Ministry of Health database. The purpose of this study was to compare maternal and perinatal/neonatal mortality and morbidity and intrapartum intervention rates for women attended by Ontario midwives who planned a home birth compared with similar low-risk women who planned a hospital birth between 2003 and 2006. The following types of pregnancies are not eligible for home birth in Ontario:

- Twins
- Breech
- Medical complications in the mother
- More than one prior cesarean section
- Gestational age less than 37 or more than 42 weeks

The database provided outcomes for all women planning a home birth at the onset of labor (n = 6,-692) and for a cohort, stratified by parity, of similar low-risk women planning a hospital birth. The rate of perinatal and neonatal mortality was very low (1/1,000) for both groups, and no difference was shown between groups in a composite measure of perinatal and neonatal mortality or serious morbidity (RR 2.4% vs 2.8%, 95% CI: 0.84 [0.68–1.03]). No maternal deaths were reported. All measures of maternal morbidity were lower in the planned home birth group, including augmentation (RR 0.76, 95% CI 0.72 to 0.80), pharmaceutical pain relief (RR 0.37, 95% CI 0.35 to 0.39), episiotomy (RR 0.73, 95% CI 0.63 to 0.84)-, assisted delivery (RR 0.67, 95% CI 0.56 to 0.80), perineal trauma (RR 0.87, 95% CI 0.83 to 0.90), and blood loss greater than 1,000 ml (RR 0.68, 95% CI 0.49 to 0.96). In addition, the rates for cesarean section were lower in the planned home birth group (5.2% vs 8.1%, RR 0.64, 95% CI 0.56 to 0.73). When stratified by parity, nulliparas were less likely to deliver at home, and had higher rates of ambulance transport from home to hospital than multiparas planning home birth. However,

nulliparas planning home birth still had rates of intervention and outcomes that were similar to, or lower than, nulliparas planning hospital births.

Janssen 2009

This study was also a retrospective cohort study utilizing a database of all births in the province of British Columbia that occurred between 2000 and 2004. Eligibility for home birth by the College of Midwives of British Columbia includes the following:

- Absence of significant pre-existing disease in the mother
- Absence of significant disease arising during pregnancy (e.g., pregnancy-induced hypertension, hemorrhage, diabetes, herpes, placenta previa, abruption)
- Singleton fetus
- Cephalic presentation
- Gestational age between 36 and 41 weeks
- No more than one prior cesarean section
- Spontaneous labor (or induced as an outpatient)
- No transfer from a referring hospital

Planned home births were compared to midwife attended planned hospital births and physician attended planned hospital births, both limited to patients who met the criteria for home birth and matched by age, parity, single parent status, maternal age, and hospital location. There were 2,899 women in the planned home birth group, 4,752 in the planned hospital birth group attended by midwives, and 5,331 in the planned hospital group attended by physicians.

The perinatal mortality rate was 0.35/1,000 births in the home birth group, 0.57/1,000 in the hospital midwife group and 0.64/1,000 in the hospital physician group, with no statistically significant differences between groups (RR for home midwife vs. hospital midwife 0.61, 95% CI 0.06 to 5.88; RR for home midwife vs. hospital physician 0.55, 95% CI 0.06 to 5.25). Infants in the planned home birth group were significantly less likely to have an Apgar score less than seven at one minute, to suffer birth trauma, or to require resuscitation or oxygen therapy for more than 24 hours when compared to either hospital group.

Compared to planned home birth, the frequency of obstetric interventions was higher in the planned hospital group (either physician or midwife), including fetal monitoring (RR 0.32, 95% CI 0.29 to 0.36 for midwife, RR 0.17, 95% CI 0.16 to 0.19 for physician), augmentation of labor (RR 0.59, 95% CI 0.55 to 0.69 for midwife, RR 0.47, 95% CI 0.44 to 0.51 for physician), assisted vaginal delivery (RR 0.41, 95% CI 0.33 to 0.52 for midwife, RR 0.22, 95% CI 0.18 to 0.27 for physician), cesarean section (RR 0.76, 95% CI 0.64 to 0.91 for midwife, RR 0.65, 95% CI 0.56 to 0.76 for physician)and episiotomy (RR 0.49, 95% CI 0.38 to 0.63 for midwife, RR 0.19, 95% CI 0.15 to 0.23 for physician). They were also more likely to have third or fourth degree perineal tears (RR 0.43, 95% CI 0.29 to 0.63 for midwife, RR 0.34, 95% CI 0.24 to 0.49 for physician).

Guidelines

The NICE guideline on intrapartum care in healthy women was ~~last~~ published in ~~2007~~December 2014. ~~However, it is in the process of being updated, with a draft being released for comment in May 2014.~~ The guideline recommends the following regarding place of birth:

Women at low risk of complications

1.1.1 Explain to women who are at low risk of complications that giving birth is generally very safe for both the woman and her baby. [new 2014]

1.1.2 Explain to both multiparous and nulliparous women that they may choose any birth setting (home, freestanding midwifery unit, alongside midwifery unit or obstetric unit), and support them in their choice of setting wherever they choose to give birth:~~Explain to the woman that she may choose any birth setting (home, freestanding midwifery unit, alongside midwifery unit or obstetric unit), and support her in her choice of setting wherever she chooses to give birth.~~ [new 2014]

~~1.1.3~~ Advise low-risk multiparous women that planning to give birth at home or in a midwifery-led unit (freestanding or alongside) is particularly suitable for them because the rate of interventions is lower and the outcome for the baby is no different compared with an obstetric unit. ~~Advise low-risk multiparous women to plan to give birth at home or in a midwifery-led unit (freestanding or alongside). Explain that this is because the rate of interventions is lower and the outcome for the baby is no different compared with an obstetric unit.~~ [new 2014]

Advise low-risk nulliparous women that planning to give birth in a midwifery-led unit (freestanding or alongside) is particularly suitable for them because the rate of interventions is lower and the outcome for the baby is no different compared with an obstetric unit. Explain that if they plan birth at home there is a small increase in the risk of an adverse outcome for the baby.~~1.1.4 Advise low-risk nulliparous women to plan to give birth in a midwifery-led unit (freestanding or alongside). Explain that this is because the rate of interventions is lower and the outcome for the baby is no different compared with an obstetric unit, but if they plan birth at home there is a small increase in the risk of an adverse outcome for the baby.~~ [new 2014]

1.1.3~~5~~ Using tables 1 and 2, explain to low-risk multiparous women

- Planning birth at home or in a freestanding midwifery unit is associated with a higher rate of spontaneous vaginal birth than planning birth in an alongside midwifery unit, and these 3 settings are associated with higher rates of spontaneous vaginal birth than planning birth in an obstetric unit
- Planning birth in an obstetric unit is associated with a higher rate of interventions, such as instrumental vaginal birth, caesarean section and episiotomy, compared with planning birth in other settings
- There are no differences in outcomes for the baby associated with planning birth in any setting. [new 2014]

Table 1. ~~(~~Rates of spontaneous vaginal birth, transfer to an obstetric unit, and obstetric interventions for each planned place of birth: low-risk multiparous women~~)~~

	Number of incidences per 1,000 multiparous women giving birth			
	Home	Freestanding midwifery unit	Alongside midwifery unit	Obstetric unit
Spontaneous vaginal birth	~~980~~984	~~975~~980	~~965~~967	~~925~~927
Transfer to an obstetric unit	~~86~~115	94	125	10**
~~Epidural~~Regional anesthesia (epidural and/or spinal)* **	28	40	60	121
Episiotomy	15	23	35	56
Cesarean birth	7	8	10	35
Instrumental birth (~~F~~forceps ~~birth~~or ventouse)	~~4~~9	~~8~~12	~~11~~23	~~20~~38
~~Ventouse (vacuum) birth~~	~~5~~	~~4~~	~~12~~	~~37~~
Blood transfusion	4	4	5	8

Table 2. ~~(~~Outcomes for the baby for each planned place of birth: low-risk multiparous women~~)~~

	Number of babies per 1,000 births			
	Home	Freestanding midwifery unit	Alongside midwifery unit	Obstetric unit
Babies without serious medical problems	997	997	998	997
Babies with serious medical problems	3	3	2	3

1.1.4 Using tables 3 and 4, explain to low-risk nulliparous women that:

- Planning birth at home or in a freestanding midwifery unit is associated with a higher rate of spontaneous vaginal birth than planning birth in an alongside midwifery unit, and these 3 settings are associated with higher rates of spontaneous vaginal birth than planning birth in an obstetric unit
- Planning birth in an obstetric unit is associated with a higher rate of interventions, such as instrumental vaginal birth, caesarean section and episiotomy, compared with planning birth in other settings
- There are no differences in outcomes for the baby associated with planning birth in an alongside midwifery unit, a freestanding midwifery unit or an obstetric unit

- Planning birth at home is associated with an overall small increase (about 4 more per 1,000 births) in the risk of a baby having a serious medical problem compared with planning birth in other settings.

Table 3. ~~(~~Rates of spontaneous vaginal birth, transfer to an obstetric unit, and obstetric interventions for each planned place of birth: low-risk nulliparous women~~)~~

	Number of incidences per 1,000 nulliparous women giving birth			
	Home	Freestanding midwifery unit	Alongside midwifery unit	Obstetric unit
Spontaneous vaginal birth	~~792~~794	~~810~~813	765	~~686~~688
Transfer to an obstetric unit	~~440~~450	363	402	10
Epidural	218	200	240	349
Episiotomy	165	165	216	242
Cesarean birth	80	69	76	121
Instrumental birth (~~F~~forceps ~~birth~~or ventouse)	~~70~~126	~~61~~118	~~81~~159	~~106~~191
~~Ventouse (vacuum) birth~~	~~62~~	~~57~~	~~78~~	~~113~~
Blood transfusion	12	8	11	16

Table 4. ~~(~~Outcomes for the baby for each planned place of birth: low-risk nulliparous women~~)~~

	Number of babies per 1,000 births			
	Home	Freestanding midwifery unit	Alongside midwifery unit	Obstetric unit
Babies without serious medical problems	991	995	995	995
Babies with serious medical problems	9	5	5	5

Medical conditions and other factors that may affect planned place of birth

1.1.1~~0~~1 Use tables 6, 7, 8 and 9 as part of an assessment for a woman choosing her planned place of birth:

- Tables 6 and 7 show medical conditions or situations in which there is increased risk for the woman or baby during or shortly after labour, where care in an obstetric unit would be expected to reduce this risk.

- The factors listed in tables 8 and 9 are not reasons in themselves for advising birth within an obstetric unit, but indicate that further consideration of birth setting may be required.
- Discuss these risks and the additional care that can be provided in the obstetric unit with the woman so that she can make an informed choice about planned place of birth. [2007, amended 2014]

Table ~~5.~~6. Medical conditions indicating increased risk suggesting planned birth at an obstetric unit

Disease Area	Medical Condition
Cardiovascular	• Confirmed cardiac disease • Hypertensive disorders
Respiratory	• Asthma requiring an increase in treatment or hospital treatment • Cystic fibrosis
Haematological	• Haemoglobinopathies – sickle-cell disease, beta-thalassaemia major • History of thromboembolic disorders • Immune thrombocytopenia purpura or other platelet disorder or platelet count below 100,000 • Von Willebrand's disease • Bleeding disorder in the woman or unborn baby • Atypical antibodies which carry a risk of haemolytic disease of the newborn
Endocrine	• Hyperthyroidism • Diabetes
Infective	• Risk factors associated with group B streptococcus whereby antibiotics in labour would be recommended • Hepatitis B/C with abnormal liver function tests • Carrier of/infected with HIV • Toxoplasmosis – women receiving treatment • Current active infection of chicken pox/rubella/genital herpes in the woman or baby • Tuberculosis under treatment
Immune	• Systemic lupus erythematosus • Scleroderma
Renal	• Abnormal renal function • Renal disease requiring supervision by a renal specialist
Neurological	• Epilepsy • Myasthenia gravis • Previous cerebrovascular accident
Gastrointestinal	• Liver disease associated with current abnormal liver function tests
Psychiatric	• Psychiatric disorder requiring current inpatient care

Table ~~6~~7. Other factors indicating increased risk suggesting planned birth at an obstetric unit

Factor	Additional Information

Previous complications	• Unexplained stillbirth/neonatal death or previous death related to intrapartum difficulty • Previous baby with neonatal encephalopathy • Pre-eclampsia requiring preterm birth • Placental abruption with adverse outcome • Eclampsia • Uterine rupture • Primary postpartum haemorrhage requiring additional treatment or blood transfusion • Retained placenta requiring manual and/or surgical removal in theatre Caesarean section • Shoulder dystocia
Current pregnancy	• Multiple birth • Placenta praevia • Pre-eclampsia or pregnancy-induced hypertension • Preterm labour or preterm prelabour rupture of membranes Placental abruption • Anaemia – haemoglobin less than 8.5 g/dl at onset of labour • Confirmed intrauterine death • Induction of labour • Substance misuse • Alcohol dependency requiring assessment or treatment • Onset of gestational diabetes • Malpresentation – breech or transverse lie • Body mass index at booking of greater than 35 kg/m2 Recurrent antepartum haemorrhage • Small for gestational age in this pregnancy (less than fifth centile or reduced growth velocity on ultrasound) • Abnormal fetal heart rate/Doppler studies • Ultrasound diagnosis of oligo-/polyhydramnios
Previous gynaecological history	• Myomectomy • Hysterotomy

Table ~~7~~8. Medical conditions indicating individual assessment when planning place of birth

Disease Area	Medical Condition
Cardiovascular	• Cardiac disease without intrapartum implications
Haematological	• Sickle-cell trait • Thalassaemia trait • Atypical antibodies not putting the baby at risk of haemolytic disease • Anemia – haemoglobin 8.5-10.5 g/dl at onset of labor
Infective	• Hepatitis B/C with normal liver function tests
Immune	• Nonspecific connective tissue disorders
Endocrine	• Unstable hypothyroidism such that a change in treatment is required

Skeletal/Neurological	• Spinal abnormalities • Previous fractured pelvis • Neurologic deficits
Gastrointestinal	• Liver disease without current abnormal liver function • Crohn's disease • Ulcerative colitis

Table ~~8~~9. Other factors indicating individual assessment when planning place of birth

Factor	Additional Information
Previous complications	• Stillbirth/neonatal death with a known non-recurrent cause • Pre-eclampsia developing at term • Placental abruption with good outcome • History of previous baby more than 4.5 kg • Extensive vaginal, cervical, or third- or fourth-degree perineal trauma • Previous term baby with jaundice requiring exchange transfusion
Current pregnancy	• Antepartum bleeding of unknown origin (single episode after 24 weeks of gestation) • Body mass index at booking of 30–~~34~~ 35 kg/m2 • Blood pressure of 140 mmHg systolic or 90 mmHg diastolic or more on two occasions • Clinical or ultrasound suspicion of macrosomia • Para 4 or more • Recreational drug use • Under current outpatient psychiatric care • Age over 35 at booking
Fetal indications	• Fetal abnormality
Previous gynaecological history	• Major gynaecological surgery • Cone biopsy or large loop excision of the transformation zone • Fibroids

Service organization and clinical governance

1.1.~~17~~ 15 Ensure that all women giving birth have prompt access to an obstetric unit in case they need transfer of care for medical reasons or because they request ~~epidural~~ regional analgesia. [new 2014]

1.1.1~~6~~8 Ensure that there are

- robust protocols in place for transfer of care between settings (see also section 1.6). [new 2014]
- clear local pathways for the continued care of women who are transferred from one setting to another, including:
  - when crossing provider boundaries
  - if the nearest obstetric or neonatal unit is closed to admissions or the local midwifery-led unit is full [new 2014]

~~1.1.19 Ensure that there are clear local pathways for the continued care of women who are transferred from one setting to another, including where this involves crossing provider boundaries. These pathways should include arrangements for occasions when the nearest obstetric or neonatal unit is closed to admissions or when the local midwifery-led unit is full. [new 2014]"~~

Other evidence

In 2013 the Oregon Public Health Division published its first report on birth outcomes by planned birth place and attendant. Because this report specifically addresses home birth outcomes in the state of Oregon, a summary is presented here.

In 2011, the Oregon Legislature passed House Bill 2380, which required the Oregon Public Health Division to add two questions to the Oregon Birth Certificate to determine planned place of birth and birth attendant, and to report annually on birth outcomes, including death, by location and attendant type. The specific questions were: "Did you go into labor planning to deliver at home or at a freestanding birthing center? If yes, what was the planned primary attendant type at the onset of labor?" In addition, for 2012, the Oregon Public Health Division conducted a special study of deaths in term infants (≥ 37 weeks' gestation) intended to deliver out-of-hospital. The perinatal fatality analysis includes fetal and early neonatal deaths ≥ 37 weeks' estimated gestational age through the first 6 days of life.

During 2012, 42,011 live term births occurred in Oregon. Of these 2,021 (4.8%) planned an out-of-hospital birth (home birth or freestanding birthing center).

Key findings of term fetal and early neonatal deaths by planned place of birth and planned birth attendant include the following:

- Sixty-two term (≥ 37 weeks' gestation) fetal deaths occurred in Oregon during 2012; 4 (6.5%) of these occurred among planned out-of-hospital births.
- Thirty term early neonatal deaths (during the first 6 days of life) occurred in Oregon during 2012; 4 (13.3%) of these occurred among planned out-of-hospital births.
- In total, 92 term fetal and early neonatal deaths occurred in Oregon during 2012; 8 (8.7%) occurred among planned out-of-hospital births. These 8 deaths underwent a fetal and neonatal mortality case review per published national guidelines.

Key findings of the perinatal fatality case review of term births planned to occur out-of-hospital include the following:

- Four term fetal and four early neonatal deaths occurred during 2012 among women who planned to deliver out-of-hospital
- Planned birth attendants: Certified Nurse Midwife (1), Licensed Direct-Entry Midwives (4), Unlicensed Midwife (1), Undetermined Licensure Midwife (1), and Naturopathic Physician (1)
- Median birth weight (3515 grams)
- Maternal characteristics were similar to the larger group of planned out-of-hospital births
- Two pregnancies had inadequate or no prenatal care
- Chart review noted that, among perinatal deaths:
    - Two pregnancies were twin gestations
    - Four mothers declined prenatal ultrasound (to confirm gestation and identify pathology)

    - Five mothers declined Group B streptococcal testing (to identify women who are carriers of GBS; treatment during labor is recommended to decrease the risk of early GBS neonatal sepsis)
    - Two mothers declined prophylaxis during labor for Group B streptococcal positive tests
- Six of eight transferred to the hospital during labor:
    - Indications for transfer to a hospital from home or birthing center included (multiple causes may apply): loss of fetal heart tones (3), prolonged labor (2), decreased fetal movement (2), and malpresentation (2)
    - One mother initially declined transfer during labor despite recommendation by birth attendant
- Six of eight pregnancies did not meet published low-risk criteria for out-of-hospital birth*:
    - More than 41 weeks gestation (4)
    - Twin gestation (2)
    - Morbid obesity (> 40 BMI) (1)
    - Planned attendants among these 6: Certified Nurse Midwife (1), Licensed Direct-Entry Midwives (3), Unlicensed Midwife (1), and Naturopathic Physician (1)
- Causes of death and major contributing factors (more than one may apply):
    - Hypoxic ischemic encephalopathy or cardiorespiratory failure (lack of blood flow) (3)
    - Chorioamnionitis (infection in the womb) (3)
    - Pre-existing or pregnancy-related maternal disease (2)
    - Respiratory failure (1)
    - Undetermined, umbilical cord wrapped around neck, large baby (1)
    - Undetermined, twin gestation, small baby (2)

The term perinatal mortality rate for planned out-of-hospital births (4.0/1,000 pregnancies) was nearly twice that of in-hospital births (2.1/1,000). When excluding those pregnancies that did not meet published criteria for being low risk, the perinatal mortality rate for planned out-of-hospital births is 1.0/1000.

Risk criteria for planned home birth

The 2014 NICE draft guideline for antepartum care clearly outlines conditions that make a woman high-risk. In addition, the Oregon Public Health Division referenced a report from the American College of Obstetrics and Gynecology (ACOG) on Planned Home Birth[1] as their published criteria for being low-risk. This includes the following requirements:

- Gestational age ≥ 36 weeks and ≤41 completed weeks of pregnancy
- Singleton
- Vertex position
- Absence of preexisting or pregnancy-related maternal disease

[1] American College of Obstetricians and Gynecologists. (2011). Planned home birth. Committee Opinion No. 476. *Obstetrics & Gynecology, 117,* 425–428.

The ACOG committee opinion references Hutton 2006 and Janssen 2009 as a source for these criteria. They also note that the low-risk criteria utilized in these two observational studies did not exclude women with a prior cesarean section; however, because of potential risks they state that ACOG "considers a prior cesarean delivery to be an absolute contraindication to planned home birth". They also note that studies showing favorable perinatal outcomes (de Jonge 2009; Hutton 2006; Janssen 2009) were conducted in settings that have "highly integrated health care systems with established criteria and provisions for emergency intrapartum transport." Therefore, ACOG "believes that the availability of timely transfer and an existing arrangement with a hospital for such transfers is a requirement for consideration of a home birth."

The final report of the Licensed Direct Entry Midwife (LDM) Staff Advisory Workgroup also recommends that planned home birth be limited to patients who are low-risk, defined as pregnancies that do not have any of the following characteristics:

- Presentation other than cephalic
- Previous cesarean delivery
- Gestational age < 36 or > 43 weeks
- Multiple gestations
- Diabetes/uncontrolled gestational diabetes or gestational diabetes controlled with medication
- Pre-eclampsia

Current Oregon law[2] outlines risk criteria which birthing centers must follow. A proposed rule would apply those same criteria to home births. Those criteria can be found in Appendix A.

All three observational studies included in this document were based on registries in countries or provinces that strictly control the practice of midwifery and adhere to established criteria for planned home birth. All three lists of criteria are provided in Appendix A.

Midwifery certification

Training and certification requirements for midwives vary among the countries referenced in this document. A summary is presented below:

The Netherlands[3]

"The midwifery training is a four year fulltime direct entry education, which eventually leads to a Bachelor's degree. The total study load is 240 ECTS and equals nearly 6,800 hours of education. Altogether, there are two years of theory, one year of primary care internships, and one year of secondary and tertiary care internships. The internships are spread equally over these four years. Students are primarily trained to become independent primary care midwives. 190 Students enroll each year nationwide. They have had an extensive assessment, which

[2] http://arcweb.sos.state.or.us/pages/rules/oars_300/oar_333/333_076.html
[3] http://www.nurse.or.jp/nursing/international/icm/report/data/2012/icm-dutch.pdf

selects the best candidates. Around three times more candidates apply for the course than places are available."

British Columbia[4]

"All current CMBC approved programs are Canadian four year direct-entry education programs leading to a university degree, or bridging programs leading to equivalency."

Ontario[5]

"1. The applicant must have at least one of the following:

- A baccalaureate degree in health sciences (midwifery) from a university in Ontario.
- A degree, diploma or certificate from a program listed in Schedule 1.
- Qualifications that are equivalent to the degree referred to in subparagraph i, as determined by the Council or by a body or bodies designated by the Council.

2. The applicant must:

- Have current clinical experience consisting of active practice for at least two years out of the four years immediately before the date of the application, and
- Have attended at least 60 births, of which at least:
    - 40 were attended as primary midwife
    - 30 were attended as part of the care provided to a woman in accordance with the principles of continuity of care
    - 10 were attended in hospital, of which at least five were attended as primary midwife, and
    - 10 were attended in a residence or remote clinic or remote birth centre, of which at least five were attended as primary midwife

3. The applicant must have successfully completed the qualifying examination that was set or approved by the Registration Committee at the time the applicant took the examination."

United Kingdom[6]

Midwifery degree

- Students are awarded both an academic and a professional qualification, through integrated study of theory and supervised midwifery practice
- Supervised midwifery practice is 50% of the program and takes place in both community and hospital settings, including antenatal clinics and wards, labour wards, postnatal wards and neonatal care
- The programs are normally three years in length and studied on a full-time basis

[4] http://www.cmbc.bc.ca/pdf.shtml?Exploring-Midwifery-as-a-Career
[5] http://www.e-laws.gov.on.ca/html/source/regs/english/2011/elaws_src_regs_r11168_e.htm
[6] http://www.nhscareers.nhs.uk/explore-by-career/midwifery/training-to-be-a-midwife/

Oregon[7]

Mandatory licensure of direct entry midwives in Oregon was established in 2013 with passage of House Bill 2997, which requires any direct entry midwife practicing after January 1, 2015, to hold a license. The Oregon Board of Direct Entry Midwifery already requires that LDMs hold a certified professional midwife (CPM) credential from the North American Registry of Midwives, complete an examination, be certified in infant and adult cardiopulmonary resuscitation, have a written plan for transport of the patient, hold a high school diploma (or equivalent), and attend and participate in, at a minimum:

- Twenty-five assisted deliveries
- Twenty-five deliveries for which the LDM applicant was the primary care provider
- One hundred prenatal care visits
- Twenty-five newborn examinations, and
- Forty postnatal examinations

North American Registry of Midwives (NARM)[8]

There are multiple routes to certification by the NARM, but in general they include a written test, a skills assessment test, and the following experience requirements:

Phase 1: Births as an Observer

- Ten births in any setting, in any capacity

Phase 2: Clinicals as Assistant under Supervision

- Twenty births, 25 prenatal exams, 20 newborn exams, 10 postpartum visits

Phase 3: Clinicals as Primary under Supervision

- Twenty births, 75 prenatal visits, 20 newborn exams, and 40 postpartum exams

It is also required that the applicant have a preceptor(s) that attests to the applicant's proficiency on "skills, knowledge, and abilities essential for competent practice" and that the applicant be certified in Adult CPR, and Neonatal Resuscitation Certification.

~~[Evidence Source]~~

EVIDENCE SUMMARY

The evidence pertaining to home birth from randomized trials is extremely sparse, limited to just 11 participants, and hence insufficient to draw conclusions from. The largest observational studies suggest that home birth results in fewer obstetrical interventions and maternal adverse outcomes. The evidence pertaining to neonatal outcomes is less clear; while one meta-analysis

[7] http://www.oregon.gov/OHLA/DEM/Pages/Midwifery_How_to_Get_Licensed.aspx
[8] http://narm.org/entry-level-applicants/

found an elevated risk of neonatal death, this was no longer true when the analysis was limited to studies in which the attendant was either a certified midwife or certified nurse midwife. Observational studies conducted in settings where there are clear criteria for appropriateness of home birth (Canada, the Netherlands) do not find an elevated neonatal death rate.

In their first year of reporting, evidence from the State of Oregon Public Health Department identified an elevated risk of perinatal death in pregnancies with a planned home delivery. However, when excluding those pregnancies that did not meet published criteria for being low-risk, the rate is not elevated compared to planned hospital births.

Criteria for low-risk pregnancy at the time of labor and delivery have been established by national or provincial governments as well as by US national and state provider organizations. These criteria have varying levels of detail, ~~but at a minimum include the following~~but each has criteria for consultation with other providers, indications requiring hospital birth and indications requiring transfer of care. ~~:~~

- ~~Gestational age ≥ 36 weeks and ≤41 **completed** weeks of pregnancy (37 weeks 0 days thru 41 weeks 6 days)~~
- ~~Singleton~~
- ~~Vertex position~~
- ~~No prior Cesarean section or other hysterotomy~~
- ~~Absence of preexisting or pregnancy-related maternal disease~~

~~Additional criteria for either consultation or transfer of care indicating planned hospital birth that have been adopted by some or all of the entities discussed in this document include the following:~~

~~Complications in a previous pregnancy~~

- ~~Unexplained stillbirth/neonatal death or previous death related to intrapartum difficulty~~
- ~~Previous baby with neonatal encephalopathy~~
- ~~Pre-eclampsia requiring preterm birth/~~
- ~~HELLP syndrome~~
- ~~Placental abruption with adverse outcome~~
- ~~Eclampsia~~
- ~~Uterine rupture~~
- ~~Postpartum hemorrhage requiring additional treatment or blood transfusion~~
- ~~Retained placenta requiring manual and/or surgical removal~~
- ~~Shoulder dystocia with or without fetal clavicular fracture~~
- ~~Cesarean section~~
- ~~Blood group incompatibility~~
- ~~Fetal growth retardation~~
- ~~Preterm birth~~
- ~~Cervical insufficiency/ prior cerclage~~
- ~~Fourth degree laceration without satisfactory functional recovery~~

- More than three first trimester spontaneous abortions, or more than one second trimester spontaneous abortion

Complications of current pregnancy

- Placenta previa, vasa previa, low lying placenta within 2cm or less of cervical os at term
- Eclampsia, or pre-eclampsia or pregnancy-induced hypertension, hypertension (before or after delivery)
- Preterm labor or preterm prelabor rupture of membranes
- Placental abruption/ abnormal bleeding
- Anemia – hemoglobin less than 6.0 to 8.5 g/dl, depending on organization
- Confirmed intrauterine death
- Induction of labor
- Substance misuse
- Alcohol dependency requiring assessment or treatment
- Body mass index at first prenatal visit of greater than 35 kg/m^2
- Recurrent antepartum hemorrhage
- Small for gestational age fetus (less than fifth percentile using ethnically-appropriate growth tables, or reduced growth velocity on ultrasound)
- Abnormal fetal heart rate/Doppler/surveillance studies
- Oligo or polyhydramnios
- Blood group incompatibility with atypical antibodies (including Rh sensitization)
- Prelabor rupture of membranes > 24 hours
- Life-threatening congenital anomalies
- No Inadequate prenatal care, including lack of infectious disease screening
- Current active infection of varicella/rubella/genital herpes in the woman or babyGenital herpes
- Chorioamnionitis or other serious infection (including toxoplasmosis, rubella, CMV, HIV, etc)
- Thick meconium staining of amniotic fluid
- Failure to progress/ failure of head to engage in active labor
- Prolapsed umbilical cord
- Laparotomy during pregnancy
- Cervical dysplasia requiring evaluation
- Hyperemesis gravidarum
- Thrombosis/ thromboembolism/ thrombocytopenia (platelets <100,000), or other maternal bleeding disorder
- Uteroplacental insufficiency
- Molar pregnancy
- Maternal mental illness requiring inpatient care
- Diabetes, Type I, Type II, uncontrolled gestational, or gestational controlled with medication
- Uterine rupture, inversion or prolapse

- Family history of genetic/ heritable disordersAge < 14

Additional criteria suggesting an indication for obstetrical consultation prior to planned out of hospital birth that have been adopted by some or all of the entities discussed in this document include the following:

Complications in a previous pregnancy

- More than three first trimester spontaneous abortions, or more than one second trimester spontaneous abortion
- Blood group incompatibility
- Pre-eclampsia in previous pregnancy, not requiring preterm birth
- Preterm birth
- Cervical insufficiency/ prior cerclage
- Intrauterine growth restriction
- Fourth degree laceration with satisfactory functional recovery
- Third degree laceration
- Perinatal death
- Prior child with congenital and/or hereditary disorder
- Prior baby > 4.5 kg

Complications of current pregnancy

- Fetal macrosomia
- Maternal hypertension, either preexisting or pregnancy-induced
- Hyperemesis gravidarum
- Family history of genetic/ heritable disorders
- Laparotomy during pregnancy
- Cervical dysplasia requiring evaluation
- Diabetes, gestational, diet-controlled
- Maternal age < 17 years or > 35 years
- Maternal recreational drug use
- Maternal mental illness under outpatient psychiatric care
- Maternal anemia with hemoglobin <10.5
- Confirmed uterine death

If out-of-hospital birth is planned, the following intrapartum and postpartum complications require transfer to hospital*: Post-partum Complications - Maternal

- Abnormal fetal heart rate/Doppler
- Thick meconium staining of amniotic fluid without reassuring heart tones and when birth is not imminent
- Raised diastolic blood pressure over 90mmHg or raised systolic blood pressure over 140mmHg on two consecutive readings taken 30 minutes apart.
- Chorioamnionitis or other serious infection (including toxoplasmosis, rubella, CMV, HIV, etc.)

- Failure to progress/ failure of head to engage in active labor
- Prolapsed umbilical cord
- Uterine rupture, inversion or prolapse
- Hemorrhage (hypovolemia, shock, need for transfusion)
- Retained placenta
- Laceration requiring hospital repair (e.g., third degree, fourth degree, periurethral)
- Enlarging hematoma
- Third or fourth degree, or periuretheral, laceration
- Infection (endometritis, UTI, wound, breast)
- Thrombophlebitis/ thromboembolism
- Bladder or rectal dysfunction
- A third- or fourth-degree laceration that is amenable to in-home repair requires consultation but may not necessitate transfer into the hospital setting

*** an attempt should be made to transfer, however, imminent fetal delivery may delay or preclude actual transfer.**

Post-partum Complications – InfantIf infant is delivered out of hospital, the following complications require transfer to a hospital:

- Low Apgar score (< 5 at 5 minutes, < 7 at 10 minutes)
- Temperature instability, fever, suspected infection or dehydration
- Hypotonia, tremors, seizures, hyperirritability
- Life-threatening congenital anomalies
- Respiratory or cardiac irregularities, cyanosis, pallor
- Failure to pass urine or meconium within 24 to 36 hours, depending on organization
- Feeding difficulties/ significant weight loss, failure to regain birth weight by 3 weeks, weight less than 5th percentile for age
- Congenital anomalies, less than 3 vessels in umbilical cord
- Excessive bruising, enlarging cephalohematoma, significant birth trauma
- Hyperglycemia/ hypoglycemia unresponsive to treatment
- Vomiting/ diarrhea
- Jaundice within the first 24 hours
- Prematurity
- More than three first trimester spontaneous abortions, or more than one second trimester spontaneous abortion
- Laparotomy during pregnancy
- Cervical dysplasia requiring evaluation

Good outcomes for planned out-of-hospital birth have been demonstrated in several countries. However, these settings have system characteristics that help to maximize safety. Chief among these is a robust system of consultation and referral/transfer that can assure seamless care for the woman and her newborn when transfer is needed. In addition, these systems include thorough education (informed consent) of women and families about the potential need for

consultation/referral/transfer and the potential risks associated with having a delay to receipt of emergency obstetric and neonatal care. Another characteristic is written agreements that cover consultation/referral/transfer and a well-defined and practiced system of transfer. Out-of-hospital birth attendants in these systems are appropriately trained and experienced in the identification and management of obstetric and neonatal emergencies, and are also licensed and certified. These providers should be capable of initiating appropriate newborn resuscitation, and be able to provide standard newborn care in addition to the routine postpartum care of women. Certification requirements for the practice of midwifery vary significantly between the US and other countries, with US requirements generally being less rigorous with regard to both years of formal education and experience.

GRADE-INFORMED FRAMEWORK

The HERC develops recommendations by using the concepts of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. GRADE is a transparent and structured process for developing and presenting evidence and for carrying out the steps involved in developing recommendations. There are four elements that determine the strength of a recommendation, as listed in the table below. The HERC reviews the evidence and makes an assessment of each element, which in turn is used to develop the recommendations presented in the coverage guidance box. Balance between desirable and undesirable effects, and quality of evidence, are derived from the evidence presented in this document, while estimated relative costs, values and preferences are assessments of the HERC members.

Indication/ Intervention	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Variability in values and preferences	Coverage recommendation	Rationale
Planned ~~home~~ out-of-hospital birth for low risk pregnancies	Possible decreased maternal morbidity, possible improved neonatal outcomes	Very low based on two large high quality retrospective database studies (downgraded because of internal validity (for which it was "Low") and external validity concerns)	Low	Low (By definition, women planning out-of-hospital birth prefer a non-hospital setting)	Recommended for coverage (*weak recommendation)*	The quality of evidence is very low given the risk of study bias and external validity, however, there is consistent poor quality evidence about improved maternal and neonatal outcomes including large numbers of women, this is a strong patient preference and involves a low level of

Indication/ Intervention	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Variability in values and preferences	Coverage recommendation	Rationale
						resources. It follows the CG Framework IIA1b pathway.
Planned ~~home~~ out-of-hospital birth for unselected pregnancies (including those with unknown or known high risk factors)	Possible lower maternal morbidity, increased neonatal mortality	Very low based on one systematic review of 12 studies (Downgraded to very low because of internal and external validity concerns)	Moderate	Low (By definition, women planning out-of-hospital birth prefer a non-hospital setting)	Not recommended for coverage *(strong recommendation)*	Based on very low evidence, and a suggestion of increased neonatal mortality, increased resources (for transfers, associated harms) this follows CG Framework pathway IIA2 and leads to a strong recommendation against.

*The Quality of Evidence rating was assigned by the primary evidence source, not the HERC Subcommittee

Note: GRADE framework elements are described in Appendix B

POLICY LANDSCAPE

Quality measures

No pertinent quality measures were identified when searching the National Quality Measures Clearinghouse.

Coverage guidance is prepared by the Health Evidence Review Commission (HERC), HERC staff, and subcommittee members. The evidence summary is prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center). This document is intended to guide public and private purchasers in Oregon in making informed decisions about health care services.

The Center is not engaged in rendering any clinical, legal, business or other professional advice. The statements in this document do not represent official policy positions of the Center. Researchers involved in preparing this document have no affiliations or financial involvement that conflict with material presented in this document.

APPENDIX A. RISK CRITERIA FOR PLANNED HOME BIRTH

Oregon birth center absolute risk criteria

Risk factors that if present **on admission** to the birthing center for labor and delivery, would prohibit admission to the birthing center

- Current substance abuse which has the potential to adversely affect labor and/or the infant
- Quadriplegia
- Hypertension >150/100 on at least two occasions
- For this pregnancy, Type I Diabetes, other diabetes requiring insulin to maintain acceptable control, or Type II Diabetes
- Thrombosis, active/current
- Severe anemia, <9 hemoglobin
- Uncontrolled seizure disorder
- Life-threatening congenital defects in fetus. This does not include documented lethal anomalies
- History of previous uterine wall surgery, including Caesarean section, if one or more of the following risk factors is present:
    - Conception occurred < 12 months following that surgery or uterine procedure;
    - Absence of ultrasound to rule out placenta previa and/or placental attachment to the surgical site;
    - History of two or more Caesarean sections without a prior successful vaginal delivery;
    - History of myomectomy which invaded the endometrium;
    - History of a known uterine perforation;
    - History of Caesarean section which included classical incision;
    - History of Caesarean section and complications including postoperative infection, diabetes, or steroid use;
    - Absence of signed, detailed informed consent

NOTE: Any woman with previous uterine wall surgery must be evaluated for the presence of risk factors, and must go through an informed consent process. The Information given to the woman must include an explanation of the risk; including non-absolute risks, of a vaginal birth after Caesarean section, and an explanation of the contingency plan in place should transport be necessary. If transport becomes necessary, the birthing center should notify the receiving facility when the transport is imminent.

- Need for Caesarean delivery this birth
- Multiple gestation without reassuring bio-physical profile of greater than or equal to 8 out of 10
- No previous prenatal care or written prenatal records available
- Abnormal fetal surveillance studies
- Fetal presentation other than vertex, when known
- Rising antibody titre -types known to affect fetal well-being; significant Rh sensitization

- Amniotic fluid index >30 at term
- Amniotic fluid index <5 without reassuring labor progress, without reassuring fetal heart tones and/or abnormal non- stress test
- Abnormal bleeding
- Need for chemical and/or pharmacological induction of labor
- Need for general or conduction anesthesia
- Eclampsia; preeclampsia with lab abnormalities
- Low-lying placenta within 2 cm. or less of cervical os; vasa previa; complete placenta previa; abruption placenta
- Genital herpes, primary; secondary uncoverable at onset of labor
- Labor or premature rupture of membranes at <36 weeks; pregnancy >43 weeks or >42 weeks with abnormal non- stress test
- Chorioamnionitis
- Thick meconium-stained amniotic fluid without reassuring Doppler heart tones
- Known pre-term fetal demise

Risk factors that if they develop **during labor and delivery**, require transfer of the client to a higher level of care

- Failure to progress in active labor with strong contractions and/or maternal/fetal compromise
- Abnormal fetal heart tone (FHT) pattern unresponsive to treatment; inability to auscultate fetal heart tones unless birth is imminent
- Thick meconium-stained amniotic fluid without reassuring Doppler heart tones and birth is not imminent
- Hypertension> 150/1 00 on at least two occasions
- Abnormal bleeding
- Prolapsed umbilical cord
- Fetal presentation other than vertex, when known, and birth is not imminent
- Multiple gestation when birth is not imminent
- Amniotic fluid index <5 without reassuring labor progress or without reassuring fetal heart tones or abnormal non-stress test
- Persistent fever of equal to or greater than 101 degrees Fahrenheit (oral) or indication of serious infection with the potential to harm the mother or the fetus
- Development of severe medical or surgical problem

Risk factors that, if they develop **during the postpartum period** in the mother or infant, would require transfer to a higher level of care

Mother

- Abnormal bleeding unresponsive to treatment and/or symptoms of hypovolemia
- Need for transfusion
- Retained placenta or incomplete placenta, with bleeding; suspected placenta accreta; retained placenta> 3 hours

Other

- Hypertension >150/100 on at least two occasions
- Shock, unresponsive to treatment
- Laceration requiring repair in a hospital
- Enlarging hematoma
- Development of preeclampsia or eclampsia
- Signs or symptoms of serious infection

Infant

- Apgar problems <5 at 5 minutes or <7 at 10 minutes
- Inability to maintain [axillary] temperature between 97 degrees Fahrenheit and 100 degrees Fahrenheit at 2 hours
- Hypotonia> 10 minutes
- Tremors, seizures, or hyperirritability
- Life-threatening congenital defects in fetus. This does not include documented lethal abnormalities; (in the presence of known and documented lethal fetal abnormalities, the denial of admission and the requirements to transfer do not apply)
- Respiratory or cardiac irregularities (examples: abnormal capillary refill time, disturbance of rate or rhythm; grunting or retracting after 30 minutes postpartum, need for oxygen> 30 minutes without improvement; cyanosis, central and persistent)
- Signs/symptoms of infection

Final report of the Obstetric Working Group of the National Health Insurance Board of the Netherlands (abridged version)

What follows is the list of specific obstetric indications, including an explanation of the description of the obstetrical care provider and guidelines on how to deal with the consultative situation.

The obstetric indication list is divided into six main groups, within which reference is made to the various obstetric and medical disorders and diseases. Where necessary, an explanation is provided about the obstetric policy related to specific indications and upon what the referral policy is based. The right-hand column shows for each indication who is the most suitable care provider.

The main purpose of the indication list is to provide a guide for risk-selection. The primary obstetric care provider, midwife, or GP is primarily responsible for this risk-selection. The Manuel is a consensus document showing the agreement reached by the professional groups on their decision-making structure.

Explanation of the codes used for the care providers

Code	Description	Care provider
A Primary obstetric care	The responsibility for obstetric care in the situation described is with the primary obstetric care provider.	Midwife/G.P.
B Consultation situation	This is a case of evaluation involving both primary and secondary care. Under the item concerned, the individual situation of the pregnant woman will be evaluated and agreements will be made about the responsibility for obstetric care (see Section 4.5).	Depending on Agreements
C Secondary obstetric care	This is a situation requiring obstetric care by an obstetrician at secondary level for as long as the disorder continues to exist.	Obstetrician
D Transferred primary obstetric care	Obstetric responsibility remains with the primary care provider, but in this situation it is necessary that birth takes place in a hospital in order to avoid possible transport risk during birth.	Midwife/G.P.

1. Pre-existing disorders – non-gynaecological

In cases of pre-existing disorders that are relevant to obstetrics, other care providers other than the midwife are regularly involved with care of the pregnant woman. In cases requiring consultation, it is necessary to involve the other care providers in the consultation.

For this reason, in disorders given code B in this section, attention should be given to collaboration with others outside the field of obstetrics. Attention should be paid to the counselling of women who are considering the possibility of becoming pregnant.

1.1	Epilepsy, without medication	A
1.2	Epilepsy, with medication Prenatal diagnostics are recommended in connection with the disorder and its medication. Optimal care requires consultation between all care providers concerned (midwife, G.P, obstetrician, neurologist).	B
1.3	Subarachnoid haemorrhage, aneurysms Care during puerperium can be at primary level.	C
1.4	Multiple sclerosis Depending upon the neurological condition, a complicated delivery and the possibility of urine retention should be taken into account. For optimal care, consultation between all care providers concerned is indicated.	B
1.5	Hernia nuclei pulposi This represents a C-situation in cases of a recently suffered HNP or where there are still neurogenic symptoms. It is an A-situation after treated hernia, especially if a previous pregnancy was normal. Both the medical history and the current clinical condition are relevant.	A/ C
1.6	Lung function disorder The opinion of the lung specialist should be taken into account during evaluation.	B
1.7	Asthma Care during pregnancy, birth and puerperium can only take place at a primary level when the asthma involves lengthy symptom-free intervals, whether or not use is made of inhalation therapy. Consultation with the GP/specialist involved is recommended.	A/ C
1.8	Tuberculosis, active Tuberculosis, non-active In cases of an active tuberculoses process and subsequent treatment, consultation should take place with the physician involved and the obstetrician regarding the clinical condition and care during pregnancy and birth. In cases of non-active tuberculosis, care during pregnancy and birth can take place at a primary level.	C A
1.9	HIV-infection	C

	As a result of the current possibilities of medical therapy for preventing vertical transmission, these patients should be cared for during pregnancy and birth in a hospital equipped for the treatment of HIV and AIDS.	
1.10	Hepatitis B with positive serology (Hbs-AG+) Since 1988 it is important that a screening programme for this serology is carried out on pregnant women.	A
1.11	Hepatitis C Consultation with the obstetrician and follow-up by the pediatrician is recommended.	B
1.12	A heart condition with haemodynamic consequences Pregnancy and birth will have an effect on the pre-existing haemodynamic relationships. A cardiac evaluation is important.	C
1.13	Thrombo-embolic process Of importance are the underlying pathology and the presence of a positive family medical history. Pre-conceptual counselling is important.	B
1.14	Coagulation disorders	C
1.15	Renal function disorders When there is a disorder in renal function, with or without dialysis, referral to secondary care is recommended.	C
1.16	Hypertension Pre-existing hypertension, with or without medication therapy, will require referral to secondary care. Hypertension has been defined by the ISSHP as: A single event of diastolic blood pressure of 110 mm Hg or more (Korotkoff IV). Diastolic blood pressure of 90 mm Hg or more at two subsequent blood pressure measurements with an interval of at least 4 hours between the two measurements. A distinction should be drawn between a diastolic blood pressure under 95 mm and a pressure of 95 mm and higher. Extra attention should be paid to a pregnant woman with a diastolic pressure between 90 and 95 mm; from 95 mm, referral to secondary care should take place.	A/ C
1.17	Diabetes mellitus	C
1.18	Hyperthyroidism	C
1.19	Hypothyroidism In cases of biochemical euthyroid, without antibodies and without medication, or stable on levothyroxine medication, care can take place at a primary level. Where levothyroxine medication is given, specific tests are recommended due to the frequent increase in medication required during pregnancy.	B
1.20	Anemia, due to a lack of iron Anemia is defined as Hb<6.0 mmol that has existed for some time.	B
1.21	Anemia, other	B

	This includes the haemoglobinopathies.	
1.22	Inflammatory Bowel Disease This includes ulcerative colitis and Crohn's disease.	C
1.23	System diseases and rare diseases These include rare maternal disorders such as Addison's disease and Cushing's disease. Also included are systemic lupus erythematosus (SLE), anti-phospholipid syndrome (APS), scleroderma, rheumatoid arthritis, periarteritis nodosa, Marfan's syndrome, Raynaud's disease and other systemic and rare disorders.	C
1.24	Use of hard drugs (heroin, methadone, cocaine, XTC, etc.) Attention should be paid to actual use. A urine test can be useful even in cases of past use in the medical history. The involvement of the pediatrician is indicated during the follow-up postpartum.	C
1.25	Alcohol abuse The fetal alcohol syndrome is important. The involvement of the pediatrician is indicated during the follow-up postpartum.	C
1.26	Psychiatric disorders Care during pregnancy and birth will depend on the severity and extent of the psychiatric disorder. Consultation with the physician in charge is indicated.	B

2. Pre-existing gynaecological disorders

2.1	Pelvic floor reconstruction This refers to colpo-suspension following prolapse, fistula and previous rupture. Depending on the cause, the operation technique used and the results achieved, the obstetrician will determine policy regarding the birth. A primary caesarean section or an early primary episiotomy can be considered, to be repaired by the obstetrician. If the chosen policy requires no special measures and no specific operating skill, then care during birth can be at primary level.	C
2.2	Cervical amputation	C
	Cervical cone biopsy	B
	Cryo- and lis-treatment The practical application of obstetric policy in this field can be worked out in local mutual agreements. If an uncomplicated pregnancy and birth have taken place following cone biopsy then a subsequent pregnancy and birth can take place at primary level.	A
2.3	Myomectomy (serous, mucous) Depending on the anatomical relationship, the possibility of a disturbance in the progress of the pregnancy or birth should be taken into account.	B
2.4	Abnormalities in cervix cytology (diagnostics, follow-up)	B/A

	There should be differentiation according to obstetric versus gynaecological policy. Gynaecological consultation can be indicated even without obstetric consequences. Participation in national cervical cancer screenings program is not provided pregnant women. The gynaecological follow-up is not an impediment to obstetric care at primary level.	
2.5	DES-daughter (untreated and under supervision) There should be a differentiation according to obstetric versus gynecological policy. Gynaecological care related to the problems surrounding DES may be necessary, while obstetric care can take place at primary level.	B
2.6	IUD in situ	B
	Status following removal of the IUD	A
2.7	Status following infertility treatment In practice, the wish of the patient to be cared for at secondary level plays a role here, even though the pregnancy and birth are otherwise normal. There is no question of an increased obstetric risk.	A
2.8	Pelvic deformities (trauma, symphysis rupture, rachitis) Consultation should take place at the start of the last trimester. It should be pointed out that care at secondary level has not been shown to have any added value in cases of pelvic instability and symphysis pubis dysfunction.	B
2.9	Female circumcision/Female genital mutilation Circumcision as such can require extra psychosocial care. Where there are serious anatomical deformities, consultation should take place in the third trimester.	A/B

3. Obstetric medical history

3.1	Active blood group incompatibility (Rh, Kell, Duffy, Kidd)	C
	ABO-incompatibility Pregnancy and birth can take place at primary care level in cases of ABO-antagonism, but one should be on the alert for neonatal problems. Consultation is indicated.	B
3.2	Pregnancy induced hypertension in the previous pregnancy	A
	Pre-eclampsia in the previous pregnancy	B
	HELLP-syndrome in the previous pregnancy	C
3.3	Habitual abortion (3 times) If an abortion should occur again, the need to carry out pathological study of fetal material should be discussed. Genetic counselling prior to pregnancy is also advised.	A
3.4	Pre-term birth (<37 weeks) in a previous pregnancy	B

	If a normal pregnancy has taken place subsequent to the premature birth, then a further pregnancy can be conducted at primary care level.	
3.5	Cervix insufficiency (and/or Shirodkar-procedure) Secondary level care during pregnancy is indicated up to 37 weeks; with a full term pregnancy, home birth is allowed. If a subsequent pregnancy was normal, then future pregnancies and deliveries can be conducted at primary care level.	C/A
3.6	Placental abruption	C
3.7	Forceps or vacuum extraction Evaluation of information from the obstetrical history is important. Documentation showing a case of an uncomplicated assisted birth will lead to the management of the present pregnancy and birth at primary care level. Consultation should take place when no documentation is available or when there are signs of a complicated assisted birth.	A/B
3.8	Caesarean section	C
3.9	Fetal growth retardation (Light for date) A birth weight of P<2.3 or obvious neonatal hypoglycemia related to fetal growth retardation.	C
3.10	Asphyxia Defined as an APGAR score of <7 at 5 minutes. It is important to know whether a pediatrician was consulted because of asphyxia at a previous birth.	B
3.11	Perinatal death Such an obstetrical history requires consultation. It is also important to know whether there was a normal pregnancy following the perinatal death. Pregnancy and birth can then be conducted at primary care level.	B
3.12	Prior child with congenital and/or hereditary disorder It is important to know the nature of the disorder and what diagnostics were carried out at the time. If no disorders can currently be discerned, then further care can be at primary care level.	B
3.13	Postpartum haemorrhage as a result of episiotomy	A
3.14	Postpartum haemorrhage as a result of cervix rupture (clinically demonstrated) The assumption is that there is a chance of a recurrence; the pregnancy and birth can be conducted at primary care level. The decision can be taken to allow birth to take place in the hospital.	D
3.15	Postpartum haemorrhage, other causes (>1000 cc) In view of the chance of a recurrence, although the pregnancy and birth can be conducted at primary care level, the decision can be taken to allow birth to take place in the hospital.	D
3.16	Manual placenta removal in a previous pregnancy In view of the increased recurrence risk, the next following pregnancy and birth can be cared for at primary care level, with the birth taking place in hospital.	D

	When the birth following one in which the manual placenta removal has taken place has had a normal course, a subsequent pregnancy and birth can be cared for at primary level. When in the previous birth a placenta accreta is diagnosed, obstetrical care at secondary level is indicated.	
3.17	4th degree perineal laceration (functional recovery/no functional recovery) If satisfactory functional recovery has been achieved following the 4th degree tear, then pregnancy and birth can be managed at primary care level. The possibility of performing a primary episiotomy during birth should be considered. If secondary repair surgery was necessary, then referral to secondary care is indicated (similarly to that which is stated for pelvic floor reconstruction). If no functional repair has been achieved following a 4th degree tear, then birth should be managed at secondary care level.	A/C
3.18	Symphysis pubis dysfunction There is no added value to managing pregnancy or birth at secondary care level in cases with a symphysis pubis dysfunction in the history or with pelvic instability.	A
3.19	Postpartum depression There is no added value to managing pregnancy or birth at secondary care level in cases with a p.p.d. in the history. Postpartum depression occurs at such a time postpartum that even the puerperium can be cared for at primary care level.	A
3.20	Postpartum psychosis It is necessary to distinguish whether there is a case of long-term medicine use. It is important to have a psychiatric evaluation of the severity of the psychosis and the risk of recurrence.	A
3.21	Grand multiparty Defined as parity >5. There is no added value to managing a pregnancy and birth at secondary care level.	A
3.22	Post-term pregnancy Post-term pregnancy in the obstetrical history has no predictive value for the course of the current pregnancy and birth.	A

4. Developed/discovered during pregnancy

In this section it is the case that supervision at secondary level care is necessary in situations given the code C, as long as the problem described still exists. If it no longer exists, then the patient can be referred back to primary level care.

4.1	Uncertain duration of pregnancy by amenorrhoea >20 weeks Consultation is required when the duration of pregnancy is uncertain after 20 weeks amenorrhoea. The primary care provider has access to sufficient additional diagnostic tools in the first 20 weeks.	B

4.2	Anemia (Hb<6.0 mmol/l) It is important that the nature and the severity of the anemia are analysed during consultation.	B
4.3	Recurrent urinary tract infections One can speak of recurrent urinary tract infection when an infection has occurred more than twice. Further analysis of the infection is required. The risk of renal function disorders and the risk of pre-term birth are important. The course of further diagnostics can take place within the local mutual agreements made between the three professional groups.	B
4.4	Pyelitis Hospital admission is required for the treatment of pyelitis, so that care will have to be at secondary level. After successful treatment of the pyelitis, further care during pregnancy and birth can be at primary level.	C
4.5	Toxoplasmosis, diagnostics and therapy Referral to secondary level is required both for diagnostics and for therapeutic policy.	C
4.6	Rubella An increased risk of fetal growth retardation, pre-term birth and visual and hearing disorders should be taken into account in a case of primary infection with rubella during pregnancy.	C
4.7	Cytomegalovirus An increased risk of perinatal death and subsequent morbidity should be taken into account.	C
4.8	Herpes genitalis (primary infection) Herpes genitalis (recurrent) During a primary infection there is a (slight) risk of transplacental fetal infection. In the first year after the primary infection, there is a higher frequency of recurrences and asymptotic virus excretion. If a primary infection occurs shortly before or during birth, there is an increased risk of neonatal herpes. Due to the possibility of treatment with antiviral drugs, referral to secondary care is indicated for primary infections. For recurrences and where herpes genitalis is in the medical history, it is advisable to carry out a virus culture from the oropharynx of the neonate. If there are frequent recurrences (>1/month) or where there is a recurrence during birth, referral is indicated due to the increased risk of infection of the neonate. It is as yet not clear whether the presence of antibodies are sufficient protection for the child.	C A
4.9	Parvo virus infection This infection can lead to fetal anemia and hydrops. Possibilities exist for treating these problems.	C
4.10	Varicella/Zoster virus infection This refers to a maternal infection. Primary infection with varicella/zoster virus	B

	(chicken pox) during the pregnancy might require treatment of the pregnant woman with VZV-immunoglobulin due to the risk of fetal varicella syndrome. If varicella occurs shortly before birth or early during the puerperium, there is a risk of neonatal infection. Treatment of the mother and child with an antiviral drug is sometimes indicated. If there is a case of manifest herpes zoster (shingles), then there is no risk of fetal varicella syndrome.	
4.11	Hepatitis B (Hbs-Ag+)	A
4.12	Hepatitis C This is an indication for referral to secondary care for consultation. Attention must be given to follow-up by the pediatrician.	B
4.13	Tuberculosis This refers to an active tuberculous process.	C
4.14	HIV-infection In connection with the present possibilities of medical therapy for preventing vertical transmission, care for these patients during pregnancy and birth should take place in a hospital/center equipped to deal with HIV and AIDS.	C
4.15	Syphilis Positive serology and treated	A
	Positive serology and not yet treated	B
	Primary infection Attention should be paid to collaboration between the primary and secondary care providers involved during referral. It is important to ensure perfect information exchange between the midwife, the GP, the obstetrician and the venereologist. Structural agreements can be worked out in local collaboration.	C
4.16	Hernia nuclei pulposi, (slipped disk) occurring during pregnancy Policy should be determined according to complaints and clinical symptoms. Where there are no complaints, (further) care can take place at primary level.	B
4.17	Laparotomy during pregnancy As soon as wound healing has occurred and if the nature of the operation involves no further obstetric risks, care for the pregnant woman can return to primary level. During hospitalisation the obstetrician will be involved in the care. If there are no further obstetric consequences then care for the pregnant woman can return to primary level.	C
4.18	Cervix cytology PAP III or higher What is important here is that further gynaecological policy (for the purpose of subsequent diagnostics) may be necessary, while the pregnancy and birth can be conducted at primary level.	B
4.19	Medicine use What is obviously important here is the effect of drugs on the pregnant woman and the unborn child. Attention should also be paid to the effect on lactation and the effects in the neonatal period. In cases of doubt, consultation should	A/ B

	take place. Note: information is available from the NIAD (030-2971100) and from the teratology center of the RIVM (030-2742017).	
4.20	Use of hard drugs (heroin, methadone, cocaine, XTC etc.) The severity of the addiction to hard drugs is important here and their effects during pregnancy and birth and in the puerperium, particularly for the neonate.	C
4.21	Alcohol abuse This involves the fetal alcohol syndrome. Obviously the long-term involvement of the pediatrician can be necessary during follow up.	C
4.22	Psychiatric disorders (neuroses/psychoses) The severity of the psychiatric problems and the opinion of the physician in charge of treatment are important.	A/ C
4.24	Hyperemesis gravidarum Referral to secondary care is necessary for treatment of this condition. After recovery the pregnancy and birth can take place at primary care level.	C
4.24	Ectopic pregnancy	C
4.25	Antenatal diagnostics Attention should be given to the presence of a risk for congenital deformities. If no deformities can be found, then further care can take place at primary level. In cases of an age-related indication, direct referral from primary care level to a genetic center can take place.	C
4.26	(Suspected) fetal deformities	B
4.27	Pre-term rupture of membranes (<37 weeks amenorrhoea)	C
4.28	Diabetes Mellitus (incl. pregnancy diabetes)	C
4.29	Pregnancy induced hypertension This refers to hypertension (according to the ISSHP definition, see 1.16) in the second half of pregnancy in a previously normotensive woman. Distinction is drawn between diastolic blood pressure up to 95 mm and blood pressure starting at 95 mm. At a diastolic pressure between 90 and 95 mm, a pregnant woman should receive extra care, from 95 mm upwards, she should be referred to secondary level care.	A/ C
4.30	Pre-eclampsia, super-imposed pre-eclampsia, HELLP-syndrome Pre-eclampsia is a combination of pregnancy induced hypertension and proteinuria. The latter is defined by an albustix ++ in a urine sample or by a total protein excretion of 30 mg or more during a period of 24 hours. A super-imposed pre-eclampsia exists when there is 'de novo' proteinuria during a pregnancy in a patient with pre-existing hypertension. The HELLP-syndrome is characterised by the combination of haemolysis, liver function disorder and a decrease in the number of platelets.	C
4.31	Blood group incompatibility	C
4.32	Thrombosis	C
4.33	Coagulation disorders	C
4.34	Recurring blood loss prior to 16 weeks	B

4.35	Blood loss after 16 weeks After the blood loss has stopped, care can take place at primary care level if no incriminating causes were found.	C
4.36	Placental abruption	C
4.37	(Evaluation of) negative size-date discrepancy A negative size-date discrepancy exists if the growth of the uterus remains 2 to 4 weeks behind the normal size for the duration of the pregnancy.	B
4.38	(Evaluation of) positive size-date discrepancy	B
4.39	Post-term pregnancy This refers to amenorrhoea lasting longer than 294 days.	C
4.40	Threat of or actual pre-term birth As soon as there is no longer a threat of pre-term birth, care during the pregnancy and birth can be continued at primary care level.	B
4.41	Insufficient cervix Once the pregnancy has lasted 37 weeks, further care can take place at primary care level.	C
4.42	Symphysis pubis dysfunction (pelvic instability) This refers to complaints that started during the present pregnancy	A
4.43	Multiple pregnancy	C
4.44	Abnormal presentation at full term (including breech presentation)	C
4.45	Failure of head to engage at full term If at full term there is a suspected cephalo-pelvic disproportion, placenta praevia or comparable pathology, consultation is indicated.	B
4.46	No prior prenatal care (full term) Attention should be paid to the home situation. The lack of prenatal care can suggest psychosocial problems. This can lead to further consultation and a hospital delivery.	A
4.47	Baby up for adoption The prospective adoption often goes hand-in-hand with psychosocial problems. This can lead to further consultation and a hospital delivery.	A
4.48	Dead fetus If the mother prefers to give birth at home, the care she receives should be the same as if the birth were to take place in a hospital. Attention should be paid to postmortem examination study and evaluation according to protocol.	C
4.49	Obstetrically relevant fibroids (myoma) Depending on the anatomical proportions, the possibility of a disturbance in the progress of pregnancy or birth should be taken into account.	B

5. Occurring during birth

For the C-category in this section, when one of the items mentioned below occurs, an attempt should still be made to achieve an optimal condition for further intrapartum care, whilst referral to secondary care level may be urgent, depending on the situation. When referring from the home situation, the risk of transporting the woman also needs to be included in the considerations.

5.1	Abnormal presentation of the child What counts here is abnormal presentation and not abnormal position.	B
5.2	Signs of fetal distress It is important that fetal distress can be expressed in various ways (fetal heart rate, meconium staining in the amniotic fluid).	C
5.3	Intrapartum fetal death Attention should be paid to post-mortem examinations	C
5.4	Pre-labour rupture of membranes Referral should take place the morning after the membranes have been broken for 24 hours.	C
5.5	Failure to progress in the first stage of labour If the contractions are good, both regarding strength and frequency, but there is no change in the cervix or progress in dilation after the latent phase for duration of 4 hours; one can speak of a failure to progress in labour. Consultation is necessary to be able to determine further treatment based on an analysis of the possible cause.	B
5.6	Failure to progress in second stage of labour This exists where there is a lack of progress, after a maximum of one hour, in cases with full dilation, ruptured membranes, strong contractions and sufficient maternal effort.	C
5.7	Excessive bleeding during birth The degree of bleeding during birth cannot be objectively measured, but needs to be estimated. Excessive loss of blood can be a sign of a serious pathology.	C
5.8	Placental abruption	C
5.9	Umbilical cord prolapse	C
5.10	(Partial) retained placenta It is not always possible to be sure of the retention of part of the placenta. If there is reasonable cause to doubt, then referral to secondary care should take place	C
5.11	Fourth degree perineal laceration	C
5.12	Meconium stained amniotic fluid	C
5.13	Fever It is obviously important to find out the cause of the fever. In particular, the	C

	possibility of an intrauterine infection should be taken into account and the administration of antibiotics intrapartum should be considered.	
5.14	Analgesia It is important to be aware of the effects on dilatation and respiratory depression. The use of painkillers during birth is a subject that can be covered during local discussions with the aid of guidelines. One should attempt to achieve well-founded consensus.	B
5.15	Vulva haematoma Treatment policy is determined according to the complaints intrapartum and in the early puerperium.	C
5.16	Symphyiolysis This refers to rupturing of the symphyseal rupture. It should be distinguished from pelvic instability. The added value of consultation in cases of pelvic instability has not been proven.	B
5.17	Birth with no prior prenatal care A lack of prenatal care can be a sign of psychosocial problems and in particular addiction. Intrapartum monitoring, serological screening and immunisation are of utmost importance.	C

6. Occurring during the puerperium

6.1	Puerperal fever It is important to know the underlying cause. In cases of reasonable doubt, referral should be considered.	A/C
6.2	(Threat of) eclampsia, (suspected) HELLP-syndrome	C
6.3	Thrombosis	C
6.4	Psychosis It is important to involve (non-obstetrically) the GP and the psychiatrist in treating the psychiatric disorder.	B
6.5	Postpartum haemorrhage	C
6.6	Hospitalisation of child It is obviously important here to involve (non-obstetrically) the GP and the pediatrician. The bonding between mother and child are important in the period following birth.	C

Ontario College of Midwives Indications for Mandatory Discussion, Consultation and Transfer of Care (effective January 2015)

According to the midwifery model of care, the midwife works in partnership with the client. As a provider of primary healthcare, the midwife is fully responsible for the clinical assessment, planning and delivery of care for each client. The client remains the primary decision-maker regarding her own care, and that of her newborn.

Throughout the antepartum, intrapartum and postpartum periods, clinical situations may arise in which the midwife will need to initiate involvement of other health care providers in the care of a client or her newborn. According to the requirements of this Standard, she will:

- **Consult** with a physician, or the most appropriate available health care provider, or
- **Transfer responsibility for primary care** to a physician

Definitions

Consultation with a Physician, or other appropriate health care provider

- Consultation is an explicit request from a midwife of a physician, or other appropriate health care provider, to give advice on a plan of care and participate in the care as appropriate.
- It is the midwife's responsibility to decide when and with whom to consult and to initiate consultations.
- Consultation may result in the physician, or other health care provider, giving advice, information and/or therapy to the woman/newborn directly or recommending a plan of care and/or therapy to be carried out by the midwife.
- After consultation with a physician, the role of most responsible provider either remains with the midwife or is transferred to the consulting physician.
- Consultation may be initiated at the client's request.

Transfer of Care to a Physician

- Transfer of care occurs when the primary care responsibilities required for the appropriate care of the client fall outside of the midwife's scope of practice.
- A transfer of care may be permanent or temporary.
- When primary care is transferred from the midwife to a physician, the physician assumes full responsibility for the subsequent planning and delivery of care to the client.
- The client remains the primary decision-maker regarding her care and the care of her newborn.
- After a transfer of care has taken place the midwife shall remain involved as a member of the health care team and provide supportive care to the client within the scope of midwifery.
- If the condition for which the transfer of care was initiated is resolved, the midwife may resume primary responsibility for the care of the mother and/or newborn.

Midwife's Responsibilities

- In all instances where another health care provider is required in the care of a midwife's client or her newborn, the midwife shall:
- Review the *Consultation and Transfer of Care Standard* with the client as part of an informed choice discussion.
- Respect the principles of informed choice, and support the client decision making process.
- Ensure that a client's decision not to pursue a consultation with another health care provider is clearly documented in the client's health record, in accord with the standards of the College of Midwives.
- Ensure that a client's decision not to follow a consultant's recommendation, once it is communicated to the midwife, is documented in the client's health record, in accord with the standards of the College of Midwives.
- Involve the other health care provider within an appropriate time frame.
- Ensure that the request for a consultation or transfer of care are both clearly articulated to the other health care provider and the client, and documented in the client's health record.[4]
- Ensure, where possible, that a consultation includes an in-person evaluation of the client or her newborn and that a consultation is initiated by phone where urgency, distance or climatic conditions make an in-person consultation impossible.
- Ensure that the subsequent plan of care, including the roles and responsibilities of the primary care providers involved, are communicated to the clinicians, and to the client and documented in the client's health record.
- Remain accountable for the care they have provided whether working collaboratively or independently.
- Throughout the course of care other indications not specifically referenced in this Standard may arise which require the involvement of other health care providers. Notwithstanding the indications listed in this Standard, midwives are expected to use their best clinical judgment supported by the highest quality available evidence and relevant guidelines, to determine when the involvement of other health care practitioners is warranted.

Indications: Initial History and Physical Examination

Consultation

- Significant current medical conditions that may affect pregnancy or are exacerbated due to pregnancy
- Significant use of drugs, alcohol or other substances with known or suspected teratogenicity or risk of associated complications
- Previous uterine surgery other than one documented low-segment cesarean section
- History of cervical cerclage
- History of more than one second-trimester spontaneous abortion
- History of three or more consecutive first-trimester spontaneous abortions
- History of more than one preterm birth, or preterm birth less than 34+ 0 weeks in most recent pregnancy

- History of more than one small for gestational age infant
- History of severe hypertension or pre-eclampsia, eclampsia or HELLP syndrome
- Previous neonatal mortality or stillbirth which likely impacts current pregnancy

Transfer of care

- Cardiac disease
- Renal disease
- Insulin-dependent diabetes mellitus
- HIV positive status

Indications: Prenatal Care

Consultation

- Significant mental health concerns presenting or worsening during pregnancy
- Persistent or severe anemia unresponsive to therapy
- Severe hyperemesis unresponsive to pharmacologic therapy
- Abnormal cervical cytology requiring further evaluation
- Significant non-obstetrical or obstetrical medical conditions arising during pregnancy
- Sexually transmitted infection requiring treatment
- Gestational diabetes unresponsive to dietary treatment
- Urinary tract infection unresponsive to pharmacologic therapy
- Persistent vaginal bleeding other than uncomplicated spontaneous abortion less than 14+0 weeks
- Fetal anomaly that may require immediate postpartum management
- Evidence of intrauterine growth restriction
- Oligohydramnios or polyhydramnios
- Twin pregnancy
- Isoimmunization
- Persistent thrombocytopenia
- Thrombophlebitis or suspected thromboembolism
- Gestational hypertension
- Vasa previa
- Asymptomatic placenta previa persistent into third trimester
- Presentation other than cephalic, unresponsive to therapy, at or near 38+0 weeks
- Intrauterine fetal demise
- Evidence of uteroplacental insufficiency
- Uterine malformation or significant fibroids with potential impact on pregnancy

Transfer of care

- Molar pregnancy
- Multiple pregnancy (other than twins)
- Severe hypertension or pre-eclampsia, eclampsia or HELLP syndrome

- Placental abruption or symptomatic previa
- Cardiac or renal disease with failure
- Gestational diabetes requiring pharmacologic treatment

Indications: Labor, Birth, and Immediate Post-Partum

Consultation

- Preterm prelabour rupture of membranes (PPROM) between 34 +0 and 36 +6 weeks
- Twin pregnancy
- Breech or other malpresentation with potential to be delivered vaginally
- Hypertension presenting during the course of labour
- Abnormal fetal heart rate pattern
- Suspected intra amniotic infection
- Labor dystocia unresponsive to therapy
- Intrauterine fetal demise
- Retained placenta
- Third or fourth degree laceration
- Periurethral laceration requiring repair

Transfer of care

- Active genital herpes at time of labour or rupture of membranes
- HIV positive status
- Preterm labour or PPROM less than 34 +0 weeks
- Fetal presentation that cannot be delivered vaginally
- Multiple pregnancy (other than twins)
- Prolapsed or presenting cord
- Placental abruption, placenta previa or vasa previa
- Severe hypertension or pre-eclampsia, eclampsia or HELLP syndrome
- Suspected embolus
- Uterine rupture
- Uterine inversion
- Hemorrhage unresponsive to therapy

Indications: Post-partum (Maternal)

Consultation

- Breast or urinary tract infection unresponsive to pharmacologic therapy
- Suspected endometritis
- Abdominal or perineal wound infection unresponsive to non-pharmacologic treatment
- Persistent or new onset hypertension
- Significant post-anesthesia complication
- Thrombophlebitis or suspected thromboembolism

- Significant mental health concerns including postpartum depression and signs or symptoms of postpartum psychosis
- Persistent bladder or rectal dysfunction
- Secondary postpartum hemorrhage
- Uterine prolapse
- Abnormal cervical cytology requiring treatment

Transfer of care

- Postpartum eclampsia
- Postpartum psychosis

Indications: Post-partum (Infant)

Consultation

- 34 +0 to 36 +6 weeks gestational age
- Suspected neonatal infection
- In utero exposure to significant drugs, alcohol, or other substances with known or suspected teratogenicity or other associated complications
- Findings on prenatal ultrasound that warrant postpartum follow up
- Prolonged PPV or significant resuscitation
- Failure to pass urine or meconium within 36 hours of birth
- Suspected clinical dehydration
- Feeding difficulties not resolved with usual midwifery care
- Significant weight loss unresponsive to interventions or adaptation in feeding plan
- Failure to regain birth weight by three weeks of age
- Infant at or less than 5th percentile in weight for gestational age
- Single umbilical artery not consulted for prenatally
- Congenital anomalies or suspected syndromes
- Worsening cephalhematoma
- Excessive bruising, abrasions, unusual pigmentation and/or lesions
- Significant birth trauma
- Abnormal heart rate, pattern or significant murmur
- Hypoglycemia unresponsive to initial treatment
- Hyperglycemia
- Suspected neurological abnormality
- Persistent respiratory distress
- Persistent cyanosis or pallor
- Fever, hypothermia or temperature instability
- Vomiting or diarrhea
- Evidence of localized or systemic infection
- Hyperbilirubinemia requiring medical treatment or any jaundice within the first 24 hours
- Suspected seizure activity

Transfer of care

- Major congenital anomaly requiring immediate intervention

College of Midwives of British Columbia: Indications for Mandatory Discussion, Consultation and Transfer of Care

As a primary caregiver, the midwife is fully responsible for decision-making, together with the client. The midwife is responsible for writing orders and carrying them out or delegating them to an appropriate regulated health professional in accordance with the standards of the College of Midwives.

The midwife discusses care of a client, consults, and/or transfers primary care responsibility according to the *Indications for Discussion, Consultation and Transfer of Care.* The responsibility to consult with a family physician/general practitioner, obstetrician, pediatrician, other specialist physician or a nurse practitioner lies with the midwife. It is also the midwife's responsibility to initiate a consultation within an appropriate time period after detecting an indication for consultation. The severity of the condition and the availability of a physician will influence these decisions.

The College of Midwives expects members to use their professional judgment in making decisions to consult or transfer care. The following list is not exhaustive. Other circumstances may arise where the midwife believes consultation or transfer of care is necessary.

The informed choice agreement between the midwife and client should outline the extent of midwifery care, so that the client is aware of the scope and limitations of midwifery care. The midwife should review the *Indications for Discussion, Consultation and Transfer of Care* with the client.

Definitions

Discussion with a midwife, a physician, or nurse practitioner

It is the midwife's responsibility to initiate a discussion with, or provide information to, another midwife or a physician in order to create an appropriate plan of care. It is also expected that the midwife will conduct regularly scheduled reviews of client charts with her colleagues to assist in planning care. Discussion should be documented by the midwife in the client record.

Consultation with a physician or a nurse practitioner

It is the midwife's responsibility to initiate a consultation in accordance with the standards of the College and to communicate clearly to the consultant that she is seeking a consultation and why. In requesting a consultation, a midwife uses her professional knowledge of the client and requests the opinion of a physician or nurse practitioner qualified to give advice in the area of clinical concern. A midwife may also seek a consultation when another opinion is requested by the client. The midwife must document each consultation in the client record in accordance with the standards of the College of Midwives.

The midwife should expect the consultant to address the problem described in the consultation request, conduct an in-person assessment(s) of the client, and promptly communicate findings

and recommendations to the client and to the referring midwife. Discussion will then normally occur between the midwife and the consultant regarding the future plan of care for the client.

Where urgency, distance or climatic conditions do not allow the client to see a physician or nurse practitioner for an in-person consultation visit, the midwife should seek advice from the consultant by phone or other similar means. The consultant may use alternative means of communication (e.g., via telehealth) to assess the client as available and appropriate. The midwife should document such requests for advice in client records, in accordance with the standards of the College of Midwives, and discuss the advice received with the client.

A consultation can involve the physician or nurse practitioner providing advice and information, and/or providing therapy to the woman/newborn, or recommending therapy for the woman/newborn to the midwife to provide within her scope of practice.

After consultation with a physician or nurse practitioner, primary care of the client and responsibility for decision-making, with the agreement of the consultant and the informed consent of the client, may:

- Continue with the midwife;
- Be shared between the midwife, nurse practitioner and/or physician; or
- Be transferred to the physician.

Once a consultation has taken place and the consultant's findings, opinions and recommendations have been communicated to the client and the midwife, the midwife must discuss the consultant's recommendations with the client and ensure that the client understands which health professional will have responsibility for primary care.

Shared primary care

In a shared care arrangement the consultant may be involved in, and responsible for, a discrete area of the client's care, with the midwife maintaining overall responsibility within her scope of practice, or vice versa. Areas of involvement in client care and the plan for communication between care providers must be clearly agreed upon and documented by the midwife and the consultant.

It is recommended that one health professional take responsibility for coordinating the client's care. This arrangement should be clearly communicated to the client and documented in the records. Responsibility can be transferred temporarily from one health professional to another, or be shared between health professionals, according to the client's best interests and optimal care. Transfer of care or an arrangement for sharing care should be discussed with the client, agreed to between the midwife and the consultant(s), and documented in the client record.

Shared primary care arrangements may vary depending on community and on the experience and comfort levels of the care providers involved. Midwives who gain more skills and abilities and experience over time may be able to manage more complex care within their scope of practice in collaboration with their physician colleagues.

Transfer to a physician for primary care

When primary care is transferred permanently or temporarily from the midwife to a physician, the physician assumes full responsibility for subsequent decision-making, together with the client. When primary care is transferred to a physician, the midwife may continue to provide supportive care, and any care within her scope of practice that is agreed to by the physician who is in the role of most responsible care provider, and that has the consent of the client.

Indications: Initial History and Physical Examination

Discussion

- Adverse socio-economic conditions
- Age less than 17 years or over 40 years
- Cigarette smoking
- Grand multipara (5 or more previous births)
- History of infant over 4,500 g
- History of one late miscarriage (after 14 weeks) or pre-term birth
- History of one low-birth-weight infant
- History of serious psychological problems
- Less than 12 months from last delivery to present due date
- Obesity
- Poor nutrition
  Previous antepartum hemorrhage
- Previous postpartum hemorrhage
- One documented previous low-segment cesarean section
- History of hypertensive disorders of pregnancy
- Known uterine malformations or fibroids
- History of trauma or sexual abuse

Consultation

- Current medical conditions, for example: cardiovascular disease, pulmonary disease, endocrine disorders, hepatic disease, neurologic disorders, severe gastrointestinal disease
- Family history of genetic disorders, hereditary disease or significant congenital anomalies
- History of cervical cerclage or incompetent cervix
- History of repeated spontaneous abortions
- History of more than one late miscarriage or pre-term birth
- History of more than one low-birth-weight infant
- History of eclampsia
- History of significant medical illness
- Previous myomectomy, hysterotomy or cesarean section other than one
- Documented previous low-segment cesarean section
- Previous neonatal mortality or stillbirth

- Rubella during first trimester of pregnancy
- Significant use of drugs, alcohol or other toxic substances
- Age less than 14 years
- History of postpartum hemorrhage requiring transfusion

Transfer

- Any serious medical condition, for example: cardiac or renal disease with failure, or insulin-dependent diabetes mellitus

Indications: Prenatal Care

Discussion

- Presentation other than cephalic at 4 weeks prior to due date
- No prenatal care before 28 weeks gestation
- Uncertain expected date of delivery

Consultation

- Anemia (unresponsive to therapy)
- Documented post-term pregnancy (42 completed weeks) suspected or diagnosed
- Fetal anomaly that may require physician management during or immediately after delivery
- Inappropriate uterine growth
- Medical conditions arising during prenatal care, for example: endocrine disorders, hypertension, renal disease, suspected or confirmed significant infection, including h1n18, hyperemesis
- Placenta previa without bleeding
- Polyhydramnios or oligohydramnios
- Gestational hypertension
- Isoimmunization, haemoglobinopathies, blood dyscrasia
- Serious psychological problems
- Sexually transmitted disease
- Twins
- Repeated vaginal bleeding other than transient spotting
- Presentation other than cephalic at 37 weeks
- Insulin-dependent gestational diabetes

Transfer

- Cardiac or renal disease with failure
- Multiple pregnancy (other than twins)
- Severe pre-eclampsia12 or eclampsia
- Symptomatic placental abruption

Indications: During Labor and Delivery

Discussion

- No prenatal care
- Thin, non-particulate meconium

Consultation

- Breech presentation
- Pre-term labor (34 – 36 + 6 weeks)
- Prolonged active phase
- Prolonged rupture of membranes
- Prolonged second stage
- Suspected placenta abruption and/or previa
- Retained placenta
- Third or fourth degree tear
- Twins
- Unengaged head in active labor in primipara
- Thick or particulate meconium
- Temperature of 38°c or greater on more than one occasion

Transfer

- Active genital herpes at time of labor
- Pre-term labor (less than 34 weeks)
- Abnormal presentation (other than breech)
- Multiple pregnancy (other than twins)
- Severe pre-eclampsia or eclampsia
- Prolapsed cord
- Placenta abruption and/or previa
- Severe hypertension
- Abnormal fetal heart rate patterns unresponsive to therapy
- Uterine rupture
- Uterine inversion
- Hemorrhage unresponsive to therapy
- Obstetric shock

Indications: Post-partum (Maternal)

Consultation

- Breast infection unresponsive to therapy
- Wound infection
- Uterine infection
- Signs of urinary tract infection unresponsive to therapy
- Temperature over 38°c on more than one occasion

- Persistent hypertension
- Serious psychological problems

Transfer

- Hemorrhage unresponsive to therapy
- Eclampsia
- Thrombophlebitis or thromboembolism
- Uterine prolapse

Indications: Post-partum (Infant)

Discussion

- Feeding problems
- Excessive moulding
- Cephalohaematoma

Consultation

- Suspicion of or significant risk of neonatal infection
- 34 to 36 +6 weeks gestational age
- Infant less than 2,500 g
- Less than 3 vessels in umbilical cord
- Abnormal findings on physical exam
- Excessive bruising, abrasions, unusual pigmentation and/or lesions
- Birth injury requiring investigation
- Congenital abnormalities, for example: cleft lip or palate, developmental dysplasia of the hip, ambiguous genitalia
- Abnormal heart rate or pattern
- Persistent poor suck, hypotonia or abnormal cry
- Persistent abnormal respiratory rate and/or pattern
- Persistent cyanosis, pallor or jitteriness
- Jaundice in first 24 hours
- Failure to pass urine or meconium within 24 hours of birth
- Suspected pathological jaundice after 24 hours
- Temperature less than 36°C unresponsive to therapy
- Temperature of 38°C or more unresponsive to therapy
- Vomiting or diarrhea
- Infection of umbilical stump site
- Significant weight loss (more than 10% of body weight)
- Failure to regain birth weight in 3 weeks
- Failure to thrive

Transfer

- Apgar score lower than 7 at 10 minutes
- Suspected seizure activity
- Significant congenital anomaly requiring immediate medical intervention, for example: omphalocele, myelomeningocele
- Temperature instability

APPENDIX B. GRADE ELEMENT DESCRIPTIONS

Element	Description
Balance between desirable and undesirable effects	The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. The narrower the gradient, the higher the likelihood that a weak recommendation is warranted
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—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

Strong recommendation

In Favor*:* The subcommittee is confident that the desirable effects of adherence to a recommendation outweigh the undesirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences.

Against: The subcommittee is confident that the undesirable effects of adherence to a recommendation outweigh the desirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences.

Weak recommendation

In Favor: The subcommittee concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences, but is not confident.

Against: The subcommittee concludes that the undesirable effects of adherence to a recommendation probably outweigh the desirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences, but is not confident.

Quality or strength of evidence rating across studies for the treatment/outcome[9]

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 effect estimate: 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 effect estimate 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 effect estimate: 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.

[9] Includes risk of bias, precision, directness, consistency and publication bias

APPENDIX C. APPLICABLE CODES

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
V22	Normal pregnancy
V23	Supervision of high-risk pregnancy
V24	Post-partum care and examination
ICD-10 Diagnosis Codes	
Z34	Encounter for supervision of normal first pregnancy, unspecified trimester
O09	Supervision of high-risk pregnancy
Z39	Encounter for care and examination of mother immediately after delivery
ICD-9 Volume 3 (Procedure Codes)	
72	Forceps, vacuum and breech delivery
73	Other procedures inducing or assisting delivery
74	Cesarean section and removal of the fetus
75	Other obstetric operations
CPT Codes	
59400-10	Vaginal delivery
59412	External cephalic version, with or without tocolysis
59414	Delivery of placenta (separate procedure)
59425-6	Antepartum care only
59430	Postpartum care only (separate procedure)
59510-15	Cesarean delivery
59610-22	Delivery after previous cesarean
HCPCS Level II Codes	
H1000-5	Prenatal care, at risk assessment

Note: Inclusion on this list does not guarantee coverage

APPENDIX D. HERC GUIDANCE DEVELOPMENT FRAMEWORK

HERC Guidance Development Framework Principles

This framework was developed to assist with the decision making process for the Oregon policy-making body, the HERC and its subcommittees. It is a general guide, and must be used in the context of clinical judgment. It is not possible to include all possible scenarios and factors that may influence a policy decision in a graphic format. While this framework provides a general structure, factors that may influence decisions that are not captured on the framework include but are not limited to the following:

- Estimate of the level of risk associated with the treatment, or any alternatives;
- Which alternatives the treatment should most appropriately be compared to;
- Whether there is a discrete and clear diagnosis;
- The definition of clinical significance for a particular treatment, and the expected margin of benefit compared to alternatives;
- The relative balance of benefit compared to harm;
- The degree of benefit compared to cost; e.g., if the benefit is small and the cost is large, the committee may make a decision different than the algorithm suggests;
- Specific indications and contraindications that may determine appropriateness;
- Expected values and preferences of patients.

Planned ~~home~~ out-of-hospital birth for low-risk pregnancies

Oregon Health Authority

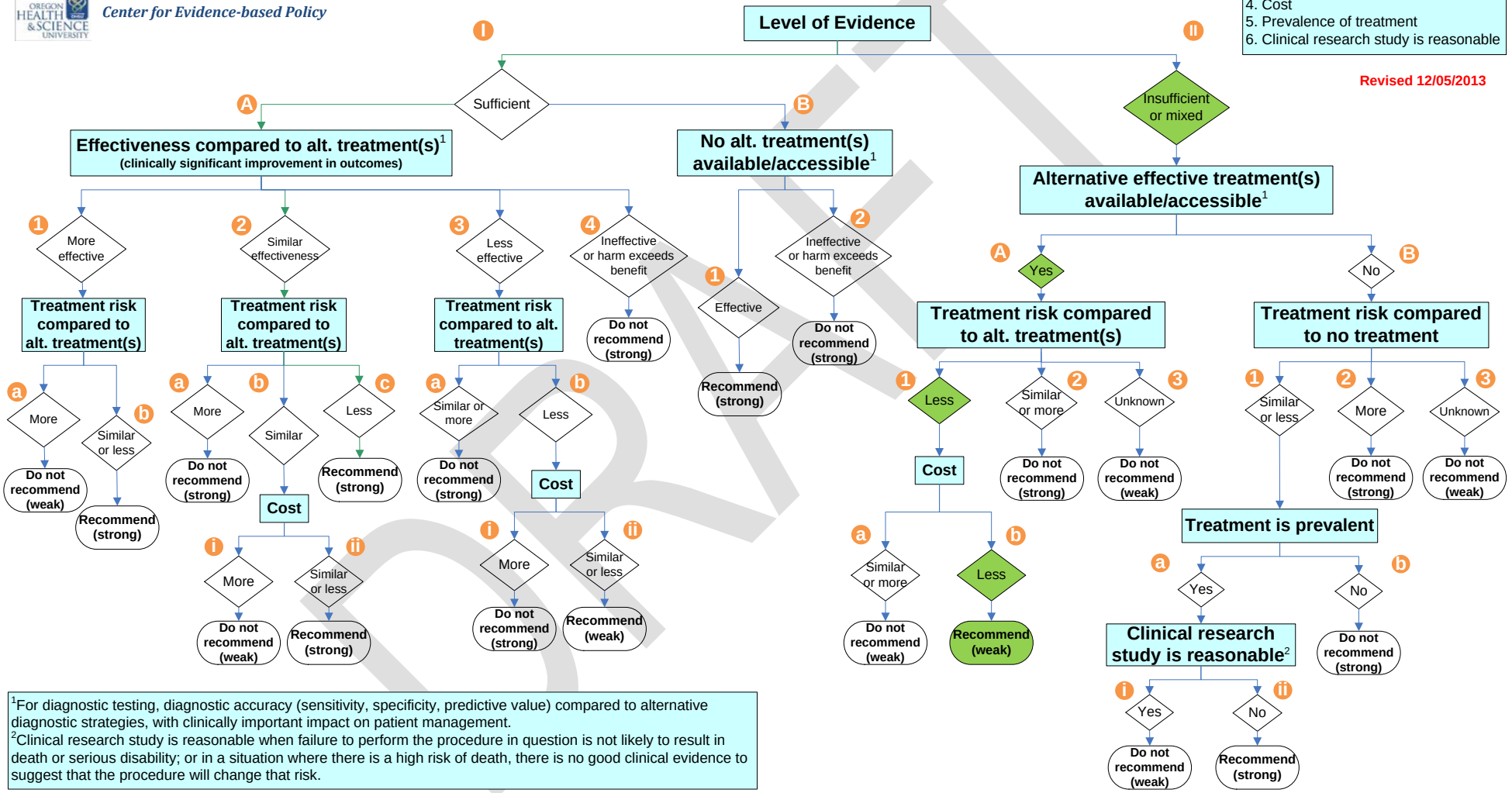
Center for Evidence-based Policy

HERC Guidance Development Framework

Refer to *HERC Guidance Development Framework Principles* for additional considerations

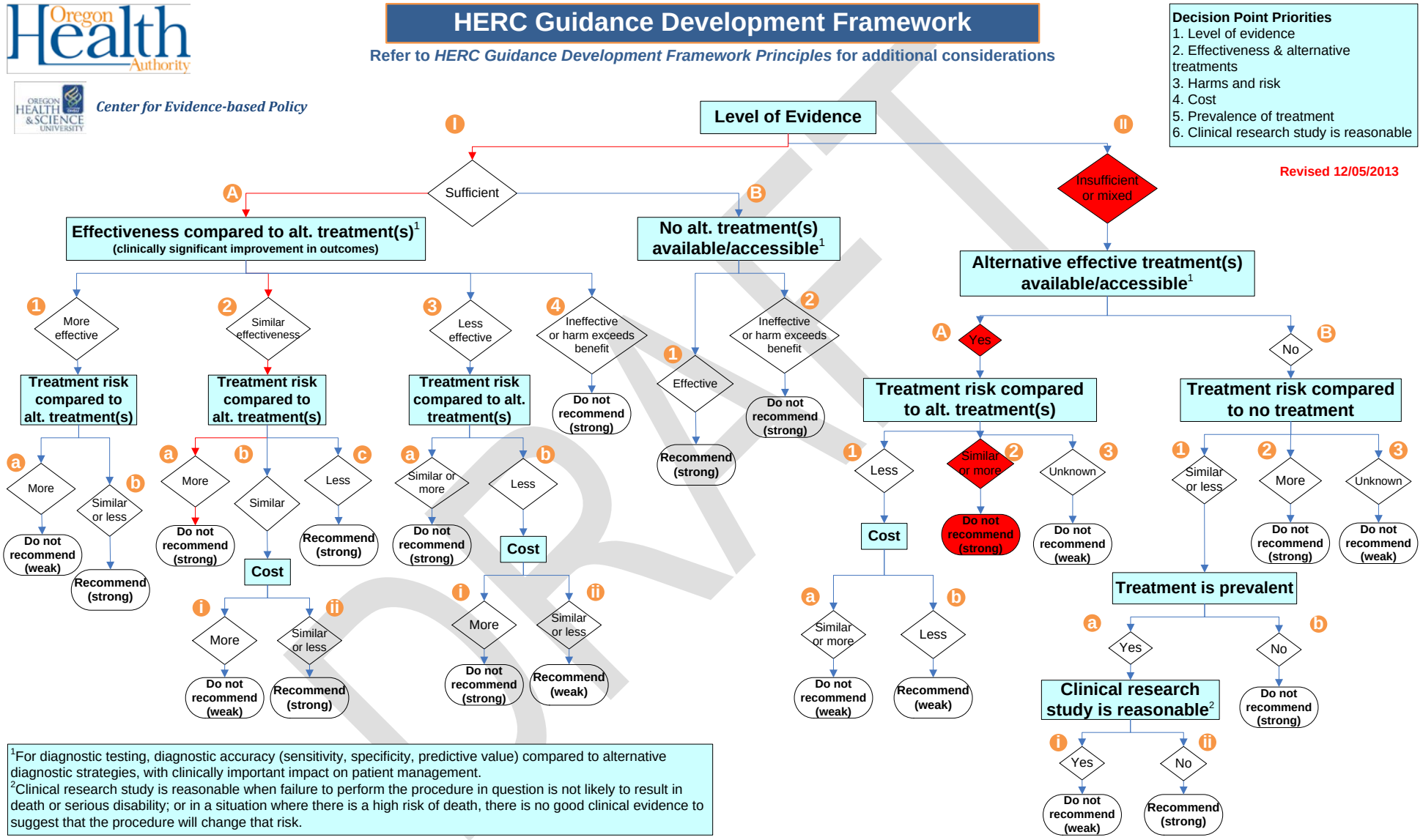
Decision Point Priorities
1. Level of evidence
2. Effectiveness & alternative treatments
3. Harms and risk
4. Cost
5. Prevalence of treatment
6. Clinical research study is reasonable

Revised 12/05/2013



[1]For diagnostic testing, diagnostic accuracy (sensitivity, specificity, predictive value) compared to alternative diagnostic strategies, with clinically important impact on patient management.
[2]Clinical research study is reasonable when failure to perform the procedure in question is not likely to result in death or serious disability; or in a situation where there is a high risk of death, there is no good clinical evidence to suggest that the procedure will change that risk.

Planned ~~home~~ out-of-hospital birth for unselected pregnancies



HERC Coverage Guidance – Home Birth
Disposition of Public Comments

Table of Contents

Commenters

Identification	Stakeholder
A	OB-Gyn physician *[Submitted December 3, 2014]*
B	CPM, LDM *[Submitted November 18, 2014]*
C	CPM, LDM *[Submitted November 18, 2014]*
D	QHOC Medical Directors *[Submitted December 9, 2014]*
E	Health plan medical director *[Submitted Dec. 10, 2014]*
F	Oregon Midwifery Council *[Submitted Dec. 10, 2014]*
G	Health Plan Midwife Committee Chairman *[Submitted Dec. 10, 2014]*
H	Oregon Pediatric Society, Doernbecher Children's Hospital, OHSU, Portland, OR [*Submitted Dec. 12, 2014*]
I	LDM *[Submitted December 15, 2014]*
J	MD, Retired Ob/Gyn *[Submitted December 15, 2014]*
K	RN *[Submitted December 15, 2014]*
L	Epidemiologist and RN *[Submitted December 15, 2014]*
M	Community Health Plan *[Submitted December 15, 2014]*

Public Comments

Ident.	#	Comment	Disposition
A	1	Two items to consider: 36 weeks' gestation is technically preterm birth, not sure a great idea for preterm births to happen at home, so consider using >/= 37 weeks.	Box language has been clarified to emphasize greater than 36 and less than 41 completed weeks of pregnancy, which would encompass EGA 37 weeks 0 days through 41 weeks 6 days, consistent with NICE guidance. Preterm is also a transfer requirement in the coverage guidance so aligning these to be 37 weeks 0 days would be appropriate.
	2	I don't see either pre-gestational or gestational diabetes on your pregnancy complications list. Certainly both put moms and babies at higher risk than genital herpes.	Diabetes (uncontrolled gestational, gestational requiring medication, or pre-existing Type I or Type II) has been added to the list of indications for planned hospital birth; diet-controlled gestational diabetes has been added to the list of indications for consultation prior to planned out-of-hospital birth.
B	1	I am a licensed midwife, practicing in Portland Oregon in a blended licensed midwife/nurse-midwife practice. We offer prenatal care, home birth and postpartum services to **low risk** women and strongly desire to include low income women in our client base. However, I am concerned that the proposed coverage guidelines for out of hospital birth is NOT based on quality research in terms of what constitutes low risk. I am requesting that your committee review the evidence on low risk (see below) and reissue your guidelines based on unbiased, research.	Commenter does not specify which criteria she disagrees with. EbGS does not believe their evidence sources are biased or poor quality.

B	2	Making normal birth a reality: Consensus statement from the Maternity Care Working Party http://mothersnaturally.org/pdfs/UKNormalBirthDocument.pdf	This is a consensus statement on the definition of a normal birth. They define normal birth as the following:
			• women whose labour starts spontaneously, progresses spontaneously without drugs, and who give birth spontaneously;
			• women who experience any of the following provided they do not meet the exclusion criteria:
			  ○ augmentation of labour
			  ○ artificial rupture of membranes (ARM) if not part of medical induction of labor
			  ○ Entonox
			  ○ Opioids
			  ○ Electronic fetal monitoring
			  ○ Managed third stage of labor

Ident.	#	Comment	Disposition
			○ Antenatal, delivery or postnatal complications (including for example post partum hemorrhage, perineal tear, repair of perineal trauma, admission to SCBU or NICU Normal delivery excludes: • induction of labor (with prostaglandins, oxytocics or ARM) • epidural or spinal • general anaesthetic • forceps or ventouse • cesarean section • episiotomy While a list of references is provided, supporting evidence is not specifically discussed.
B	3	http://www.bmj.com/content/330/7505/1416.full?ehom=	Duplicate of the above document.
B	4	Citizens for Midwifery Resources Webpage http://cfmidwifery.org/resources/	Website states that Citizens for Midwifery are "a non-profit, volunteer, grassroots organization. Founded by several mothers in 1996, it is the only national consumer-based group promoting the Midwives Model of Care." No evidence specifically identified.
C	1	I heard that the HERC is currently taking public comment on what constitutes low-risk for out of hospital birth. I have read the draft recommendations and am concerned about the proposed recommendations because they appear to risk women out for a large number of things that midwives are trained and qualified to handle. This is important to me because I am both a home birth midwife and a mother who has (safe, successful) had out of hospital births. I am concerned because I've known women who have chosen to have unassisted births because of similar strict sets of risk criteria. There are many women, who, when denied coverage due to unreasonable risk factors, will refuse to go to a hospital and will then be exposed to greater risks because of a lack of provider at their birth.	EbGS bases its decisions on the balance of benefits and harms according to the best available evidence, while taking into account patient values and preferences and limited resources. We understand that women have strong and highly variable preferences and that this report is a coverage guidance, which defines when home birth should be reimbursed as a safe and effective service. The coverage recommendation language now distinguishes between complications requiring consultation and those which require transfer or planned hospital birth, recognizing that some conditions require a planned hospital birth or transfer of care, while other risk factors require consultation to evaluate an individual situation and inform the patient's decision and provider's recommendation about where to plan to have her

Ident.	#	Comment	Disposition
			baby.
C	2	Oregon's licensed midwives and birth centers both have sets of reasonable risk criteria that could be used to define coverage for out of hospital birth. The Midwives Association of Washington State also has a well-researched set of risk criteria that could be used in this situation (http://www.washingtonmidwives.org/documents/MAWS-indications-4.24.08.pdf). Please consider using these pre-existing sets of criteria when you consider who to offer coverage to.	Oregon birth center risk criteria are included in the guidance document as Appendix A. No reference provided for Oregon licensed midwives risk criteria. Washington criteria are provided in Appendix 1 of this document. They are similar to the other risk criteria already included. Commenter does not identify which of the proposed criteria she disagrees with.
D	1	The possibility of VBAC is concerning given that many hospitals, especially in rural areas, cannot even offer VBAC. It would not be acceptable for these hospitals to be back up. And it is concerning that a condition that is too high risk for a hospital would be acceptable to be done at home.	Box language already indicated that women with prior Cesarean are not considered low-risk (and thus not candidates for out-of-hospital birth). The coverage recommendation has been modified to clarify the requirement for risk assessment at intake, during prenatal care and during labor and specify indications which require planned hospital birth, consultation or transfer.
D	2	Teen pregnancy is also a higher risk condition	Guidelines from British Columbia specify age less than 17 or over 40 as indication for discussion, and age less than 14 as indication for consultation. The recommendation has been edited to require consultation during prenatal care when the maternal age is under 14.
E	1	Should any of the complications occur at any point in the pregnancy, there should be a re-evaluation to determine the risk/status level; a. Low risk criteria should include an ultrasound between 12 – 30 weeks (standard accepted practice); b. Low risk criteria should include maternal and paternal age parameters such as 18 – 45 years of age;	HERC's existing coverage guidance on Ultrasound in Pregnancy reports the following: "Routine US in early pregnancy (< 24 weeks) does not change patient management, substantially alter delivery modes, or improve health outcomes, at least not in high-resource settings." and "Evidence has not shown routine US in late pregnancy (> 24 weeks) to change patient management, affect delivery mode, or improve health outcomes." Regarding age, see comment D2. NICE guidance recommends consultation for age > 35 years at booking. Box language has

Ident.	#	Comment	Disposition
			been edited to include "Maternal age < 14 years or > 35 years" as indication for consultation prior to planned out of hospital birth. Our evidence sources make no mention of paternal age as a risk factor for planned home birth. Coverage recommendation has been updated to require risk assessment throughout prenatal and labor period.
E	2	a. Complications should include having had an IUD in place; b. Complications should include third degree lacerations as well as fourth degree lacerations; c. Complications should include fractured clavicle and shoulder dystocia; d. Complications should include parental Jehovah's Witness status – due to inability to transfuse; e. Complications should include history of large babies (>9 pounds); f. Complications should include 'incomplete prenatal testing' such as strep and all STDs g. Complications should include VBACs (we agree with Cascade CCO); and h. Complications should include severe mental health issues not well controlled or addressed;	a. There is no evidence supporting history of IUD use as a high-risk condition in pregnancy. "Status following removal of the IUD" is Category A in the Netherlands guidelines. b. History of third-degree laceration is listed as an indication for consultation. History of fourth-degree laceration is listed as an indication for consultation or planned hospital birth depending on whether functional recovery has been achieved (following Netherlands). For laceration requiring hospital repair, see comment F24. c. Shoulder dystocia with or without fetal clavicular fracture in a previous pregnancy is currently listed as a high risk criterion indicating planned hospital birth. d. No evidence is presented by commenter on Jehovah's Witness status. All women giving birth out of hospital should have a full informed consent procedure, including information about what would be done if transfusion is indicated but declined. Personal or cultural objection to transfusion is not found as risk exclusion criterion in other systems identified. e. NICE recommends consultation if a prior baby was > 4.5 kg; this appears in our recommendation. f. Inadequate prenatal care is listed as an indication requiring planned hospital birth. Consider adding definition: Less than five prenatal visits or care began in the third trimester. g. Absence of prior cesarean or other hysterotomy is a minimum criterion for low-risk pregnancy

Ident.	#	Comment	Disposition
			h. Substance misuse and alcohol dependency requiring assessment or treatment have been added as indications for planned hospital birth; occasional maternal use of alcohol/marijuana has been added as an indication for consultation. Maternal mental illness under outpatient psychiatric care has been added to coverage guidance as requiring consultation prior to planned out-of-hospital birth, consistent with NICE guidance in table 9. Maternal psychiatric illness requiring inpatient care is added as an indication for planned hospital birth, again consistent with NICE guidance (table 6). For EbGS discussion.
E	3	I thought there was criteria regarding specific distance requirements from a hospital that could perform resuscitative procedures and emergency C-sections.	No such requirement was identified in any of the sources used to generate the risk criteria. For discussion.
F	1	I am writing on behalf of the Oregon Midwifery Council, which represents Direct-Entry Midwives in Oregon, to express my serious concern about the Draft Coverage Guidance on Planned Home Birth. Firstly, I am concerned that the HERC makes only a weak recommendation for the coverage of planned home birth for low risk pregnancies when the evidence is strong that planned home birth with a trained midwife in low risk pregnancies is a safe option for women and babies.	Thank you for your comment. "Weak recommendation" is a language that comes from the GRADE system and indicates the degree of confidence for a recommendation (see HERC methodology for details.) In this case, because of the potential for bias in the observational studies, the subcommittee elected to make a weak recommendation for coverage of planned out-of-hospital birth.
F	2	Secondly, many items on the "High Risk Conditions" list are completely out of line with the research on the safety of planned home birth with midwives. The list is much longer than is appropriate for coverage guidance for a provider type that is both skilled at, and required by OAR to use, risk assessment, consultation, referral, and transfer of care as needed. The current draft "high risk" list would prevent many healthy pregnant women from accessing basic maternity care with the provider type and at the location of their choice.	The list of "high risk criteria" was compiled from the trusted sources utilized by the EbGS – the Netherlands, British Columbia, and Ontario guidances as well as the Oregon Birth Center absolute risk criteria. There are situations in which consultation is indicated to address appropriateness for home birth, but transfer to a hospital setting may not be required.

Ident.	#	Comment	Disposition
			The recommendation has been clarified to specify which indications require consultation, change of planned delivery location, or transfer to hospital care. For some indications requiring consultations, out of hospital birth may still be an appropriate option. See revised coverage recommendation language.
F	3	The HERC itself identifies the Cochrane Review and the Guidelines on the Care of Healthy Women and Their Babies During Childbirth of the National Institute for Clinical Excellence as its only two trusted sources in its review of the evidence on planned home birth yet somehow arrives at a different conclusion than either of these sources. The Cochrane Review states clearly that there is no evidence to favor planned hospital or planned home birth for low risk women. In fact the review states, It seems increasingly clear that impatience and easy access to many medical procedures at hospital may lead to increased levels of intervention which in turn may lead to new interventions and finally to unnecessary complications. In a planned home birth assisted by an experienced midwife with collaborative medical back up in case transfer should be necessary these drawbacks are avoided while the benefit of access to medical intervention when needed is maintained. Increasingly better observational studies suggest that planned hospital birth is not any safer than planned home birth assisted by an experienced midwife with collaborative medical back up, but may lead to more interventions and more complications. (Olsen, Clausen 2012).	This information is correct, quoted from the Plain Language Summary in the Cochrane review (p. 2). The NICE guideline review does review other studies beyond the Cochrane review in making its recommendation as well. This coverage guidance does not favor either planned hospital birth or planned out-of-hospital birth for low risk women. Rather, the coverage guidance recommends that out-of-hospital birth be covered under health plans as a safe and effective option for low risk women, and defines indications which may put a woman and her baby at risk for poor outcomes in a planned or actual out-of-hospital birth based on a review of high-risk criteria from other internationally-recognized bodies.
F	4	Additionally, the NICE guidelines explicitly state that, for low-risk women, out-of-hospital birth is "particularly suitable for them because the rate of interventions is lower and the outcome for the baby is no different compared with an obstetric unit (National Institute for Clinical Excellence 2014)." The HERC is charged with making an evidence based recommendation and it must remedy this significant departure from that obligation.	This information is correct. See comment F 3 above.

Ident.	#	Comment	Disposition
F	5	While the HERC has identified a number of fully recognized, research based-risks for home birth such as multiple gestation, non-vertex presentation, and pre-existing disease in the mother that negatively impacts pregnancy outcomes (e.g. chronic hypertension), it has also included potential risk factors that are either not based in research or are absolutely not appropriate for inclusion in coverage guidance. Coverage guidance should be based on risks that can be identified at the start of care or upon reassessment at term. It is inappropriate to include emergency occurrences that the midwife could not have foreseen. If these occur, is this guidance asserting that the midwife should not be compensated for all care before and after the event?	This coverage guidance recommends coverage for out-of-hospital birth for women with low risk pregnancies. See response to comment F 2.
F	6	In addition, there are far too many risk factors included in this guidance that are outside of accepted guidelines in the US, Canada, and the UK (health systems with which we normally compare ourselves). The HERC Coverage Guidance on Planned Home Birth should only include those risk factors in the "High Risk" list that are based in high-quality evidence and are in common usage in comparable health systems that have good outcomes from out-of-hospital midwifery care such as Canada and the UK.	The risk factors included in this coverage guidance are all derived directly from the guidelines listed by the commenter. That said, systems of midwifery care in Canada and the UK are sufficiently distinct from those in the US as to make direct translation impractical. Not all conditions that are amenable to out-of-hospital management in those systems are appropriate for such in the US. See comment F2.
F	7	Further, when the HERC creates such a lengthy list of "high risk" conditions (beyond those included in a basic absolute risk guideline) that would exclude a patient from coverage for home birth it circumvents the rights of low-income patients to make informed choices about their own health care. This draft "high risk" list is not equivalent to recommending against payment for an experimental or medically unnecessary surgery, it is actually a recommendation against coverage for basic maternity and newborn care for many healthy women experiencing normal pregnancies. Consider, for example, that a woman with a history of genital herpes with no outbreak in the past two years, who has hyperemesis until 14 weeks, but is able to gain weight normally, and has a brother with down syndrome is "risked" out three times even though she is a perfectly reasonable candidate for home birth as long as she does not have a herpes outbreak at the time of birth.	See comment F2.
F	8	There are a number of items that should be removed from the draft "High-Risk" list as they are not research-based and are not included in the high-risk or exclusion criteria from the 2014 Guidelines on the Care of Healthy Women and Their Babies During Childbirth of the National Institute for Clinical Excellence, The Indications for Discussion, Consultation, and Transfer of Care from the College of Midwives of British Columbia, or the Consultation and Transfer of Care	See comment F2

Ident.	#	Comment	Disposition
		Guidelines of the College of Midwives of Ontario, the three main Guidelines that the HERC has reviewed. Many of these items are absolutely appropriate for evaluation and consultation, but to exclude them from coverage is nonsensical because without the evaluation or consultation process we can't know if significant risk is found in that particular case.	
F	9	The following items should be removed from the "High Risk" list for the above-stated reasons: **Pregnancy past 41 weeks (The NICE guidelines specifically include pregnancy to 41+6 weeks)** **History of preterm birth** **History of fourth degree laceration** **History of more than three first trimester spontaneous abortions, or more than one second trimester spontaneous abortion** **Failure to progress/ failure of head to engage in active labor** **Cervical dysplasia requiring evaluation** **Hyperemesis gravidarum** **Family history of genetic/ heritable disorders** **Age < 14**	See comment F2 as well as comments about specific indications below. The risk factor for post-term pregnancy has been clarified to define low risk as than 41 **completed** weeks (that is, the cutoff is > 41 weeks, 6 days.) Our recommendation includes history of preterm birth as an indication for consultation, following the Netherlands guidance, which rates it as category B (consultation) History of 4th-deg laceration is listed by Netherlands guidance as category A or C, depending on whether satisfactory function is restored. The recommendation has been clarified that without functional recovery requires hospital birth, with functional recovery requires consultation. Box language on history of abortions is taken from the Ontario guidance (consultation recommended) Failure to progress/engage is taken from the Oregon birth center ARC. Both the Ontario and Netherlands guidance recommend it as an indication for consultation. Cervical dysplasia requiring evaluation is Netherlands category B (consultation) Hyperemesis gravidarum is recommended by Netherlands guidance as requiring a higher level of care until resolved. Language was changed to say "refractory" hyperemesis gravidarum. Family history of genetic/heritable disorders is taken from the British Columbia guidance as requiring consultation Age < 14: Please see comment D2.

Ident.	#	Comment	Disposition
			For EbGS discussion.
F	10	Beyond these, there are a number of items that should either be removed from the high-risk list for a variety of reasons or edited for clarity. I have addressed these items individually below: **History of Pre-eclampsia/ HELLP syndrome**. Of the three guidelines used in the HERC review, only the NICE guidelines do include history of pre-eclampsia but only if preterm birth was required. We know that risk of pre-eclampsia decreases for multiparas and we know that pre-eclampsia is a very broad diagnosis. While a history of pre-eclampsia may be a significant risk factor it should be further defined or specified if it is going to be included in the high risk list. For instance "HELLP syndrome and/or pre-eclampsia requiring preterm birth." All patients will be evaluated for signs of pre-eclampsia in each pregnancy which is the more appropriate risk assessment tool in this case.	NICE lists history of pre-eclampsia as necessitating individual assessment (table 8). The coverage guidance has been edited to clarify which high-risk conditions require a planned hospital birth, and those indicating antenatal consultation (to be defined) prior to planned out of hospital birth. Pre-eclampsia requiring preterm birth and history of HELLP syndrome are indications for planned hospital birth. Pre-eclampsia not requiring preterm birth is an indication for consultation prior to planned out of hospital birth. See revised box language.
F	11	**History of Unexplained stillbirth/neonatal death or previous death related to intrapartum difficulty**. This is a broad category that is best suited to careful evaluation, consultation, and informed consent rather than use as a risk for coverage exclusion. There are many cases included in this category that could be completely appropriate for a home birth, for instance a history of an intrapartum demise due to a cord accident should not exclude someone from a subsequent home birth. Additionally a person who had a previous unexplained stillbirth with no other past or current clinical risk factors could be an excellent candidate for home birth with full informed consent about the risks involved and should not face an additional financial hardship as a result of this choice.	History of unexplained stillbirth is listed in multiple sources (NICE, Netherlands, Ontario, and British Columbia) as requiring consultation. NICE guidance does include "Unexplained stillbirth/neonatal death or previous death related to intrapartum difficulty" as a condition indicating planned hospital birth. Both of these are reflected in the updated box language.
F	12	**History of postpartum hemorrhage requiring additional treatment or blood transfusion.** The research is not clear as to whether history of postpartum hemorrhage is predictive of future postpartum hemorrhage (Prata 2011). If this item is to be included in the high risk list it should be further clarified so that it relates to truly concerning hemorrhages. A woman who had a 500 cc blood loss and received pitocin for it ("further treatment") would currently be defined as high risk which is not appropriate. Perhaps it could be worded "Postpartum hemorrhage requiring blood transfusion."	Our recommendation follows NICE table 6, which lists "primary postpartum hemorrhage requiring additional treatment or blood transfusion" as an indication for birth at an obstetric unit, and specifies "additional pharmacologic treatment or blood transfusion."

Ident.	#	Comment	Disposition
			The Prata 2011 study cited was a prospective cohort conducted in Egypt with 2510 women experiencing singleton pregnancies. There were 93 cases of primary PPH in the cohort. The authors found that "history of PPH in a previous pregnancy increased the risk of PPH by almost 69 times" (OR 68.61, p<0.001), although this was based on only seven women with a history of PPH, five of whom had repeat PPH and two of whom did not. For EbGS discussion
F	13	**History of retained placenta requiring manual removal.** This item is concerning because it may exclude many women with histories that are not actually clinically concerning for the current pregnancy. History of retained placenta may or may not be predictive for future complications and the appropriate clinical course of action is ultrasound evaluation for abnormal implantation.	Our recommendation follows NICE table 6, which lists "retained placenta requiring manual removal in theatre" as an indication for birth at an obstetric unit. For EbGS discussion.
F	14	**History of shoulder dystocia**. While a history of shoulder dystocia is a risk factor for future births this is an item that should necessitate careful evaluation of the records and current pregnancy course and consultation to determine whether the risk is significant for the current pregnancy rather than immediate denial of coverage without evaluation. A woman with tightly controlled blood glucose levels in a subsequent pregnancy with a smaller baby is likely, for example, not to experience a repeat complication.	Our recommendation follows NICE table 6, which lists "Shoulder dystocia" as a previous complication indicating birth at an obstetric unit. See also comment E2. For EbGS discussion.
F	15	**History of cesarean section**. The two studies that include significant numbers of out-of-hospital vaginal births after cesareans (where the increased risk of rupture from tocolytics is not a factor as they are outside of scope of practice) showed good outcomes for mothers and babies as long as no other significant risk factors (e.g. breech, twins) were present (Cheyney et al 2014, Stapleton et al 2013).	Our recommendation follows NICE table 6, which lists "Caesarean section" as a previous complication indicating birth at an obstetric unit. Stapleton et al 2013 is a retrospective cohort study of 15,574 women receiving care in US birth centers from 2007-2010. There were only 56 TOLACs in this cohort (0.004%), of which 39 (70%) had successful VBAC. Because of the very small sample size, the authors do not separately analyze outcomes by prior cesarean status.

Ident.	#	Comment	Disposition
			Cheney 2014 is a retrospective cohort study of 16,924 women who planned home births in the US between 2004-2010. This cohort included 1054 women with prior cesarean (0.06%), of whom 915 (87%) had successful VBAC. Authors found that TOLAC patients experienced "an increased risk of intrapartum fetal death, when compared to multiparous women with no prior cesarean (2.85/1000 TOLAC vs 0.66/1000 multiparas without a history of cesarean, P = 0.05)" and no increase in neonatal death. For EbGS discussion.
F	16	**Placenta previa, vasa previa, low lying placenta**. This item should specify placenta previa at term as placenta previa in early pregnancy is not relevant and simply requires reevaluation. Low lying placenta should be removed as it is vague, not research-based and is not included in other relevant guidelines	NICE table 7 lists "Placenta praevia" as a complication of current pregnancy indicating birth at an obstetric unit. Oregon birth center absolute risk criteria list "Low-lying placenta within 2 cm or less of cervical os; vasa previa; complete placenta previa" as prohibiting admission to the birth center. Ontario guidelines list vasa previa and asymptomatic placenta previa persistent into third trimester as indications for antenatal consultation, and symptomatic previa as an indication for transfer. See revised box language. Coverage guidance has been edited to specify "Placenta previa, vasa previa, or low-lying placenta within 2 cm or less of cervical os at term."
F	17	**Confirmed intrauterine death**. This is an odd item to include in the high risk list as it is not a risk for the mother unless there are signs of infection or DIC after the passage of significant time. A family who has had a confirmed intrauterine death should have the option to have a home birth covered if they have received informed consent and it is what they want for their care during such a personal and trying process. This is yet another item that should necessitate careful evaluation, consultation, and informed consent but is not a reason for exclusion from coverage	NICE table 7, which lists "Confirmed intrauterine death" as a complication of current pregnancy indicating birth at an obstetric unit. "Dead fetus" is Netherlands C (requiring secondary obstetric care); however, Ontario guidelines list "Intrauterine fetal demise" as an indication for consultation only.

Ident.	#	Comment	Disposition
			For EbGS discussion
F	18	**Body mass index at first prenatal visit of greater than 35 kg/m2**. BMI on its own is not appropriate for inclusion in the high risk list. Many larger women are excellent candidates for home birth as long as other risk factors, such as uncontrolled gestational diabetes or limited mobility are not present. This is another item for careful evaluation, consultation, and informed consent, not for exclusion from coverage	Our recommendation follows NICE table 7, which lists "BMI at booking > 35 kg/m^2" as a complication of current pregnancy indicating birth at an obstetric unit.
F	19	**Small for gestational age fetus**. This item needs to be clarified so that it does not unnecessarily exclude babies who are small but well within normal limits. The NICE guidelines do include this risk factor but specify that they mean less than 5th percentile. Additionally, if this item is to be included in the high risk list it should be specified that ethnically specific charts should be used so that babies of smaller ethnicities are not erroneously identified.	As noted by commenter, NICE specifies < 5%ile or reduced growth velocity on US as indicating planned hospital birth. Coverage guidance was edited to clarify this, with additional language to specify ethnically-appropriate growth tables.
F	20	**Prelabor rupture of membranes > 24 hours.** While the risk of infection does seem to increase somewhat after 24 hours of ruptured membranes that risk is still small, especially in the home birth setting and with minimal vaginal exams and other interventions. This should be a matter for the informed consent of the client within the OARs and practice standards of the provider.	Our recommendation follows the Netherlands and NICE sources. Netherlands guidance recommends secondary obstetric care after 24 hours (category C). NICE recommends transfer to obstetric care after "rupture of membranes more than 24 hours before the onset of established labour."
F	21	**Genital herpes.** While this is an important risk factor and is already included in the OARs, it is not appropriate for all genital herpes to fall under the high risk list. Both the British Columbia and the Ontario College of Midwives guidelines call for transfer when there is an active herpes outbreak in labor or at rupture of membranes. Many HSV positive women are excellent candidates for homebirth as long as they do not have an outbreak at the time of labor.	Guidance language has been changed to "Current active infection of varicella/rubella/genital herpes in the woman or baby" in accordance with NICE language in Table 6.
F	22	**Thick meconium staining of amniotic fluid.** While this is a recognized risk factor, this item is more appropriate for rule and practice standard and does not make sense in coverage guidance. Home birth providers will be in situations where they are dealing with thick meconium staining and each case will need to be considered individually by the provider taking into account distance from hospital, if delivery is imminent, and other factors.	Our inclusion of thick meconium as a factor requiring transfer is based rating as a Netherlands C (secondary obstetric care) indication. From the Netherlands guidance: "When one of the items mentioned below occurs, an attempt should still be made to achieve an optimal condition for further

Ident.	#	Comment	Disposition
			intrapartum care, whilst referral to secondary care may be urgent, depending on the situation. When referring from the home situation, the risk of transporting the woman also needs to be included in the considerations." Language has been added to the coverage recommendation to allow for emergency situations where transfer may not be possible. *For EbGS discussion*
F	23	**Retained placenta**. This is a strange item to include in coverage guidance because retained placentas do happen and the provider at hand will need to determine what is the safest course of action depending on the clinical picture. There will be cases where the safest course of action will be administration of anti-hemorrhagics and/or attempted manual removal before or during initiation of transport to hospital. This is an item that should be, and is, in rule and practice standards but does not make sense for coverage guidance.	Retained placenta is an indication for transfer to a hospital, whether or not management by an out-of-hospital provider is initiated before or during transfer. NICE recommends urgent transfer if uterine exploration is necessary. Ontario – consultation indication Netherlands – C (secondary care) For EbGS discussion
F	24	**Third or fourth degree, or periuretheral, laceration.** This item is confusing for a coverage recommendation especially alongside "laceration requiring hospital repair" as third and fourth degree repairs are outside of our scope of practice, but sometimes a physician or nurse-midwife will come do these repairs in the home setting so as not to interrupt the postpartum period. For these reasons this item seems inappropriate for coverage guidance.	"Laceration requiring hospital repair (e.g., third degree, fourth degree, periurethral)" is listed in the box language as an intrapartum complication requiring transfer to hospital. Third-degree and fourth-degree laceration occurring in a previous pregnancy are listed as high-risk conditions necessitating obstetrical consultation prior to planned out-of-hospital birth. This is consistent with NICE guidance as found in Table 9: "Extensive vaginal, cervical, or third- or fourth-degree perineal trauma." Coverage guidance could be further amended to include third- or fourth-degree laceration not requiring hospital repair as an indication for consultation without transfer. For EbGS discussion

Ident.	#	Comment	Disposition
F	25	Please seriously reconsider the length and scope of the high-risk list. Healthy pregnant women who are covered by the Oregon Health Plan have a right to informed choice of provider type and place of birth. The HERC should be cautious in recommending against coverage for basic maternity and newborn care in healthy women and restrict its recommendations to those conditions that are truly high risk for an out of hospital setting.	Coverage guidance has been edited to reflect a distinction between conditions indicating planned hospital birth, and those that necessitate antepartum consult when planning out of hospital birth.
G	1	As chairman of the Midwife Committee for the All Care Health Plan in Grants Pass, Oregon, I am writing to convey our concerns regarding the coverage guidance for planned home birth.	Thank you for your comments.
G	2	In addition to the concerns detailed below, we ask that a temporary rule change be made to not allow home births until the guidelines can be finalized. In their current state, we feel the guidance violates all aspects of the triple aim. If a bad maternal or fetal outcome occurs during a home birth that could have been prevented by improved guidelines, that decreases the quality of the patient's experience, directly lowers the quality of care, and will substantially increase the cost of care. Therefore, we ask that you seriously consider the additions/changes to the guidelines below.	Home birth is currently covered by fee-for-service Oregon Health Plan. HERC will review the Coverage Guidance and consider it in making potential changes to the Prioritized List of Health Services for the Oregon Health Plan. Once any changes to the Prioritized List are complete, rule changes would need to be made.
G	3	Before getting to those specific details, there are other vital points we ask that you also consider. • Need for midwives to have appropriate malpractice insurance. • Need for increased litigation protection for OB and Pediatric physicians who take care of failed planned home births and/or their subsequent complications. • Patients who refuse to adhere the guidelines needs to sign an informed refusal consent form.	All women giving birth out of hospital should have a full informed consent procedure. System characteristics associated with safe out of hospital birth include a system of consultation and referral/transfer that can assure seamless care. Written agreements that cover consultation/referral/transfer and a well-defined and practiced system of transfer are important as noted in the coverage guidance document. Whether a specific informed consent document should be required is to be discussed. For EbGS discussion.
G	4	Below are our overall recommendations: • Gestational age should be between 37 weeks/0 days and 40 weeks/6 days, thereby preventing a preterm or postdates birth.	See comment A 1.
G	5	• Maternal age should be between 18 and 37 years old	See comment D 2.

Ident.	#	Comment	Disposition
G	6	• Place of planned home birth should be less than 15 min from the hospital providing obstetrical and pediatric care. Our past experience has proven that transfer plans are poor at best, and significantly contribute to the maternal/fetal morbidity and mortality.	See comment E 3.
G	7	• Written transfer plan needs to be in effect that the accepting OB and pediatrician agree with.	A "well-defined system of transfer" is specified in the box language as a characteristic of a successful home birth.
G	8	• Increase the current time from 30 to 60 days where an infant stays on open card before being assigned to an appropriate health plan	Enrollment issues are outside the scope of this coverage guidance.
G	9	• A first trimester screening should be done with an OB to establish the due date and review maternal history to decide if home birth is a viable option.	Other types of maternity care providers, including midwives as well as family physicians, are qualified to assess dating, maternal history, and infectious disease screening.
G	10	• A 2nd trimester anatomy ultrasound done with an OB to rule out any gross physical abnormalities.	See comment E 1.
G	11	• Subsequent revaluation by OB if any complication arises later in pregnancy.	Complications of pregnancy necessitating consultation or transfer are listed in the box language.
G	12	• The following labs needs to obtained, as they constitute standard of care: CBC, type and screen, hepatitis B, HIV, syphilis, gonorrhea, chlamydia, urine toxicology screen, gestational diabetes screen and repeat CBC at 28 weeks gestational age, and group B Strep screen at 35+ weeks gestational age.	See comment E 2 (f). Urine toxicology screening may be appropriate in some patients at higher risk but is not universally recommended. Some of these labs may not be obtained due to a variety of factors including patient preference. Inadequate prenatal care may be a proxy for measurement, and women may refuse one or more of these tests. NICE says: At the booking appointment, for women who choose to have screening, the following tests should be arranged: • blood tests (for checking blood group and rhesus D status and screening for haemoglobinopathies, anaemia, red-cell alloantibodies, hepatitis B virus, HIV,

Ident.	#	Comment	Disposition
			rubella susceptibility and syphilis), ideally before 10 weeks • urine tests (to check for proteinuria and screen for asymptomatic bacteriuria) • ultrasound scan to determine gestational age using: ○ crown–rump measurement between 10 weeks 0 days and 13 weeks 6 days ○ head circumference if crown–rump length is above 84 millimetres • Down's syndrome screening using: ○ 'combined test' at 11 weeks 0 days to 13 weeks 6 days serum screening test (triple or quadruple) at 15 weeks 0 days to 20 weeks 0 days. Then discusses 28 weeks, Etc. Defining this based on prenatal care visits versus laboratory testing is significant. For EbGS discussion . For EbGS discussion.

Ident.	#	Comment	Disposition
G	13	Below are our other recommendation that would negate a home birth or require transfer to a hospital: • Complications in previous pregnancy/maternal medical history o History of 3rct or 4th degree laceration o History of prior fetal clavicle fracture o History of a blood clot, or bleeding disorder o History of a group B Step septic infant o History of gestational diabetes o History of diabetes mellitus (Type 1or Type 2) o History of prior birth weight 2'.. 9 lbs o Any history of genital herpes	Lacerations—see comments F9, F24. Fetal clavicle fracture—see comment E2 Bleeding or coagulation disorder is Netherlands Category C (secondary obstetric care) and bleeding disorder in the mother is a NICE crieterion for planned hospital birth. NICE table 6 lists "Risk factors associated with group B streptococcus whereby antibiotics in labour would be recommended" as indicating birth in an obstetrical unit. However, qualified providers in Oregon may administer group B strep prophylaxis outside the hospital setting and so this is not by itself a contraindication to out of hospital birth. Diabetes mellitus and gestational diabetes mellitus—see comment A2. Genital herpes-see comment F21.
G	14	Complications in current pregnancy o Any patient who would refuse a blood transfusion, as any postpartum hemorrhage can turn into a life-threatening event o Prolonged rupture of membranes greater than 18 hours, thereby increasing chance of neonatal sepsis and necessitating other treatment o Maternal seizure disorder o Severe maternal psychiatric disease o Any undiagnosed vaginal bleeding o Maternal hemoglobin < 11 o Maternal platelet count < 150,000 o Suspected macrosomia o Substance abuse, including marijuana	See comment E 2 regarding refusal of transfusion Prelabor rupture of membranes > 24 hours is an indication for planned hospital birth; none of the trusted sources provide evidence for an 18-hour cutoff. See also F20. Maternal seizure disorder: Netherlands B if medicated; should indicate consultation prior to planned home birth. Severe maternal psychiatric disease—see E2h. NICE specifies hemoglobin 8.5-10.5 as indication for individual assessment. Our recommendation requires consultation at 10.5 and planned hospital birth at 8.5. Abnormal bleeding is listed as an indication for planned hospital birth or transfer, based on Oregon Birth Center Criteria Thrombocytopenia is listed as an indication for planned hospital birth, based on Oregon Birth Center and NICE criteria. Ontario lists it as an indication for consultation. See also comment J4. For EbGS discussion. Fetal macrosomia is added as an indication for consultation prior to planned home birth

Ident.	#	Comment	Disposition
			Substance misuse and severe mental health disorder are listed in box language as requiring planned hospital birth. Maternal mental illness under outpatient psychiatric care is an indication for consultation. *For EbGS discussion*
G	15	• Transfer to hospital o Any meconium, not just thick meconium	Thick meconium is currently mentioned in the Oregon Birth Center absolute risk criteria. Meconium (any) is Netherlands C (secondary obstetric care) British Columbia lists "thick or particulate meconium" as indication for consultation See revised box language and comment F22. For EbGS discussion.
G	16	We fully realize the volatile and emotional aspects of home birth. We admit that we have dealt with past disastrous maternal/fetal outcomes, and as such we feel very strongly about this issue. Again, in their current state, we feel the guidelines violate all three aspects of the triple aim. We ask for your consideration for the above details. If we can provide any more information, please feel free to contact us.	Thank you for your comments
H	1	The Oregon Pediatric Society provides the following public comment regarding Oregon's Home Birth Policy. When home births occur we support the American Academy of Pediatrics Policy Statement on Planned Home Birth: "The safest setting for a child's birth is a hospital or birthing center, but the AAP recognizes that women and their families may desire a home birth for a variety of reasons. Pediatricians should advise parents who are planning a home birth that AAP and ACOG recommend only midwives who are certified by the American Midwifery Certification Board. There should be at least one person present at the delivery whose primary responsibility is the care of the newborn infant and who has the appropriate training, skills and equipment to	Thank you for your comments and for including the American Academy of Pediatrics policy statement.

Ident.	#	Comment	Disposition
		perform a full resuscitation of the infant. All medical equipment, and the telephone, should be tested before the delivery, and the weather should be monitored. A previous arrangement needs to be made with a medical facility to ensure a safe and timely transport in the event of an emergency. AAP guidelines include warming, a detailed physical exam, monitoring of temperature, heart and respiratory rates, eye prophylaxis, vitamin K administration, hepatitis B immunization, feeding assessment, hyperbilirubinemia screening and other newborn screening tests. If warranted, infants may also require monitoring for group B streptococcal disease and glucose screening. Comprehensive documentation and follow-up with the child's primary health care provider is essential." Although not detailed above, "other newborn screening tests" would include newborn blood spot screening as described by the Northwest Regional Newborn Screening Program, pulse oximetry screening for critical congenital heart disease and newborn hearing screening.	
H	2	In practice, the manner by which infants are assessed for their candidacy for planned home birth is sometimes of concern. We agree that only those infants who are deemed "low risk" be candidates for home birth, but that their candidacy be determined based on widely accepted and complete prenatal care. This includes, but is not limited to a high quality prenatal ultrasound and completed testing for all routine maternal screenings, including HIV.	See comment E 1.
H	3	Lastly, we believe the gestational age definitions included in the online report are too permissive. The March of Dimes has initiated successfully the "Healthy Babies are Worth the Wait" campaign to protect against elective birth prior to 39 weeks. This is because a broad literature describes the risks to infants born between 37 and 39 weeks which include respiratory difficulties, hypoglycemia, hypothermia, jaundice, feeding difficulties, learning challenges, and even death. We do not support planned home birth for infants < 37 weeks.	See comment A 1. The literature referenced here applies primarily to non-spontaneous labor occurring prior to 37 weeks' gestation. Coverage recommendation on gestational age has been modified to 37 weeks 0 days through 41 weeks 6 days. For EbGS discussion
I	1	This is to register my great concern on the HERC's guidelines on planned homebirth in Oregon. I have read the proposed guidelines and do not think these are in the best interest of	Thank you for your comments.

Ident.	#	Comment	Disposition
		childbearing women in Oregon. Although it is vital to understand and to educate that certain very high-risk pregnancies will be better served in the hospital, using these (proposed) guidelines, in many cases, would rule out basic choice in basic maternity and newborn care for *HEALTHY WOMEN WHO ARE EXPERIENCING NORMAL PREGNANCIES.* Licensed midwives in Oregon work under risk assessment guidelines which are evidence-based and we continually assess and reassess women to evaluate who may need a consult with an MD or OB or other specialist and who may be too high risk for out of hospital birth.	
I	2	I have read [commenter F]'s letter to HERC on behalf of the Oregon Midwifery Council, and must say that I agree with [their] very specific comments, point by point, and I would refer you to that letter rather than renaming those points here. [Their} statements are a reflection of [their] extensive experience as a midwife and as an ardent researcher in the maternity care literature. As per [commenter F]'s letter, I agree that apparently, the HERC has identified certain risks for home birth that are truly research-based but has included as well many potential risk factors that are NOT based in research or that have no reason to be included in guidance for coverage. These items need to be addressed and hopefully removed from the list so that the HERC guidelines can be considered to have integrity and to be actually true to the task of providing "Evidence Based Recommendations." From my own limited experience as a midwife (>400 births) I can say that I have helped women with each of ([commenter F]'s named) risk factors and have had good outcomes. Risk assessment is an ongoing task for the midwife throughout the prenatal and birth and postnatal period, so that each woman and baby are assured the best outcomes.	See comments C 1, C 2, and F 2.
J	1	The ingredients necessary for good outcomes in out of hospital (OOH) births are not a secret. The literature shows that you need well-trained midwives, good transfer policies, and appropriate candidate selection.	Thank you for your comments.

Ident.	#	Comment	Disposition
		I agree with your concept of adopting coverage guidelines for Oregon that incorporate the risk criteria used in Canada, UK, and the Netherlands.	
J	2	I have a few suggestions for changes in the wording that I think would improve the draft. "Planned Home Birth" should be changed back to "Planned Out-of-hospital birth." The coverage guidelines should pertain to all OOH births, both home and birth center. In Oregon, many birth attendants work both in birth centers and also do home births. Birth centers do not provide any additional safety features over home birth for high risk situations. The current birth center rules exclude twins and breech, but allow Previous C-section, postterm pregnancies up to 43 weeks, and hypertension up to 150/100. I think it is already confusing to the consumer that there are two sets of rules – one for LDMs through the BDEM, and another for Birth Centers. I think it would compound the confusion to have two sets of coverage guidelines.	The Licensed Direct Entry Midwife Staff Advisory Workgroup specifically requested the HERC to develop a coverage guidance related to planned home birth. The primary source (NICE) groups home birth and freestanding or alongside midwifery-led units as appropriate choices for low-risk women. In light of this, we have changed the title to "Planned out-of-hospital birth." It is appropriate to have a single set of guidelines pertaining to all types of out of hospital births. *For EbGS discussion*
J	3	In my view, "High risk conditions necessitating consultation or transfer include….." should be changed to "High risk conditions necessitating transfer to a hospital provider include……." In Canada, the UK, and the Netherlands, the licensed midwives have admitting privileges to hospitals. The criteria for consultation and transfer apply to women who labor both in and out of hospitals. There are some patients who have high risk conditions that make them inappropriate candidates for OOH births, but whose labors can still be attended by midwives in the hospital in consultation with a physician. In Oregon, the vast majority of midwives who attend OOH births do not have hospital privileges, so high risk clients should be transferred to a provider with hospital privileges. Currently, Oregon rules for LDMs regarding consultations for high risk clients, OAR 332-025-0021 (7) and (8), do not require that the consultation be with a physician with hospital privileges. The consultation can be with a physician, a PA, a CNM, a Naturopath, or another LDM with "direct experience". I believe the word "consultation" in your draft should be removed.	Coverage guidance has been edited to reflect a distinction between conditions indicating planned hospital birth, and those that necessitate antepartum consultation with a provider who has expertise in caring for higher risk pregnancies and when planning out of hospital birth and the ability to admit to a hospital. See also comment F2 and revised coverage recommendations.

Ident.	#	Comment	Disposition
J	4	I would recommend more precise definitions of certain risk criteria to avoid confusion. There are some discrepancies between the LDM rules, the birth center rules, and standard definitions in the medical literature. My suggestions are: a. "Fetal growth retardation" should be changed to "Intrauterine growth restriction". b. "Eclampsia, pre-eclampsia or pregnancy-induced hypertension, hypertension (before or after delivery) with blood pressure >140/90." Both ACOG and SOGC use a systolic of 140 or a diastolic of 90 to define gestational hypertension. (1,2) NICE (p. 30) recommends transfer to obstetric care for "either raised diastolic blood pressure (over 90 mmHg) or raised systolic blood pressure (over 140 mm Hg) on 2 consecutive readings taken 30 minutes apart." c. "Chorioamnionitis or other serious infection with fever >38 C." Three out of the eight OOH fetal/ neonatal deaths in Oregon in 2012 had chorioamnionitis. d. "Thrombopenia" should be changed to "Thrombocytopenia with platelets <100,000." e. "Uteroplacental Insufficiency and Intrauterine Growth Restriction." f. "Retained placenta >1 hour."	a. "Fetal growth retardation" language was taken from the Netherlands guidance and has been changed to "Intrauterine growth restriction" for consistency. b. Box language has been edited to reflect NICE cutoffs for hypertension as an indication for transfer. c. Box language presently includes "chorioamnionitis or other serious infection." Maternal temperature is only one piece of the diagnostic criteria for chorioamnionitis. d. The word "thrombopenia" has been changed to "thrombocytopenia" for consistency. NICE table 6 does include cutoff of 100,000. e. "Uteroplacental insufficiency" and "Intrauterine growth restriction" are presently listed separately in the box language. f. Box language recommends transfer for retained placenta without a defined time cutoff. Oregon birth center criteria list a 3-hour cutoff. NICE, Netherlands, Ontario, and British Columbia guidances do not define a time cutoff for retained placenta. A three-hour cutoff has been added to coverage guidance to be consistent with birth center criteria.
J	5	I think "failure to progress" also needs to be defined. Two out of the eight OOH fetal/neonatal deaths in Oregon in 2012 had prolonged labor. Some options: a. The Dutch criteria for failure to progress in the first stage of active labor is "no change in the cervix or progress in dilation after the latent phase for a duration of 4 hours". Failure to progress in the second stage of labor is "lack of progress after a maximum of one hour, in cases with full dilation, ruptured membranes, strong contractions and sufficient maternal effort." b. NICE (p. 57) states that delay in the first stage of active labor is suspected if cervical dilatation is less than 2 cm in 4 hours. Diagnosis of delay in the active second stage (p. 60) is after 2 hours for nulliparous woman and one hour for	The definitions in a. through d. are correct. The box language does not presently include a definition of delay of labor. Defining "delay of labor" is a practice guideline definition outside the scope of coverage guidance.

Ident.	#	Comment	Disposition
		multiparous woman. c. ACOG recently defined arrest of labor in the first stage of labor as no cervical change in 4 hours of adequate contractions or 6 hours of inadequate contractions. In the second stage, 2 hours of pushing in multiparous women and 3 hours in nulliparous women.(3) d. LDM rule OAR 332-025-0021 (5)(b)(F)(i) defines lack of adequate progress in second stage for vertex presentation "is when there is no progress after a maximum of three hours in cases with full dilation, ruptured membranes, strong contractions and sufficient maternal effort. (Note: In this rule, this situation is considered non-absolute and requires a consultation, but not necessarily transfer.) e. My preference is a hybrid: First stage – no change in the cervix or progress in dilation after the latent phase for a duration of 4 hours. Second stage – 2 hours of pushing in multiparous women and 3 hours in nulliparous women. (Non-emergency transport can take up to an additional hour.)	
J	6	For Postpartum complications, "Transfer to a higher level of care is recommended in the following circumstances:" should be changed to "The following post-partum complications require transfer to a hospital:"	Thank you for the suggestion. See revised box language.
J	7	I agree that Previous Cesarean Section is a situation that should remain on the high risk list. In the recent MANAstats dataset of home births in the US, the intrapartum + neonatal death rate for term VBACs was 4.75/1000 compared to 1.24/1000 for women with no previous C-section in the same study. (4) OOH births use intermittent auscultation for fetal surveillance which is appropriate for low risk labors if done properly, but is not appropriate for VBACs. Quoting from the SOGC guidelines for intrapartum fetal surveillance: "For women attempting VBAC, there is little controversy. All professional jurisdictions recommend continuous electronic fetal monitoring." That includes ACOG, SOGC, and RCOG. (5)	Thank you for your comment.
K	1	My name is [commenter K] and I am a licensed Registered Nurse in the state of Oregon. I have had the choice and privilege to birth my three children safely and gently at home over the past several years. I am pleased that you have put forth a great effort to lay out guidelines for women in Oregon	Thank you for your comments.

Ident.	#	Comment	Disposition
		who want more comprehensive choices in their prenatal care and birth experiences. I am also thankful that these choices will be more readily available to women on OHP and related health insurances. I am concerned, however, with some of the restrictions placed in the proposed guidelines, and fear that some of them may inappropriately hinder otherwise healthy candidates for home births with safe outcomes. Some of the proposed restrictions on what is defined as "high risk" pregnancy fail to take into consideration individual situations and the possibility of individualized care rather than providing "blanket labels" on what is or isn't "safe enough."	
K	2	My firstborn was born at 41 weeks and 2 days; 2 days beyond your recommended 36-41 week window, and I had a safe birth and healthy and safe outcomes for my child and myself. I understand that it is not uncommon for first births to be as much as 10 days late, give or take, with no adverse outcomes. I took care to monitor en-utero activity on a daily basis, as recommended both by my midwives, and also by literature I had received from an OB clinic before my transfer of care to a midwife team.	Thank you for sharing your experience. Cutoff of 41 weeks is endorsed by ACOG. NICE does include pregnancy up to 41 completed weeks, or 41 weeks+ 6 days. The coverage guidance language uses 41 completed weeks of gestation which comports with the NICE definition.
K	3	According to a simple calculator, I have a BMI over 35, but you would never guess that just looking at me. Just a few years ago, I was 5ft 6in and 180lb. (BMI about 30), but I was fit enough to run a 10K in one hour, thin enough to count all my ribs in the mirror, and lean enough to not be able to float in a pool to save my life. (I'd sink like a rock without actively swimming...it was impossible for me to do a dead-mans-float.) I had a flat stomach, and I ran a couple miles every day...but the BMI chart said I was overweight. Now, a little heavier and a little less active, I'm actually at just over a BMI of 35, but I'm still active, still healthy, have low cholesterol, and no indicators of diabetes, pre-diabetes, or high blood pressure. The typical BMI scale and chart doesn't accurately reflect my health status, but through an objective lens, a well-trained care provider would tell you that I'm a little overweight, but otherwise healthy. I know I'm not the only person like this. There are other women out there who are predisposed to higher muscle mass, whether genetically and/or through training. A BMI chart should be a tool in the overall evaluation of a candidate, not a defining point in whether or not services can or cannot be provided.	NICE table 7 lists "Body mass index at booking of greater than 35 kg/m^2"as indicating increased risk, suggesting planned hospital birth.

Ident.	#	Comment	Disposition
K	4	I also have O- (RH negative) blood, and my husband has the Rh factor (Rh+), and all my children were consequently born with Rh+ blood, but I have had safe and healthy outcomes in all my pregnancies and births. My trained midwives were attentive to my needs and I had regular lab draws to monitor for any adverse reactions. A trained midwife is still a trained healthcare provider, and should be treated as such. Everything I was told that I would have available to me in the OB setting, I still had available to me in the midwife/home-birth setting of my care (Rhogam shots, appropriate and recommended lab draws, regular urine screening, blood glucose screening, newborn hearing screening, newborn lab draws, etc.)	Active blood group incompatibility is Netherlands category C (secondary obstetric care). NICE also lists "atypical antibodies which carry a risk of haemolytic disease of the newborn" as indicating birth in an obstetrical unit. The coverage guidance has been revised to include "Blood group incompatibility with atypical antibodies (including Rh sensitization)" as an indication for hospital birth
K	5	As a trained healthcare provider myself, I see great potential in allowing women a better spectrum of choices in their prenatal and birthing experience. From firsthand experience, my care has been infinitely better and more comprehensive with a team of midwives versus a trained OB. For one, a typical OB visit is 15 minutes and they don't have the time or availability to provide holistic care to their clients. Their agenda is compressed into a "one-size-fits-all/most" model of the pregnancy process and they miss much opportunity to address specific points or concerns related to the individual woman. Consequently, if problems arise (even minor ones), the OB is forced to be reactive to the situation rather than proactive before the issue arises.	Thank you for your comments.
K	6	With a midwife as the trained provider, the average prenatal visit is one hour, and each visit is tailored to the individual woman and her pregnancy experience. In-depth discussions are focused on things like diet, rest and exercise, new or ongoing stressors in the mother-to-be's life, etc. and all of which may have a direct impact on the pregnancy and/or birthing experience. More time is also afforded to discuss various treatment plans and options that relate to the individual woman and her preferences. Skilled midwives, therefore, have more of an ability to be proactive in a woman's care and to address potential risks before they start or get out of hand. In this sense, having a trained midwife can be viewed as choosing a more prophylactic route to a positive pregnancy and birth outcome.	Thank you for your comments.
K	7	A skilled midwife, like a skilled OB, will have the client's best interest in mind, and will transfer care to a more skilled group if the situation necessitates. Just like an OB may transfer care of a high-risk patient to a more skillfully trained OB or specialist, or refer a woman to a more acute facility (Hospital instead of a birthing facility, or higher level hospital instead of community hospital), a midwife also has the ability and duty to refer a client to a more skilled professional	See comment C 1.

Ident.	#	Comment	Disposition
		or facility if the situation exceeds her scope of care. Autonomy should not be stripped from a trained and skilled provider. I think the stringency of the guidelines in the proposal should be modified so that trained and licensed midwives can still practice within the scope of what they were trained. Even VBAC's and Breach births can have healthy and safe outcomes at home if attended by a skilled midwife. And sometimes less intervention is more as far as quality of care and outcome.	
L	1	I am not sure if or how this information will be of use to you, but HERC should know these things. **The HERC draft greatly understates the mortality difference between planned hospital births and planned out-of-hospital (OOH) births in Oregon in 2012.** The report on 2012 Oregon births by planned birth place (1) and HERC draft both say that "The term perinatal mortality rate for planned OOH birth (4.0/1,000 pregnancies) was nearly twice that of in-hospital births (2.1/1,000)" (1). That is true, but the comparison is misleading because the perinatal mortality rate for planned hospital births included an unknown but relatively large number of antepartum (AP) fetal deaths that occurred *before* the mother was in labor. Eighty-five to 90 percent of all fetal deaths in developed countries are *stillbirths prior to labor* (2), and the incidence increases with gestational age (3) and thus is highest among term births. Most women whose babies die before labor go to a hospital to have labor induced and deliver their dead fetus in the hospital. In contrast to antepartum fetal deaths, intrapartum (IP) fetal deaths *during labor* are very rare in hospitals in developed countries, *only about 1 per 10,000* births (4). There were no intrapartum fetal deaths in a prospective 1980s study of almost 35,000 hospital births using either selective (for high-risk pregnancies) or universal electronic fetal monitoring (5). Antepartum fetal deaths comprise the vast majority of all fetal deaths that occur in American hospitals. Fifty-eight term fetal deaths were *associated with* 39,990 planned hospital births in Oregon in 2012 (1). We don't know how many were IP, but it is highly unlikely that more than six fetal deaths occurred during labor in Oregon hospitals that year. Four intrapartum fetal deaths were associated with planned OOH births in Oregon in 2012. All four were investigated by a public health pediatrician; all of them were intrapartum. It is misleading to compare a perinatal mortality rate that included an unknown but relatively	Thank you for the information. We have discussed the effects of misclassification bias on our understanding of safety and place of birth. This is a major concern if using birth certificates alone. Research based on data registries that use an intention-to–treat design (intended place of birth in 3rd trimester and at onset of labor) are more reliable. These studies also review all mortalities in the sample, allowing for more accurate classification. For EbGS discussion.

Ident.	#	Comment	Disposition
		high proportion of the 58 term fetal deaths associated with nearly 40,000 planned hospital births in Oregon in 2012 with the perinatal mortality rate for planned 2,021 planned OOH births, which included 4 early neonatal deaths and 4 intrapartum fetal deaths but no antenatal fetal deaths.	
L	2	**The draft Guidance does not address the educational qualifications of home-birth attendants in Oregon.** The reviewed evidence is based primarily on studies from the Netherlands, Ontario and British Columbia. *All* midwives who attend home births in those jurisdictions are educated to the standards in the International Confederation of Midwives (ICM) Definition of the Midwife (6) and Global Standards for Basic Midwifery Education (7), as are all certified nurse-midwives (CNMs) in the United States (US). ICM defines a "midwife" in part as a person who has completed a three-year midwifery education program, or 18 months for students who enter as nurses or other healthcare professionals (6,7). In contrast to home births in those jurisdictions, most OOH births in Oregon are attended by direct entry midwives (DEMs), naturopaths and others with less midwifery education. In 2012, 62 percent of all planned out-of-hospital (OOH) births were attended by DEMs, 25 percent by CNMs, 11 percent by naturopaths (1). DEMs are limited to OOH births. Although some are knowledgeable and competent, some aren't; very few have completed a midwifery curriculum that meets ICM standards. Most, including certified professional midwives (CPMs), are trained through apprenticeship and self-study (8,9). Most naturopaths who attend births in Oregon graduated from the National College of Naturopathic Medicine (NCNM) in Portland. One three-credit lecture course in natural childbirth is part of the curriculum for all naturopathic physicians (10). NCNM also offers four three-credit lecture courses, one each on pregnancy, labor and birth, the postpartum period, and neonatology. Films are used to enhance lectures on techniques for monitoring the fetal/maternal condition and progress of labor, complications of labor and birth are discussed and skills needed to respond to them are demonstrated. Although NCNM does not provide any supervised clinical experience with pregnant women (10), to be licensed in Oregon naturopaths	Thank you for your comment and information. Oregon law allows practice by midwives and other providers who do not have ICM standards of education. The draft guidance states "Certification requirements for the practice of midwifery vary significantly between the US and other countries, with US requirements being less rigorous with regard to both years of formal education and experience. See also comment F 6. Box language requires home birth providers to be certified and licensed.

Ident.	#	Comment	Disposition
		must have observed and assisted in 50 births supervised by a naturopath or obstetrician, pass a test and complete 15 hours of continuing education every year (11). CNMs attended only 25 percent of all planned OOH births in Oregon in 2012. All CNMs are educated to ICM standards in masters' degree programs, including one at OHSU. The IP fetal death rates from studies of home births attended by midwives who meet ICM education standards were zero in the small study from British Columbia, 0.31/1000 births in the very large study from the Netherlands, 0.45 in Ontario, and 0.36/1000 in England (12,13). In comparison the rate was 1.3 in a 2014 study of nearly 17,000 home births attended by members of the Midwives Alliance of North America (MANA) (14), four times higher than the mean rate if findings from all four of the ICM-education standard studies were combined. Eighty-five percent of births in the MANA study were attended by midwives who don't meet ICM education standards (15). The Ontario study reported total neonatal mortality (NN) instead of early NN mortality. ENN is preferable and was reported by the other three studies. The IP+NN rate for the Ontario study was 1.35/1000 births and 2.07/1000 for the MANA study. The IP+ENN mortality rates for the studies from British Columbia, the Netherlands and England were 0.35, 0.64 and 0.65 respectively. At 1.71/1000, the IP+ENN morality rate for the MANA study (14) was more than three times higher than the average for the studies based on births attended by midwives who meet ICM education standards. Intermittent auscultation is used to monitor the fetal heart rate in OOH births (15). It requires concentrated attention and a deep understanding of fetal heart rate changes and their significance during labor. Home birth midwives must be proficient in intermittent auscultation.	
L	3	**HERC should add distance or time (not more than 30 minutes) from the home-birth residence to a hospital staffed and equipped to provide emergency care to a parturient woman or newborn to the criteria for coverage**.	See comment E 3. *For EbGS discussion: Should a minimum time to appropriate back-up hospital be added to coverage guidance.the box language currently discusses the need for informed consent regarding risks of delay in transfer.*
M	1	The Health Evidence Based Rules Commission (HERC) is in the process of developing Home Birth Draft Coverage Guidance defining low risk pregnancy that would be appropriate for planned home birth, as well as for maternal or pregnancy conditions that would indicate the need for a higher level of prenatal, antenatal or postpartum care. Trillium Community health Plan would	See comments D2, E1, E2, G14.

Ident.	#	Comment	Disposition
		like to provide a list of additional guidelines to consider when drafting coverage guidance. • Should complications occur at any point in the pregnancy, a re-evaluation should be performed to determine risk/status level. • Low risk characteristics should include an ultrasound between 12 – 30 weeks. • Low risk characteristics should include maternal and paternal age parameters such as 18 – 45 years of age. • Complications in a previous pregnancy should include third degree lacerations. • Complications of a previous pregnancy should include fractured clavicle and shoulder dystocia. (currently just shoulder dystocia) • Complications of a previous pregnancy should include history of large babies (>9 pounds). • Complications of current pregnancy should include having an IUD in place when becoming pregnant. • Complications of a current pregnancy should include parental Jehovah's Witness status – due to inability to transfuse. • Complications of current pregnancy vaginal delivery after C section. • Complications of a current pregnancy should include incomplete prenatal testing such as strep and all STDs. • Complications of a current pregnancy should include severe mental health issues not well controlled or addressed. • Transfer to a higher level of care considerations should include a transfer plan or protocol for DEMWs to include a transfer or back up plan for Obstetricians should be included.	

References Provided by Commenters

Commenter	References
B1	Making normal birth a reality: Consensus statement from the Maternity Care Working Party http://mothersnaturally.org/pdfs/UKNormalBirthDocument.pdf
	Provided webpage that isn't working http://www.bmj.com/content/330/7505/1416.full?ehom=

Commenter	References
	Citizens for Midwifery Resources Webpage http://cfmidwifery.org/resources/
C2	Midwives' Association of Washington State INDICATIONS FOR DISCUSSION, CONSULTATION, AND TRANSFER OF CARE IN AN OUT-OF-HOSPITAL MIDWIFERY PRACTICE http://www.washingtonmidwives.org/documents/MAWS-indications-4.24.08.pdf
F12	Prata N, Hamza S, Bell S, Karasek D, Vahidnia F, Holston M. Inability to Predict postpartum Hemorrhage: Insights from Egyptian Intervention Data. BMC Pregnancy and Childbirth. 2011 Nov 28;11:97
F15	Cheyney M, Bovbjerg M, Everson C, Gordon W, Hannibal, Vedam S. Outcomes of Care for 16,924 Planned Home Births in the United States: The Midwives Alliance of North America Statistics Project, 2004 to 2009. Journal of Midwifery & Women's Health. Jan-Feb 2014; **59(1):** 17–27
F15	Stapleton SR, Osborne C, Illuzi J. Outcomes of Care in Birth Centers: Demonstration of a Durable Model. Journal of Midwifery & Women's Health. 2013 Jan-Feb;58(1):3-14
J4	The American Congress of Obstetricians and Gynecologists (ACOG). Ob-Gyns Issue Task Force Report on Hypertension in Pregnancy: Preeclampsia Diagnosis No Longer Requires Presence of Proteinuria. Retrieved from http://www.acog.org/About-ACOG/News-Room/News-Releases/2013/Ob-Gyns-Issue-Task-Force-Report-on-Hypertension-in-Pregnancy Magee, L., Pels, A., Helewa, M., Rey, E., & von Dadelszen, P. (2014). Diagnosis, Evaluation, and Management of the Hypertensive Disorders of Pregnancy: Executive Summary. Journal of Obstetrics and Gynecology Canada, 36(5): 416-438.
J5	American College of Obstetricians and Gynecologists (2014). Safe prevention of the primary cesarean delivery. American Journal of Obstetrics & Gynecology, 123: 693-711.
J7	Cheyney, M., Bovbjerg, M., Everson, C., Gordon, W., Hannibal, D., et. al. (2014). Outcomes of Care for 16,924 Planned Home Births in the United States: The Midwives Alliance of North America Statistics Project, 2004 to 2009. Journal of Midwifery & Women's Health, 59(1): 17-27. Rowe, T. (2007). Fetal Health Surveillance: Antepartum and Intrapartum Consensus Guideline. Journal of Obstetrics and Gynecology Canada, 29(9): S3-S50.
L1	1. Oregon Health Authority. (2013). Oregon birth outcomes by planned birth place and attendant, Pursuant to: HB 2380 (2011). Accessed September 1, 2013, from https://public.health.oregon.gov/BirthDeathCertificates/VitalStatistics/birth/Documents/PlannedBirthPlaceandAttendant.pdf 2. Kramer MS, Liu S, Luo Z, Yuan H, Platt RW, Joseph KS; Fetal and Infant Health Study Group of the Canadian Perinatal Surveillance System. Analysis of perinatal mortality and its components: time for a change? Am J Epidemiol. 2002 Sep 15;156(6):493-7. 3. Rosenstein MG, Snowden JM, Cheng YW, Caughey AB. The mortality risk of expectant management compared with delivery stratified by gestational age and race and ethnicity. Am J Obstet Gynecol. 2014 Dec;211(6):660.e1-8. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3719843/

Commenter	References
	4. Fretts RC. Etiology and prevention of stillbirth. Am J Obstet Gynecol. 2005 Dec;193(6):1923-35. 5. Leveno KJ, Cunningham FG, Nelson S, Roark M, Williams ML, Guzick D, Dowling S, Rosenfeld CR, Buckley A. A prospective comparison of selective and universal electronic fetal monitoring in 34,995 pregnancies. N Engl J Med. 1986 Sep 4;315(10):615-9.
L2	6. International Confederation of Midwives (ICM). International Definition of the Midwife. Revised and adopted by ICM Council June 15, 2011. http://www.internationalmidwives.org/assets/uploads/documents/Definition%20of%20the%20Midwife%20-%202011.pdf 7. ICM. Global Standards for Basic Midwifery Education (2010, amended in 2013). http://www.internationalmidwives.org/assets/uploads/documents/CoreDocuments/ICM%20Standards%20Guidelines_ammended2013.pdf 8. North American Registry of Midwives, Midwifery Education Accreditation Council, National Association of Certified Professional Midwives, Midwives Alliance of North America. Certified Professional Midwives in the United States. June 2008. https://www.google.com/search?q=Issue+Brief%E2%80%94Certifi+ed+Professional+Midwives+in+the+United+States&oq=Issue+Brief%E2%80%94Certifi+ed+Professional+Midwives+in+the+United+States&aqs=chrome..69i57.3411j0j7&sourceid=chrome&es_sm=91&ie=UTF-8 9. North American Registry of Midwives (NARM). 10 Things You Should Know About PEP. April 20, 2009. http://narm.org/forum/viewtopic.php?f=3&t=3#p3 10. National College of Naturopathic Medicine. Course Catalogue 2013-2014. Portland, Oregon. 2014. <http://www.ncnm.edu/images/Publications/coursecatalog/2013-2014_Course_Catalog_FINAL_web.pdf> 11. Oregon Licenses, Permits and Registrations, Detailed Information for Natural Childbirth Certificate (Naturopathic) http://licenseinfo.oregon.gov/index.cfm?fuseaction=license_seng&link_item_id=14456 12. Birthplace in England Collaborative Group, Brocklehurst P, Hardy P, Hollowell J, Linsell L, Macfarlane A, McCourt C, Marlow N, Miller A, Newburn M, Petrou S, Puddicombe D, Redshaw M, Rowe R, Sandall J, Silverton L, Stewart M. Perinatal and maternal outcomes by planned place of birth for healthy women with low risk pregnancies: the Birthplace in England national prospective cohort study. BMJ. 2011 Nov 23;343:d7400. 13. Birthplace in England Study Appendix 8. (Data from that appendix is use in some of the table in the HERC draft, so I know that you have access.) 14. Cheyney M, Bovbjerg M, Everson C, Gordon W, Hannibal D, Vedam S. Outcomes of care for 16,924 planned home births in the United States: the midwives alliance of north america statistics project, 2004 to 2009. J Midwifery Womens Health. 2014 Jan-Feb;59(1):17-27. 15. American College of Nurse-Midwives. Intermittent Auscultation for Intrapartum Fetal Heart Rate Surveillance (replaces ACNM Clinical Bulletin #9, March 2007). J Midwifery Womens Health. 2010 Jul-Aug;55(4):397-403.

Commenter	References

Appendix 1

Midwives' Association of Washington State

INDICATIONS FOR DISCUSSION, CONSULTATION, AND TRANSFER OF CARE IN AN OUT-OF-HOSPITAL MIDWIFERY PRACTICE

2. DEFINITIONS:

2.1 DISCUSSION WITH ANOTHER MIDWIFE, AN ARNP, OR A PHYSICIAN

A discussion refers to a situation in which the midwife seeks advice or information from a colleague about a clinical situation, presenting her management plan for feedback.

2.1.1 It is the midwife's responsibility to initiate a discussion with and provide accurate and complete clinical information to another midwife, a nurse practitioner, or a physician in order to plan care appropriately. This discussion can take place between midwives in the same practice.

2.1.2 Discussion should occur in a timely manner soon after the clinical situation is discovered.

2.1.3 Discussion may occur in person, by phone, fax, or e-mail.

2.1.4 Discussion may include review of relevant patient records.

2.1.5 Discussion may include request for prescriptive medication based on signs or symptoms and/or laboratory results.

2.1.6 Discussion should be documented by the midwife in her records. Documentation of discussion should refer only to practitioner type without specifying the name of the practitioner contacted. Documentation should also include the midwife's management plan.

2.1.7 Discussion need not occur if the midwife has previously encountered a particular situation, discussed it with a colleague, developed a management plan, and is currently managing the same clinical presentation. In this case, documentation of the management plan and discussion with the client of the management plan is sufficient.

2.2 CONSULTATION WITH A PHYSICIAN

A consultation refers to a situation in which the midwife, using her professional knowledge of the client and in accordance with this document, or by client request, seeks the opinion of a physician competent to give advice in the relevant field. The consultant will either conduct an in-person assessment of the client or will evaluate the client's records in order to address the problem that led to the consultation.

2.2.1 It is the midwife's responsibility to initiate a consultation and to communicate clearly to the consultant that she is seeking a consultation.

2.2.2 A consultation can involve the physician providing advice and information, and/or providing care to the woman/newborn, and/or prescribing treatment for the woman or newborn.

2.2.3 In the case of an in-person consultation, the midwife should expect that the consultant will promptly communicate findings and recommendations to the client and the referring midwife after the consultation has taken place.

2.2.4 Where urgency, distance, or climatic conditions do not allow an in-person consultation with a physician when it would otherwise be appropriate, the midwife should seek advice from the physician by phone or other similar means. The midwife should document this request for advice in her records and discuss the consultant's advice with the client.

2.2.5 It is the midwife's responsibility to provide all relevant medical records to the consultant, including a written summary of the client's history and presenting problem, as appropriate.

2.2.6 Consultation must be fully documented by the midwife in her records, including the consultant's name, date of referral, and the consultant's findings, opinions, and recommendations. The midwife must then discuss the consultant's recommendations with the client.

2.2.7 After consultation with a physician, care of the client and responsibility for decision making, with the informed consent of the client, either continues with the midwife, is shared collaboratively by the midwife and the consultant, or transfers completely to the consultant. Transfer or sharing of care should occur only after dialogue and agreement among the client, the midwife, and the consultant.

2.3 TRANSFER TO A PHYSICIAN OR OTHER QUALIFIED HOSPITAL-BASED PROVIDER

When care is transferred permanently or temporarily from the midwife to a qualified hospital based provider, the receiving practitioner assumes full responsibility for subsequent decision making, together with the client. For guidance about intrapartum transfers, see also the MAWS document Planned Out-of-Hospital Birth Transport Guideline.

3.1 PRE-EXISTING CONDITIONS AND INITIAL HISTORY

Discussion:

- family history of significant genetic disorders, hereditary disease, or congenital anomalies
- history of pre-term birth (< 36 weeks)

- history of IUGR
- history of severe postpartum hemorrhage
- history of severe pre-eclampsia
- history of gestational diabetes

Consultation:

- history of uterine surgery, including: myomectomy, hysterotomy, or prior cesarean birth
- current or significant history of cardiovascular disease, renal disease, hepatic disorders, neurological disorders, severe gastrointestinal disease
- current or significant history of endocrine disorders (excluding controlled mild hypothyroidism)
- pulmonary disease/active tuberculosis/asthma if severe
- collagen-vascular diseases
- significant hematological disorders
- current or significant history of cancer
- history of cervical cerclage
- history of 3 consecutive spontaneous abortions
- significant uterine anomalies
- essential hypertension
- history of eclampsia or HELLP
- previous unexplained neonatal mortality or stillbirth
- isoimmunization with an antibody known to cause hemolytic disease of the newborn
- history of postpartum hemorrhage requiring transfusion
- current severe psychiatric illness
- no prenatal care prior to third trimester
- current or history of epilepsy

Transfer:

- absent prenatal care at term
- any serious medical condition, for example: cardiac disease, renal disease with failure, insulin-dependent diabetes mellitus, or uncontrolled asthma

3.2 ANTEPARTUM CONDITIONS

Discussion:

- urinary tract infection unresponsive to treatment

- significant abnormal ultrasound finding
- well-controlled gestational diabetes
- persistent size/dates discrepancies

Consultation:

- significant abnormal Pap
- significant abnormal breast lump
- pyelonephritis
- ectopic pregnancy
- molar pregnancy
- thrombosis
- fetal demise after 14 weeks gestation
- persistent anemia, unresponsive to treatment
- primary herpes infection
- significant vaginal bleeding
- premature pre-labor rupture of membranes (PPROM)
- isoimmunization, hemoglobinopathies
- persistent abnormal fetal heart rate or rhythm
- significant placental abnormalities
- documented intrauterine growth restriction
- unresolved polyhydramnios or oligohydramnios
- significant infection the treatment of which is beyond the midwife's scope of practice
- 42 completed weeks with reassuring fetal surveillance
- presentation other than cephalic at 37 weeks

Transfer:

- multiple gestation
- persistent transverse lie, oblique lie, or breech presentation
- persistent hypertension, HELLP, pre-eclampsia, or eclampsia
- placenta previa at term
- clinically significant placental abruption
- cardiac or renal disease with failure
- uncontrolled gestational diabetes
- known fetal anomaly or condition that requires physician management during or immediately after delivery

3.3 INTRAPARTUM CONDITIONS

In certain intrapartum situations, the midwife may need to act immediately and transport may not be the most prudent course of action in that moment. It is expected that the midwife will use her clinical judgment and expertise in such situations, access 9-1-1 if appropriate, and then transport if and when it becomes necessary.

Discussion:

- arrested active phase of labor (>6 hours of regular, strong contractions without any significant change in cervix and/or station and/or position)
- arrested 2nd stage of labor (>3 hours of active pushing without any significant change)
- prolonged rupture of membranes (>48 hours)

Transfer:

- labor before 37 weeks
- transverse lie, oblique lie, or breech presentation
- multiple gestation
- sustained maternal fever (>100.4 F) or other evidence of maternal infection
- moderate or thick meconium
- persistent non-reassuring fetal heart rate pattern
- maternal exhaustion unresponsive to rest/hydration
- abnormal bleeding during labor
- suspected placental abruption
- suspected uterine rupture
- persistent hypertension
- pre-eclampsia
- maternal seizure
- ROM >72 hours or ROM >18 hours with unknown GBS status and no prophylactic antibiotics or GBS+ and no prophylactic antibiotics
- prolapsed cord or cord presentation
- significant allergic response
- active genital herpes in vaginal, perineal or vulvar area in labor or after ROM
- client's clear desire for pain relief or hospital transport

3.4 POSTPARTUM CONDITIONS

Discussion:

- urinary tract infection unresponsive to treatment

- mastitis unresponsive to treatment
- subinvolution

Consultation:

- breast abscess
- retained products/unresolved subinvolution
- sustained hypertension
- significant abnormal Pap
- postpartum depression

Transfer:

- significant postpartum hemorrhage unresponsive to treatment, with or without sustained maternal vital sign instability or shock
- retained placenta (>1 hour or active bleeding and manual removal unsuccessful)
- lacerations beyond midwife's ability to repair
- unusual or unexplained significant pain or dyspnea
- significant hematoma
- endometritis
- postpartum psychosis
- maternal seizure
- anaphylaxis
- persistent uterine prolapse or inversion

3.5 NEWBORN CONDITIONS

It is strongly recommended that all newborns be seen by an appropriate pediatric provider by 2 weeks of age. The following conditions warrant contact sooner.

Discussion:

- low birth weight infant (< 2500 gm = 5 lbs 8 oz)
- loss of greater than 10% of birth weight

Consultation:

- persistent cardiac arrhythmias or murmurs
- significant clinical evidence of prematurity
- failure to thrive
- hypoglycemia
- significant jaundice in first 24 hours or pathologic jaundice at any time

Transfer:

- seizure
- persistent respiratory distress
- persistent central cyanosis or pallor
- persistent temperature instability
- persistent hypoglycemia
- Apgar score less than 7 at five minutes of age and not improving
- major apparent congenital anomalies
- birth injury requiring medical attention

Home Birth Discussion Guide for the February 5, 2015 EbGS meeting

In response to public comment, there are key questions EbGS needs to address.

1) **Should the Coverage Guidance Title be changed from "Home Birth" to "Planned Out-of-Hospital Birth"?**

   Issue: Commenters discussed the two sets of rules between home birth and birthing centers. The birth center criteria are also discussed in rule and are expected to be modified in response to this coverage guidance. Creating a standard definition across home birth and birthing center settings that is based on evidence would be appropriate.

   - Comment J2 excerpt

     "Planned Home Birth" should be changed back to "Planned Out-of-hospital birth."

     The coverage guidelines should pertain to all OOH births, both home and birth center. In Oregon, many birth attendants work both in birth centers and also do home births. Birth centers do not provide any additional safety features over home birth for high risk situations. The current birth center rules exclude twins and breech, but allow Previous C-section, postterm pregnancies up to 43 weeks, and hypertension up to 150/100.

     I think it is already confusing to the consumer that there are two sets of rules – one for LDMs through the BDEM, and another for Birth Centers. I think it would compound the confusion to have two sets of coverage guidelines.

   HERC Staff Recommendation

   a. Change the title and scope from planned "home" birth to planned "out of hospital" birth.
   b. Changes in the OAR for this and other recommendations will need to follow once the Coverage Guidance is approved by HERC.

2) **Should the coverage guidance summary and box language be clarified to identify conditions that are appropriate for consult versus transfer?**

Issue: There were a number of comments about specific conditions being highly appropriate for simply consultation, rather than requiring transfer. The source documents largely separate out these categories as well. The degree of risk differs significantly between these two. It is both more clear and more specific to separate these risk criteria out based on whether transfer or consultation is indicated, and separating these categories also relies directly on the source documents.

a. Example comment: F7

"Further, when the HERC creates such a lengthy list of "high risk" conditions (beyond those included in a basic absolute risk guideline) that would exclude a patient from coverage for home birth it circumvents the rights of low-income patients to make informed choices about their own health care. This draft "high risk" list is not equivalent to recommending against payment for an experimental or medically unnecessary surgery, it is actually a recommendation against coverage for basic maternity and newborn care for many healthy women experiencing normal pregnancies. Consider, for example, that a woman with a history of genital herpes with no outbreak in the past two years, who has hyperemesis until 14 weeks, but is able to gain weight normally, and has a brother with down syndrome is "risked" out three times even though she is a perfectly reasonable candidate for home birth as long as she does not have a herpes outbreak at the time of birth".

HERC Staff Recommendation

a. Separate out lists of high risk criteria that indicate consultation versus transfer. Modify the i) evidence summary to reflect this and ii) the box language.

b. Address the specific concerns (genital herpes, hyperemesis, and relative with down syndrome) in the separate discussion section (Table 1) about additions/~~deletions~~/modifications

3) If a patient is transferred according to criteria, would the midwife be compensated for her care? (F5)

i. Response: If an indication arises intrapartum or postpartum, and the patient is transferred appropriately, that situation would meet current guidance. The HERC guidance does not change the rules for coding and

billing of services. There are codes for labor management and these may be appropriate to bill for care delivered prior to transfer. However, implementation of compensation is outside the scope of this guidance. This may be better addressed in administrative rule development.

ii. **ACTION - No change made. Question of intent.**
    1. **Consider referring back to the direct entry midwifery workgroup**

4) **Should VBAC be considered a high risk condition requiring planned hospital birth?**
    i. **F15** – Concern that VBAC is not a high risk condition given that… The two studies that include significant numbers of out-of-hospital vaginal births after cesareans (where the increased risk of rupture from tocolytics is not a factor as they are outside of scope of practice) showed good outcomes for mothers and babies as long as no other significant risk factors (e.g. breech, twins) were present (Cheyney et al 2014, Stapleton et al 2013).
    ii. In contrast, J7 says "I agree that Previous Cesarean Section is a situation that should remain on the high risk list. In the recent MANAstats dataset of home births in the US, the intrapartum + neonatal death rate for term VBACs was 4.75/1000 compared to 1.24/1000 for women with no previous C-section in the same study. (4) OOH births use intermittent auscultation for fetal surveillance which is appropriate for low risk labors if done properly, but is not appropriate for VBACs. Quoting from the SOGC guidelines for intrapartum fetal surveillance: "For women attempting VBAC, there is little controversy. All professional jurisdictions recommend continuous electronic fetal monitoring." That includes ACOG, SOGC, and RCOG. (5)
    iii. Response: NICE indicates that hx of Cesarean section indicates birth should be an obstetric unit. Many hospitals across Oregon are unable to provide TOLAC capabilities because of a lack of emergent/urgent Cesarean section and anesthesia ability. There are significant concerns including that these hospitals would theoretically be the backup hospital for the failed TOLAC at home. This juxtaposition was felt to be inappropriate to some commenters. It is important to acknowledge however that different women with history of a cesarean section may have different risk levels (such as one who has had a vaginal delivery prior). While overall risk may be lower for some women performing VBAC, if uterine rupture occurs this would be an emergency.

    iv. **ACTION**

1. **Modifications: Box language clarified that Absence of prior cesarean section (or hysterotomy) is within the core definition of low risk. The presence of either prior cesarean or hysterotomy requires planned hospital delivery.**

5) **Should language be added acknowledging at times the time between identification of high risk criteria and transfer may not be possible due to imminent delivery?** There are individual considerations in examples such as thick meconium (F22) in which transferring may challenging given imminent delivery.
   i. From the Netherlands guidance. "Thick meconium is Netherlands C (secondary obstetric care) and is an indication for planned hospital birth". "When one of the items mentioned below occurs, an attempt should still be made to achieve an optimal condition for further intrapartum care, whilst referral to secondary care may be urgent, depending on the situation. When referring from the home situation, the risk of transporting the woman also needs to be included in the considerations."
   ii. Rationale – Sources differ on recommendations about meconium. Aspiration can happen with thick or thin meconium, it is a subjective assessment, and the ability to temporize and manage the neonatal airways is within Neonatal Rescuscitation protocol. Any meconium does place newborns at risk for meconium aspiration syndrome.
   iii. The immediacy of delivery may make transfer impossible or inadvisable, not just with meconium but with many of these indications.
   iv. Actions:
      1. **Consider adding language to the section on transferring to a hospital: * an attempt should be made to transfer the woman and/or her newborn, however, imminent fetal delivery may delay preclude actual transfer prior to birth.**
      2. **Delete "without reassuring fetal heart tones"**
      3. **Either delete the meconium criteria altogether or leave this as "thick" meconium**

6) **How shall the HERC address a number of serious concerns about the context of home delivery?** These include (G3):
   i. Need for midwives to have appropriate malpractice insurance
   ii. Need for increased litigation protection for maternity and newborn providers who take care of planned out of hospital births requiring additional levels of care and/or their subsequent complications.

iii. The commenter argues patients who refuse to adhere to the guidelines needs to sign an informed refusal consent form.
iv. Rationale - Developing a document used in early care that discusses risks/benefits upfront. A care plan needs to be established when an urgent/emergent situation is not underway and should be established at the onset of the relationship. There is currently care agreements based on OAR individualized by each practice that used in Oregon. These may need to be modified based on the final CG.
v. Actions
    1. **Malpractice insurance is outside of the scope of the HERC. No action.**
    2. **For discussion: Should HERC specify items to be included in informed consent documentation or require the use of a specific standardized informed consent document? It is currently discussed in the box paragraph about the context of safe home birth.**

7) Is the mortality rate underestimated for home births? L1

i. It is misleading to compare a perinatal mortality rate that included an unknown but relatively high proportion of the 58 term fetal deaths associated with nearly 40,000 planned hospital births in Oregon in 2012 with the perinatal mortality rate for planned 2,021 planned OOH births, which included 4 early neonatal deaths and 4 intrapartum fetal deaths but no antenatal fetal deaths.
ii. Actions
    1. **Discuss whether this information changes appreciably the assessment of safety of home birth for Oregonians.**

8) **How should the differences in education/training of direct entry Oregon midwives compared to other international settings be addressed? L2**

i. The relative training between different countries is described in the text of the Coverage Guidance. This is already in OAR.
ii. Actions
    1. **Box language is strengthened to address that providers need to be licensed, credentialed, and be able to respond to emergencies and perform appropriate care.**
    2. **Consider adding language in the box about relative training/experience in the U.S. compared to other systems (in which many of the studies were done).**

9) **Should a minimum time to an appropriately equipped back-up hospital (not more than 30 minutes) be added to coverage guidance? L3**
    i. Transfer may need to occur in scheduled, urgent, or emergent fashion. If an obstetric emergency occurs at home, the transfer time itself may cause significant harm. Informing women of this risk would be appropriate as part of informed consent. The length of the trip to an equipped hospital may theoretically further impact the safety of mother or infant. However, there are significant concerns about liability issues and therefore a specific time limit may not be helpful.
    ii. **Actions – Consider adding language**
        1. **A hospital capable of providing maternity/newborn care should be no more than 30 minutes away from the site of planned out-of -hospital birth. [multiple concerns with this language]**
        OR
        2. **PREFERRED Include language about risks associated with delays of transfer in the box language (and would be included in the informed consent document)**

10) **Should language be added about initial and continuous risk assessment to determine appropriate location of planned birth?**
    i. Risks may actively evolve in the antepartum, intrapartum, and postpartum time periods. Therefore ongoing assessment of risk is indicated to ensure that criteria for consultation or transfer do not develop.
    ii. **ACTION - Consider adding the following language:**
        1. **Risk assessment should be done initially when planning location of birth and monitored throughout pregnancy, labor, delivery and the initial postpartum period to determine if planned out of hospital birth is still appropriate, or consultation/transfer is required.**

11) **How should consultation be defined?**
    i. **Consider adding the following language: Consultation must be with a provider of maternity care who is credentialed to admit and manage pregnancies in a hospital.**

12) Coverage Guidance Additions, Deletions, and Modifications (see Table 1 additions/~~deletions~~/modifications)

a. Suggested additions: 16
b. Suggested deletions: 19
c. Suggested modifications: 9

Table 1. High risk conditions proposed for additions/~~deletions~~/modifications disposition

The HERC received many public comments on the list of proposed "High risk conditions necessitating consultation or transfer." It was deemed more suitable that high risk conditions should be divided into separate lists; one encompassing conditions that would indicate planned hospital birth (or transfer), the other noting those conditions where consultation would be appropriate to assure the appropriateness of planned out of hospital birth.

In the table below, conditions that were raised as concerns in public comments are listed to the left. Disposition of these items to a list indicating consultation or transfer/planned hospital birth is noted, with evidence sources cited on the right.

Pregnancy Complication (Comment)	Requires consultation with higher level of care	Requires transfer to higher level of care	Staff Recommendation/Rationale	Source(s)
Gestational age of 36 weeks (proposed **modification** to minimum low-risk criteria)		X	Low-risk criteria were clarified. Intention is 36 **completed** weeks of pregnancy (i.e. 37 weeks + 0 days) as recommended by NICE is required to be considered low-risk; therefore any point during 36th week requires transfer.	NICE guideline
Pregnancy past 41 weeks (proposed **modification** to minimum low-risk criteria)		X	Low-risk criteria were clarified. Intention is to be consistent with NICE guidance on **completed** weeks of pregnancy. Box language was modified to indicate upper limit is 41 weeks + 6 days. Of note, Oregon Birth Center risk criteria place the upper limit at 43 weeks, or 42 weeks with abnormal non-stress test.	NICE guideline recommends 41 completed weeks. Oregon Birth Center risk criteria place the upper limit at 43 weeks, or 42 weeks with abnormal non-stress test.

Pregnancy Complication (Comment)	Requires consultation with higher level of care	Requires transfer to higher level of care	Staff Recommendation/Rationale	Source(s)
Prior Cesarean section (Proposed **addition** to minimum low-risk criteria)		X	EbGS agrees that patients with prior Cesarean section are not low-risk for out-of-hospital birth. See comment F15, commenter cites two studies.	NICE guideline, Table 6
Ultrasound between 12-30 weeks (proposed **addition** to minimum low-risk criteria)			Not added to low-risk criteria based on previous evidence review finding no change in management of pregnancy based on routine ultrasound.	HERC Coverage Guidance on Ultrasound in Pregnancy
Diabetes, pre-existing or gestational (proposed **addition**)	X (Gestational, diet- and exercise-controlled only)	X (Type I, Type II, uncontrolled gestational, or gestational controlled with medication)	Previously was incorporated into nonspecific language about maternal disease. Add gestational diet- and exercise -controlled diabetes mellitus to consultation and all other types as indications for planned hospital birth.	Oregon LDM low-risk criteria and birth center absolute risk criteria exclude existing diabetes, uncontrolled GDM or GDM controlled with medication. NICE guideline lists diabetes as an indication for hospital birth. Ontario suggests transfer of care for insulin-requiring diabetics and consultation for those unresponsive to dietary treatment. Netherlands guidance lists diabetes as indicating secondary-level obstetric care.
Having had an IUD (proposed **addition**)			Not added to list based on absence of evidence of risk.	Netherlands lists "Status following removal of the IUD" as category A (midwife/GP)
Extremes of maternal age (proposed **addition**; prior box language said age <14)	X (maternal age <14 or >35 years)		Commenters suggest <17 should be an indication for hospital birth, sources only recommend consultation for age less than 14. EbGS to decide.	NICE recommends consultation for maternal age >35 but does not put a lower age limit on home birth. Guidelines from British Columbia specify age less than 17 or over 40 as

Pregnancy Complication (Comment)	Requires consultation with higher level of care	Requires transfer to higher level of care	Staff Recommendation/Rationale	Source(s)
				indication for discussion, and age less than 14 as indication for consultation.
Prior third-degree laceration (proposed **addition** in E2) Prior fourth-degree laceration (proposed **deletion** in F9)	X		NICE lists "third- or fourth-degree perineal trauma" as indicating consultation when planning place of birth.	NICE lists "Extensive vaginal, cervical, or third- or fourth-degree perineal trauma" as a consultation indication; Netherlands guidance recommends midwife/GP care if function was restored (category A) and secondary obstetrical care if it was not (category C).
Intrapartum third- or fourth- degree laceration (proposed **deletion** in F24)		X	Laceration requiring hospital repair (e.g., extensive vaginal, cervical or third/fourth degree trauma), is included in box language on the list of intrapartum complications requiring transfer. Coverage guidance could be further amended to include third- or fourth-degree laceration not requiring hospital repair as an indication for consultation without transfer.	British Columbia and Ontario list third and fourth degree lacerations as indicating consultation. Netherlands lists fourth-degree laceration as an indication for transfer to secondary obstetrical care.

Pregnancy Complication (Comment)	Requires consultation with higher level of care	Requires transfer to higher level of care	Staff Recommendation/Rationale	Source(s)
Prior fractured clavicle and shoulder dystocia (proposed **addition**)		X (Shoulder dystocia with or without fetal clavicular fracture)	NICE lists shoulder dystocia as an indication for planned hospital birth. Fetal clavicular fracture would presumably be secondary to dystocia so we have added clarification. Commenter's concern "A woman with tightly controlled blood glucose levels in a subsequent pregnancy with a smaller baby is likely, for example, not to experience a repeat complication." Is not addressed by NICE.	NICE guideline
Maternal Jehovah's Witness status (proposed **addition**)			No evidence was discovered or provided to support inclusion of maternal objection to transfusion as a high-risk condition.	No evidence sources
Maternal seizure disorder/epilepsy (proposed **addition**)	X		Added to seizure disorder not requiring medication criteria for consultation, and epilepsy requiring medication to indications for planned hospital birth	Netherlands B if medicated NICE guideline indicates transfer regardless of medication status
Prior infant > 9 lbs (proposed **addition**)	X (History of baby >4.5kg or 9lb14oz)		NICE recommends history of previous baby >4.5kg as an indication for consultation.	NICE guideline
Suspected macrosomia (proposed **addition**)	X (Suspected fetal macrosomia)		Clinical or ultrasound suspicion of macrosomia in the current pregnancy is also an indication for consultation and was therefore also added.	NICE guideline

Pregnancy Complication (Comment)	Requires consultation with higher level of care	Requires transfer to higher level of care	Staff Recommendation/Rationale	Source(s)
Incomplete prenatal testing e.g. strep, STI, GDM (see comment G12) (proposed **addition**)		X	Inadequate prenatal care is an indication for hospital birth, given inability to determine presence of all low-risk criteria necessary for out of hospital birth. Discuss whether screening labs need to be incorporated into this definition.	USPSTF recommends the following screening tests & preventive services for pregnant women: EtOH misuse screening; bacteriuria screening; breastfeeding counseling; CT & GC; GDM screening;HIV; iron-deficient anemia screening; syphilis screening; tobacco use counseling NICE recommends screening if mother is willing on booking.
Severe mental health issues not well-controlled (proposed **addition**)	X (Maternal mental illness under outpatient psychiatric care)	X (Maternal mental illness requiring inpatient care)	Follow more specific NICE guideline.	NICE lists "psychiatric disorder requiring current inpatient care" as an indication for hospital birth, and "Under current outpatient psychiatric care" as an indication for consultation. Under the Netherlands guidance, psychiatric illness is category B (consultation situation), noting severity and extent of the disorder will determine the best course.

Pregnancy Complication (Comment)	Requires consultation with higher level of care	Requires transfer to higher level of care	Staff Recommendation/Rationale	Source(s)
Intrapartum or postpartum complications (proposed **deletion**)			EbGS feels it is important to note intrapartum and postpartum complications of mother and infant that would necessitate transfer to a higher level of care. This does not imply that the services provided by an out of hospital provider who was compliant with the guidance prior to development of a complication, who then transferred the patient(s) appropriately, would not be covered.	
History of preterm birth (proposed **deletion**)	X		Continue to include preterm birth as requiring consultation to be consistent with Netherlands and Ontario guidance, but do not delete.	NICE does not list a history of preterm birth as a high-risk indication. A history of preterm birth is listed by Netherlands guidance as category B (consultation situation). Ontario guidance recommends consultation for "History of more than one preterm birth, or preterm birth less than 34 weeks 0 days in most recent pregnancy."
History of more than three first trimester spontaneous abortions, or more than one second trimester spontaneous abortion (proposed **deletion**)	X		Retain box language including history of spontaneous abortions (i.e. miscarriage) as requiring consultation as taken from the Ontario guidance	Ontario guidance

Pregnancy Complication (Comment)	Requires consultation with higher level of care	Requires transfer to higher level of care	Staff Recommendation/Rationale	Source(s)
Failure to progress/ failure of head to engage in active labor (proposed **deletion**)		X	Retain failure to progress/engage as requiring transfer as taken from the Oregon birth center ARC.	Oregon birth center states this as a reason to transfer. Both the Ontario and Netherlands guidance recommend it as an indication for consultation.
Cervical dysplasia requiring evaluation (proposed **deletion**)	X		Retain requirement as recommended by The Netherlands, which lists this as category B (consultation situation).	Netherlands guidance
Hyperemesis gravidarum (proposed **deletion**)		X	Keep in transfer, but modify to "refractory hyperemesis gravidarum"	Hyperemesis requires secondary level care until it is resolved (Netherlands guidance). Ontario and British Columbia also list refractory hyperemesis as an indication for consult.
Family history of genetic/heritable disorders (proposed **deletion**)	X		Retain to follow guidance from British Columbia.	Guidance from British Columbia lists "Family history of genetic disorders, hereditary disease or significant congenital anomalies" as an indication requiring consultation.
History of pre-eclampsia/HELLP syndrome (proposed **deletion**)	X (if did not necessitate preterm birth)	X (if necessitated preterm birth)	Commenter requests further refinement if this is to be included (see comment F 10) Box language modified to align with NICE/Netherlands on when consultation vs transfer necessary for history of pre-eclampsia.	NICE lists history of pre-eclampsia as necessitating individual assessment; and history of pre-eclampsia requiring preterm birth as an indication for planned hospital birth. Netherlands lists prior HELLP syndrome as an indication for secondary care (category C).

Pregnancy Complication (Comment)	Requires consultation with higher level of care	Requires transfer to higher level of care	Staff Recommendation/Rationale	Source(s)
History of unexplained stillbirth/neonatal death or previous death related to intrapartum difficulty (proposed **deletion**)	X (unexplained stillbirth/neonatal death or previous death unrelated intrapartum difficulty)	X (unexplained stillbirth/neonatal death or previous death related to intrapartum difficulty)	Commenter says this is a broad category best suited to careful evaluation, consultation and informed consent. Gives example of cord accident. (See comment F 11) Retain requirement of transfer to follow NICE guidance when related to intrapartum difficulty. Consult appropriate for unexplained stillbirth unrelated to intrapartum difficulty.	NICE guidance does include "Unexplained stillbirth/neonatal death or previous death related to intrapartum difficulty" as a condition indicating planned hospital birth. History of unexplained stillbirth is listed in multiple sources (Netherlands, Ontario, and British Columbia) as requiring consultation.
History of postpartum hemorrhage requiring additional treatment or blood transfusion (proposed **deletion**)		X	This language is being retained as it is taken directly from NICE as an indication for planned hospital birth, however, it is unclear as to what "additional treatment" entails. See comment F12 for study submitted by commenter, who says research is unclear. Proposed draft specifies "additional pharmacologic treatment or blood transfusion."	NICE guideline

Pregnancy Complication (Comment)	Requires consultation with higher level of care	Requires transfer to higher level of care	Staff Recommendation/Rationale	Source(s)
History of retained placenta requiring manual removal (proposed **deletion**)		X	Commenter says this will exclude women with histories that are not actually clinically concerning for the current pregnancy, and that ultrasound evaluation is the appropriate course of action. This language is being retained as an indication for planned hospital birth to follow NICE. Even with ultrasound evaluation, the patient is at increased risk of undetected abnormal placentation. Also add manual and/or surgical removal language.	NICE guideline
Placenta previa, vasa previa, low lying placenta (proposed **modification**)		X (Complete placenta previa or low lying placenta within 2 cm or less of the cervical os at term; known vasa previa)	Commenter asked that this be clarified to specify placenta previa at term. Language modified to follow the combined criteria in Oregon Birth Center ARC and NICE guideline, and address commenter's concern.	Oregon birth center absolute risk criteria list "Low-lying placenta within 2 cm or less of cervical os; vasa previa; complete placenta previa" as prohibiting admission to the birth center. NICE table 7 lists "Placenta praevia" as a complication of current pregnancy indicating birth at an obstetric unit.

Pregnancy Complication (Comment)	Requires consultation with higher level of care	Requires transfer to higher level of care	Staff Recommendation/Rationale	Source(s)
Confirmed intrauterine death (proposed **deletion**)	X		Commenter expressed that the only risk to the mother is if there are signs of infection or DIC after the passage of significant time, and suggested that families should have home birth as an option after consultation and informed consent if safe. Proposed coverage guidance language is retained to be consistent with Ontario recommendation.	NICE lists "Confirmed intrauterine death" as a complication of current pregnancy indicating birth at an obstetric unit. In addition, "Dead fetus" is Netherlands C (requiring secondary obstetric care); however, Ontario guidelines list "Intrauterine fetal demise" as an indication for consultation only.
Body mass index at first prenatal visit of greater than 35 kg/m^2 (proposed **deletion**)		X	Commenter expressed that many larger women are excellent candidates for home birth if other risk factors are present and recommended allowing home birth after consultation. Retained language is consistent with NICE criteria listing "BMI at booking > 35 kg/m^2" as a complication of current pregnancy indicating birth at an obstetric unit.	NICE guideline
Small for gestational age fetus (proposed **modification**)		**X** (<5th percentile or with reduced growth velocity on ultrasound)	As noted by commenter, NICE specifies < 5th percentile or reduced growth velocity on ultrasound as indicating planned hospital birth. Coverage guidance was edited to clarify this, with additional language to specify ethnically-appropriate growth tables.	NICE guideline

Pregnancy Complication (Comment)	Requires consultation with higher level of care	Requires transfer to higher level of care	Staff Recommendation/Rationale	Source(s)
Prelabor rupture of membranes > 24 hours (proposed **deletion**)		X	Language retained to follow NICE/Netherlands guidance. Commenter F said that risk of infection is small after 24 hours especially in home birth setting with minimal vaginal exams and recommends it be included in informed consent. Commenter G suggested > 18 hours as increasing chance for sepsis and necessitating other treatment.	NICE recommends transfer to obstetric care after "rupture of membranes more than 24 hours before the onset of established labour." Netherlands guidance also recommends secondary obstetric care after 24 hours (category C).
Genital herpes (proposed **modification**)		**X** (current active infection)	Conflicting public comments (any history of genital herpes vs. active.) Guidance language changed to "Current active infection of chicken pox/rubella/genital herpes in the woman or baby" in accordance with NICE and to address one commenter's concern.	NICE guideline
Thick meconium staining of amniotic fluid (proposed **deletion**)		**X** Possibly add language about imminent birth. Leave out language about reassuring tones.	Commenter said this should be considered individually and expressed concern about imminent deliveries. Revise language to include "Thick meconium staining of amniotic fluid." As an indication for transfer. Together with the indication about fetal heart rhythm, this matches the Oregon Birth Center ARC. Language about imminent deliveries was added, but not specifically to this indication.	Under Oregon birth center ARC, transfer is required for "Thick meconium-stained amniotic fluid without reassuring Doppler heart tones and birth is not imminent." Thick meconium is Netherlands C (secondary obstetric care) and is an indication for planned hospital birth.

Pregnancy Complication (Comment)	Requires consultation with higher level of care	Requires transfer to higher level of care	Staff Recommendation/Rationale	Source(s)
Retained placenta (proposed **deletion**)		X	Commenter says the provider will need to determine safest course based on clinical picture, and this is covered in rule and practice standards. Retained placenta is an indication for transfer to a hospital, whether or not management by an out-of-hospital provider is initiated before or during transfer.	NICE recommends urgent transfer if uterine exploration is necessary. Ontario lists it as a consultation indication. Netherlands category C (secondary care)
Written transfer plan needs to be in effect that the accepting OB and pediatrician agree with (proposed **addition**)			No change made. A "well-defined system of transfer" is already specified in the box language as a characteristic of a successful home birth.	
History of a blood clot, or bleeding disorder (proposed **addition**)		**X** (blood clot, or other maternal bleeding disorder)	Alternate language added related to current maternal disorders to follow Netherlands/NICE criteria.	Bleeding or coagulation disorder is Netherlands Category C (secondary obstetric care) and bleeding disorder in the mother is a NICE criterion for planned hospital birth.
Maternal hemoglobin <11 (proposed **modification**)	**X** (Maternal hemoglobin <10.5)	X (Maternal hemoglobin <8.5)	Box language will be modified to reflect 10.5 as cutoff for consultation with 8.5 retained as cutoff for transfer	NICE specifies 8.5-10.5 as indication for individual assessment.

Pregnancy Complication (Comment)	Requires consultation with higher level of care	Requires transfer to higher level of care	Staff Recommendation/Rationale	Source(s)
History of a group B Step septic infant (proposed **addition**)			No change made as qualified providers in Oregon may administer group B strep prophylaxis outside the hospital setting and so this is not by itself a contraindication to out of hospital birth.	NICE lists "Risk factors associated with group B streptococcus whereby antibiotics in labour would be recommended" as indicating birth in an obstetrical unit.
Pregnancy-induced hypertension, pre-existing hypertension (proposed **modification**)		**X**	Commenter requested that blood pressure > 140/90 before or after delivery be added as a risk factor. Box language was added to reflect NICE cutoffs for hypertension as an indication for intrapartum transfer.	NICE guideline indicates a raised diastolic blood pressure over 90 mmHg or raised systolic blood pressure over 140 mmHg on two consecutive readings taken 30 minutes apart as an indication for intrapartum transfer. Oregon birth center ARC specifies blood pressure >150/100 on at least two occasions.
Thrombopenia (proposed **modification**)		**X**	Commenter requested maternal platelet count < 150,000 as a high-risk indication. Another requested <100,000. The word "thrombopenia" has been changed to "thrombocytopenia" and a cutoff of 100,000 is being added for consistency with NICE.	NICE guideline Oregon Birth Center Criteria
Chorioamnionitis or other serious infection *with fever >38 C* (proposed **modification**)		X	No change is being made. Box language presently includes "chorioamnionitis or other serious infection." Maternal temperature is only one piece of the diagnostic criteria for chorioamnionitis.	

Pregnancy Complication (Comment)	Requires consultation with higher level of care	Requires transfer to higher level of care	Staff Recommendation/Rationale	Source(s)
Retained placenta >1 hour (proposed **modification**)		X (after 3 hours)	Original box language recommended transfer for retained placenta without a defined time cutoff. A three-hour cutoff has been added to coverage guidance to be consistent with birth center criteria.	Oregon birth center criteria list a 3-hour cutoff. NICE, Netherlands, Ontario, and British Columbia guidances do not define a time cutoff for retained placenta.
Blood group incompatibility (proposed **deletion**)		X (with atypical antibodies)	The coverage guidance has been revised to include "Blood group incompatibility *with atypical antibodies* (including Rh sensitization)" as an indication for hospital birth to align with NICE.	NICE lists "atypical antibodies which carry a risk of haemolytic disease of the newborn" as indicating birth in an obstetrical unit. Active blood group incompatibility is Netherlands category C (secondary obstetric care).
Fetal growth retardation (proposed **modification**)	X		Has been changed as requested to "intrauterine growth restriction" for consistency. This is an indication for consultation.	

Pregnancy Complication (Comment)	Requires consultation with higher level of care	Requires transfer to higher level of care	Staff Recommendation/Rationale	Source(s)
Substance abuse, including marijuana (proposed addition)	X (occasional recreational use of alcohol or marijuana)	X (substance misuse)	Substance misuse is added to the list of indications for planned hospital birth. Recreational use (occasional use of alcohol or marijuana) is added to consultation list.	NICE Table 7 lists both "Substance misuse" and "alcohol dependency requiring assessment or treatment" as factors indicating planned hospital birth. Netherlands list "Use of hard drugs" as necessitating secondary obstetrical care. Ontario suggests consultation for "Significant use of drugs, alcohol, or other substances with known or suspected teratogenicity or risk of associated complications." British Columbia also recommends consultation for "Significant use of drugs, alcohol, or other toxic substances."