Health Evidence Review Commission (HERC) Coverage Guidance: Planned Out-of-Hospital Birth

DRAFT for 8/13/2020 HERC/VbBS Meeting Materials

HERC Coverage Guidance

Planned out-of-hospital birth is recommended for coverage for pregnant women who are at low risk for adverse obstetric or birth outcomes (weak recommendation). The high-risk conditions outlined below would either preclude coverage of planned out-of-hospital birth, necessitate a consultation, or require transfer of the mother or infant to a hospital setting. When a condition requiring transfer arises during labor, an attempt should be made to transfer the mother and/or her newborn; however, imminent fetal delivery may delay or preclude actual transfer prior to birth.

Coverage of prenatal, intrapartum, and postpartum care is recommended with the performance of appropriate risk assessments (at initiation of care and throughout pregnancy and delivery) and the out-of-hospital birth attendant's adherence to the consultation and transfer criteria as outlined below.

Planned out-of-hospital birth is not recommended for coverage for pregnancies with identified high-risk factors necessitating a planned hospital birth, or when the listed criteria for consultation and transfer of care are not followed by the birth attendant (*strong recommendation*).

When a high-risk condition develops that requires transfer or planned hospital birth, coverage is recommended when appropriate care is provided until the point the high-risk condition is identified. For women who have a high-risk condition requiring consultation, ongoing coverage of planned out-of-hospital birth care is recommended as long as the consulting provider's recommendations are then appropriately managed by the out-of-hospital birth attendant in a planned out-of-hospital birth setting.

HIGH-RISK CONDITIONS

Conditions in the red (darker) boxes indicate high-risk conditions that require planned hospital birth (when present on intake) or transfer of the mother or infant to hospital-based care (when condition develops).

Conditions in the yellow (lighter) boxes indicate potentially risky conditions that require consultation. Consultations may be with 1) a provider (MD/DO or CNM) who has active admitting privileges to manage pregnancy in a hospital and/or 2) appropriate specialty consultation (e.g., maternal-fetal medicine, hepatologist, hematologist, psychiatrist).

This list of high-risk conditions is not exhaustive, and other, physical health, behavioral health, obstetric, or fetal high-risk conditions may arise that require consultation and/or transfer to hospital-based care. Having multiple risk conditions requiring consultation may increase the risk sufficiently to indicate the need for transfer of care.



| MEDICAL HISTORY OR OBSTET | RIC HISTORY | | |
|--|---|--|--|
| Cancer | Active gynecologic cancer | | |
| Cardiovascular Disease | Cardiovascular disease causing functional impairment | | |
| Connective Tissue Disorders | Systemic lupus erythematous Scleroderma Rheumatoid arthritis Any collagen-vascular disease | | |
| Delivery History | Prior cesarean section | | |
| Diabetes Mellitus | Type 1 diabetesType 2 diabetes | | |
| Endocrine Conditions | Significant endocrine conditions other than diabetes (e.g. hyperthyroidism) | | |
| Fetal Demise or Stillbirth | Prior stillbirth/neonatal death | | |
| Hematologic Disorders | Maternal bleeding disorder Hemoglobinopathies History of thrombosis or thromboembolism History of postpartum hemorrhage requiring transfusion or other advanced treatment (e.g. Bakri balloon) | | |
| Hypertensive Disorders | Eclampsia Pre-eclampsia requiring preterm birth HELLP syndrome (hemolysis, elevated liver enzymes, low platelets) Pre-existing or chronic hypertension | | |
| Infectious Diseases | HIV positive | | |
| Isoimmunization | Blood group incompatibility and/or Rh sensitization in a prior pregnancy | | |
| Neonatal Encephalopathy in prior pregnancy | Neonatal encephalopathy in prior pregnancy | | |
| Neurological disorders | Neurological disorders or active seizure disorders that would impact maternal or neonatal health (e.g. epilepsy, myasthenia gravis, previous cerebrovascular accident) | | |
| Placental Conditions | History of retained placenta requiring surgical removal | | |
| Psychiatric Conditions | History of postpartum mood disorder with high risk to the infant (e.g. psychosis) Schizophrenia, other psychotic disorders, bipolar I disorder or schizotypal disorders | | |

| MEDICAL HISTORY OR OBSTETRIC HISTORY | | |
|--------------------------------------|---|--|
| Pulmonary Disease | Chronic pulmonary disease (e.g. cystic fibrosis) | |
| Renal Disease | Renal disease requiring supervision by a renal specialist Renal failure (Preeclampsia and related conditions are listed separately) | |
| Shoulder Dystocia | History of, with or without fetal clavicular fracture | |
| Uterine Conditions | Prior myomectomy Prior hysterotomy | |



| CONDITIONS OF CURRENT PREGNANCY | | |
|---|---|--|
| Abnormal Bleeding in pregnancy | Antepartum hemorrhage, recurrent Hemorrhage (hypovolemia, shock, need for transfusion, vital sign instability) | |
| Amniotic Membrane Rupture | Before 37 weeks 0 daysPre-labor rupture > 24 hours | |
| Congenital or Hereditary Anomaly of the fetus | Evidence of congenital anomalies requiring immediate assessment and/or management by a neonatal specialist | |
| Diabetes, Gestational | Requiring medication or uncontrolled | |
| Fetal Growth | Uteroplacental insufficiency IUGR (defined as fetal weight less than fifth percentile using ethnically-appropriate growth tables, or concerning reduced growth velocity on ultrasound) | |
| | Inappropriate uterine growth (size-date discrepancy). (An ultrasound read by a qualified physician constitutes a consultation) | |
| Fetal presentation | Breech or noncephalic presentation | |
| Gestational age | < 37 weeks 0 days ≥42 weeks 0 days (unless already in active labor at 41 weeks 6 days) | |
| | Expected date of delivery (EDD) uncertain | |
| Hematologic conditions | Anemia with hemoglobin < 8.5 g/dL (current pregnancy) Suspected or diagnosed thrombosis or thromboembolism Thrombocytopenia (platelets < 100,000) Hemoglobin < 10 g/dL, unresponsive to treatment | |
| Hepatic disorders | Disorders including uncontrolled intrahepatic cholestasis of pregnancy and/or abnormal liver function tests | |
| Hyperemesis gravidarum | Refractory | |

| Hypertensive disorders | Elevated blood pressure on two occasions 30 minutes apart (e.g. gestational hypertension or pregnancy-induced hypertension) Systolic ≥ 140 or diastolic ≥ 90 Elevated blood pressure on one occasion Systolic ≥ 160 or diastolic ≥ 110, or Systolic ≥ 140 or diastolic ≥ 90, with severe pre-eclampsia features Pre-eclampsia Eclampsia HELLP syndrome | |
|---|---|--|
| Infectious conditions | HIV, Hepatitis B or syphilis positive Chorioamnionitis Maternal temperature ≥ 38.0 C in labor/postpartum Genital herpes at time of labor Maternal infection postpartum (e.g., endometritis, sepsis, wound) requiring hospital treatment Rubella Tuberculosis (other than latent) Toxoplasmosis Varicella (active at labor) | |
| Isoimmunization | Blood group incompatibility and/or Rh sensitization in current pregnancy | |
| Labor management | Induction Failure to progress/failure of head to engage in active labor Lack of adequate progress in 2nd stage with cephalic presentation | |
| Miscarriage/non-viable pregnancy | Molar | |
| Multiple gestations | Multiple gestations | |
| Oligohydramnios or polyhydramnios Perineal laceration or obstetric anal sphincter injury | Oligohydramnios Polyhydramnios 3rd degree requiring hospital repair or beyond expertise of attendant 4th degree | |
| | Enlarging hematoma | |

| Placental conditions | Low lying placenta within 2 cm or less of cervical os at 38 weeks 0 days or later Placenta previa Vasa previa Abruption Retained placenta > 60 minutes |
|-------------------------------|---|
| Psychiatric conditions Renal | Maternal mental illness requiring psychological or psychiatric intervention Patient currently taking psychotropic medications Acute pyelonephritis |
| Substance Use Umbilical cord | Drug or alcohol misuse with high risk for adverse effects to fetal or maternal health Prolapse |
| Uterine condition | Anatomic anomaly (e.g. bicornuate, large fibroid impacting delivery) Uterine prolapse Uterine rupture, inversion |

Note: Definitions for strength of recommendation are in Appendix A. *GRADE Table Element Descriptions*.

Rationales for each recommendation appear below in the GRADE table.

Table of Contents

| Coverage Guidance: Planned Out-of-Hospital Birth | 1 |
|--|-----|
| Rationale for development of coverage guidances and multisector intervention reports | 8 |
| GRADE Table | 10 |
| Background | 17 |
| Federal Innovations- Strong Start | 19 |
| Oregon Public Health Data | 19 |
| Evidence Review | 20 |
| Comparative Studies | 20 |
| Subgroup Findings | 29 |
| Noncomparative Studies | 40 |
| Evidence Summary | 40 |
| Policy Landscape | 41 |
| Guidelines from Others | 41 |
| Regulatory Guidance | 42 |
| Guidelines and Regulatory Guidance Summary | 42 |
| Payer Coverage Policies | 44 |
| References | 51 |
| Appendix A. GRADE Table Element Descriptions | 59 |
| Strong recommendation | |
| Weak recommendation | 59 |
| Confidence in estimate rating across studies for the intervention/outcome | 59 |
| Appendix B. GRADE Evidence Profile | 61 |
| Appendix C. Methods | 62 |
| Scope Statement | 62 |
| Search Strategy | 63 |
| Appendix D. Applicable Codes | 65 |
| Appendix E. Characteristics of Comparative Observational Studies | 66 |
| Appendix F. Outcome Data from Comparative Observational Studies | 115 |
| Appendix G. Outcome Data by Subgroups for Comparative Observational Studies | 172 |
| Appendix H. Characteristics of Noncomparative Observational Studies | 184 |
| Appendix I. Risk Criteria Matrix: Maternal/Fetal | 203 |
| Annendix I. Risk Criteria Matrix: Newborn | 227 |

Rationale for development of coverage guidances and multisector intervention reports

Coverage guidances are developed to inform coverage recommendations for public and private health plans in Oregon as plan administrators seek to improve patients' experience of care, population health, and the cost-effectiveness of health care. In the era of public and private sector health system transformation, reaching these goals requires a focus on maximizing the benefits and minimizing the harms and costs of health interventions.

HERC uses the following principles in selecting topics for its reports to guide public and private payers:

- Represents a significant burden of disease or health problem
- Represents important uncertainty with regard to effectiveness or harms
- Represents important variation or controversy in implementation or practice
- Represents high costs or significant economic impact
- Topic is of high public interest

HERC bases its reports on a review of the best available research applicable to the intervention(s) in question. For coverage guidances, which focus on diagnostic and clinical interventions, evidence is evaluated using an adaptation of the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) methodology. For more information on coverage guidance methodology, see Appendix A.

Multisector interventions can be effective ways to prevent, treat, or manage disease at a population level. In some cases, HERC has reviewed evidence and identified effective interventions, but has not made formal coverage recommendations when these policies are implemented in settings other than traditional health care delivery systems because effectiveness could depend on the environment in which the intervention is implemented.

Use of GRADE System

HERC develops recommendations by using the concepts of the GRADE system. GRADE is a transparent and structured process for developing and presenting evidence and for performing the steps involved in developing recommendations. The table below lists the elements that determine the strength of a recommendation. HERC reviews the evidence and assesses each element, which in turn is used to develop the recommendations presented in the coverage guidance box. Estimates of effect are derived from the evidence presented in this document. The level of confidence in the estimate is determined by HERC based on the assessment of two independent reviewers from the Center for Evidence-based Policy.

In some cases, no systematic reviews or meta-analyses encompass the most current literature. In those cases, HERC may describe the additional evidence or alter the assessments of confidence in light of all available information. Such assessments are informed by clinical epidemiologists from the Center for Evidence-based Policy. Unless otherwise noted, statements regarding resource allocation, values and preferences, and other considerations are the assessments of HERC, as informed by the evidence reviewed, public testimony, and subcommittee discussion.

Recommendations for coverage are based on the balance of benefit and harms, resource allocation, values and preferences and other considerations. See Appendix A for more details about the factors that constitute the GRADE table.



GRADE Table

The Resource Allocation, Values and Preferences, and Other Considerations columns of this table appear as rows at the bottom of this table to improve readability.

| | Estimate of Effect for Outcome/ | | |
|---|--|---|--|
| Outcomes | Confidence in Estimate | | |
| | U.S. Studies | Non-U.S. Studies | |
| Mode of Delivery (Critical outcome) Data from comparative studies of good (3) and fair (1) methodological quality reported. Findings from poor- | Nonoperative Vaginal Delivery (1 study) 93.8% vs. 71.9% for planned home or birth center birth compared to planned hospital birth Absolute risk difference (ARD) = 27.5 Number needed to treat (NNT) = 3 Adjusted Odds Ratio (aOR) 5.63, 95% CI 4.84 to 6.55 | Nonoperative Vaginal Delivery (3 studies) Range from 81% to 92.8% for planned home or birth center birth vs. 64.7% to 86% for planned hospital birth ARD range from 3.0 to 19.0 NNT range from 5 to 33 aOR range from 1.57 to 3.61 in favor of planned home or birth center birth | |
| methodological-quality studies (14) not included in GRADE table. | Cesarean Delivery (1 study) 5.3% vs. 24.7% for planned home or birth center birth compared to planned hospital birth ARD = 19.4 favoring planned home or birth center birth NNT = 5 aOR = 0.18, 95% CI 0.16 to 0.22 | Cesarean Delivery (2 studies) Range from 2.8% to 4.0% for planned home or birth center birth vs. 11.1% to 11.7% for planned hospital birth ARD range from 7.6 to 8.3 favoring planned home or birth center birth NNT range from 12 to 13 aOR range from 0.31 to 0.76 in favor of planned home or birth center birth | |
| | ●●○ (low confidence, based on 4 good- or fair-methodological-quality observational studies, 1 from U.S.) | | |

| Outcomes | Estimate of Effect for Outcome/ Confidence in Estimate | | |
|---|---|--|--|
| | U.S. Studies Non-U.S. Studies | | |
| Perinatal or neonatal mortality (Critical outcome) Data from comparative studies of good (2) and fair (2) methodological quality reported. Findings from poormethodological-quality studies (11) not included | Neonatal death from 0 to 27 days (2 studies) Range from 0.12% to 0.16% for planned home or birth center vs. 0.03% to 0.06% for planned hospital births ARD range from 0.09 to 0.1 in favor of planned hospital birth Number needed to harm (NNH) range from 1,111 to 1,000 Standardized mortality ratio (SMR) 4.13, 95% CI 3.38 to 4.88; aOR 2.87, 95% CI 1.10 to 7.47 | Intrapartum or neonatal death from 0 to 7 days (2 studies) Range from 0.06% to 0.15% for planned home or birth center vs. 0.01% to 0.18% for planned hospital birth Adjusted odds ratios not statistically significant across both studies | |
| in GRADE table. | ● ः (very low confidence, based on 4 good | or fair-quality observational studies, 2 from U.S.) | |
| Neonatal Morbidity (Important outcome) Data from comparative studies of good (2) and fair (2) methodological quality reported. Findings from poor- methodological-quality studies (16) not included in GRADE table. | Apgar < 7 at 5 minutes (1 study [Oregon]) 2.3% vs. 1.8% for planned home or birth center birth compared to planned hospital birth aOR = 1.31, 95% CI 1.04 to 1.66 Apgar < 4 at 5 minutes (1 study [Oregon]) 0.6% vs. 0.4% for planned home or birth center birth compared to planned hospital birth aOR = 1.56, 95% CI 0.98 to 2.47 Neonatal seizures (1 study [Oregon]) 0.13% vs. 0.04% for planned home or birth center birth compared to planned hospital birth ARD = 0.09 Adjusted risk difference (RD) estimates from two different methods: 0.07, 0.06 in favor of planned hospital birth NNH = 1,111 (from adjusted RD 1,428 to 1,666) aOR 3.60, 95% CI 1.36 to 9.50 | Apgar < 7 at 5 minutes (1 study) 1.2% vs. 2.8%, aOR 0.57, 95% CI 0.25 to 1.35 Birthplace Composite (stillbirth after onset of labor care, neonatal death 0 to 7 days, neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured humerus or clavicle) International (2 studies): 0.05% to 3.5% for planned home or birth center birth vs. 0.05% to 4.4% for planned hospital birth Adjusted odds ratios not statistically significantly different across both studies | |

| Outcomes | | Estimate of Effect for Outcome/ Confidence in Estimate | |
|----------|--|---|--|
| | U.S. Studies | Non-U.S. Studies | |
| | Neonatal intensive care unit (NICU) admission (1 study) 1.7% vs. 2.9% for planned home or birth center birth compared to planned hospital birth ARD = 1.2 favoring planned home or birth center birth Adjusted RD estimates from two different methods 0.95, 0.85 in favor of planned hospital birth NNT = 83 (from adjusted RD 105 to 117) home or birth center births to avoid 1 NICU admission aOR 0.71, 95% CI 0.55 to 0.92 Ventilator support (1 study) 3.8% vs. 3.3% for planned home or birth center birth compared to planned hospital birth ARD = 0.5 in favor of planned hospital birth Adjusted RD estimates from two different methods: 0.97. 1.05 in favor of planned hospital birth NNH = 200 (adjusted 95 to 103) aOR 1.36, 95% CI 1.14 to 1.62 | | |

| Estimate of Effect for Outcome/ Confidence in Estimate | |
|--|---|
| U.S. Studies | Non-U.S. Studies |
| Postpartum hemorrhage of ≥ 1000 ml No U.S. studies of this outcome Maternal blood transfusion (1 study) Unadjusted 0.6% vs. 0.4% for planned home or birth center birth compared to planned hospital birth ARD = 0.2 in favor of planned hospital birth Adjusted RD estimates from two different methods 0.27, 0.28 in favor of planned hospital birth NNH = 500 (adjusted 357 to 370) aOR 1.91, 95% CI 1.25 to 2.93 Third or fourth degree perineal laceration (1 study) 0.9% vs. 1.3% for planned home or birth center birth compared to planned hospital birth ARD = 0.54, in favor of planned home or birth center birth Adjusted RD from two different methods 0.45, 0.54 in favor of planned home or birth center birth NNT = 185, adjusted 222 aOR 0.69 (95% CI 0.49 to 0.98) | Postpartum hemorrhage of ≥ 1000 ml (4 studies) 0.38% to 29.2% for planned home or birth center birth vs. 1.04% to 39.9% for planned hospital birth ARD = 0.66 to 10.7 NNT = 9 to 151 aOR ranged from 0.4, 95% Cl 0.3 to 0.6, to 0.88, 95% Cl 0.52 to 1.47 Adjusted risk ratio (aRR) 1.10, 95% Cl 0.67 to 1.79, p = 0.23 Maternal blood transfusion (1 study) 0.5% to 0.6% for planned home or birth center birth compared to 1.2% for planned hospital birth ARD = 0.2 in favor of planned hospital birth (adjusted 0.27 to 0.28) NNT = 142 to 166 aOR 0.48 (95% Cl 0.32 to 0.73) to aOR 1.91 (95% Cl 1.25 to 2.93) Third or fourth degree perineal laceration (2 studies) Range from 1.9% to 4.9% for planned home or birth center birth vs. 3.2% to 4.2% for planned hospital birth ARD = 0.6 to 1.3 (adjusted 0.45 to 0.54) NNT = 76 to 166 aOR 0.77, 95% Cl 0.57 to 1.05 to aOR 0.90, 95% Cl 0.56 to 1.45 |
| | U.S. Studies Postpartum hemorrhage of ≥ 1000 ml No U.S. studies of this outcome Maternal blood transfusion (1 study) Unadjusted 0.6% vs. 0.4% for planned home or birth center birth compared to planned hospital birth ARD = 0.2 in favor of planned hospital birth Adjusted RD estimates from two different methods 0.27, 0.28 in favor of planned hospital birth NNH = 500 (adjusted 357 to 370) aOR 1.91, 95% CI 1.25 to 2.93 Third or fourth degree perineal laceration (1 study) 0.9% vs. 1.3% for planned home or birth center birth compared to planned hospital birth ARD = 0.54, in favor of planned home or birth center birth Adjusted RD from two different methods 0.45, 0.54 in favor of planned home or birth center birth NNT = 185, adjusted 222 |

| Outcomes | Estimate of Effect for Outcome/ Confidence in Estimate | |
|----------------------------|---|---|
| | U.S. Studies | Non-U.S. Studies |
| Breastfeeding (Important | No U.S. studies with long-term outcomes identified. | Exclusive breastfeeding at 6 months postpartum |
| outcome) | | 4% to 22% for planned home or birth center birth vs. 1% |
| Longest outcome data | | to 9% |
| from a single fair- | | ARD = 3 to 13 |
| methodological-quality | | NNT = 7 to 33 |
| studies (1) reported (non- | | aOR 2.24, 95% CI 1.14 to 4.03 |
| U.S.). Findings from poor- | | |
| methodological-quality | | |
| studies (7) or of short | | |
| follow-up duration (1) not | | |
| included in GRADE table. | ● ○ (very low confidence, based | d on 1 fair-quality observational study) |

Resource Allocation:

Planned out-of-hospital birth is likely to cost much less than planned hospital birth given both the lower number of maternal surgical interventions and decreased costs associated with setting. Serious neonatal morbidity could result in highly expensive and potentially long-term expensive care, but these events are rare. Transfers of care from the out-of-hospital to hospital setting, both intrapartum and postpartum, would also decrease the cost favorability. However, overall, resource allocation is expected to be in favor of planned out-of-hospital birth.

Values and Preferences:

Women deciding about birth setting are likely to have strong values and preferences toward a specific place (out-of-hospital or hospital). Women would prefer health care choices that improve the health of both the mother and the infant. In the context of informed consent, women's values vary widely in how they weigh the rare—but sometimes severe—risks to the infant associated with out-of-hospital birth in the U.S. against the less severe—but more common—maternal harms associated with hospital birth. For women who prefer out-of-hospital birth, their assessment of the benefit to the mother from reduced medical interventions may outweigh any risk of harms to the infant, since these harms are quite rare. Women who prefer out-of-hospital birth often have strongly held values about birth as a natural process and preferences to give birth in a less institutional setting. For women who prefer hospital birth, the increased risk of harms to the infant and availability of obstetric interventions, including pain management and emergency interventions, may weigh much more strongly than a higher chance of vaginal delivery. Overall, there is high variability in values and preferences regarding planned out-of-hospital birth.

| Outcomes | Estimate of Effect for Outcome/ Confidence in Estimate | |
|----------|--|------------------|
| | U.S. Studies | Non-U.S. Studies |

Other Considerations:

Much of the evidence and guidelines informing this coverage guidance might not have direct applicability in the Oregon setting. Some of the guidelines are based in places where out-of-hospital birth and out-of-hospital birth attendants are well-integrated into the health care delivery system, which is not uniformly the case in Oregon. In addition, minimum requirements for education and training are less stringent in Oregon than in these other contexts. Expectations and regulatory standards for birth attendants regarding acceptable risk levels for out-of-hospital births are different and less variable in other health systems reviewed in this coverage guidance.

Balance of benefits and harms:

An assessment of the balance of benefits and harms is significantly limited by the low or very low confidence in the outcomes. The balance of benefits and harms favors planned out-of-hospital birth in dyads without significant risk factors. The evidence suggests a benefit to the mother (with lower rates of cesarean section) for planned out-of-hospital birth. However, evidence also suggests harms to the neonate (a significantly increased fetal/neonatal death rate with planned out-of-hospital birth, although these events remain rare). Some higher-risk conditions are associated with even greater risk of fetal/neonatal death including (but not limited to) advanced maternal age, postdates, nulliparity, prior cesarean delivery, multiple gestation, and breech presentation. Guidelines in areas with robust systems of care suggest numerous specific risk criteria for which risks outweigh benefits. In consideration of the limited evidence and current guidelines, for women with certain risk factors, the balance of benefits and harms weighs against coverage of out-of-hospital birth.

Rationale:

In the Oregon setting, the balance of benefits and harms for out-of-hospital birth appears favorable for the mother, but less favorable or unfavorable to the infant, depending on risk factors. This assessment is largely based on very low-quality but consistent evidence. The Commission recognizes the high value many women place on choosing their birth setting and holds that value in tension with concerns about the personal and societal costs of potential catastrophic harms to the infant in the out-of-hospital setting.

Resource allocation favors out-of-hospital birth as less costly for low-risk births, although frequent transfers of care and rare severe harms to the infant could affect the population-level cost.

In Oregon, out-of-hospital births are not universally well-integrated into the health care system, potentially resulting in delays and poor coordination of care at critical times during pregnancy, labor, and delivery. In addition, standards of care and educational requirements for birth attendants are highly variable in Oregon.

In balancing these considerations, the Commission recommends coverage for out-of-hospital birth for pregnancies free of specified conditions or characteristics which increase the risk of adverse obstetric or birth outcomes. In addition, coverage is recommended with specific requirements for ongoing risk assessment, consultation or transfer for specific high-risk conditions. The recommendation is weak because of

| Outcomes | Estimate of Effect for Outcome/ Confidence in Estimate | | |
|----------|---|------------------|--|
| | U.S. Studies | Non-U.S. Studies | |

the very low confidence in the evidence and because our recommendation includes pregnancies with certain risk factors (nulliparity, advanced maternal age) for which evidence suggests planned out-of-hospital birth results in a higher infant death rate.

The Commission recommends noncoverage of planned out-of-hospital birth when the specified risk factors exist, when required risk assessments are not performed, or when criteria for consultation or transfer of care are not followed by the birth attendant. This is a strong recommendation because of concern about the serious risks to the infant and the likelihood that systems issues might further exacerbate these risks.

Coverage Recommendation:

See box language for details.

Note: GRADE table elements are described in Appendix A. A GRADE Evidence Profile is in Appendix B.

Background

The vast majority of births in Oregon and the U.S. occur in hospitals, although an increasing number of women choose to give birth in settings outside the hospital, including in homes or birthing centers. In the U.S., out-of-hospital births (planned or unplanned) represented 1.6% of all live births in 2017, an 85% increase from 2004 to 2017. The rate of out-of-hospital births varied greatly from state to state: the lowest rates were in Alabama (0.43%), Louisiana (0.46%), New Jersey (0.51%), and Rhode Island (0.51%). The highest rates of out-of-hospital births occurred in Alaska (7.9%), Montana (4.1%), Washington (3.8%), Idaho (3.8%), Oregon (3.6%), and Pennsylvania (3.5%) (MacDorman & Declercq, 2016). While the 2003 revision of the U.S. Standard Certificate of Live Birth included language clarifying if a birth location in the home was planned or unplanned, the implementation was staggered over the next fifteen years (Center for Disease Control and Prevention [CDC], 2017a). While this addition may help to identify the population of births intentionally occurring in the home or birth center, women planning an out of hospital birth but who transferred to and ultimately delivered in a hospital setting may be misattributed as having had a planned hospital birth.

The Oregon legislature passed a bill in 2011 (HB 2380) requiring birth certificates to include the question, "Did you go into labor planning to deliver at home or at a freestanding birthing center?" In 2017, planned out-of-hospital births accounted for 1,758 (4.0%) of the 44,160 births in Oregon. Compared to women who planned hospital births, women who planned out-of-hospital births were more likely to be 30 years or older (61% vs. 49%), White non-Hispanic (85 vs. 67%), and college-educated (49% vs. 32%) (Oregon Health Authority [OHA], 2019).

Table 1. Planned Attendant for Planned Out-of-Hospital Births, Oregon, 2017

| Attendant | Number | Percentage |
|---|--------|------------|
| Doctors (MDs) and Doctors of Osteopathic Medicine (DOs) | 0 | 0% |
| Naturopathic Physicians | 238 | 14% |
| Certified Nurse Midwives | 548 | 31% |
| Licensed Direct-Entry Midwives | 794 | 45% |
| Unlicensed Direct-Entry Midwives | 136 | 8% |
| Other | 42 | 2% |
| TOTAL | 1,758 | 100% |

Table 1 shows the planned attendants for 2017 planned out-of-hospital births and that 85% of births were attended by one of the three types of midwives. Among planned hospital births, 79% were attended by MDs or DOs, and 21% (n = 8,937) were attended by midwives, all of whom were certified nurse midwives (CNMs). Among the planned out-of-hospital births, 280 (16%) resulted in an intrapartum transfer to a hospital, and another 30 (2%) involved a neonatal transfer (OHA, 2018).

In the U.S., birth attendants with a range of education and training requirements can practice in out-of-hospital settings. Table 2 shows the training and licensing requirements for various birth attendants in Oregon. With prior authorization, the Oregon Health Plan reimburses licensed out-of-hospital birth

providers for prenatal, labor and delivery, and postpartum care (OHA, 2017). Thus, unlicensed direct-entry midwives are not eligible Oregon Health Plan providers. However, unlicensed direct-entry midwives and other attendants constitute nearly 10% of all planned out of hospital births (OHA, 2019).

Table 2. Training and Licensing Requirements for Birth Attendants in Oregon

| | Unlicensed Direct- Entry Midwives | Licensed Direct- Entry Midwives (LDEMs) | Certified Nurse Midwives (CNMs) | Naturopathic Doctors (NDs) | Osteopathic or Allopathic Doctors (DOs/MDs) | Chiropractors (DCs) |
|-----------------------------------|--|--|--|---|--|---|
| Accredited Training Program | | √* *or judged to have equivalent training | | v* *Additional training that meets board standards | | v* *Additional training that meets board standards |
| Undergraduate Degree | | | ٧ | V | ٧ | √ * Chiropractic school or college |
| Graduate Degree | | | ٧ | ٧ | ٧ | |
| Postgraduate Training | | | | | ٧ | |
| Settings | Home | Home, birth center | Home, birth center, hospital | Home, birth center | Hospital | Home, birth center |
| Licensing Board | None | Board of Direct- Entry Midwifery | Oregon State Board of Nursing | Oregon Board of Naturopathic Medicine | Oregon Medical Board | Board of Chiropractic Examiners |

About 60% of out-of-hospital births were in the mother's home, and about 40% were in freestanding birth centers. There are 15 licensed birth centers in Oregon, mostly located in the Willamette Valley, in the cities of Portland, Aurora, Dundee, Salem, Corvallis, and Lebanon. Southern Oregon birth centers are located in Springfield, Medford, Grants Pass, and Gold Beach (not currently providing birthing services at the center); Klamath Falls and Bend also have birth centers (OHA 2019b). Licensed birth centers in Oregon must have policies and procedures that meet North American Registry of Midwives standards (OAR 333-076-0670). Nine of the 15 licensed birth centers in Oregon are accredited by the American Association of Birth Centers, which has national standards for birth centers.

The level of integration of home birth within health care systems can be a factor in the differences in outcomes among studies of out-of-hospital births from different countries. Regulations of out-of-hospital births, provider qualifications, and accessibility of emergency care could affect the safety of out-of-hospital births. For example, there are stronger midwifery education and training requirements in some countries compared to the U.S., including Iceland (two-year Master of Midwifery after completion of a Bachelor of Science in Nursing), the Netherlands (four-year direct-entry baccalaureate program), and England (18-month postgraduate program after completion of Bachelor of Science in Nursing or three-year direct-entry baccalaureate program). In contrast, Oregon does not have any requirements for college completion for licensed or unlicensed direct-entry midwives (see Table 2 above). Midwives have hospital admitting privileges in some countries (Canada, New Zealand, Norway), and that is not always the case in the U.S. In Oregon, hospitals can grant CNMs admitting privileges. This ability is not granted to licensed or unlicensed direct-entry midwives. Requirements for midwives to carry emergency medical supplies varies across countries, and sometimes varies within a country. These contextual differences could limit the generalizability of findings from international settings to the U.S. (Comeau et al., 2018).

The differences in antenatal model of care further complicate the interpretation of birth outcomes by intended place of birth. The care provided by certified nurse midwives, certified midwives, and directentry midwives differs from care delivered by most physicians in its foundational view of birth as a natural process, midwifery's holistic approach to care of women, and avoidance of intervention (Rooks, 1999). A 2016 systematic review of birth outcomes for low-risk women by model of care reinforces this difference (Sandal et al., 2016). In this study, midwife-led models were associated with reduced risk of epidural anesthesia, episiotomy, instrumental delivery, and reduced risk fetal loss or neonatal death compared to physician led models (Sandal et al., 2016).

Federal Innovations- Strong Start

The Strong Start for Mothers and Newborns initiative is an example of the role of antenatal care models on birth outcomes, specifically for Medicaid enrollees (Hill et al., 2018). Funded through the Patient Protection and Affordable Care Act, Strong Start supported three models of enhanced prenatal care for Medicaid enrollees: accredited birth centers, group prenatal care, and maternity care homes (Hill et al., 2018). Strong Start participants receiving antenatal care at an accredited birth center were less likely to have a preterm delivery, a low birth weight infant, or cesarean section (17.5% versus 29.0%) compared to a similar risk cohort of Medicaid enrollees receiving traditional care regardless of place of birth. Costs were lower for birth center attendees as well (Hill et al., 2018). Additionally, Strong Start recipients received more prenatal education, psychosocial support, and referrals to non-medical services (e.g., nutritional support, housing, transportation, childcare) compared to women receiving traditional care under Medicaid. Based on these findings, the Centers for Medicare and Medicaid Services (CMS) suggests state Medicaid programs may consider expanding access to accredited birth centers to improve outcomes for enrollees (CMS, 2018).

Oregon Public Health Data

Planned out-of-hospital births in Oregon have decreased from 1,903 births (4.6%) in 2012 to 1,636 (4.1%) in 2017 (OHA, 2018). By county, planned out-of-hospital births range from 0.7% (Lake) to 10.1% (Curry) of all births (OHA, 2018). Women planning out-of-hospital birth are more often older, white, married, college-educated, and self-paying for delivery (OHA, 2018). They are also more likely to have inadequate (8.0% vs. 5.1%) or no (1.9% vs. 0.4%) prenatal care (OHA, 2018).

Infants born to low-risk women planning an out-of-hospital birth (i.e., gestational age \geq 37 weeks to < 42 weeks, singleton, no history of prior cesarean section) have a decreased risk of neonatal intensive care unit (NICU) admission consistently, most recently 17 per 1,000 compared to 31.2 per 1,000 births for planned in-hospital births (OHA 2018). Fetal and neonatal deaths through 6 days of life (i.e., perinatal deaths) remain a rare event for births planned to be in and or out of a hospital. From 2012 to 2017, Oregon perinatal mortality rates were 2.0 per 1,000 for planned out-of-hospital birth compared to 1.7 per 1,000 for planned hospital births (absolute risk difference [ARD 0.03], number needed to harm [NNH] 3,333) (OHA, 2018).

A previous investigation into Oregon perinatal death disparities for planned out-of-hospital births was conducted in 2012 after the Oregon birth certificate was changed to record information about the planned place of birth. In the 2012 analysis, the perinatal mortality rate was 4.0 per 1,000 deaths (compared to 2.1 per 1,000 for planned hospital birth). The analysis revealed that for the eight perinatal deaths in 2012 that occurred in out- of- hospital settings, two of the mothers had inadequate or no prenatal care, four declined ultrasound in pregnancy, five declined group B streptococcal (GBS) screening, and two declined intrapartum GBS prophylaxis for positive carrier status (OHA, 2013). Additionally, for six of the eight deaths, the mothers did not meet the criteria for having a low-risk pregnancy because of either multiple gestations, advanced gestational age (> 41 weeks), or morbid obesity (> 40 body mass index) (OHA, 2013).

Evidence Review

Comparative Studies

Studies reporting findings for each of the five outcomes selected for this coverage guidance are summarized below. A summary of identified comparative studies and methodological quality is reported, followed by a high-level summary of the findings. Greater detail is available in the subsequent paragraphs by U.S.-based or international setting or different birth location (home or birth center if available). Findings from subgroups are reported in a separate section.

Outcome: Mode of Delivery

Summary

Table F1 in Appendix F provides findings of the 19 comparative cohort studies reporting mode of delivery for planned home or birth center births compared to planned hospital births. The majority (14) of studies were of poor methodological quality (Davies-Tuck et al., 2018; Halfdansdottir et al., 2018; Halfdansdottir et al., 2015; Hutton et al., 2016; Hutton et al., 2009; Janssen et al., 2009; Katoaka et al., 2018; Kennare et al., 2010; Laws et al., 2014; Øian et al., 2018; Schroeder et al., 2017; Sprague et al., 2018; Thornton et al., 2017; Wiegerinck et al., 2015). One study was assessed as having fair methodological quality (Monk et al., 2014), and three of good methodological quality (Birthplace in England Collaborative, 2011; Snowden et al., 2015; van der Kooy et al., 2017). An additional seven studies reporting findings only by parity, the most common subgroup reported across studies, are in Table F1 (Bailey, 2017; Bolten et al., 2016; Christensen & Overgaard, 2017; Hermus et al., 2017; Hollowell et al., 2017 Li et al., 2015; van Haaren-ten Haken et al., 2015).

Planned home or birth center birth was consistently associated with a greater likelihood of vaginal birth and reduction in cesarean or operative vaginal delivery compared to planned hospital birth. Studies of

higher methodological quality were more likely to account for planned home or birth center transfers to a hospital, thus eliminating differential misclassification bias that would have favored planned home or birth center birth, as negative outcomes would be attributed to hospitals in the event of transfer.

Estimates of spontaneous vaginal birth from fair- or good-methodologic-l quality studies reported an absolute risk difference of 20 to 27% in favor of planned home or birth center birth (four to five women needed to treat with planned out-of-hospital birth compared to planned hospital birth to avoid one non-spontaneous vaginal birth). Estimates of operative vaginal or cesarean deliveries from good- or fair-methodological-quality studies observed an absolute risk difference in favor of planned home birth (3% to 17% or 5 to 33 women with planned delivery at home or birth center to avoid one operative vaginal or cesarean delivery). However, comparative evidence on delivery mode for U.S. women is limited. Notably, aside from a single Australian study with a 27% hospital cesarean rate (Kennare et al., 2010), all studies were conducted in sites with fewer hospital cesarean deliveries than typically observed in U.S. hospitals where the cesarean delivery rate was 31% in 2016 (CDC, 2017b).

U.S. Studies

Two studies reported mode of delivery for U.S.-based settings (Snowden et al., 2015; Thornton et al., 2017). In a good-quality study from Oregon, planned home or birth center births were associated with a reduced risk of cesarean delivery compared to planned hospital delivery (absolute risk difference -24%, 95% CI -26.6 to -21.4, p < 0.001) and operative vaginal delivery (absolute risk difference -4.7%, 95% CI -5.8 to -3.5%, p < 0.001) with greater rates of spontaneous vaginal delivery (absolute risk difference 27.5%, 95% CI 24.9 to 30.2, p < 0.001) (Snowden et al., 2015). In a poor-quality separate analysis of planned home or birth center births in 43 states, cesarean deliveries were less common for planned home or birth center births compared to planned hospital births (aOR 0.63, 95% CI 0.50 to 0.79) (Thornton, et al., 2017).

Non-U.S. Studies

Fifteen studies reported comparative mode of delivery outcomes for women by intended place of birth in non-U.S. based settings (Birthplace, 2011; Davies-Tuck et al., 2018; Halfdansdottir et al., 2018; Halfdansdottir et al., 2015; Hutton et al., 2009; Hutton et al., 2016; Janssen et al., 2009; Katoaka et al., 2018; Kennare et al., 2010; Laws et al., 2014; Monk et al., 2014; Schroeder et al., 2017; Sprague et al., 2018; van der Kooy et al., 2017; Wiergerinck et al., 2015). Findings from the two good-quality studies demonstrated increased rates of spontaneous vaginal deliveries (aOR 3.61, 95% CI 2.97 to 4.38) (Birthplace, 2011) and decreased risk of operative or cesarean delivery (aOR 0.77, 95% CI 0.75 to 0.78) (van der Kooy et al., 2017).

Vaginal birth rates were consistently higher for planned home or planned birth center births (over 90% across studies) compared to hospital births in non-U.S. settings. Estimates ranged across studies comparing planned home to planned hospital births from a 30% to 60% reduced odds of cesarean delivery for planned home or birth center births compared to planned hospital birth. Rates of operative vaginal delivery (forceps, vacuum, or both) were reduced for planned home or birth center births compared to planned hospital deliveries. The magnitude of effect ranged across studies from 20% to 60% reduced odds of an operative delivery.

Outcome: Perinatal or Neonatal Mortality

Estimates of fetal or neonatal mortality were not consistently defined across identified studies, encompassing definitions that ranged from 20 weeks gestation through 27 days of life. As able, we provided specific timing of mortality to allow more direct comparisons across studies. If the study authors provided absolute numbers and used an unadjusted odds ratio as their estimate of effect, we provided a calculated unadjusted risk ratio (relative risk) estimate.

Summary

Table F2 provides findings of the 16 comparative studies reporting perinatal mortality outcomes for planned home or birth center births compared to planned hospital births. The majority of these studies were of poor methodological quality (Davies-Tuck et al., 2018; Grigg et al., 2017; Grunebaum, McCullough, Arabin et al., 2017; Hutton et al., 2016; Hutton et al., 2009; Janssen et al., 2009; Katoaka et al., 2018; Kennare et al., 2010; Thornton et al., 2017; Wiegerinck et al., 2015). We assessed four studies as having fair methodological quality (Grunebaum, McCullough, Sapra et al., 2017; Halfdansdottir et al., 2015; Homer et al., 2014; van der Kooy et al., 2011), and two as having good methodological quality (Birthplace, 2011; Snowden, et al., 2015). An additional three studies, reporting findings only by parity, the most common subgroup, are also in Table F2 (Bailey et al., 2017; de Jonge et al., 2013; van Haarenten Haken et al., 2015).

International studies consistently observe very low rates of intrauterine, intrapartum, and neonatal mortality that are similar for home, birth center, and hospital settings for all women. However, U.S.-based studies reported increased risks of neonatal death (from 0 to 27 days) for planned home births compared to planned hospital births using national vital statistics data (Grunebaum, McCullough, Sapra et al., 2017; Snowden et al., 2015). Comparisons of U.S. studies to international settings are limited by differences in outcome definition, provider types, health system delivery, and the reliance on administrative vital statistics in the U.S. that limits ability of authors to adjust for confounding.

U.S. Studies

Three studies reported comparative mortality outcomes for births in U.S.-based settings (Grunebaum, McCullough, Sapra et al., 2017; Snowden, et al., 2015; Thornton et al., 2017). In the first study, a fair-quality study of national vital statistics data, neonatal death from 0 to 27 days was more common in planned home births attended by a midwife (provider type confirmed by personal communication, A. Grunebaum, June 4, 2019) compared to planned hospital birth attended by a certified nurse midwife from 2009 to 2013 (0.12% vs. 0.03%, standardized mortality ratio 4.13, 95% CI 3.38 to 4.88) (Grunebaum, McCullough, Sapra et al., 2017).

The second study, a good-quality study conducted in Oregon, the risk of fetal death (\geq 20 weeks), intrapartum, or neonatal death (0 to 27 days) was higher for planned home and birth center births compared to planned hospital births from 2012 to 2013 (absolute difference 0.158 percentage points, 95% CI 0.055 to 0.261, p = 0.003) (Snowden et al., 2015). Overall, 634 women would need to have a planned hospital birth to avoid one fetal or neonatal death in the planned home or birth center setting.

In the third study, which we rated as poor quality, intrapartum or newborn death (days of life not reported) was similar for planned birth centers and planned hospital births in data from 43 states and 79 birth centers from 2006 to 2011 (OR 0.86, 95% CI 0.09 to 8.3, p = 0.99; RR calculated 0.96, 95% CI 0.54 to 1.70) (Thornton et al., 2017).

Non-U.S. Studies

Seven studies reported comparative mortality outcomes for births in settings outside the U.S. (Davies-Tuck et al., 2018; Grigg et al., 2017; Janssen et al., 2009; Katoaka et al., 208; Kennare et al., 2010; van der Kooy et al., 2011; Wiegerinck, et al., 2015). In a good quality study from the Netherlands, from 2000 to 2007 intrapartum or neonatal deaths (0 to 7 days) did not differ for planned home and planned hospital births attended by a midwife (aOR 1.05, 95% CI 0.91 to 1.21) (van der Kooy et al., 2011).

Estimates from poor-quality studies reported similar findings from the Netherlands (Wiegerinck et al., 2015), British Columbia (Janssen et al., 2009), Australia (Davies-Tuck et al., 2018; Kennare et al., 2010), New Zealand (Grigg et al., 2017), and Japan (Katoaka et al., 2018)..

A cohort of Dutch women from 2005 to 2008 observed similar intrapartum or neonatal deaths (OR 1.30, 95% CI 0.63 to 2.67) (Wiegerinck et al., 2015). Planned home births in British Columbia, Canada, had similar rates of fetal (≥ 20 weeks), intrapartum, or neonatal deaths (0 to 7 days) compared to planned hospital births attended by midwives and a cohort of births attended by physicians, matched for maternal demographics (RR 0.61, 95% CI 0.06 to 5.88; RR 0.55, 95% CI 0.06 to 5.25; respectively) (Janssen et al., 2009). Rates of intrauterine or neonatal death were not statistically different for planned home births compared to planned hospital births in two studies from two states in Australia (Victoria, South Australia) with over 10 years of registry data (Davies-Tuck et al., 2018; Kennare et al., 2010). In a small study (n < 1,000) from New Zealand, there were no intrauterine, intrapartum, or neonatal deaths (0 to 27 days) for hospital births compared to 3 (0.74%) for planned birth center births (Grigg et al., 2017). No intrauterine or intrapartum deaths were observed for planned birth center births in Japan, compared to 11 (0.3%) for planned hospital births (Katoaka et al., 2018).

Outcome: Neonatal Morbidity

Summary

Neonatal morbidity encompasses a range of outcomes including but not limited to admission to a hospital, admission to a specialized neonatal unit or NICU, low Apgar score at birth, neonatal seizures, hypoxic ischemic encephalopathy, and sepsis. These outcomes were reported individually or as composites, depending on the study.

Table F3 provides findings of the 20 comparative studies reporting neonatal morbidity outcomes for planned home or birth center births compared to planned hospital births. The majority of studies were of poor methodological quality (Davies-Tuck et al., 2018; Grigg et al., 2017; Halfdansdottir et al., 2018; Halfdansdottir et al., 2015; Hitzert et al., 2016; Hutton et al., 2016; Hutton et al., 2009; Janssen et al., 2009; Katoaka et al., 2018; Kennare et al., 2010; Li et al., 2017; Øian et al., 2018; Schroeder et al., 2017; Sprague et al., 2018; Thornton et al., 2017; Wiegerinck et al., 2015). We rated two studies as fair methodological quality (Homer et al., 2014; Monk et al., 2014), and two of good methodological quality (Birthplace in England Collaborative, 2011; Snowden, et al., 2015). An additional five studies reporting findings only by parity, the most common subgroup, are in Table F3 (Bailey et al., 2017; Christensen & Overgaard, 2017; de Jonge et al., 2015; Hollowell et al., 2017; Li et al., 2015; van Haaren-ten Haken et al., 2015).

Three studies reported comparative neonatal morbidity outcomes for women in U.S. settings. Two reported single state findings from Oregon (Snowden et al., 2015) and South Carolina (Li et al., 2017). The third reported outcomes from freestanding birth centers in 43 states (Thornton et al., 2017).

Findings from these U.S. studies demonstrated a small but increased risk of seizures and need for ventilator support in Oregon from 2012 to 2013 data (Snowden et al., 2015). Older data from South Carolina also demonstrated greater rates of neonatal morbidity for planned home or birth center births versus planned hospital births without formal statistical analysis, including neonatal seizures (0.15% vs. 0.0% vs. 0.02%) and convulsions (0.61% vs. 0.24% vs. 0.24%) (Li et al., 2017).

Generally, findings from international studies of planned home or birth center births compared to planned hospital births did not observe statistically significant differences across neonatal morbidity outcomes. However, in subgroup analyses, nulliparous women appeared to experience a greater likelihood of neonatal morbidity in the Birthplace study from England (i.e., Birthplace composite outcome) even after restricting to the lowest-risk group (Birthplace et al., 2011; Hollowell et al., 2017). However, that relationship was not consistent across a study from Australia (Homer et al., 2014).

U.S. Studies: Planned Home and Birth Center Settings

A study conducted in Oregon from 2012 to 2013 found that the risk of admission to an NICU was lower for planned home or birth center births compared to planned hospital births (absolute difference -0.85 percentage points, 95% CI -1.57 to -0.14, NNT = 117) (Snowden et al., 2015). The risk of all the following outcomes was higher for planned home or birth center births compared to planned hospital births:

- A lower Apgar score at five minutes of less than seven (unadjusted 2.3% vs. 1.8%, adjusted absolute difference 0.50, 95% CI 0.07 to 0.93, NNH = 200) and less than four (unadjusted 0.6% vs. 0.4%, adjusted absolute difference 0.18, 95% CI 0.00 to 0.37, NNH = 555)
- Neonatal seizures (unadjusted 0.13% vs. 0.04%, absolute difference, 0.07 percentage points, 95% CI 0.02 to 0.13, calculated NNH = 1,428)
- Ventilator support (unadjusted 3.8% vs. 3.3%, adjusted absolute difference, 1.05 percentage points, 95% CI 0.48 to 1.62, calculated NNH = 95) (Snowden et al., 2015)

In a study conducted in South Carolina from 2003 to 2013, the frequency of neonatal seizures and convulsions was higher for planned home births (0.15%, 0.61% respectively) compared to planned birth center (none, 0.24%) and hospital settings (0.02%, 0.24%); no formal statistical analysis was reported (Li et al., 2017).

U.S. Studies: Birth Center Setting

In a poor-quality study of birth centers in 43 states, women planning a birth center birth experienced similar odds of a lower Apgar score at five minutes (score 3 to 7; aOR 1.60, 95% CI 0.82 to 3.16), and short-term positive pressure ventilation (< 10 minutes; aOR 1.31, 95% CI 0.95 to 1.82) compared to those planning a hospital birth (Thornton et al., 2017). The odds of needing a newborn sepsis evaluation was reduced for planned birth center birth (aOR 0.51, 95% CI 0.32 to 0.81). The odds of a composite outcome consisting of mortality, hypoxic injury, low Apgar, seizure, respiration support, and meconium aspiration syndrome were also similar across settings (aOR 1.44, 95% CI 0.95 to 1.82).

Non-U.S. Studies: Home Birth Setting

The odds of a composite outcome encompassing death after the start of care in labor, early neonatal death, neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, and fractured humerus or clavicle were similar across planned home and planned hospital births in a good-quality study from England (aOR 1.16, 95% CI 0.76 to 1.77) (Birthplace, 2011) and a fair-quality study from Australia (aOR 1.06, 95% CI 0.44 to 2.56) (Homer et al., 2014). The odds of a composite outcome of

Apgar score less than four at five minutes and need for positive pressure ventilation or chest compressions were similar for planned home and planned hospital births in two poor-quality studies from Ontario, Canada (RR 0.95, 95% CI 0.6 to 1.48) (Hutton et al., 2016), which is consistent with findings from an earlier cohort (RR 0.82, 95% CI 0.66 to 1.01) (Hutton et al., 2009).

In a poor-quality study conducted in the Netherlands, planned home births were associated with decreased odds of NICU admission for over 24 hours (OR 0.64, 95% CI 0.43 to 0.95), and similar odds of an Apgar score less than seven at five minutes (OR 0.93, 95% CI 0.75 to 1.15) (Wiegerinck et al., 2015). In a poor-quality study from the state of South Australia conducted in a 14-year period, the odds of Apgar score less than seven at five minutes (aOR 1.43, 95% CI 0.66 to 3.07) and needs for specialized neonatal care (aOR 0.80, 95% CI 0.62 to 1.03) were not different for planned home and planned hospital births (Kennare et al., 2010). The odds of an Apgar score less than seven at five minutes (aOR 0.82, 95% CI 0.27 to 2.52), need for respiratory support (aOR 0.97, 95% CI 0.63 to 1.50), and admission to a neonatal nursery unit (aOR 1.44, 95% CI 0.70 to 2.96) were similar for planned midwifery birth center births and planned obstetric hospital births in a small, poor-quality study from New Zealand (n < 1,000) (Grigg et al., 2017).

Infants whose mothers had planned home births in British Columbia, Canada, experienced a decreased risk of birth weight < 2,500g (RR 0.44, 95% CI 0.25 to 0.78), a lower rate of need for resuscitation (RR 0.23, 95% CI 0.14 to 0.37), and birth trauma (RR 0.26, 95% CI 0.11 to 0.58) compared to midwife-attended hospital births. Relative risk of an Apgar score less than seven at five minutes (RR 0.92, 95% CI 0.58 to 1.47), asphyxia (RR 0.79, 95% CI 0.30 to 2.05), meconium aspiration (RR 0.83, 95% CI 0.38 to 1.81), seizures (RR 0.61, 95% CI 0.12 to 3.03), and assisted ventilation over 24 hours (RR 1.02, 95% CI 0.34 to 3.04) were not statistically different across settings in a poor-quality study (Janssen et al., 2009).

The frequency of Apgar scores < five at five minutes (0.9% vs. 1.2%, p = 0.08), hypoxic ischemic encephalopathy (0% vs. 0.2%, p = 0.44), and other perinatal morbidities were not statistically different in a poor-quality study conducted in the state of Victoria in Australia from 2000 to 2008; no formal statistical analysis was reported (Davies-Tuck et al., 2018). There were more admissions to an NICU (0.4% vs. 0.2%, p = 0.03) among planned home births. Admission to a special care nursery 1.8% vs. 8.3%, p < 0.001), birth trauma (1.4% vs. 6.6%, p < 0.001), intrauterine hypoxia (1.5% vs. 5.8%, p < 0.001), and composite morbidity (e.g., NICU admissions, birth trauma, hypoxia) (3.6% vs. 13.4%, p < 0.001) were less common in planned home births than planned hospital births.

Non-U.S. Studies: Birth Center Settings

In fair- to good-quality studies, the odds of a composite outcome encompassing stillbirth after the start of care in labor, early neonatal death, neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, and fractured humerus or clavicle were similar across planned birth center and planned hospital births in England (aOR 0.92, 95% CI 0.58 to 1.46) (Birthplace, 2011) and Australia (aOR 0.87, 95% CI 0.69 to 1.10) (Homer et al., 2014).

In a poor-quality study, admission to an NICU was similar (aRR 1.3, 95% CI 0.9 to 2.0) for planned birth center births and planned midwife-attended hospital births in Ontario, Canada, in the first year after the introduction of the birth center (2014 to 2015) (Sprague et al., 2018).

Outcome: Maternal Harm

Summary

Outcomes related to maternal harm include but are not limited to third or fourth degree perineal injuries or obstetric anal sphincter injuries, immediate postpartum hemorrhage, blood transfusion, admission to a hospital or an intensive care unit (ICU), infection, uterine rupture, and manual removal of the placenta. Definitions for outcomes varied across studies, particularly for postpartum hemorrhage and blood transfusion; some studies only reported findings for large transfusion volume (i.e., over 4 units).

Table F4 provides findings of the 20 comparative studies reporting maternal harm outcomes for planned home or birth center births compared to planned hospital births. The methodological quality of the included studies was largely poor (Davies-Tuck et al., 2018; Grigg et al., 2017; Halfdansdottir et al., 2018; Halfdansdottir et al., 2015; Hutton et al., 2016; Hutton et al., 2009; Janssen et al., 2009; Katoaka et al., 2018; Kennare et al., 2010; Laws et al., 2014; Øian et al., 2018; Schroeder et al., 2017; Thornton et al., 2017; Wiegerinck et al., 2015). We assessed four studies as having fair methodological quality (de Jonge et al., 2013; Davis et al., 2012; Monk et al., 2014; Nove et al., 2012;) and two as good methodological quality (Birthplace in England Collaborative, 2011; Snowden et al., 2015). An additional five studies reported findings only by parity and are also in Table F4 (Bailey, 2017; Bolten et al., 2016; Christensen & Overgaard, 2017; Hollowell et al., 2017; van Haaren-ten Haken et al., 2015).

Only two of the 20 included studies reported outcomes for U.S.-based settings (Snowden et al., 2015; Tilden et al., 2017). Overall, estimates of maternal harm for planned home or birth center births are limited in the U.S. because they rely on vital statistics data. In the two included studies, planned home or birth center births observed a decreased risk of third or fourth degree perineal tear with an increased risk of blood transfusion (Snowden et al., 2015; Tilden et al., 2017). In international studies, the authors observed mixed results in estimates of maternal harm, often with no statistical differences in harms or a reduced frequency in the home birth group.

U.S. Studies

In a good-quality study conducted in Oregon using data from 2012 to 2013, women planning a home or birth center birth experienced a decreased risk of severe perineal lacerations (adjusted risk difference 0.54 in favor of planned home or birth center, 95% CI -0.98 to -0.11, p = 0.02), but also had an increased risk of blood transfusion (adjusted risk difference 0.27 favoring planned hospital birth, 95% CI 0.08 to 0.46 p = 0.006) (Snowden et al., 2015). In a poor-quality study, postpartum hemorrhage frequency was not statistically different for planned birth center and planned hospital groups (aOR 1.25, 95% CI 0.99 to 1.58) (Thornton et al., 2017).

Non-U.S. Studies: Home Births

Estimates of third or fourth degree tears were similar in one good-quality study (1.9% vs. 3.2%, aOR 0.77, 95% CI 0.57 to 1.05)((Birthplace, 2011) and one poor-quality study (1.0% vs. 1.8%, aOR 0.77, 95% CI 0.34 to 1.74, p = 0.53 (Kennare et al., 2010) and decreased in three poor-quality studies (1.0% vs. 2.0%, p < 0.001; 1.3% vs. 2.3%, RR 0.57, 95% CI 0.47 to 0.69; 1.2% vs. 2.9%, RR 0.43, 95% CI 0.29 to 0.63) (Davies-Tuck et al., 2018; Hutton et al., 2016; Janssen et al., 2009) for women in planned home birth settings compared to planned hospital births. Obstetric anal sphincter injuries were less common in

planned home birth groups in two poor-quality studies (2.5% vs. 3.1%, p = NR; 2.6% vs. 3.0%, aOR 0.97, 95% CI 0.41 to 2.27) (Halfdansdottir et al., 2018; Halfdansdottir et al., 2015).

In eight poor- to fair-quality studies conducted in multiple countries, women in the planned home birth group were less likely to have a documented postpartum hemorrhage (9.1% vs. 12.9%, p < 0.001; 29.2% vs. 39.9%, p = NR; 3.0% vs. 3.7%, aOR 0.64, 95% CI 0.24 to 1.67; 0.8% vs. 1.2%, RR 0.68, 95% CI 0.49 to 0.96; 2.5% vs. 3.0%, RR 0.82, 95 % CI 0.70 to 0.96; 3.8% vs. 6.0%, RR 0.43, 95% CI 0.29 to 0.63; 0.38% vs. 1.04%, aOR 0.4, 95% CI 0.3 to 0.6, p < 0.001; 4% vs. 5%, OR 0.68, 95% CI 0.62 to 0.74, p < 0.001)(Davies-Tuck et al., 2018; de Jonge et al., 2013; Halfdansdottir et al., 2015; Hutton et al., 2009; Hutton et al., 2016; Janssen et al., 2009; Nove et al., 2012; Wiegerinck et al., 2015). The frequency of estimated blood loss at time of delivery of \geq 1000 mL was not statistically different in 2 poor to fair quality studies (1.0% vs. 1.1%, aRR 0.93, 95% CI 0.49 to 1.74, p = 0.97; 4.4% vs. 5.5%, aOR 0.72, 95% CI 0.47 to 1.11, p = 0.14)(Davis et al., 2012; Kennare et al., 2010).

Estimates of the need for blood transfusion were similar for planned home and hospital births (0.6% vs. 1.2%, aOR 0.72, 95% CI 0.47 to 1.12) in a good-quality study (Birthplace, 2011). The frequency of blood transfusion was less common in two poor- to fair-quality studies (de Jonge et al., 2013; no formal statistical analysis reported; Halfdansdottir et al., 2015). Manual removal of the placenta was less frequent for planned home birth groups; however, neither study reported statistical analysis (de Jonge et al., 2013; Janssen et al., 2009).

In 2 poor to fair quality studies, women in the planned home birth group were less likely to be admitted to a hospital or an ICU (0.2% vs. 0.6%, p = 0.002; 0.3% vs. 0.7%, p = NR) (Davies-Tuck et al., 2018; de Jonge et al., 2013). Frequency of maternal postpartum infection was similar for planned home and hospital births in a single poor-quality study without statistical analysis (Janssen et al., 2009).

Non-U.S. Studies: Birth Centers

Findings from birth centers related to third or fourth degree perineal lacerations observed similar rates (2.2% vs. 1.8%, aOR 1.43, 95% CI 0.46 to 4.42, p > 0.05) (Grigg et al., 2017) or lower rates compared to planned hospital births (2.5% vs. 3.0%, aOR 0.85, 95% CI 0.74 to 0.99) (Law et al., 2014). Overall, perineal laceration rates were lower in the birth center setting compared to planned hospital (40.9% vs. 66.1%, aOR 0.38, 95% CI 0.35 to 0.42; Katoaka et al., 2018).

Studies demonstrated conflicting outcomes for frequency of blood loss \geq 1,000 ml for planned birth center births compared to planned hospital births: higher in one study (3.6% vs. 2.4%, aOR 1.77, 95% CI 1.35 to 2.32) (Katoaka et al., 2018), similar in two studies (5.9% vs. 4.6%, aOR 1.74, 95% CI 0.85 to 3.59, p > 0.05; 3.6% vs. 139 4.4%, aOR 0.88, 95% CI 0.52 to 1.47, p = 0.618) (Grigg et al., 2017; Monk et al., 2014), and lower in another study (8.6% vs. 10.6%, aOR 0.79, 95% CI 0.73 to 0.86) (Laws et al., 2014). Women planning birth center births were also less likely to have a uterine rupture (0.03% vs. 0.08%, aOR 0.17, 95% CI 0.04 to 0.73), postpartum infection (1.0% vs. 1.4%, aOR 0.74, 95% CI 0.59 to 0.92), and ICU admission (0.02% vs. 0.08%, aOR 0.12, 95% CI 0.02 to 0.89) (Laws et al., 2014).

Outcome: Breastfeeding

Summary

Table F5 provides findings of the nine comparative studies reporting breastfeeding outcomes for planned home or birth center births compared to planned hospital births. The majority of the identified studies are of poor methodological quality (de Cock et al., 2015; Grigg et al., 2017; Hutton et al., 2016;

Hutton et al., 2009; Laws et al., 2014; MacDorman & Declercq, 2016; Thornton et al., 2017); two are of fair methodological quality (Monk et al., 2014; Quigley et al., 2016).

Two of the studies provided outcomes for U.S.-based settings (MacDorman & Declercq, 2016; Thornton et al., 2017). Across all studies, the timing of breastfeeding outcomes ranged from rates of initiation in the birth setting to exclusive breastfeeding at six months. Only two studies (Hutton et al., 2016; Hutton et al., 2009) provided outcomes for nulliparous and multiparous women separately, with the remaining studies reporting aggregate outcomes for all women.

Early rates of breastfeeding (initiation, at time of discharge, or within the first two weeks) were consistently higher for planned home or birth centers compared to hospital births. However, estimates that control for confounding and examine breastfeeding at a time point further from delivery did not observe differences between planned home birth, birth center, and planned hospital groups in international settings. There were no U.S.-based studies with comparative breastfeeding outcomes that reported data past discharge from the birth setting. A retrospective survey reported that rates of exclusive breastfeeding at six months were higher for individuals reporting a planned home birth, but the findings were well below World Health Organization (WHO) goals and based on two surveys with low participation rates (Quigley et al., 2016).

U.S. Studies

Two poor-quality studies reported comparative estimates of breastfeeding by place of birth in the U.S. (MacDorman & Declercq, 2016; Thornton et al., 2017). Breastfeeding initiation rates from birth certificate data from 2004 to 2014 were higher for planned home or birth center births, 97.9% and 98.1% respectively, compared to 80.8% for planned hospital births; no formal statistical analysis was provided (MacDorman & Declercq, 2016). Analysis of data from the American Association of Birth Centers from 2006 to 2011 observed that infants born in a planned birth center were more likely to be breastfed at the time of discharge compared to infants born in a planned hospital birth (94.5% vs. 72.2%, aOR 9.12, 95% CI 7.45 to 11.16, p = NR) (Thornton et al., 2017).

Non-U.S. Studies

Seven poor- to fair-quality studies reported comparative estimates of breastfeeding by place of birth in Australia, Canada, Ireland, the Netherlands, New Zealand, and the United Kingdom (de Cock et al., 2015; Grigg et al., 2017; Hutton et al., 2016; Hutton et al., 2009; Laws et al., 2014; Monk et al., 2014; Quigley et al., 2016). Largely, rates of breastfeeding were higher for planned home birth groups compared to planned hospital births across all time points. Exclusive breastfeeding at six months of life was reported by a single fair-quality study using retrospective data from Irish and UK national surveys (Quigley et al., 2016). In Ireland, 22% of infants from a planned home birth group compared to 9% of those with planned hospital births were exclusively breastfed at six months (aOR 2.77, 95% CI 1.78 to 4.33, p = 0.0073). In the United Kingdom, the proportion of infants with exclusive breastfeeding at six months declined, but was still higher for the planned home birth cohort compared to the planned hospital cohort (4% vs. 1%, aOR 2.24, 95% CI 1.14 to 4.03, p < 0.001).

Although the proportion of infants exclusively breastfed at a median of five weeks postpartum was lower for planned hospital births compared to planned home births in a small study from the Netherlands (n = 712), the difference was not statistically significant after adjusting for potential confounders of age, parity, education level, ethnicity, smoking, and birth weight (68.5% vs. 75%, aOR 0.79, 95% CI 0.53 to 1.18) (de Cock et al., 2015). Similarly, in New Zealand, rates of exclusive

breastfeeding at six weeks were statistically similar for planned birth in primary midwifery units (i.e., birth centers) compared to tertiary maternity hospitals (i.e., hospital births) after adjusting for potential confounders of age, smoking, parity, term, and need for augmentation or induction (80.6% vs. 78.6%, aOR 1.14, 95% CI 0.76 to 1.70, p > 0.05) (Grigg et al., 2017).

A study from Canada found that breastfeeding rates were higher at 10 days for planned home compared to planned hospital births (87.8% vs. 78.9%, RR 1.11, 95% CI 1.10 to 1.13) (Hutton et al., 2016). The likelihood of breastfeeding at discharge was higher for planned home births in Australia in both the studies by Laws et al. (aOR 2.32, 95% CI 2.04 to 2.65, p = NR) and Monk et al. (aOR 1.59, 95% CI 1.14 to 2.24 p = 0.007), after adjusting for potential confounders.

Subgroup Findings

The following section outlines comparative findings across identified subpopulations or subgroups for all outcomes prioritized for this coverage guidance. Reported subgroups are parity, maternal age, other risk factors, history of cesarean section, breech position, gestational age, and race/ethnicity. Studies commonly reported outcomes for all participants, then separately reported outcomes for nulliparous and multiparous women. Additionally, studies reported outcomes for a specific subpopulation (e.g. women with a prior cesarean delivery, high-risk pregnancy [based on differing definitions]).

A summary is provided for each subgroup, followed by specifics for each outcome. As above, findings are reported for U.S-based studies separately from non-U.S. studies. Findings from U.S-based studies by subgroup only report neonatal mortality or morbidity outcomes. Please see the tables in Appendix G for detailed findings.

Subgroup: Parity

Summary

Comparisons by parity were the most commonly reported subgroup and included mode of delivery, fetal or neonatal mortality, neonatal harm, maternal harm, and breastfeeding. Findings from U.S. settings were limited to neonatal mortality rates from two studies. Both studies observed higher rates of neonatal death for all women; nulliparous women were at the highest risk. International studies consistently observed more optimal delivery mode outcomes and similar intrapartum and early neonatal death rates across birth settings for nulliparous and multiparous women.

Rates of neonatal harm, specifically the Birthplace composite outcome, were higher for nulliparous women in the planned home but not planned birth center setting compared to planned hospital setting in the original Birthplace cohort study. This finding was not observed in a study of similar quality conducted in Australia.

Mode of Delivery

No U.S.-based study reported comparative mode of delivery outcomes by parity. In non-U.S. studies, nulliparous and multiparous women were likely to experience more optimal delivery mode outcomes (i.e., increased odds of vaginal delivery, lower odds of instrumental [forceps or vacuum assisted] or cesarean delivery) in the planned home or birth center groups compared to women in planned hospital births, based on good- or fair-methodological-quality studies.

Non-U.S. Studies: Home Birth Settings

Ten non-U.S.-based studies reported mode of delivery outcomes by parity (Bailey et al., 2017; Bolten et al., 2016; Christensen & Overgaard, 2017; Halfdansdottir et al., 2017; Hollowell et al., 2017; Hutton et al., 2009; Hutton et al., 2016; Janssen et al., 2009; Li et al., 2015; van Haaren-ten Haken et al., 2015).

Nulliparous and multiparous women planning a home birth were more likely to experience a straightforward vaginal birth (one without instrumentation, a third or fourth degree tear, or requiring blood transfusion) than similar women planning hospital birth in the good-quality Birthplace study conducted in England (aRR 1.63, 95% CI 1.47 to 1.81 for nulliparous women; aRR 1.20, 95% CI 1.16 to 1.23 for multiparous) (Li et al., 2015).

Across studies of poor quality, nulliparous and multiparous women experienced more optimal delivery mode outcomes in the planned home birth group (i.e., increased odds of vaginal delivery, lower odds of instrumental or cesarean delivery) compared to planned hospital birth; the magnitude of the benefit was greater for multiparous women across all modes for planned home birth compared to planned hospital birth; for example, a study conducted in the Netherlands found greater odds of spontaneous vaginal delivery for multiparous women (aOR 2.29, 95% CI 1.21 to 4.36 compared to aOR 1.38, 95% CI 1.08 to 1.76 for nulliparous women, no formal statistical comparison reported) (Bolten et al., 2016). Similar benefits were observed in nulliparous and multiparous women in Ontario, Canada (Hutton et al., 2016). In studies only reporting comparative rates, with no formal statistical analysis, women who had planned home births experienced lower cesarean delivery rates in British Columbia (Janssen et al., 2009) and Iceland (Halfdansdottir et al., 2015), and in older data from Ontario, Canada (Hutton et al., 2009).

Non-U.S. Studies: Birth Center Settings

Four non-U.S. based studies reported outcomes from birth center settings: two studies were poor quality (Bailey et al., 2017; Christensen & Overgaard, 2017) and one was fair quality (Hollowell et al., 2017) and one was good quality (Hermus et al., 2017). In the Netherlands, nulliparous and multiparous women experienced similar rates of vaginal delivery in a birth center as in a hospital or home setting (Hermus et al., 2017). Rates of instrumental delivery also did not differ by planned place of birth (Hermus et al., 2017). Nulliparous and multiparous women planning to give birth at a freestanding birth center in the United Kingdom were more likely to have a spontaneous vaginal delivery and less likely to have an instrumental delivery, but had similar odds of cesarean delivery compared to planned hospital births after adjusting for maternal characteristics and complicating conditions at the start of labor (Hollowell et al., 2017).

Unadjusted estimates from Denmark demonstrated greater odds of uncomplicated birth, one "leaving both mother and infant in good condition" and lower odds of instrumental delivery for nulliparous and multiparous women planning a birth center birth compared to a matched hospital birth group. The odds of uncomplicated birth were greater for multiparous women than for nulliparous women (OR 2.9, 95% CI 2.0 to 4.2 compared to OR 2.2, 95% CI 1.4 to 3.3); nulliparous women experienced a greater reduction in the odds of cesarean delivery (OR 0.4, 95% CI 0.2 to 0.9 compared to OR 0.8, 95% CI 0.3 to 2.2). The reduction in instrumental delivery was similar for both groups (OR 0.4, 95% CI 0.2 to 0.7 nulliparous, OR 0.3, 95% CI 0.1 to 0.9 multiparous) (Christensen & Overgaard, 2017).

Nulliparous and multiparous women planning a birth center birth in New Zealand experienced similar reductions in odds of instrumental delivery, with a small reduction in the risk of cesarean delivery for

multiparous women (aOR 0.34, 95% CI 0.26 to 0.46) compared to that for nulliparous women (aOR 0.51, 95% CI 0.44 to 0.59) (Bailey et al., 2017).

Fetal or Neonatal Mortality

Two studies of poor and fair quality reported comparative mortality outcomes by parity in the U.S. from 2008 to 2012 (Grunebaum, McCullough, Arabin et al., 2017) and 2009 to 2013 (Grunebaum, McCullough, Sapra et al., 2017). In the first study, neonatal death (0 to 27 days) was higher in the planned home birth group (attended by a certified nurse or other midwife) compared to hospital births attended by a certified nurse midwife for nulliparous (RR 5.34, 95% CI 3.9 to 7.4) and multiparous women (RR 3.1, 95% CI 2.4 to 4) (Grunebaum, McCullough, Arabin et al., 2017). The authors did not report adjusted estimates to account for possible confounding.

The findings were similar for the later time period (2009 to 2013) with a higher standardized mortality ratio (SMR) in planned home births for nulliparous (SMR 6.06, 95% CI 4.30 to 7.83) and multiparous women (SMR 3.49, 95% CI 2.68 to 4.30) (Grunebaum, McCullough, Sapra et al., 2017). The planned home birth cohort in this analysis was not limited by provider type to certified nurse or other midwife, as above, and included births that were purposely not attended by a trained professional. Estimates in this study were reported as standardized mortality ratios, attempting to account for parity and other maternal demographics in comparisons.

Eight non-U.S.-based studies reported comparative perinatal mortality outcomes by parity in Australia (Homer et al., 2014), Iceland (Halfdansdottir et al., 2015), New Zealand (Bailey et al., 2017), the Netherlands (de Jonge et al., 2015; Hermus et al., 2017; van Haaren-ten Haken et al., 2015) and Ontario, Canada (Hutton et al., 2016; Hutton et al., 2009). Of these, one good-quality (Hermus et al., 2017) and two fair-quality studies reported findings by parity (Homer et al., 2014; de Jonge et al., 2015).

Nulliparous women in Australia did not experience statistically different rates of neonatal death across birth settings (home vs. hospital: aOR 2.48, 95% CI 0.34 to 18.02; birth center vs. hospital: aOR 0.99, 95% CI 0.52 to 1.88 (Homer et al., 2014). No cases of intrapartum or neonatal deaths (0 to 7 days) were observed for multiparous women in home or birth center settings. In the same eight-year time period, 96 events were observed in planned hospital births for multiparous women (0.103% of births; due to absence of deaths in the home and birth center groups, no further statistical analysis was performed).

In a large study conducted in the Netherlands (N = 743,070), the risk of intrapartum death was similar across settings for nulliparous (aOR 1.02, 95% CI 0.76 to 1.37) and multiparous women (aOR 1.31, 95% CI 0.89 to 1.94) (de Jonge et al., 2015). Neonatal death, 0 to 7 days, was also similar across settings by parity (nulliparous: aOR 0.98, 95% CI 0.70 to 1.36; multiparous: aOR 1.07, 95% CI 0.70 to 1.65)(de Jonge et al., 2015). Neonatal death, 0 to 27 days, also did not differ by setting for nulliparous and multiparous women (aOR 0.97, 95% CI 0.70 to 1.34; aOR 1.07, 95% CI 0.70 to 1.62, respectively) (de Jonge et al., 2015). In a small study from the Netherlands (N = 3455), rates of perinatal mortality within 24 hours were extremely rare (n = 1) and did not differ significantly by planned place of birth for nulliparous or multiparous women (Hermus et al., 2017).

Additional findings from poor-quality studies either observed similar rates of neonatal death or no cases of death. Intrapartum and neonatal death from 0 to 27 days were similar for planned home and planned hospital births for nulliparous women (RR 1.17, 95% CI 0.39 to 3.47) and multiparous women (unadjusted RR 0.67, 95% CI 0.11 to 3.99) in Ontario, Canada (Hutton et al., 2016). Death from

peripartum hypoxia was similar in planned birth center and planned hospital births for nulliparous women (unadjusted OR 1.30, 95% CI 0.46 to 3.23; calculated RR 1.27, 95% CI 0.65 to 2.49) and multiparous women in New Zealand (OR 1.70, 95% CI 0.47 to 5.90) (Bailey et al., 2017). Two small studies (n < 500) did not observe any deaths across birth settings for multiparous women in the Netherlands or Iceland (van Haaren-ten Haken et al., 2015; Halfdansdottir et al., 2015).

Neonatal Morbidity

No U.S. studies reported comparative neonatal morbidity outcomes by parity. Six non-U.S. studies provided comparative neonatal morbidity outcomes by parity (Bailey et al., 2017; Christensen & Overgaard, 2017; de Jonge et al., 2015; Hollowell et al., 2017; Li et al., 2015; van Haaren-ten Haken et al., 2015). Five studies provided overall estimates with separate analyses by parity (Birthplace, 2011; Homer et al., 2014; Halfdansdottir et al., 2015; Hutton et al., 2016; Hutton et al., 2009). Reported outcomes included the Birthplace composite outcome (stillbirth after the start of care in labor, early neonatal death, neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured humerus or clavicle), NICU admission, and Apgar scores.

Home Birth Setting

In the good-quality Birthplace study (Birthplace, 2011) the composite outcome did not differ by setting (see Outcome: Neonatal Morbidity section). When stratified by parity, for multiparous women, there was no difference across birth settings (aOR 0.72, 0.41 to 1.27) compared to all study participants (aOR 1.16, 95% CI 0.76 to 1.77). Infants of nulliparous women were at increased odds for the composite outcome in the planned home birth group compared to planned hospital group (9.3% vs. 5.3%, aOR 1.75, 1.07 to 2.86). In a fair-quality study conducted in Australia (2000 to 2008), the Birthplace composite for all births was not different in planned home compared to planned hospital births when stratified by parity (nulliparous women: aOR 1.72, 95% CI 0.64 to 4.63 compared to aOR 0.47, 95% CI 0.07 to 3.38) (Homer et al., 2014).

In a good-quality secondary analysis of the Birthplace cohort, adding admission to an NICU for over 48 hours (beginning within 48 hours of birth) to the composite outcomes for nulliparous and multiparous women did not result in a difference across planned home and planned hospital settings for nulliparous women (aRR 0.60, 95% CI 0.25 to 1.43); multiparous women remained at lower risk (aRR 0.47, 95% CI 0.25 to 0.88) (Li et al., 2015).

In a fair-quality study conducted in the Netherlands, low Apgar scores and admission to NICU (within 28 days) did not differ across birth settings for nulliparous women (aOR 0.95, 95% CI 0.87 to 1.02; aOR 1.05, 95% CI 0.92 to 1.18 respectively). Multiparous women were at decreased odds of an Apgar score less than seven at five minutes (aOR 0.77, 95% CI 0.69 to 0.86), similar odds for an Apgar score less than four at five minutes (aOR 0.92, 95% CI 0.70 to 1.20), and decreased odds of admission to NICU within 28 days (aOR 0.79, 95% CI 0.66 to 0.93) (de Jonge et al., 2015).

In a poor-quality study from Ontario, Canada, the odds of a composite outcome consisting of intrapartum or neonatal mortality, Apgar score less than four at five, positive pressure ventilation, or chest compressions remained similar in subgroup analyses by parity (nulliparous: RR 1.04, 95% CI 0.61 to 1.78; multiparous: RR 0.79, 95% CI 0.36 to 1.73) (Hutton et al., 2016).

In a poor-quality study, the frequency of NICU admission, an Apgar score less than seven at five minutes, and need for resuscitation was quantitatively similar (no statistical analysis provided) in planned home

and planned hospital settings in Iceland. When stratified by parity, nulliparous women experienced greater frequency of NICU admission (18.8% vs. 12%), an Apgar score less than seven at five minutes (6.3% vs. 3.1%), and need for neonatal resuscitation (6.3% vs. 1.6%); however, no formal statistical analysis was reported (Halfdansdottir et al., 2015).

Birth Center Setting

In the fair-quality Birthplace study, the composite outcome was similar for planned birth center and planned hospital births for nulliparous women (0.045% vs. 0.027%, aOR 0.96, 95% CI 0.51 to 1.82, p = 0.91) and multiparous women (0.047% vs. 0.024%, aOR 1.14, 95% CI 0.52 to 2.50, p = 0.745) (Hollowell et al., 2017).

In a fair-quality study from Australia analyzing data from 2000 to 2008, the Birthplace composite outcome) for all women (aOR 0.87, 95% CI 0.69 to 1.10) remained similar for nulliparous women in planned birth center births compared to planned hospital births (nulliparous women: aOR 1.04, 95% CI 0.81 to 1.34). Infants of multiparous women experienced a reduction in the odds of the composite outcome (aOR 0.45, 95% CI 0.26 to 0.81) (Homer et al., 2014).

Admissions to NICUs were lower for planned birth center births compared to planned hospital births in a poor-quality New Zealand study, but the difference was only statistically significant for nulliparous women (aOR 0.70, 0.58 to 0.86 compared to aOR 0.85, 95% CI 0.71 to 1.01 for multiparous women) (Bailey et al., 2017).

Maternal Harm

No U.S-based studies reported comparative maternal harm outcomes by parity. In one large, fair-quality non-U.S. study, a composite measure of severe acute maternal morbidity was lower for planned home birth compared to planned hospital birth (1.5% vs. 2.7%, no statistical analysis reported) (de Jonge et al., 2013). When analyzed by parity, there was no statistically significant difference for nulliparous women (aOR 0.77, 95% CI 0.56 to 1.06); reduced odds were observed for multiparous women (aOR 0.43, 95% CI 0.29 to 0.63, RRR 58.3%, 95% CI 33.2% to 87.5%) (de Jonge et al., 2013). Similarly, for the following outcomes, a statistically significant reduction in the odds was only observed in multiparous women in the planned home birth group compared to planned hospital birth:

- Need for a blood transfusion of four or more units (0.09% vs. 0.19%, aOR 0.45, 0.30 to 0.68, RRR 52.7, 95% CI 24.9 to 85.3)
- Postpartum hemorrhage (1.96% vs. 3.76%, aOR 0.50, 95% CI 0.46 to 0.55, RRR 47.9%, 95% CI 41.2% to 54.7%)
- Manual removal of the placenta (0.85% vs. 1.96%, aOR 0.41, 95% CI 0.36 to 0.47, RRR 56.9%, 95% CI 47.9% to 66.3%) (de Jonge et al., 2013).

In a good-quality study from the Netherlands, Hermus et al. observed significantly lower rates of third or fourth degree lacerations for women with a planned hospital birth (0.9%, 2 out of 348) compared to birth center (4%, 38 out of 939) (p < 0.01). Rates of blood loss (> 1000 mL), need for blood transfusion, and need for manual placental removal did not differ by planned place of birth (Hermus et al., 2017).

In one poor-quality study, the need for blood transfusion was lower for planned birth center births compared to planned hospital births for nulliparous (0.9% vs. 2.4%, aOR 0.40, 95% CI 0.25 to 0.62) and multiparous women (0.4% vs. 1.0%, aOR 0.54, 95% CI 0.35 to 0.83) (Bailey et al., 2017).

Estimates of obstetric anal sphincter injury were inconsistent. Two poor-quality studies observed either an increased risk in planned home birth groups compared to planned hospital for nulliparous women (5.3% vs. 3.2%, aOR 1.75, 95% CI 1.01 to 3.03) (Bolten et al., 2016) or decreased risk (3.1% vs. 4.7%, RR 0.67, 95% CI 0.53 to 0.83) (Hutton et al., 2016). One poor-quality study observed similar rates of obstetric anal sphincter injury in the planned birth center group compared to planned hospital birth for nulliparous (OR 0.9, 95% CI 0.4 to 2.0) and multiparous women (OR 0.6, 95% CI 0.2 to 1.7) (Christensen & Overgaard, 2017). One poor-quality study observed similar rates for planned home birth group compared to planned hospital birth group in Iceland for nulliparous (6.3% vs. 6.3%, aOR 1.37, 95% CI 0.40 to 4.63) and multiparous women (1.6% vs. 2.2%, aOR 0.73, 95% CI 0.20 to 2.59) (Halfdansdottir et al., 2015).

Studies observed statistically similar rates of postpartum hemorrhage in planned home and planned hospital births for nulliparous and multiparous women (Bolten et al., 2016; van Haaren-ten Haken et al., 2015). Postpartum hemorrhage was similar in planned home births compared to planned hospital births for nulliparous (3.2% vs. 3.6%, RR 0.89, 95% CI 0.71 to 1.12) and reduced in multiparous women (2.1% vs. 2.7%, RR 0.77, 95% CI 0.63 to 0.95) in one poor-quality study (Hutton et al., 2016).

Breastfeeding

No U.S-based studies reported comparative breastfeeding outcomes by parity. Two poor-quality studies reported comparative breastfeeding outcomes for nulliparous women in Ontario, Canada (Hutton et al., 2009; Hutton et al., 2016). At day 10 of life, infants in the planned home birth group were more likely to be breastfed compared to infants in the planned hospital birth group (84.8% vs. 75.9%, RR 1.13, 95% CI 1.11 to 1.16) (Hutton, et al., 2016). Exclusive breastfeeding at six weeks of life was reported for 89.1% of planned home birth infants compared to 76.7% for planned hospital births; no formal statistical analysis was reported (Hutton et al., 2009). These two studies also reported comparative breastfeeding outcomes for multiparous women (Hutton et al., 2009; Hutton et al., 2016). At day 10 of life, infants in the planned home birth group were more likely to be breastfed compared to infants in the planned hospital birth group (89.6% vs. 81.2%, RR 1.10, 95% CI 1.09 to 1.12) (Hutton, et al., 2016). Exclusive breastfeeding at six weeks of life was reported for 91.1% of infants in the planned home birth group compared to 82.2% for infants in the planned hospital birth group; no formal statistical analysis was reported (Hutton et al., 2009).

Subgroup: Maternal Age

Summary

Findings from U.S.-based studies reporting outcomes by maternal age are limited to neonatal mortality. Neonatal mortality in U.S. studies was higher for all women; women 35 years and older had higher risk than younger women.

International studies reported mode of delivery, neonatal harm, and maternal harm findings by maternal age. Overall, increasing maternal age was associated with a slightly increased risk in operative or cesarean delivery across birth settings, but actual rates of operative or cesarean delivery were lower across age groups. Similarly, risk of neonatal harm increased for every five-year increase in age; nulliparous women over 40 were at the highest risk of neonatal harm (including death or NICU admission).

Mode of Delivery

No U.S. based study reported comparative mode of birth outcomes by maternal age. A single good-quality study from England (Birthplace) reported mode of delivery outcomes for women by age and parity (Li, et al., 2014). The risk of instrumental and cesarean delivery increased with every five-year increment in age for nulliparous and multiparous women after controlling for maternal characteristics and intended birth setting (aRR ranged from 1.15 to 1.27, 95% CI ranged 1.05 to 1.32). The risk of a maternal composite outcome, incorporating delivery mode and maternal harms, increased with every five-year increase in age from 16 to 40 years, and was greater for planned out-of-hospital births (all non-hospital planned settings: aRR 1.21, 95% CI 1.18 to 1.25) compared to planned hospital births (aRR 1.12, 95% CI 1.10 to 1.15) (Li et al., 2014). The composite included augmentation, instrument delivery, intrapartum cesarean delivery, general anesthesia, blood transfusion, third or fourth degree tear, and admission to a higher level of care. However, the absolute rates of the maternal composite outcome were lower for nulliparous and multiparous women in the planned out-of-hospital group than the planned hospital group. The magnitude of the benefit decreased with increasing age (nulliparous women age 16 to 19: aRR 0.49, 95% 0.42 to 0.58 and women 40 and older: aRR 0.70, 95% CI 0.53 to 0.93).

Fetal or Neonatal Mortality

Two studies of poor to fair quality reported comparative U.S. estimates of neonatal death (0 to 27 days) by maternal age, from 2008 to 2012 (Grunebaum, McCullough, Arabin et al., 2017) and 2009 to 2013 (Grunebaum, McCullough, Sapra et al., 2017). Across both time periods, the risk of neonatal death was higher in planned home births compared to planned hospital births. When stratified by age, older women (≥ 35 years) experienced greater neonatal mortality than younger women. The two studies used different effect estimates (unadjusted relative risk and standardized mortality ratios (SMR), respectively) (≥ 35 years: RR 4.1, 95% CI 2.6 to 6.5; <35 years: RR 3.9, 95% CI 2.8 to 4.4) (Grunebaum, McCullough, Arabin et al., 2017); (≥ 35 years: SMR 5.11, 95% CI 3.19 to 7.03; < 35 years: SMR 3.72, 95% CI 2.95 to 4.50) (Grunebaum, McCullough, Sapra et al., 2017).

Neonatal Harm

We identified no studies that reported neonatal morbidity by maternal age in a U.S. setting. In a good-quality non-U.S. study, the risk of a composite outcome consisting of NICU admission over 48 hours (within 48 hours or birth) and the Birthplace composite (i.e., stillbirth after the start of care in labor, early neonatal death, neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured humerus or clavicle) was increased for nulliparous women over 40 compared to women aged 25 to 29 (aRR 2.29, 95% CI 1.28 to 4.09). For every 5 year increase in age, the adjusted relative risk was not statistically significant for nulliparous (aRR 1.06, 95% CI 0.95 to 1.17) and multiparous women (aRR 0.98, 95% CI 0.84 to 1.15) (Li et al., 2014).

Maternal Harm

No studies reported maternal harm by maternal age in U.S. settings. In a single good-quality study from England, controlling for birth setting, nulliparous women experienced a small, but statistically significant, increased risk of third or fourth degree tear for every five-year increase in age (aRR 1.12, 95% CI 1.02 to 1.23) (Li et al., 2014). The need for blood transfusion, controlling for place of birth, was not increased for nulliparous or multiparous women with higher maternal age.

Breastfeeding

No studies from U.S. or non-U.S. settings reported breastfeeding by maternal age.

Subgroup: Prior Cesarean Delivery

Summary

Findings from two U.S.-based studies observed conflicting estimates of effect: one study showed increased risk of neonatal death in planned home or birth center settings and the other did not observe a statistically significant difference. International studies observed greater frequency of neonatal harms in planned home or birth center settings, but the findings were not statistically significantly different. International studies observed that women with a history of cesarean delivery had higher rates of vaginal delivery in planned home or birth center settings.

Mode of Delivery

No U.S.-based study reported comparative mode of delivery outcomes for women with a prior cesarean delivery. A single good-quality, non-U.S.-based study reported comparative delivery mode outcomes for women with a prior cesarean section in England (Rowe et al., 2016). Compared to planned hospital birth, women with a history of cesarean delivery planning home birth were more likely to have a vaginal birth, including spontaneous vertex or breech vaginal births, or vaginal births assisted by forceps or vacuum (aRR 1.19, 95% CI 1.06 to 1.24).

Fetal or Neonatal Mortality

A single fair-quality study reported comparative mortality outcomes for women planning home birth with a prior cesarean delivery in U.S. settings (Grunebaum, McCullough, Sapra et al., 2017). The standardized perinatal mortality ratio (birth to day 27) for women with a prior cesarean delivery (SMR 8.33, 95% CI 2.59 to 14.07) was higher compared to women without a prior cesarean delivery (SMR 3.72, 95% CI 3.01 to 4.43).

A single fair-quality study reported comparative mortality outcomes for women planning home or birth center birth with a prior cesarean delivery (Tilden et al., 2017). Women planning home or birth center births experienced a greater frequency of neonatal death (0.13% vs. 0.08%), but the difference was not statistically significant (aOR 2.10, 95% CI 0.73 to 6.05, p > 0.05). No non-U.S. based studies reported comparative fetal or neonatal mortality outcomes for women with a prior cesarean delivery.

No non-U.S. based studies reported comparative fetal or neonatal mortality outcomes for women with a prior cesarean delivery.

Neonatal Harm

A single fair-quality study conducted in the U.S. reported comparative neonatal morbidity outcomes for women with a prior cesarean section (Tilden et al., 2017). Poor neonatal outcomes were more common for home or birth center births compared to planned hospital births for the following outcomes: Apgar scores less than four (0.73% vs. 0.40%, aOR 1.77, 95% CI 1.12 to 2.79, p = 0.016), Apgar scores less than seven (4.42% vs. 2.68%, aOR 1.62, 95% CI 1.35 to 1.96, p < 0.001), and neonatal seizures (0.19% vs. 0.02%, aOR 8.53, 95% CI 2.87 to 25.4, p = 0.003). Rates of NICU admission were lower for planned home or birth center births compared to planned hospital births (1.11% vs. 3.10%, aOR 0.40, 95% CI 0.29 to

0.57, p < 0.001). There were no statistically significant differences across groups in the need for ventilator support (0.38% vs. 0.29%, aOR 1.36, 95% CI 0.75 to 2.46, p = 0.31).

A single good-quality study reported comparative neonatal morbidity outcomes for women with a prior cesarean section in England (Rowe et al., 2016). Comparing planned home versus planned hospital births, the risk of a composite of intrapartum death or an Apgar score less than seven at five minutes (1.87% vs. 1.57%, RR 1.19, 95% CI 0.41 to 3.44) and admission to a neonatal unit (3.71% vs. 3.04%, RR 1.22, 95% CI 0.57 to 2.59) did not differ among women with a history of cesarean delivery in the planned home birth group compared to planned hospital birth

Subgroup: Breech Position of Fetus

Summary

Outcomes for breech position are limited to fetal or neonatal mortality. Breech position was associated with an increased risk of neonatal death in a single U.S. study.

Fetal or Neonatal Mortality

A single fair-quality study conducted in the U.S. observed higher standardized mortality ratios for cephalic and breech infants in planned home birth groups compared to planned hospital births attended by midwives (Grunebaum, McCullough, Sapra et al., 2017). The point estimate for breech presentation was over a twofold increase (SMR 8.14, 95% 2.17 to 14.11) compared to cephalic (SMR 3.61, 95% CI 2.92 to 4.31).

Subgroup: Other Factors

Summary

This section includes outcomes for several combinations of risk factors for low- and high-risk groups. Studies attempting to examine the most low-risk group, women without complicating conditions at the start of labor, excluded women with meconium-stained fluids, preeclampsia, non-cephalic position, abnormal fetal heartrate, or prolonged rupture of membranes. Other definitions of risk were not consistent across settings, which limited comparisons across studies.

Findings for U.S.-based studies were limited to fetal or neonatal mortality outcomes and observed higher risk for several combinations of factors, particularly for nulliparous women of older age, or advanced gestational age. International studies reported delivery mode, fetal or neonatal mortality, and neonatal harm outcomes by risk factor groupings. Nulliparous women without complicating conditions at the start of labor experienced a small but statistically significant increased odds of neonatal harm in planned home birth groups that was similar to that observed for all nulliparous women; from international studies.

Mode of Delivery

No U.S.-based study reported comparative delivery mode outcomes for women by other risk factor groupings. Three studies conducted outside of the U.S. reported delivery mode outcomes for women with or without an array of risk factors: we rated one as good quality (Birthplace, 2011) and two as poor quality (Halfdansdottir et al., 2018; Davies-Tuck et al., 2018)...

Women without a complicating condition at the start of labor (e.g., meconium-stained amniotic fluid) were more likely to experience a birth without induction, epidural or spinal analgesia, general

anesthesia, or assisted or cesarean delivery in planned home or planned birth center settings than in planned hospital settings (aOR 4.12, 95% CI 3.37 to 5.04 for home births, aOR 3.42, 95% CI 2.74 to 4.27 for birth centers, both compared to hospital birth) (Birthplace, 2011). However, as the authors noted, the use of an odds ratio for this common outcome likely overstated the actual magnitude of the effect.

Women with a known contraindication to home birth (e.g., BMI > 35, after 42 weeks completed gestation, chronic diseases, prematurity, previous cesarean delivery) were no more likely to have an operative delivery compared to women planning home birth without a contraindication in a small study of 1,228 women in Iceland (OR 5.42, 95% CI 0.60 to 48.99) (Halfdansdottir et al., 2018).

In a study conducted in Australia, high-risk women also experienced beneficial delivery mode outcomes more often in planned home birth settings compared to a planned hospital setting (i.e., lower rates of cesarean delivery, instrumental deliveries, and higher rates of spontaneous vaginal deliveries; no formal statistical analysis reported) (Davies-Tuck et al., 2018). Although there were higher NICU admission rates for the infants (1.6% vs. 0.4%, p < 0.001) and intrauterine hypoxia (3.2% vs. 6.6%, p < 0.001), rates of other maternal and neonatal outcomes were not statistically significantly different (i.e., perinatal morbidity (meconium aspiration syndrome, pneumonia, or respiratory distress syndrome), Apgar score less than seven at five minutes, composite morbidity). Rates of birth trauma (brachial plexus injury, fractured clavicle or humerus) were reduced for high-risk planned home births compared to planned hospital births (3.1% vs. 7.6%, p < 0.001).

Fetal or Neonatal Mortality

A single fair-quality study from the U.S. observed increased risk of neonatal mortality (0 to 27 days) for several combinations of risk factors for planned home births (all providers) compared to planned hospital births attended by a midwife (Grunebaum, McCullough, Sapra et al., 2017). The greatest risk was seen in nulliparous women, 35 years and older (SMR 12.41, 95% CI 4.33 to 20.49) and nulliparous women at 41 weeks of pregnancy or later (SMR 9.57, 95% CI 5.84 to 13.30); other groups experienced increased risk.

A single fair-quality Australian study limited to women without complicating conditions at the start of labor (i.e., prolonged rupture of membranes, preeclampsia, gestational hypertension, antepartum hemorrhage, eclampsia, gestational diabetes or pre-pregnancy diabetes; 8.9% of entire study sample), observed no cases of intrapartum or early neonatal death (0 to 7 days) for planned home births from 2000 to 2008. Estimates after adjusting for negative values (by adding 0.5 to all counts) were not statistically significantly different for all home, birth center, and planned hospital births (Homer et al., 2014).

Neonatal Harm

No U.S. based study reported comparative neonatal harm outcomes for women by other risk factor groupings. In a subgroup comparison from the good-quality Birthplace study limited to nulliparous women without complicating conditions at the start of labor (e.g., meconium-stained fluids) experienced increased odds of the Birthplace composite outcome (stillbirth after start of care in labor, early neonatal death, neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured humerus or clavicle) in planned home birth (unadjusted aOR 2.80, 95% CI 1.59 to 4.92 compared to aOR 1.75, 95% CI 1.07 to 2.86 for all nulliparous women planned home compared to planned hospital). Although the effect estimate was higher, the incidence was similar (3.5 per 1,000 vs. 9.5 per 1,000; the wider confidence interval is likely a result of the smaller sample in the analysis of

women without complicating conditions.. Risk the Birthplace composite was similar in planned birth center settings compared to planned hospital (aOR 1.40, 95% CI 0.74 to 2.65) (Birthplace, 2011).

In a fair-quality Australian study of women without complications at the start of labor, there were no statistically significant differences in the composite outcome comparing planned home to planned hospital births (aOR 0.87, 95% CI 0.33 to 2.35) or comparing planned birth center to planned hospital births (aOR 0.82, 95% CI 0.64 to 1.05) (Homer et al., 2014).

For women at higher risk at the start of labor (e.g., gestational diabetes, BMI > 35, 42 to 44 weeks gestation, known high-risk medical conditions), but without complicating conditions at the start of labor (e.g., meconium-stained fluids), in the Birthplace cohort, the small number of nulliparous women (n = 288) fared similarly in home and hospital settings (aRR 0.43, 95% CI 0.16 to 1.16); multiparous women (n = 1,201) were at a lower risk of adverse perinatal outcomes (i.e., Birthplace composite) (aRR 0.41, 95% CI 0.18 to 0.89) (Li et al., 2015).

In a poor-quality study conducted in Australia, high-risk women (e.g., obese, with chronic medical conditions, non-cephalic presentation, prior cesarean delivery) in the planned home birth group more commonly experienced NICU admissions for their infants (1.6% vs. 0.4%, p < 0.001). Rates of other outcomes were not statistically significantly different or favored home birth for reduced composite morbidity (7.8% vs. 16.9%, p < 0.001), intrauterine hypoxia (3.2% vs. 6.6%, p < 0.001), and birth trauma (3.1% vs. 7.6%, p < 0.001) (Davies-Tuck, et al., 2018).

In a poor-quality study conducted in Iceland, women with a known contraindication to home birth, but who elected to proceed with home birth, experienced similar odds of NICU admission (OR 1.88, 95% CI 0.41 to 8.64), Apgar score of less than seven at five minutes (OR 8.37, 95% CI 0.37 to 189.36), neonatal resuscitation (OR 1.89, 95% CI 0.14 to 9.68), and overall morbidity (OR 1.16, 95% CI 0.65 to 5.51) compared to women without a contraindication, but the results were all imprecise (i.e., had wide confidence intervals) (Halfdansdottir et al., 2018)

Subgroup: Gestational Age

Summary

Outcomes by gestational age were limited to fetal or neonatal mortality from a single U.S. study.

Fetal or Neonatal Mortality

Estimates of neonatal mortality by gestational age in U.S. settings were reported by two studies of poor to fair quality that had overlapping time periods (Grunebaum, McCullough, Arabin et al., 2017; Grunebaum, McCullough, Sapra et al., 2017). Neonatal mortality (0 to 27 days) was higher for planned home births across both gestational age groups (\geq 37 to < 41 weeks, and \geq 41 weeks) in both studies. In the 2009 to 2013 dataset, both groups experienced increased rates of neonatal mortality at \geq 37 to < 41 weeks (SMR 3.37, 95% CI 2.95 to 4.50) and \geq 41 weeks (SMR 4.78, 95% CI 3.43 to 6.12) (Grunebaum, McCullough, Sapra et al., 2017). The 2008 to 2012 dataset also demonstrated higher risk of neonatal mortality for home birth attended by a CNM or other midwife compared to hospital birth attended by a midwife at \geq 37 to < 41 weeks (RR 3.25, 95% CI 2.6 to 4.2) and \geq 41 weeks (RR 4.43, 95% CI 3.1 to 6.3) (Grunebaum, McCullough, Arabin, et al., 2017).

Subgroup: Race or Ethnicity

Summary

Outcomes by race or ethnicity were limited to fetal or neonatal mortality from a single U.S. study.

Fetal or Neonatal Mortality

A single poor-quality study reported standardized mortality ratios for white, non-Hispanic women and women of all other races or ethnicities combined. Both groups experienced an increased risk of neonatal death (0 to 27 days) compared to planned hospital births attended by a midwife, but the estimates overlapped (RR 3.71, 95% CI 3 to 4.6 for white women; RR 2.65, 95% CI 1.4 to 5 for all other race/ethnicities combined) (Grunebaum, McCullough, Arabin et al., 2017).

Noncomparative Studies

We identified 14 noncomparative studies that reported on relevant outcomes from planned home or birth center births. Seven of the studies analyzed U.S. data (Bachilova et al., 2018; Bovbjerg et al., 2017; Cheyney et al., 2014; Cox et al., 2015; Nethery et al., 2017; Stapleton et al., 2013; Stephenson-Famy et al., 2017), and four of these studies relied on data from the Midwives Alliance of North America Statistics Project (MANA Stats), which combines outcome data from planned home and birth center births (Bovbjerg et al., 2017; Cheyney et al., 2014; Cox et al., 2015; Nethery et al., 2017). One study used a combination of Canadian and U.S. data (Johnson & Daviss, 2005), and the remaining six studies were based in Australia (Catling-Paull et al., 2013), Japan (Eto et al., 2017; Suto et al., 2015), the Netherlands (Schuit et al., 2016), and Nordic countries (Blix et al., 2015; Edqvist et al., 2016). Sample sizes across the studies ranged from 1,521 (Suto et al., 2015) to 746,642 (Schuit et al., 2016). There were high levels of heterogeneity in the outcomes reported across studies. At least six of the 14 noncomparative studies reported on delivery mode, maternal genital tract trauma, perinatal mortality, and neonatal morbidity.

The noncomparative studies demonstrated favorable delivery mode outcomes (i.e., high rates of vaginal deliveries, low rates of assisted or cesarean deliveries). In general, the studies reported greater risks of maternal and neonatal harms for nulliparous women and women with a previous history of cesarean or instrument-assisted vaginal delivery. In addition, breech presentation, multiple gestation, and high-risk maternal conditions (e.g., hypertension) were associated with higher risks of adverse neonatal events. Many of the noncomparative studies excluded high-risk populations, and thus these findings might not be directly applicable to typical populations of planned home and birth center births. Appendix H provides additional details on the study characteristics of the included noncomparative observational studies.

Evidence Summary

Planned out-of-hospital birth is associated with favorable outcomes for women, but with increased risk of harm to neonates in U.S. studies. Rates of vaginal births for women having planned home or birth center births were consistently greater than for women having planned hospital births, as reported across U.S. and international studies of fair to good methodological quality. Maternal harms were also more favorable in planned out-of-hospital settings. Estimates of breastfeeding by planned place of birth tended to favor out-of-hospital settings, but the quality of evidence is very low.

Although overall rates of infant harm were similar from fair- to good-methodological-quality international studies, there were estimates of increased harm, particularly higher rates of death, for infants in planned out-of-hospital births compared to planned hospital births as observed in U.S.-based studies of similar methodological quality.

The risk of neonatal morbidity or death within subgroups was higher for nulliparous women in U.S-studies, whereas non-U.S.-based studies observed higher or similar risks. In U.S. studies, higher maternal age, later gestational stage, breech position, and prior cesarean delivery were associated with increased risk of neonatal death. In the U.S., rates of death for newborns also increased for combinations of risk, notably for nulliparous older women or at advanced gestational age. The magnitude of the neonatal risk difference was greater in U.S.-based studies than international studies because neonatal death was less common across international studies.

Policy Landscape

Guidelines from Others

A search of MEDLINE, Center core sources, and professional societies relevant to planned out-of-hospital birth identified documents from the American Academy of Pediatrics (AAP) (2016), American Association of Birth Centers (AABC) (2017), American College of Nurse Midwives (ACNM) (2015), American College of Obstetricians and Gynecologists (ACOG) (2017), the National Institute for Health and Care Excellence (NICE) (2017), and the Society of Obstetricians and Gynecologists of Canada (SOGC) (2019). In-person public comment from the June 2019 EBGS meeting identified guidance from the Oregon Midwifery Council (OMC) (2019). The Midwives Alliance of North America (2005) and the National Association of Certified Professional Midwives (2004) had no updated guidance in the last 15 years.

The 2015 HERC Coverage Guidance used guidance from NICE (2014), the College of Midwives of British Columbia (CMBC) (2014), the College of Midwives of Ontario (2015), and the Obstetric Working Group of the National Insurance Board of the Netherlands (n.d.). Updated documents were only identified from the College of Midwives of British Columbia (2018) and NICE (2017). The College of Midwives of Ontario published *Professional Standards for Midwives* in 2018, but this document does not make specific recommendations about clinical care, eligibility, or transfers (College of Midwives of Ontario, 2018). The most current standards for consultation and transfers from the College of Midwives of Ontario remain the 2015 guidance, included in the prior HERC coverage guidance (College of Midwives of Ontario, 2015).

Only the NICE guideline included information on evidence review methods for the guideline *Intrapartum Care for Healthy Women and Babies*, which was updated in 2017 and is available publicly at: https://www.nice.org.uk/guidance/cg190 (NICE, 2017). This guideline was assessed as having good methodological quality. No other identified documents included the methods of development. These documents should be considered expert opinion and of poor methodological quality.

The information contained within the identified documents is vast in scope. Specific guidance on system-level practices, emergency planning, and life support training requirements for birth attendants is summarized in this section; specific risk assessment levels are abstracted in Appendix I for maternal indications and Appendix J for newborn indications.

Regulatory Guidance

An additional source is included in this Coverage Guidance because it is relevant to the Oregon regulatory environment. The proposed administrative rules (as of May 2019) from the Oregon Health Authority's State Board of Direct Entry Midwifery (OR DEM) are also included for reference in Appendices I and J (OR DEM, 2019).

Guidelines and Regulatory Guidance Summary

Table 3 lists all included guidelines and regulatory guidance, along with a billing guide from the state of Washington's Medicaid program (WA) identified in the policy search (see below). The Washington guide is included in this section because it provides specific guidance on risk assessment, consultation, and referrals criteria for planned home or birth center births. The policy search did not identify any guidance on out-of-hospital birth from chiropractic or naturopathic professional societies.

Table 3. Included Guidelines, Regulations, and Professional Society Guidance

| Organization | Year | Specific Risk Assessment Protocols |
|--|------------------------|---------------------------------------|
| American Academy of Pediatrics | 2013 (reaffirmed 2016) | Yes |
| American Association of Birth Centers | 2017 | Yes |
| American College of Nurse-Midwives | 2015 | Yes |
| American College of Obstetricians and Gynecologists | 2017 | Yes |
| College of Midwives of British Columbia | 2018 | Yes |
| College of Midwives of Ontario | 2018 | No |
| National Institute for Health and Care Excellence | 2014, updated 2017 | Yes |
| Oregon Midwifery Council | 2019 | No |
| Society of Obstetricians and Gynecologists of Canada | 2019 | No |
| State Board of Direct Entry Midwifery, Oregon | 2019, proposed | Yes |
| Washington Medicaid Billing Guide | 2017 | Yes |

System-Level Recommendations

This section summarizes recommendations on health system-level practices to improve outcomes for planned out-of-hospital births. Canada's "systems-based approach," supporting safety for home birth within its integrated health system, is posited as the reason for improved perinatal and obstetric outcomes observed in Canada compared to the United States (SOGC, 2019).

Regarding transfer, multiple organizations recommend that a relationship with a medical facility should be in place in the event of transfer, and the attendant should have readily available consultation (AAP, 2016; ACNM, 2015; ACOG, 2017). The AABC standards include recommendations for an established system for consultation, collaboration, or referral for emergency and non-emergency events (AABC, 2017). Transfers should occur in a timely and safe fashion (AAP, 2016; ACNM, 215; ACOG, 2017).

The AAP and the ACOG both recommend hospitals or birth centers as the safest place of birth in the U.S (AAP, 2016; ACOG, 2017). Acknowledging that women may, after participating in an informed risk and

benefit discussion, elect to pursue a home birth, the AAP and ACOG recommend that to reduce perinatal mortality, the birth should be within an integrated and regulated health system attended by a certified nurse midwife, certified midwife, or midwife meeting International Confederation of Midwives' Global Standards for Midwifery Education (AAP, 2016; ACOG, 2017).

According to the AAP, care of the newborn immediately after birth should adhere to the *Guidelines for Perinatal Care* published by the ACOG and AAP, including but not limited to transitional care after birth, monitoring for group B streptococcal disease, glucose screening, eye gonococcal prophylaxis, vaccination for hepatitis B, provision of vitamin K prophylaxis, assessment of feeding, screening for hyperbilirubinemia, and newborn screening (AAP, 2016). Additionally, all infants should receive an evaluation by a "health care professional who is knowledgeable and experienced in pediatrics within 24 hours of birth and subsequently within 48 hours of that first evaluation" (AAP pg. 1019, 2016). This evaluation should also include an assessment for congenital heart disease in addition to but not limited to hydration, jaundice, integration of clinical laboratory testing, and breastfeeding (AAP, 2016).

Emergency Planning and Life Support Training

The AAP recommends that each delivery, regardless of location, be attended by 2 individuals, 1 with training in infant resuscitation (i.e., Neonatal Resuscitation Program) whose sole responsibility is the newborn, allowing the other to attend to the mother (AAP, 2016). This is similar to guidance from the SOCG, which notes that a second care provider is required to accompany a registered midwife for a home birth (SOCG, 2019). The SOGC also notes that registered midwives attending homebirths are required to maintain hospital privileges, bring emergency equipment and supplies, and have emergency transportation protocols (SOGC, 2019, pg. 224). Similarly, NICE recommends that protocols be in place for patient transfer with development oversight by a multidisciplinary regulatory body with midwifery, obstetric, anesthesia, and neonatal experts (NICE, 2017).

Specifically in the case of the presence of meconium, NICE recommends transfer to hospital setting, with providers trained in fetal blood sampling and neonatal life support present at the delivery (NICE, 2017).

Eligibility and Risk Assessment, Transfer or Consultation Criteria

The majority of identified guideline documents concur that women planning an out-of-hospital birth should be at low risk and have uncomplicated pregnancies, but vary in the level of detail with which they describe low-risk candidates (AABC 2017; AAP 2016; ACNM 2015; ACOG 2017; CMBC 2017; NICE 2017; SOGC 2019;). Ongoing risk assessment over the course of pregnancy is recommended (AABC 2017; ACNM 2015; CMBC 2017; NICE 2017; OR DEM 2019; OMC 2019; SOGC 2019). Specific instructive language on what to do in the event of a risk factor varies across documents. For example, a consultation in the Washington guidance may include telephone, written, or electronic mail with an MD/DO, co-management, referral for exam or treatment, or transfer (WA, 2017). In the guidance from CMBC, a consultation is an in-person evaluation by a consultant resulting in recommendations for continuing care with a registered midwife, co-management, or transfer (CMBC, 2018). This recommendation language would be a "referral" in the Washington guidance. For the purposes of this document, conditions are categorized as high-risk historical conditions or complications of current pregnancy requiring hospital birth (3), conditions requiring consultation (2), or eligible for planned out-of-hospital birth provided there are no other complications (1).

Specific risk criteria for consultation, transfer, or contraindications/exclusions vary in level of detail across documents. When language aligned, similar recommendations are summarized together on the same line within Appendices I and J. In an attempt to ease comparisons across guidance documents, recommendations were color and number coded as described in Appendices I and J. When no formal recommendation for a condition was identified (--) was placed in the cell. At times, a recommendation for one condition may be superseded by another, which is denoted by the abbreviation for nonapplicable, NA. For example, a recommendation for consultation with rupture of membranes at 35 weeks by one guideline (i.e., category 2), might not be applicable to a different organization that lists gestational age under 36 weeks as high-risk exclusion (i.e., category 3). When it was possible, we attempted to clarify whether a listed condition referred to a history of the condition or as a new condition arising in the current pregnancy. Risk criteria recommendations also reflect variation in the integration of out-of-hospital birth and the scope of midwife practice. For example, within the National Health Service of the United Kingdom when risk factors are identified that suggest birth in a hospital setting is safer than out of hospital, the midwife is compelled to inform the woman and engage in an informed consent process but not required to transfer. Ensuring women are informed of the risk is required, balanced by personal autonomy of the woman to make the decision to transfer (NICE, 2017).

Appendix I catalogues maternal risk factor recommendations from the 2015 Coverage Guidance, additional guidance published in the interim, and relevant documents from Washington State (2017) and the Oregon Health Authority, OR DEM Board proposed rules (2019). Appendix J provides the same details for neonatal conditions.

Fetal malpresentation, multiple gestation, and prior cesarean are high-risk contraindications to planned out-of-hospital birth by the AAP, AABC, ACNM, ACOG, CMBC, NICE, and the Washington guidance, which concurs with the 2015 HERC Coverage Guidance (AAP 2016; AABC 2017; ACOG 2017; CMBC 2017; NICE 2017; WA 2017). The OR DEM Board (2019) considers frank or complete breech and/or prior cesarean delivery to be acceptable risk factors for out-of-hospital birth (OR DEM, 2019). The OMC lists out-of-hospital birth past 42 completed weeks of gestation (i.e., 43 weeks 0 days) as "outside of our community standard of care" and recommends starting fetal surveillance testing at 41 weeks and 3 days gestation (OMC 2019, pg. 11).

Across most guidelines are statements regarding the general medical health of the women attempting a planned out-of-hospital birth, specifically that they be free of chronic medical conditions or conditions that would be expected to worsen during pregnancy, or require treatment with pharmacotherapy (AABC 2017; ACNM 2015; CMBC 2018; NICE 2017).

Payer Coverage Policies

Medicaid

The policy for the <u>Washington Medicaid Program</u> (effective 1/1/2019) covers planned home births and births in agency-approved, licensed birthing centers attended by a qualified licensed midwife, a certified nurse midwife, or a physician. For coverage, the pregnancy must be low risk (see criteria below) and the woman must be expected to deliver the child vaginally and without complication.

Planned home birth providers and birthing center providers must:

- Have evidence of current cardiopulmonary resuscitation (CPR) training for adult CPR and neonatal resuscitation
- Have written, appropriate plans for consultation, emergency transfer, and transport of client and newborn to a hospital
- Obtain from the client a signed informed consent form

Home birth providers must also provide documentation of:

- Names and national provider identifier (NPI) number of back-up midwives that are current
 Washington Apple Health providers and will provide 24 hour-per-day coverage
- Local emergency medical services and emergency response capability in the area
- Professional consultation plan and referral
- Midwife's informed consent that includes newborn screening, prophylactic eye ointment, and vitamin K injection
- Participation in a formal, state sanctioned, quality assurance/improvement program or professional liability review process
- Midwife's or birthing center's professional liability policy

Washington Medicaid does not cover planned home births or births in birthing centers for women with a history of or identified with any of these factors:

- Cesarean section delivery
- Known multiple gestation
- Known breech presentation in labor with delivery not imminent
- Significant hematological disorders/coagulopathies
- Deep venous thrombosis or pulmonary embolism
- Cardiovascular disease causing functional impairment
- Chronic hypertension
- Significant endocrine disorders including pre-existing diabetes
- Hepatic disorders including uncontrolled intrahepatic cholestasis of pregnancy or abnormal liver function tests
- Isoimmunization, including evidence of Rh sensitization/platelet sensitization
- Neurologic disorders or active seizure disorders
- Pulmonary disease
- Renal disease
- Collagen-vascular diseases
- Cancer affecting site of delivery
- Other significant deviations from normal as assessed by the provider

In addition, coverage is not provided to women with current alcohol/drug addiction or abuse or current severe psychiatric illness.

Washington Medicaid requires consultation with a physician (MD/DO) and may require referral to a physician when any of the following conditions arise during the pregnancy:

- Breech at 37 weeks
- Polyhydramnios/Oligohydramnios
- Significant vaginal bleeding

- Persistent nausea and vomiting causing a weight loss of > 15 lbs.
- Post-dates pregnancy (> 42 completed weeks)
- Fetal demise after 12 completed weeks gestation
- Significant size/dates discrepancies
- Abnormal fetal non-stress test (NST)
- Abnormal ultrasound findings
- Acute pyelonephritis
- Infections whose treatment is beyond the scope of the provider
- Evidence of large uterine fibroid that may obstruct delivery or significant structural uterine abnormality
- No prenatal care prior to the third trimester
- Other significant deviations from normal, as assessed by the provider

Referral to a physician is required when any of the following conditions arise during pregnancy:

- Evidence of pregnancy-induced hypertension (BP>140/90 for >6 hours with client at rest)
- Hydatidiform mole (molar pregnancy)
- Gestational diabetes not controlled by diet
- Severe anemia unresponsive to treatment (Hgb<10, Hct (hematocrit)<28)
- Known fetal anomalies or conditions affected by site of birth
- Documented placental abnormalities, significant abruption past the first trimester, or any evidence of previa in the third trimester
- Rupture of membranes before the completion of 37 weeks gestation
- Positive HIV antibody test
- Documented intrauterine growth retardation (IUGR)
- Primary genital herpes past the first trimester
- Noncompliance with the plan of care (e.g., frequent missed prenatal visits)
- Development of any of the high-risk conditions that result in non-coverage of planned home birth or birthing center births

Washington Medicaid requires consultation with a physician and may require referral to a physician when any of the following conditions arise intrapartum:

- Prolonged rupture of membranes, >24 hours and not in active labor
- Other significant deviations from normal as assessed by the provider

Referral to a physician or hospital is required when any of the following emergency conditions arise intrapartum:

- Labor before the completion of 37 weeks gestation, with known dates
- Abnormal presentation or lie at time of delivery, including breech
- Persistent non-reassuring fetal heart rate (requires emergency transport)
- Active genital herpes at the onset of labor
- Thick meconium-stained fluid with delivery not imminent
- Prolapse of the umbilical cord (requires emergency transport)
- Sustained maternal fever
- Maternal seizure (requires emergency transport)

- Abnormal bleeding (hemorrhage requires emergent transfer)
- Hypertension with or without additional signs or symptoms of pre-eclampsia
- Prolonged failure to progress in active labor
- Sustained maternal vital sign instability or shock (requires emergency transport)
- Maternal desire for pain medication, consultation, or referral

Washington Medicaid requires consultation with a physician and may require referral to a physician when any of the following conditions arise postpartum in the first 24 hours after delivery of the placenta:

- Development of any of the applicable conditions listed for prenatal or intrapartum referral
- Significant maternal confusion or disorientation
- Other significant deviations from normal as assessed by the provider

Referral to a physician is required when any of the following conditions arise postpartum:

- Anaphylaxis or shock (requires emergency transport)
- Undelivered adhered or retained placenta with or without bleeding
- Significant hemorrhage not responsive to treatment (requires emergency transport)
- Maternal seizure (requires emergency transport)
- Third or fourth degree lacerations, if repair is beyond provider's level of expertise
- Sustained maternal vital sign instability and/or shock (requires emergency transport)
- Development of maternal fever, signs/symptoms of infection or sepsis
- Acute respiratory distress (requires emergency transport)
- Uterine prolapse or inversion (requires emergency transport)

Washington Medicaid requires consultation with a pediatric physician and may require referral to a pediatric physician when any of the following conditions arise in a neonate:

- Apgar score ≤ 6 at five minutes of age
- Birth weight < 2,500 grams
- Abnormal jaundice
- Other significant deviations from normal as assessed by the provider

Referral to a pediatric physician is required when any of the following conditions arise in a neonate:

- Birth weight < 2,000 grams
- Persistent respiratory distress (requires emergency transport)
- Persistent cardiac abnormalities or irregularities (requires emergency transport)
- Persistent central cyanosis or pallor (requires emergency transport)
- Prolonged temperature instability when intervention has failed
- Prolonged glycemic instability (requires emergency transport)
- Neonatal seizure (requires emergency transport)
- Clinical evidence of prematurity (gestational age < 35 weeks)
- Loss of > 10% of birth weight/failure to thrive
- Birth injury requiring medical attention
- Major apparent congenital anomalies
- Jaundice prior to 24 hours

Medicare

No National Coverage Determinations or Local Coverage Determinations were identified for out-of-hospital births.

Private Payers

Coverage policies for out-of-hospital births were assessed for four private payers: Aetna, Cigna, Moda, and Regence. All four payers cover deliveries in birthing centers. The policy for Aetna (last review 3/28/2019) considers planned home births not medically appropriate. The policies for Cigna (effective 1/15/2019), Moda (last review 4/3/2018), and Regence (webpage dated 2019) cover planned home births attend by certified nurse midwives. None of these private payers include coverage criteria regarding low-risk pregnancies, other than requiring that attending midwifes need to be performing duties within the scope of their licensure.

Cigna

Midwife Services

Coverage of professional fees for midwife services is subject to the terms, conditions, and limitations of the applicable benefit plan and may be limited based on health care professional certification/licensure requirements. In addition, coverage of midwife services may be governed by state mandates; please note that licensure and regulations related to midwifery practice and prescriptive authority vary among states.

In addition, midwife services and/or birthing centers are excluded from network adequacy/network exception or transition of care provisions.

Services provided by a Licensed/Certified Nurse Midwife are eligible for coverage. Services provided by non-nurse midwives (e.g., Certified Midwife [CM], Certified Professional Midwife [CPM], Direct-Entry Midwife, Lay Midwife), may be covered depending on state requirements.

Licensed/Certified Nurse Midwife

Cigna covers services provided by a Licensed/Certified Nurse Midwife acting within the scope of license or certification under the applicable state law

Non-Nurse Midwife

Cigna ONLY covers services provided by a non-nurse midwife (e.g., Certified Midwife [CM)] Certified Professional Midwife [CPM], Direct-Entry Midwife, Lay Midwife) when acting within the scope of license or certification under the applicable state law.

Not Covered

Cigna does not cover ANY of the following:

- Services provided by an out-of-network midwife (e.g., Licensed/Certified Nurse Midwife, Certified Midwife) when out-of-network benefits are not available.
- Services at the in-network benefit level, for services provided by an out-of-network health care
 provider (i.e., network exception) when a qualified in-network health care professional who
 provides obstetrical services is available, unless required by state regulations or mandates.

- Services provided by a midwife (e.g., Licensed Certified Midwife, Certified Midwife) acting outside the scope of license or certification under the applicable state law.
- Doula services (e.g., childbirth education and support services during pregnancy by a trained non-clinician), absent state mandates.

Home Birth Services

Coverage of a planned home birth may be governed by state mandates.

A planned home birth is an elective alternative to delivery in a birthing center or hospital setting. Coverage of professional fees for a home birth (i.e., elective, planned delivery in the home setting) is subject to the terms, conditions, and limitations of the applicable benefit plan and may be limited based on health care professional certification/licensure requirements.

Cigna covers the professional fee for services provided to a mother eligible for coverage under a Cigna health benefit plan for a home birth, including delivery and immediate medically necessary postpartum care, when services are provided by a health care provider who is acting within the scope of his/her license or certification under the applicable state law.

Cigna does not cover any of the following services associated with a home birth:

- Services provided by an out-of-network provider when out-of-network benefits are not available
- Services at the in-network benefit level, for services provided by an out-of-network health care
 provider (i.e., network exception) when a qualified in-network health care professional who
 provides obstetrical services is available, unless required by state regulations
- Services that are not considered eligible for reimbursement (e.g., other than a health care
 provider who is acting within the scope of that provider's license or certification under the
 applicable state law)
- Duplication of services (e.g., services provided by a licensed physician and licensed certified nurse-midwife simultaneously [i.e., at the same time])
- Services considered not medically necessary (e.g., non-routine maternity services, additional
 prenatal counseling sessions, prenatal evaluation and management services specifically related
 to home birth)
- Items that are excluded or otherwise not covered under the benefit plan (e.g., equipment, supplies [e.g., emergency kits], supplies specifically related to home birth, modifications to the home, standby services [e.g., support personnel])
- Facility charges for the home setting

Moda

Home Births

Eligible professional fees by the Certified Nurse Midwife or Nurse Practitioner Midwife are eligible for coverage. Other home birth expenses are not eligible for reimbursement and are generally excluded by the member's contract. This includes but is not limited to travel, portable hot tubs, supplies, and transportation of equipment, etc.

Regence

Home/birthing center deliveries and postpartum services are subject to this reimbursement policy in the same manner as services performed by physicians and other health care professionals who deliver in the hospital setting.



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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.

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Appendix A. GRADE Table Element Descriptions

| Element | Description |
|-------------------------------|---|
| Balance of benefits and harms | The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. An estimate that is not statistically significant or has a confidence interval crossing a predetermined clinical decision threshold will be downgraded. |
| Quality of evidence | The higher the quality of evidence, the higher the likelihood that a strong recommendation is warranted |
| Resource allocation | The higher the costs of an intervention—that is, the greater the resources consumed in the absence of likely cost offsets—the lower the likelihood that a strong recommendation is warranted |
| Values and preferences | The more values and preferences vary, or the greater the uncertainty in values and preferences, the higher the likelihood that a weak recommendation is warranted |
| Other considerations | Other considerations include issues about the implementation and operationalization of the technology or intervention in health systems and practices within Oregon. |

Strong recommendation

In Favor: The subcommittee concludes that the desirable effects of adherence to a recommendation outweigh the undesirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors.

Against: The subcommittee concludes that the undesirable effects of adherence to a recommendation outweigh the desirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors.

Weak recommendation

In Favor: The subcommittee concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects, considering the balance of benefits and harms, resource allocation, values and preferences and other factors., but further research or additional information could lead to a different conclusion.

Against: The subcommittee concludes that the undesirable effects of adherence to a recommendation probably outweigh the desirable effects, considering the balance of benefits and harms, cost and resource allocation, and values and preferences, but further research or additional information could lead to a different conclusion.

Confidence in estimate rating across studies for the intervention/outcome

Assessment of confidence in estimate includes factors such as risk of bias, precision, directness, consistency and publication bias.

High: The subcommittee is very confident that the true effect lies close to that of the estimate of the effect. Typical sets of studies are RCTs with few or no limitations and the estimate of effect is likely stable.

Moderate: The subcommittee is moderately confident in the estimate of effect: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. Typical sets of studies are RCTs with some limitations or well-performed nonrandomized studies with additional strengths that guard against potential bias and have large estimates of effects.

Low: The subcommittee's confidence in the estimate of effect is limited: The true effect may be substantially different from the estimate of the effect. Typical sets of studies are RCTs with serious limitations or nonrandomized studies without special strengths.

Very low: The subcommittee has very little confidence in the estimate of effect: The true effect is likely to be substantially different from the estimate of effect. Typical sets of studies are nonrandomized studies with serious limitations or inconsistent results across studies.



Appendix B. GRADE Evidence Profile

| | Quality Assessment (Confidence in Estimate of Effect) | | | | | | |
|-------------------|---|-----------------|---------------|--------------|-------------|---------------|---------|
| No. of Studies | Study Design(s) | Risk of Bias | Inconsistency | Indirectness | Imprecision | Other Factors | Quality |
| Mode of De | livery | | | | | | |
| 18 | Observational | Not | Not serious | Serious | Not Serious | | Low |
| | | serious | | | | | ••0 |
| | | | | | | | |
| Perinatal or | Neonatal Morta | ality | | | | | |
| 16 | Observational | Not | Serious | Serious | Serious | | Very |
| | | serious | | | | | Low |
| | | | | | | | •00 |
| Neonatal M | orbidity | | | | | | |
| 20 | Observational | Not | Serious | Serious | Not serious | | Very |
| | | serious | | | | | Low |
| | | | | | | | •00 |
| Maternal Ha | arm | | | | | | |
| 20 | Observational | Not | Serious | Serious | Not serious | | Very |
| | | serious | | | | | Low |
| | | | | | | | •00 |
| Breastfeedi | ng | | | | | | |
| 9 | Observational | Serious | Serious | Serious | Not serious | | Very |
| | | | | | | | Low |
| | | | | | | | •00 |

Appendix C. Methods

Scope Statement

Populations

Pregnant women

Population scoping notes: None

Interventions

Planned out-of-hospital birth (home or birth center)

Intervention exclusions: None

Comparators

Planned birth in a hospital

Outcomes

Critical: Delivery mode (cesarean, operative vaginal delivery, spontaneous vaginal delivery), perinatal mortality, serious neonatal morbidity (e.g., seizures, NICU admission, low Apgar's, hypoxic ischemic encephalopathy, sepsis), serious maternal harm (e.g., postpartum hemorrhage, serious infection, mortality)

Important: Breastfeeding

Considered but not selected for the GRADE table: None

Key Questions

KQ1: What is the comparative effectiveness of planned out-of-hospital birth compared to hospital birth?

KQ2: Does the comparative effectiveness of planned out-of-hospital birth vary by:

- a. Patient characteristics (demographics)
- b. Risk factors (pregnancy or pre-pregnancy) and comorbidities
- c. Setting (including home, out-of-hospital birth center)
- d. Location (U.S. vs. non-U.S.)

KQ3: What are the harms of planned out-of-hospital birth compared to hospital birth?

KQ4: Do the harms of planned out-of-hospital birth vary by:

- a. Patient characteristics (demographics)
- b. Risk factors (pregnancy or pre-pregnancy) and comorbidities
- c. Setting (including home, out-of-hospital birth center)
- d. Location (U.S. vs. non-U.S.)
- e. Provider characteristics

Contextual Questions

CQ1: What do applicable guidelines recommend as standards for consultation and referral or transfer of patients planning out-of-hospital birth?

- a. What conditions require consultation?
- b. What conditions require transfer?

CQ2: What systems factors (e.g., coordination with consultants, hospitals, and emergency transportation) are associated with differential outcomes in out-of-hospital birth?

CQ3: What is the rate of expected transfer to a hospital setting with a planned out-of-hospital birth?

CQ4: What are example coverage criteria from other public and private payers?

Search Strategy

Sources from the previous <u>Coverage Guidance: Planned Out-of-Hospital Birth</u> (2015) were included in this evidence review. Then, a full search of the core sources was conducted to identify systematic reviews, meta-analyses, and technology assessments that met the criteria for the scope described above. Searches of core sources were limited to citations published since 2015.

The following core sources were searched:

- Agency for Healthcare Research and Quality (AHRQ)
- Canadian Agency for Drugs and Technologies in Health (CADTH)
- Cochrane Library (Wiley Online Library)
- Institute for Clinical and Economic Review (ICER)
- Medicaid Evidence-based Decisions Project (MED)
- National Institute for Health and Care Excellence (NICE)
- Tufts Cost-effectiveness Analysis Registry
- Veterans Administration Evidence-based Synthesis Program (ESP)
- Washington State Health Technology Assessment Program

A MEDLINE® search was also conducted to identify systematic reviews, meta-analyses, and technology assessments, randomized controlled trials, and comparative and noncomparative observational studies using the search terms for home births, birth centers, and out-of-hospital births. The search was limited to publications in English published since 2015.

Searches for clinical practice guidelines were limited to those published since 2013. A search for relevant clinical practice guidelines was also conducted using MEDLINE® and the following sources:

- Australian Government National Health and Medical Research Council (NHMRC)
- Canadian Agency for Drugs and Technologies in Health (CADTH)
- Centers for Disease Control and Prevention (CDC), Community Preventive Services
- National Institute for Health and Care Excellence (NICE)
- Scottish Intercollegiate Guidelines Network (SIGN)
- United States Preventive Services Task Force (USPSTF)

• Veterans Administration/Department of Defense (VA/DoD) Clinical Practice Guidelines

Inclusion/Exclusion Criteria

Studies were excluded if they were not published in English, did not address the scope statement, or were study designs other than systematic reviews, meta-analyses, technology assessments, randomized controlled trials, comparative or noncomparative observational studies, or clinical practice guidelines.



Appendix D. Applicable Codes

| CODES | DESCRIPTION |
|------------------|---|
| CPT Codes | |
| 59400 | Routine obstetric care including antepartum care, vaginal delivery (with or without |
| | episiotomy, and/or forceps) and postpartum care |
| 59409 | Vaginal delivery only (with or without episiotomy and/or forceps); |
| 59410 | Vaginal delivery only (with or without episiotomy and/or forceps); including postpartum care |
| 59412 | External cephalic version, with or without tocolysis |
| 59414 | Delivery of placenta (separate procedure) |
| 59425 | Antepartum care only; 4-6 visits |
| 59426 | Antepartum care only; 7 or more visits |
| 59430 | Postpartum care only (separate procedure) |
| 59510 | Routine obstetric care including antepartum care, cesarean delivery, and postpartum care |
| 59514 | Cesarean delivery only; |
| 59514 | Cesarean delivery only; including postpartum care |
| | Subtotal or total hysterectomy after cesarean delivery (List separately in addition to code |
| 59525 | for primary procedure) |
| 59610 | Routine obstetric care including antepartum care, vaginal delivery (with or without |
| | episiotomy, and/or forceps) and postpartum care, after previous cesarean delivery |
| 59612 | Vaginal delivery only, after previous cesarean delivery (with or without episiotomy and/or forceps); |
| 59614 | Vaginal delivery only, after previous cesarean delivery (with or without episiotomy and/or forceps); including postpartum care |
| 59618 | Routine obstetric care including antepartum care, cesarean delivery, and postpartum care, following attempted vaginal delivery after previous cesarean delivery |
| 59620 | Cesarean delivery only, following attempted vaginal delivery after previous cesarean delivery; |
| 59622 | Cesarean delivery only, following attempted vaginal delivery after previous cesarean delivery; including postpartum care |
| HCPCS Cod | les |
| H1000-5 | Prenatal care, at risk assessment |

Note: Inclusion on this list does not guarantee coverage.

Appendix E. Characteristics of Comparative Observational Studies

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|---|--|--|---|
| Bailey, 2017 New Zealand Routinely collected maternity outcome data compiled from Counties-Manukau District Health Board (CMDHB) maternity facilities 2003 to 2010 Poor quality | N = 47,381 Planned Birth Center n = 10,448 Planned Hospital n = 36,933 | Inclusion criteria: Single pregnancy, cephalic presentation, labored spontaneously at ≥37 weeks gestation Exclusion criteria: Previous cesarean delivery, specific indications for a cesarean delivery, pregestational or gestational diabetes, malpresentation, lethal congenital abnormality, multiple pregnancy, intrauterine fetal death before onset of labor, preterm labor, induction of labor | Planned Birth Center (n = 10,448) vs. Planned Hospital (n = 36,933) Parity Nulliparous: 3,438 (32.9%) vs. 11,915 (32.3%) Parity ≥5: 363 (3.5%) vs. 2,149 (5.8%) Maternal age Age <20 years: 1,100 (10.5%) vs. 3,777 (10.2%) Age ≥35 years: 1,436 (13.7%) vs. 4,868 (13.2%) Ethnicity European: 5,086 (48.7%) vs. 4,868 (22.5%) Maori: 3,258 (31.2%) vs. 8,884 (24.1%) Pacific Island: ,1363 (13.0%) vs. 14,029 (38.0%) Other: 926 (7.1%) vs. 5,714 (15.4%) Deprivation score Decile 1-4: 2,510 (24.3%) vs. 4,427 (12.3%) Decile 5-8: 3,230 (31.2%) vs. 7,538 (20.9%) Decile 9-10: 4,603 (44.5%) vs. 24,110 (66.8%) New Zealand Deprivation index based on domicile, using socioeconomic measures from census data, then stratified into deciles |

| Citation, Location,Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|---|---|---|---|
| Birthplace in England Collaborative, 2011 United Kingdom Birthplace April 2008 to April 2010 Good quality | n = 16,840 Planned Freestanding Midwifery Unit n = 11,282 Planned Obstetric Unit n = 19,706 Planned Alongside Midwifery Unit n = 16,710 | Any NHS midwife attendance in part or all of labor, at 37 or more weeks in spontaneous labor Exclusion criteria: Elective cesarean delivery, prior cesarean delivery, preterm labor, multiple gestations, no prenatal care, fetal demise before onset of labor (i.e., stillbirth), presence of any medical or obstetric risk factor listed in the NICE intrapartum care guideline | Planned Home vs. Planned Freestanding Midwifery Unit vs. Planned Alongside Midwifery Unit vs. Planned Obstetric Unit Maternal age (years) <20: 218 (1.3%) vs. 677 (6.0%) vs. 1,069 (6.4%) vs. 1,506 (7.7%) 20−24: 1,706 (10.2%) vs. 2,132 (18.9%) vs. 3,489 (20.9%) vs. 4,251 (21.6%) 25−29: 4,346 (25.9%) vs. 3,267 (29.0%) vs. 5,001 (30.0%) vs. 5,701 (29.0%) 30−34: 5,848 (34.8%) vs. 3,248 (28.8%) vs. 4,582 (27.5%) vs. 5063 (25.7%) 35−39: 4,017 (23.9%) vs. 1,690 (15.0%) vs. 2,232 (13.4%) vs. 2,640 (13.4%) ≥40: 671 (4.0%) vs. 254 (2.3%) vs. 299 (1.8%) vs. 520 (2.6%) Ethnic group White: 15,937 (94.8%) vs. 10,329 (91.6%) vs. 13485 (80.9%) vs. 16068 (81.7%) Indian: 67 (0.4%) vs. 87 (0.8%) vs. 509 (3.1%) vs. 477 (2.4%) Pakistani: 41 (0.2%) vs. 164 (1.5%) vs. 545 (3.3%) vs. 636 (3.2%) Bangladeshi: 14 (0.1%) vs. 147 (1.3%) vs. 130 (0.8%) vs. 297 (1.5%) Black Caribbean: 127 (0.8%) vs. 48 (0.4%) vs. 198 (1.2%) vs. 265 (1.3%) Black African: 112 (0.7%) vs. 94 (0.8%) vs. 520 (3.1%) vs. 670 (3.4%) |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|---|-------|----------------------------------|---|
| | | | Mixed: 280 (1.7%) vs. 124 (1.1%) vs. 293 (1.8%) vs. 328 (1.7%) |
| | | | Other: 241 (1.4%) vs. 284 (2.5%) vs. 993 (6.0%) vs. 938 (4.8%) |
| | | | <u>Understanding of English</u> Fluent: 16,724 (99.5%) vs. 10,927 (97.1%) vs. 15,196 (91.3%) vs. 18,044 (92.3%) Some: 75 (0.4%) vs. 273 (2.4%) vs. 1176 |
| | | | (7.1%) vs. 1,130 (5.8%) None: 15 (0.1%) vs. 55 (0.5%) vs. 274 (1.6%) vs. 380 (1.9%) |
| | | | Marital or partner status |
| | | | Married or living with partner: 16,056 (96.0%) vs. 10,444 (93.6%) vs. 15,014 (91.2%) vs. 17,097 (88.2%) |
| | | | Single or unsupported by partner: 673 (4.0%) vs. 718 (6.4%) vs. 1,453 (8.8%) vs. 2,289 (11.8%) |
| | | | Mean BMI in pregnancy: 24.0 ± 3.7 vs. 24.1 ± 3.7 vs. 24.0 ± 3.8 vs. 24.4 ± 4.0 |
| | | | Mean gestation (completed weeks: 39.8 ± 1.0 vs. 39.8 ± 1.0 vs. 39.8 ± 1.1) |
| | | | <u>Complications per woman</u> 0: 15 757 (94.6%) vs. 10,643 (94.5%) vs. 15,512 (93.1%) vs. 15,794 (80.5%) |
| | | | 1: 847 (5.1%) vs. 572 (5.1%) vs. 1,078 (6.5%) vs. 3345 (17.0%) |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|--|---|---|---|
| | | | ≥2: 51 (0.3%) vs. 50 (0.4%) vs. 78 (0.5%) vs. 490 (2.5%) |
| Bolten et al., 2016 The Netherlands DELIVER (Data EersteLljns VERloskunde) Study 2009 to 2010 Poor quality | N = 3,495 Planned Home n = 2,050 Planned Hospital n = 1,445 | Inclusion criteria: Low-risk women who were in midwife-led care at the onset of labor Exclusion criteria: Women who were transferred to obstetrician-led care during pregnancy, and who received midwife-led care but had a 'medium risk' indication (according to VIL), including a history of postpartum hemorrhage or manual removal of the placenta, and who had prolonged rupture of membranes without contractions | Maternal age <25: 145 (16.7%) vs. 131 (18.3%) 25 to 35: 651 (75.0%) vs. 490 (68.3%) ≥35: 72 (8.3%) vs. 96 (13.4%) Ethnic background Dutch: 785 (90.4%) vs. 540 (75.3%) Non-Dutch Western: 37 (4.3%) vs. 82 (11.4%) |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|--|--|--|--|
| | | | Dutch: 1,030 (87.1%) vs. 532 (73.1%) Non-Dutch Western: 82 (6.9%) vs. 69 (9.5%) Non-Western: 65 (5.5%) vs. 125 (17.2%) |
| | | | Prepregnancy BMI <25: 842 (71.2%) vs. 481 (66.1%) ≥25: 292 (24.7%) vs. 216 (29.7%) |
| | | | Socioeconomic status High: 321 (27.2%) vs. 205 (28.2%) Middle: 581 (49.2%) vs. 325 (44.6%) Low: 277 (23.4%) vs. 194 (26.6%) |
| Christensen & Overgaard, 2017 Denmark | - | Inclusion criteria: Freestanding Midwifery Unit - considered | Planned Birth Center (n = 839) vs. Planned Obstetric Unit (n = 839) |
| Data collected on sociodemographic characteristics, present and previous pregnancies and births, | n = 839 Planned Obstetric Unit n = 839 | low obstetric risk, presented with | Parity |
| neonatal outcomes and transfers March 2004 to October 2008 Poor quality | | group only if they represented a strict | Ethnicity Nordic or Western European: 805 (96%) vs. 809 (96.4%) Other ethnicity: 34 (4.0%) vs. 30 (3.6%) |
| , , | | Exclusion criteria: NR | Education level No postsecondary education 230 (27.4%) vs. 230 (27.4%) |
| | | | Postsecondary education 609 (72.6%) vs. 609 (72.6%) |
| | | | Occupation level |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|--|---|--|--|
| Davies-Tuck et al., 2018 Australia Victorian Perinatal Data Collection 2000 to 2015 Poor quality | N = 833,231 Planned Home n = 3,945 Planned Hospital n = 829,286 <u>High Risk</u> | Inclusion criteria: Women who gave birth from 2000 to 2015 who had planned before the onset of labor to give birth either at home with a midwife or in a hospital, who delivered at or past 37 weeks gestation. | Low level of employment: 535 (63.8%) vs. 535 (63.8%) High level of employment 304 (36.2%) vs. 304 (36.2%) Mean BMI: 24.2 ± 3.9 vs. 24.0 ± 3.9 Mean age: 29.4 ± 4.6 vs. 30.2 ± 4.5 Low risk, Planned Home (n = 3,202) vs. Planned Hospital (n = 701,058) Maternal Age <20: 19 (0.6%) vs. 21,845 (3.1%) 20 to 30: 870 (27.2%) vs. 292,891 (41.8%) ≥30: 2,269 (70.9%) vs. 385,833 (55%) |
| | N = 128,971 Planned Home n = 743 Planned Hospital n = 128,228 | Pregnancies were classified as high or low risk: high risk pregnancy was defined as: a multiple pregnancy, a post-term (> 41 + 6 weeks of gestation) pregnancy, a noncephalic presentation in labor, obesity, a prior cesarean delivery, previous uterine surgery, grand multiparity (≥5 previous births), any significant maternal medical condition such as preexisting diabetes, hypertension, renal, cardiac, liver, respiratory, endocrine, immunological, renal, or gastrointestinal disease | <u>BMI</u> |

| Citation, Location,Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|--|---|----------------------------------|--|
| | presentation in labor, obesity (BMI Class 2 or greater), a prior cesarean, previous uterine surgery, grand multiparity (≥5 previous births), any significant maternal medical condition such as preexisting diabetes, hypertension, renal, cardiac, liver, respiratory, endocrine, immunological, renal, or gastrointestinal disease as determined by individual ICD-10 codes. Low risk defined as absence of any high risk condition. | | 3rd or subsequent birth: 912 (82.5%) vs. 135,181 (19.3%) Index of Relative Social Disadvantage quintile 1 Most Disadvantaged: 365 (11.4%) vs. 130,638 (18.6%) 2: 544 (17.0%) vs. 130,782 (18.7%) 3: 567 (17.7%) vs. 135,146 (19.3%) 4: 740 (21.1%) vs. 132,770 (18.9%) 5 Least Disadvantaged: 846 (26.4%) vs. 132,991 (19.0%) High risk, Planned Home (n = 743) vs. Planne Hospital (n = 128,228) Maternal Age <20: 2 (0.3%) vs. 2,051 (1.6%) 20 to 30: 162 (21.8%) vs. 44,543 (34.7%) ≥30: 573 (77.1%) vs. 81,605 (63.6%) BMI <18.5: 15 (2.0%) vs. 1,310 (1.0%) 18.5 to 24.9: 196 (26.4%) vs. 25,437 (19.8%) 25 to 29.9: 85 (11.4%) vs. 16,288 (12.7%) ≥30: 73 (9.8%) vs. 32,406 (25.3%) Country of Birth Australian/NZ: 606 (81.6%) vs. 87,369 (68.1% Non-Australian: 91 (12.3%) vs. 35,301 (27.5%) Parity |

| Citation, Location,Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|--|---|--|--|
| | | | Second birth: 294 (39.6%) vs. 48,341 (37.7%) 3rd or subsequent birth: 306 (41.2%) vs. 36,829 (28.7%) Index of Relative Social Disadvantage quintile 1 Most Disadvantaged: 84 (11.3%) vs. 29,013 (22.6%) 2: 110 (14.8%) vs. 26,024 (10.3%) 3: 134 (18.0%) vs. 23,966 (18.7%) 4: 177 (23.8%) vs. 21,320 (16.6%) 5 Least Disadvantaged: 176 (23.7%) vs. 19,244 (15.0%) |
| Davis et al., 2012 New Zealand New Zealand College of Midwives research database, managed by the Midwifery Maternity Provider Organisation 2006 to 2007 Fair quality | Planned Home n = 1,830 Planned Primary Unit n = 2,877 Planned Secondary Hospital n = 7,380 Planned Tertiary Hospital n = 4,123 | Inclusion criteria: Low risk - see exclusion criteria Exclusion criteria: Previous cesarean delivery, stillbirth, fetal death before commencement of labor, multiple birth, labor on or before 36 weeks + 6 days or after 41 weeks + 6 days, induced labor, breech or shoulder presentation, transverse lie, and elective cesarean delivery, previous postpartum hemorrhage (>1,000 mL), severe pregnancy-induced hypertension, gestational diabetes, Rh sensitization, ABO incompatibility, essential hypertension, diabetes, thyroid disease, drug or alcohol abuse, heart disease, pulmonary disease/asthma, | Mean age: 30.4 ± 5.4 vs. 27.9 ± 6.0 vs. 27.7 ± 6.0 vs. 29.3 ± 5.9 , p < 0.001 Mean parity: 1.4 ± 1.4 vs. 1.1 ± 1.2 vs. 0.9 ± 1.2 vs. 0.7 ± 1.0 , p < 0.001 Mean length of labor: 5.1 ± 4.8 vs. 6.1 ± 4.8 |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|---|---|--|--|
| | | hematological disorder, neurological disorder, renal/urinary tract disorder, muscular skeletal disorder, consultation with or transfer of care to another practitioner during antenatal period | <u>Proportion of active management</u> : 25.9% vs. 47.1% vs. 73.2% vs. 77.8%, p < 0.001 |
| de Cock et al., 2015 The Netherlands Survey data, DELIVER study September 2009 to April 2011 Poor quality | N = 712 Home: n = 547 Planned hospital- Midwife: n = 165 | Inclusion criteria: Singleton pregnancy, fetus in cephalic presentation, low-risk and in primary care at the onset of labor, started labor spontaneously between 37 and 42 weeks, stated intention to breastfeed prior to birth Exclusion criteria: Previous cesarean delivery, medical or obstetric risk factors that are an indication for secondary care, women who gave birth in hospital under the supervision of an obstetrician, place of birth unknown, child had congenital anomaly, completed questionnaire in the first week postpartum or after six months postpartum | Dutch/other western: 529 (96.9%) vs. 154 (94.5%) Non-western: 17 (3.1%) vs. 9 (5.5%) Education level woman (p = 0.34) Low/medium 203 (37.1%) vs. 68 (41.2%) High 344 (62.9%) vs. 97 58.8%) Education level partner (p = 0.42) Low/medium: 263 (48.5%) vs. 85 (52.1%) High: 279 (51.5%) vs. 78 (47.9%) Age (p = 0.35) |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|---|--|--|--|
| | | | Nulliparous: 172 (31.4%) vs. 60 (36.4%) Parous: 375 (68.6%) vs. 105 (63.6%) |
| de Jonge et al., 2015 The Netherlands Netherlands Perinatal Registry 2000 to 2009 Fair quality | N = 743,070 Planned Home n = 466,112 Planned Hospital- Midwife n = 276,958 | Inclusion criteria: Low-risk women in midwife-led care at the onset of labor, single pregnancy, spontaneous labor at ≥37 weeks gestation, no medical indication for hospital birth Exclusion criteria: Medium-risk women, women who had not received prenatal care, missing national perinatal database-1 form, unknown planned place of birth, prolonged ruptured membranes for more than 24 hours without contractions, an intrauterine death before labor began, a child with a congenital abnormality, gestational age <37 or >42 weeks | Planned Home (n = 466,112) vs. Planned Hospital-Midwife (n = 276,958) Parity Nulliparous: 198,515 (42.5%) vs. 137,168 (49.5%) Parous: 267,526 (57.5%) vs. 139,740 (50.5%) Maternal age <25 years: 44,621 (9.6%) vs. 48,083 (17.4%) 25 to 34 years: 341,617 (73.3%) vs. 181,763 (65.6%) ≥35 years: 79,700 (17.1%) vs. 47,006 (17.0%) Ethnicity Dutch: 423,853 (90.9%) vs. 184,433 (66.6%) Non-Dutch: 38,999 (8.3%) vs. 90,276 (32.6%) Socioeconomic status Low: 113,091 (24.3%) vs. 103,230 (37.3%) Medium: 230,767 (49.5%) vs. 106,461 (38.4%) High: 116,641 (25.0%) vs. 62,635 (22.6%) Missing: 5,542 (1.2%) vs. 4,582 (1.7%) |
| de Jonge, et al., 2013 The Netherlands LEMMoN study merged with Netherlands Perinatal Registry | N = 146,752 Planned Home n = 92,333 | Inclusion criteria: Singleton, cephalic, without medical or obstetric risk factors (e.g., history of prior | Planned Home (n = 92,333) vs. Planned Hospital (n = 54,419) <u>Parity</u> 0: 38,728 (41.9%) vs. 26,499 (48.7%) |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|--|--|--|--|
| August 2004 to August 2006 Fair quality | Planned Hospital n = 54,419 | cesarean delivery), spontaneous onset of labor between 37 and 42 weeks Exclusion criteria: ROM > 24 hours without contractions, "medium risk" history: prior postpartum hemorrhage or retained placenta, unknown planned place of birth | 1+: 53,602 (58.1%) vs. 27,919 (51.3%) Gestational age 37+0 to 37+6: 3,404 (3.7%) vs. 2,296 (4.2%) 38+0 to 40+6: 67,507 (73.1%) vs. 40,256 (74.0%) 41+0 to 41+6: 21,422 (23.2%) vs. 11,867 (21.8%) Maternal age (years) <25: 9,142 (9.9%) vs. 9,407 (17.3%) 25-34: 66,554 (72.1%) vs. 35,137 (64.6%) ≥35: 16,630 (18.0%) vs. 9,868 (18.1%) Ethnicity Dutch: 83,629 (90.9%) vs. 36,126 (66.9%) Non-Dutch: 8,385 (9.1%) vs. 17,904 (33.1%) Socioeconomic position High: 23,243 (25.5%) vs. 12,324 (23.0%) Medium: 45,320 (49.7%) vs. 21,099 (39.4%) Low: 22,671 (24.8%) vs. 20,190 (37.7%) |
| Grigg et al., 2017 New Zealand Maternity and Midwifery Provider Organization data 2010 to 2011 Poor quality | N = 692 PMUs n = 407 TMH n = 285 Freestanding Primary Level Midwife-led Maternity Units (PMUs) vs. Tertiary- level Obstetric-led | Inclusion criteria: All women booked to give birth at birthing centers near Christchurch, New Zealand between March 2010 and August 2011 Exclusion criteria: Previous cesarean delivery, expecting twins, BMI > 40, neurological disorder | Planned Birthing Center (n = 407) vs. Planned Hospital (n = 285) Mean age: 30.8 vs. 32.1 <25: 56 (13.8%) vs. 26 (9.2%) 25 to 29: 127 (31.2%) vs. 67 (23.6%) 30 to 34: 142 (34.9%) vs. 120 (42.3%) ≥35: 83 (20.2%) vs. 71 (25.0%) Median parity: 1 (0.9) vs. 0 (0.5) |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|---|--------------------|----------------------------------|---|
| | Maternity Hospital | | Nulliparous: 167 (41.0%) vs. 157 (54.1%) |
| | (ТМН) | | Ethnicity NZ European: 308 (75.7%) vs. 226 (79.3%) Māori: 30 (7.4%) vs. 6 (2.1%) Other: 69 (17.0%) vs. 53 (18.6%) |
| | | | Smoker: 31 (7.6%) vs. 15 (5.3%) Residence City or semirural: 308 (75.7%) vs. 248 (87.0% Rural or remote rural: 99 (25.3%) vs. 37 (13.0%) |
| | | | Has a partner: 377 (92.4%) vs. 260 (91.6%) BMI <25: 233 (58.7%) vs. 196 (69.3%) 25 to 35: 149 (37.5%) vs. 79 (27.9%) >35: 15 (3.8%) vs. 8 (2.8%) |
| | | | Income <\$25,000 per annum before tax: 20/326 (6.1%) vs. 14/226 (6.2%) \$25,000 to \$50,000: 95/326 (29.1%) vs. 34/226 (15.0%) \$50,000 to \$75,000: 99/326 (30.4%) vs. 70/226 (31.0%) >NZ\$75,000: 112/326 (34.4%) vs. 108/226 |
| | | | (47.8%) Education |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|---|------------------------------------|--|---|
| | | | No post school completed: 67/331 (20.2%) vs. 36/230 (15.7%) Apprenticeship, certificate: 55/331 (16.6%) |
| | | | vs. 32/230 (13.9%) Diploma: 56/331 (16.9%) vs. 41/230 (17.8%) Degree: 153/331 (46.2%) vs. 121/230 (52.6%) |
| Grunebaum, McCullough, Arabin et al., 2017 U.S. | Planned Home n = 95,657 | Inclusion criteria: Liveborn, singleton, term (≥ 37 weeks), birth weight ≥ 2500g, delivered by physician, CNM, or other midwife. | Planned Home (n = 95,657) vs. Planned Hospital-CNM (n = 1,363, 199) vs. Planned Hospital-Physician (n = 14,447,355) |
| CDC-linked birth-infant death data set 2008 to 2012 | n = 1,363,199 Planned Hospital- | Exclusion criteria: Preterm, low birthweight (<2,500g), other | |
| Poor quality | 14 447 255 | deliverer, other location than home or hospital | 728,918 (53.5%) vs. 7,779,467 (53.8%) <u>Nulliparous</u> : 22,773 (23.8%) vs. 540,582 (39.7%) vs. 5,896,748 (40.8%) |
| | | | 41+ weeks: 27,825 (29.1%) vs. 297,534 (20.5%) vs. 2,252,777 (15.6%) |
| | | | Maternal age ≥35: 20,807 (21.8%) vs. 146,339 (10.7%) vs. 2,087,544 (14.4%) |
| Grunebaum, McCullough, Sapra et al., 2017 U.S. | Planned Home n = 96,815 | Inclusion criteria: Term (≥37 weeks), weight ≥2,500 g, singleton, nonanomalous, states using | Planned Home Birth (n = 96, 815) vs. Planned Hospital-CNM (n = 1,077,197) vs. Planned Hospital-Physician (n = 11,779,659) |
| CDC-linked birth-infant death files 2009 to 2013 | n = 1,077,197 Planned Hospital- | the 2003 revised birth certificate Exclusion criteria: Birthplace outside hospital or home, | Maternal ethnicity Non-Hispanic white: 87,253 (90.1%) vs. 577,665 (53.6%) vs. 6,276,662 (53.3%) |
| Fair quality | Physician | unintended home birth, multiple gestations, residents of a foreign country | Black: 1,890 (2.0%) vs. 137,484 (12.8%) vs. 1,539,889 (13.1%) |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|---|---|----------------------------------|--|
| Dates, Quality Assessifient | | | |
| | | | Hispanic: 4,643 (4.8%) vs. 283,687 (26.3%) vs. 3,042,950 (25.8%) |
| | | | Other: 1,614 (1.7%) vs. 71,335 (6.6%) vs. 828,184 (7.0%) |
| | | | Unknown: 1,415 (1.5%) vs. 7,026 (0.7%) vs. 91,974 (0.8%) |
| | | | Maternal age, years |
| | | | <25: 15,294 (15.8%) vs. 390,660 (36.3%) vs. 3,745,494 (31.8%) |
| | | | 25 to 34: 61,409 (63.4%) vs. 567,481 (52.7%) vs. 6,336,325 (53.8%) |
| | | | ≥35: 20,106 (20.8%) vs. 119,030 (11.0%) vs. 1,697,022 (14.4%) |
| | | | Maternal education, years |
| | | | <13: 38,443 (39.7%) vs. 496,538 (46.1%) vs. 4,998,057 (42.4%) |
| | | | ≥13: 57,729 (59.6%) vs. 566,134 (52.6%) vs. 6,642,060 (56.4%) |
| | | | Prenatal visits, n |
| | | | 0: 2,652 (2.7%) vs. 8,839 (0.8%) vs. 145,689 (1.2%) |
| | | | 1-5: 13,255 (13.7%) vs. 49,372 (5.6%) vs. 519,504 (4.4%) |
| | | | ≥6: 79,765 (82.4%) vs. 973,834 (90.4%) vs. 10,679,376 (90.7%) |
| | | | <u>Insurance</u> |
| | | | Private: 12,174 (12.6%) vs. 294,262 (27.3%) vs. 3,464,544 (29.4%) |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|---|---|----------------------------------|---|
| | | | Government: 6,145 (6.3%) vs. 319,590 |
| | | | (29.7%) vs. 3,337,667 (28.3%) |
| | | | Self-pay/other: 42,808 (44.2%) vs. 47,071 (4.4%) vs. 423,746 (3.6%) |
| | | | Unknown: 3,055 (3.2%) vs. 12,945 (1.2%) vs. 89,663 (0.8%) |
| | | | Not reported: 32,633 (33.7%) vs. 89,663 (0.8%) vs. 4,464,039 (37.9%) |
| | | | <u>Parity</u> |
| | | | Nulliparous: 20,125 (20.8%) vs. 424,060 (39.4%) vs. 4,756,609 (40.4%) |
| | | | Parous: 75,809 (78.3%) vs. 641,625 (59.6%) vs. 6,952,531 (59.0%) |
| | | | Unknown: 881 (0.9%) vs. 11,512 (1.1%) vs. 70,519 (0.6%) |
| | | | Previous cesarean delivery |
| | | | No: 92,199 (95.2%) vs. 1,048,436 (97.3%) vs. 9,961,948 (84.6%) |
| | | | Yes: 4,273 (4.4%) vs. 22,176 (2.1%) vs. 1,782,055 (15.1%) |
| | | | Unknown: 343 (0.4%) vs. 6,585 (0.6%) vs. 35,656 (0.3%) |
| | | | Newborn weight, g |
| | | | 2,500 to 3,900: 76,428 (78.9%) vs. 982,994 (91.3%) vs. 10,744,142 (92.2%) |
| | | | ≥ 4,000: 20,387 (21.1%) vs. 94,203 (8.7%) vs. 1,035,517 (8.8%) |
| | | | Gestational age (week) |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|---|--------------|---|---|
| | | | 37-38: 14,205 (14.7%) vs. 256,151 (23.8%) vs. 3,341,327 (28.4%) |
| | | | 39-40: 54,232 (56.0%) vs. 606,165 (56.3%) vs. 6,645,173 (56.4%) |
| | | | ≥41: 28,378 (29.3%) vs. 214,881 (19.9%) vs. 1,793,159 (15.2%) |
| | | | <u>Presentation</u> Cephalic: 93,462 (96.5%) vs. 1,036,683 (96.2%) vs. 10,977,624 (93.2%) |
| | | | Breech: 553 (0.6%) vs. 1,921 (0.2%) vs. 300,204 (2.5%) |
| | | | Other: 470 (0.5%) vs. 11,189 (1.0%) vs. 259,162 (2.2%) |
| | | | Unknown: 2,330 (2.4%) vs. 27,404 (2.5%) vs. 242,669 (2.1%) |
| | | | Risk composite |
| | | | No risk present: 37,286 (38.5%) vs. 414,744 (38.5%) vs. 3,464,701 (29.4%) |
| | | | Any risk present: 57,831 (59.7%) vs.637,530 (59.2%) vs. 8,124,803 (69.0%) |
| | | | Unknown: 1,698 (1.8%) vs. 24,923 (2.3%) vs. 190,155 (1.6%) |
| Halfdansdottir et al., 2018 | N = 1,228 | Inclusion criteria: | <u>Overall</u> |
| Iceland Maternity notes review | N = 1 129 | Women who intended to give birth at a home under the care of a midwife in Iceland before the onset of labor in 2005 | <u>Mean age</u> : 30.3 ± 4.7 < 25: 136 (11.1%) |
| 2005 to 2009 Poor quality | Planned Home | to 2009, and hospital births matched on | 25 to 34: 857 (69.8%) ≥35: 235 (19.1%) |

| Citation, Location,Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|--|---|--|---|
| | Planned Hospital n = 851 <u>High Risk</u> N = 99 Planned Home n = 29 | risks, and year of birth to similar hospital births Exclusion criteria: Hospital births that did not meet the criteria for home birth, unless matched on specific risk to a contraindicated home birth | Residence Capital (all ≤ 20 min): 931 (75.8%) Rural ≤ 20 min: 196 (16.0%) Rural > 20 min: 101 (8.2%) Marital status |
| | | | 25 to 29.99: 356 (30.0%) ≥30: 156 (13.1%) Maternal smoking: 35 (2.9%) Place of birth |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|--|---|--|--|
| Halfdansdottir et al., 2015 Iceland Review of midwives' and doctors' original hand-written maternity notes 2005 to 2009 Poor quality | N = 1,228 Planned Home n = 307 Planned Hospital n = 921 | Inclusion criteria: All planned home births accepted for midwifery care in Iceland at the onset of labor in 2005–2009, and births in a hospital or alongside midwifery unit matched on matched on parity (primipara vs. multipara); contraindications (if present in the home birth); residence (capital vs. rural, by transfer time to hospital); maternal age (±2 years); and year of birth (next in chronological order) Exclusion criteria: Unplanned and unattended home births, births in a hospital or midwifery unit that were not matched to the include home birth cases, women with any of 67 predefined contraindications (supporting information), based on the Directorate of Health's guidelines for home births, were excluded when matching low-risk home births without contraindications | 25 to 34: 202 (65.8%) vs. 655 (71.1%) ≥35: 72 (23.5%) vs. 163 (17.7%), p = 0.084 Marital status Married: 143 (46.6%) vs. 362 (39.3%) Cohabiting: 156 (50.8%) vs. 494 (53.7%) Single: 8 (2.6%) vs. 64 (7.0%) Occupation Specialist: 170 (59.4%) vs. 399 (54.7%) Semispecialist: 89 (31.1%) vs. 215 (29.5%) Nonspecialist: 27 (9.4%) 115 vs. (15.8%) |
| | | | <u>Parity</u> Primipara: 64 (20.8%) vs. 192 (20.8%) |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|--|---|----------------------------------|---|
| | | | Multipara: 243 (79.2%) vs. 729 (79.2%) |
| | | | Previous home births |
| | | | No: 235 (77.0%) vs. 920 (100.0%) |
| | | | Yes: 70 (23.0%) vs. 0 (0.0%) |
| | | | Previous instrumental births |
| | | | No: 275 (90.2%) vs. 813 (88.4%) |
| | | | Yes: 30 (9.8%) vs. 107 (11.6%) |
| | | | BMI |
| | | | <25: 171 (59.2%) vs. 505 (56.2%) |
| | | | 25 to 29.99: 88 (30.4%) vs. 268 (29.8%) |
| | | | ≥30: 30 (10.4%) vs. 126 (14.0%) |
| | | | Smoking |
| | | | No: 294 (97.0%) vs. 895 (97.2%) |
| | | | Little: 9 (3.0%) vs. 26 (2.8%) |
| | | | Mental health problems |
| | | | No: 290 (94.5%) vs. 885 (96.1%) |
| | | | Yes: 17 (5.5%) vs. 36 (3.9%) |
| | | | <u>Contraindications</u> |
| | | | No: 278 (90.6%) vs. 851 (92.4%) |
| | | | Yes: 29 (9.4%) vs. 70 (7.6%) |
| | | | Contraindications: hypertensive disorders; |
| | | | previous cesarean delivery; isoimmunization; |
| | | | prolonged pregnancy; hyperthyroidism; |
| | | | bipolar affective disorder; abnormal findings on antenatal screening; macrosomia or |
| | | | anticipated maternal–fetal disproportion; |
| | | | BMI >35 or <18 |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|---|--|---|--|
| Good quanty | N = 3455 Planned Home n = 1086 Planned Birth Center n = 1668 Planned Hospital n = 701 | Inclusion criteria: Term (≥ 37 weeks) starting labor under care of a community midwife Exclusion criteria: Any woman with a medium-risk or higher condition on the List of Obstetric Indications. Any woman with no specific planned place of birth at one set of labor | Planned Home (n = 1086) vs. Planned Birth Center (n = 1668) vs. Planned Hospital (n = 701) (Birth center reference group) Maternal background Dutch: 1035 (95.3%) vs. 1274 (76.4%) vs. 531 (75.7%) Non-Dutch: 51 (4.7%) vs. 394 (23.6%) vs. 170 (24.3%) Socioeconomic status Low: 53 (4.9%) vs. 244 (14.6%) vs. 80 (11.4%) Medium: 888 (81.8%) vs. 1113 (66.7%) vs. 482 (68.8%) High: 136 (12.5%) vs. 278 (16.6%) vs. 109 (15.5%) |
| Poor quality | N = 990 Planned Home n = 350 Planned Birth Center n = 263 Planned Hospital- Midwife n = 262 Planned Hospital- Obstetrician n = 115 | Inclusion criteria: Postpartum women under the care of community midwives in 82 randomly recruited midwifery practices between August 1 and December 31, 2013 | Planned Home (n = 350) vs. Planned Birth Center (n = 263) vs. Planned Hospital-Midwife (n = 262) vs. Hospital-Obstetrician (n = 115) Age ≤25: 21 (6.5%) vs. 12 (4.6%) vs. 14 (5.8%) vs. 3 (2.7%) 26 to 35: 238 (73.2%) vs. 195 (75.0%) vs. 174 (72.5%) vs. 76 (69.1%) ≥36: 66 (20.3%) vs. 53 (20.4%) vs. 52 (21.7%) vs. 31 (28.2%) Parity Primiparous: 126 (38.0%) vs. 154 (58.8%) vs. 113 (46.5%) vs. 47 (42.3%) |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|--|---|--|---|
| | | | Multiparous: 206 (62.0%) vs. 108 (41.2%) vs. 130 (53.5%) vs. 64 (57.7%) |
| | | | Education Low: 26 (8.0%) vs. 16 (6.1%) vs. 14 (6.0%) vs. 10 (9.4%) Middle: 120 (36.9%) vs. 64 (24.4%) vs. 72 (30.9%) vs. 35 (33.0%) High: 179 (55.1%) vs. 182 (69.5%) vs. 147 (63.1%) vs. 61 (57.5%) |
| | | | Ethnicity Dutch: 312 (96.3%) vs. 247 (93.9%) vs. 203 (84.6%) vs. 93 (85.3%) Non-Dutch: 12 (3.7%) vs. 16 (6.1%) vs. 37 (15.4%) vs. 16 (14.7%) |
| Hollowell et al., 2017 England Birthplace in England national prospective cohort study April 2008 to April 2010 Fair quality | Planned Birthing Center n = 11,265 Planned Hospital n = 16,673 | Inclusion criteria: Low-risk single pregnancy, received prenatal care from an NHS midwife, not known to have any medical or obstetric risk factors Exclusion criteria: Presented with labor <37 weeks, no prenatal care, experienced stillbirth prior to onset of labor | Planned Birthing Center (n = 11,265) vs. Planned Hospital (n = 16,673) Parity Nulliparous: 5,187 (46.0%) vs. 8,350 (50.1%) Multiparous: 6,078 (54.0%) vs. 8,323 (49.9%) Maternal age < 20 years: 676 (6%) vs. 1,054 (6%) 20 to 24 years: 2,129 (19%) vs. 3,208 (19%) 25-29 years: 3,258 (29%) vs. 4,994 (30%) 30-34 years: 3,244 (29%) vs. 4,574 (27%) 35 to 39 years: 1,690 (15%) vs. 2,227 (13%) 40+: 254 (2%) vs. 298 (2%) |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|--|---|--|---|
| | | | BMI 10 to 18.4: 234 (2.1%) vs. 437 (2.6%) 18.5 to 24.9: 5,596 (50%) vs. 8,202 (49.2%) 25.0 to 29.9: 2,648 (23.5%) vs. 3,784 (22.7%) 30.0 to 35.0: 911 (8.1%) vs. 1,269 (7.6%) Not Recorded: 1,861 (16.5%) vs. 2,915 (17.5%) |
| Homer et al., 2014 Australia Perinatal Data Collection, Admitted Patient Data Collection, Register of Congenital Conditions, Registry of Birth Deaths and Marriages, and the Australian Bureau of Statistics 2000 to 2008 Fair quality | N = 258,161 Planned Home n = 742 Planned Birth Center n = 14,483 Planned Hospital n = 242,936 | Inclusion criteria: Women who gave birth to a singleton baby in a cephalic presentation following spontaneous labor at >37 weeks gestation from July 1, 2000, up to and including June 30, 2008 Exclusion criteria: Women who had an elective cesarean delivery, the baby was born before arrival to hospital, the birth occurred before 37 completed weeks gestation, had received no antenatal care, were attempting a vaginal birth after previous cesarean delivery (VBAC) for this birth, the baby was diagnosed with a congenital abnormality (that is, registered on the NSW Register of Congenital Conditions), had labor induced for any reason, or had a baby who had received a diagnosis (as recorded on the birth and subsequent admission data on the Admitted Patient Data Collection) of a congenital condition | 20 to 24: 240 (22 6%) vs. 4 788 (22 1%) vs. |

| Citation, Location,Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|--|--|--|--|
| | | and who died within the first week of life resulted in that woman and baby pair being excluded from the cohort | ≥3: 59 (8.0%) vs. 552 (3.8%) vs. 14,259 (5.9%) |
| Hutton et al., 2016 Ontario, Canada Chart review March 2016 to April 2009 Poor quality | N = 22,986 Planned Home n = 11,493 Planned Hospital n = 11,493 | Inclusion criteria: Term (≥ 37 weeks), single prior cesarean delivery Exclusion criteria: Alcohol or drug dependency, chronic hypertension, diabetes, heart condition, hepatitis B, HIV, isoimmunization, anemia unresponsive to treatment, antepartum bleeding, eclampsia, gestational diabetes, IUGR, SGA, oligohydramnios, pregnancyinduced hypertension, preterm delivery (<37 weeks), breech presentation, multiple gestations, medical induction (oxytocin or prostaglandin), lethal congenital anomaly | <u>Parity</u> |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|--|--|---|--|
| Hutton et al., 2009 Canada Ontario Ministry of Health database 2003 to 2006 Poor quality | N = 13,384 Planned Home n = 6,692 Planned Hospital n = 6,692 | Inclusion criteria: Midwife-attended births that occurred between April 1, 2003, and March 31, 2006 who planned a home birth at the outset of labor, and a comparable lowrisk group of women who planned a hospital birth at the outset of labor, and groups were matched with respect to parity and previous lower segment cesarean delivery | Planned Home (n = 6,692) vs. Planned Hospital Midwife (n = 6,692) Age <25: 729 (10.9%) vs. 844 (12.6%) 25 to 34: 4,428 (66.1%) vs. 4,630 (69.2%) ≥35: 1,503 (22.5%) vs. 1,199 (17.9%) Parity 0: 2,293 (34.3%) vs. 2,298 (34.3%) 1 to 4: 4,172 (62.3%) vs. 4,289 (64.1%) >4: 221 (3.3%) vs. 105 (1.6%) Previous cesarean delivery 0: 6,479 (96.8%) vs. 6,485 (96.9%) 1: 200 (3.0%) vs. 207 (3.1%) >1: 6 (0.1%) vs. 0 (0%) |
| Janssen et al., 2009 British Columbia, Canada Perinatal Database Registry and vital statistics 2000 to 2004 Poor quality | N = 12,982 Planned Home n = 2,889 Planned Hospital- Midwife n = 4,752 Matched Sample of Physician-attended Hospital Births n = 5,331 | Inclusion criteria: Planned home birth - Singleton fetus, cephalic presentation, gestational age greater than 36 and less than 41 completed weeks, no more than 1 previous cesarean delivery, labor is spontaneous or induced on an outpatient basis, absence of significant preexisting disease (including heart disease, hypertensive chronic renal disease or type 1 diabetes), absence of significant disease arising during pregnancy (including pregnancy-induced hypertension with proteinuria, | Planned Home (n = 2,889) vs. Planned Hospital-Midwife (n = 4,752) vs. Matched Sample of Physician-attended Hospital Births (n = 5,331) Age 15 to 19: 48 (1.7%%) vs. 116 (2.4%) vs. 92 (1.7%) 20 to 24: 336 (11.6%) vs. 584 (12.3%) vs. 629 (11.8%) 25 to 29: 892 (30.8%) vs. 1,371 (28.9%) vs. 1,644 (30.8%) 30 to 34: 1,025 (35.4%) vs. 1,682 (35.4%) vs. 1,883 (35.3%) |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|---|---|----------------------------------|--|
| | | | ≥ 35: 598 (20.6%) vs. 999 (21.0%) vs. 1,083 (20.3%) Nulliparous: 1,215 (41.9%) vs. 2,428 (51.1%) vs. 2,204 (41.3%) Mean gestational age at first prenatal contact: 12.2 ± 7.0 vs. 12.2 ± 6.8 vs. 11.8 ± 5.9 Mean number of antenatal visits: 11.8 ± 3.3 vs. 11.2 ± 3.6 vs. 9.3 ± 2.7 Mean BMI: 22.8 ± 4.0 vs. 23.3 ± 4.3 vs. 23.2 ± 4.3 Single parent: 91 (3.1%) vs. 252 (5.3%) vs. 163 |
| | | | 4,633 (86.9%) Income quintile 1 (lowest): 650 (23.4%) vs. 906 (19.8%) vs. 1,088 (21.1%) |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|---|--|---|--|
| Katoaka et al., 2018 Japan Review of medical records Birth centers: 2001 to 2006, one hospital: 2004 to 2006, other hospital: 2008 Poor quality | Planned Birth Center n = 5,379 Planned Hospital n = 4,209 | Inclusion criteria: Vaginal delivery, gestation at ≥22 weeks, singleton, and cephalic presentation Exclusion criteria: Transportation to other facilities, cesarean delivery, and twin pregnancies | 2: 593 (21.3%) vs. 910 (19.9%) vs. 1,163 (22.6%) 3: 525 (18.9%) vs. 913 (20.0%) vs. 1,006 (19.5%) 4: 543 (19.5%) vs. 984 (21.5%) vs. 1,020 (19.8%) 5 (highest): 460 (16.5%) vs. 862 (18.8%) vs. 875 (17.0%) Planned Birth Center (n = 5,379) vs. Planned Hospital (n = 4,209) Age <20: 20 (0.4%) vs. 20 (0.5%) 20 to 29: 1,537 (28.7%) vs. 1,273 (30.3%) 30 to 39: 3,669 (68.6%) vs. 2,762 (65.7%) ≥40: 122 (2.3%) vs. 147 (3.5%) Parity 0: 1,579 (29.4%) vs. 2,675 (63.6%) 1: 2,345 (43.6%) vs. 1,235 (29.3%) 2: 1,132 (21.0%) vs. 252 (6.0%) 3: 246 (4.6%) vs. 42 (1.0%) ≥4: 77 (1.4%) vs. 5 (0.1%) |
| Kennare et al., 2010 Australia Pregnancy Outcome Unit of South Australia Health perinatal data for all births and data on perinatal deaths | Planned Home n = 1,141 Planned Hospital n = 297,192 | Inclusion criteria: Live births and stillbirths of at least 400 g birthweight or 20 weeks' gestation Exclusion criteria: No antenatal care, termination of pregnancy | Planned Home (n = 1,141) vs. Planned Hospital (n = 297,192) <u>Mean age</u> : 31.3 ± 5.5 vs. 29.2 ± 5.5 <u>Nulliparous</u> : NR (31.2%) vs. NR (41.0%), p < 0.001) |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|---|--|--|---|
| 1991 to 2006 Poor quality | | | Indigenous: NR (1.0%) vs. NR (2.2%), p = 0.003 Live in the metropolitan area: NR (79.8%) vs. NR (76.0%), p = 0.003) Post-term pregnancies (42 weeks' gestation): NR (3.8%) vs. NR (1.2%), p < 0.001 |
| Laws et al., 2014 Australia Registry of Births, Deaths, and Marriages, Midwives Data Collection, Admitted Patient Data Collection 2001 to 2009 Poor quality | Planned Birth Center n = 15,742 Planned Hospital n = 66,190 | Inclusion criteria: All women intending to give birth in birth centers, to singleton babies at 37 or more weeks' gestation, with a spontaneous onset of labor, born between January 1, 2001, and December 31, 2009, plus 66,190 women intending to give birth in the co-located hospitals during the same period | |

| Citation, Location,Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|---|--|---|--|
| | | | Multiparous: 6,048 (38.4%) vs. 25,428 (38.4%) |
| | | | Smoke during pregnancy: 1,440 (9.1%) vs. 8,959 (13.5%) |
| Li et al., 2017 South Carolina Birth certificates 1996 to 2013 Poor quality | N = 948,343 2004 to 2013 n = 550,239 1996 to 2003 n = 398,104 Planned Home n = 2,562 Planned Birth Center n = 1,274 Planned Clinic n = 22 Planned Hospital n = 944,299 | Inclusion criteria: Live births born from 1996 to 2013 (of at least 20 weeks of gestation and 500 g birthweight) with linked datasets, including birth certificates and death certificates, statewide hospital discharge abstracts for inpatient and emergency room visits, and Medicaid claims data for both inpatient and outpatient visits and physician office visits in South Carolina Exclusion criteria: NR | NR |
| Li et al., 2015 United Kingdom Birthplace national prospective cohort study April 2008 to April 2010 Good quality | N = 8,180 higher risk Planned Home n = 1,489 Planned Hospital (i.e., obstetric unit) n = 6,691 n = 16,619 "low risk" women | Inclusion criteria: Birthplace cohort limited to "those with specified medical or obstetric risk factors known prior to the onset of labor or with post-term pregnancies (gestational age 42+1 weeks or more)" Exclusion criteria: Planned induction of labor | Patient characteristics stratified by nulliparous and parous women, then by planned home and planned obstetric unit. See table 1 in original study for details. Medical and obstetrics risk factors known prior to onset of labor Nulliparous- Planned Home (n = 288) vs. Planned Hospital (n = 2,524) Confirmed cardiac disease: 5 (1.54%) vs. 49 (2.00%) |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|--|---|----------------------------------|---|
| | | | <u>Hypertensive disorders</u> : 7 (2.17%) vs. 225 (8.59%) |
| | | | <u>Asthma</u> : 9 (3.55%) vs. 64 (2.40%) |
| | | | Group B strep: 22 (7.43%) vs. 337 (13.07%) |
| | | | Hyperthyroidism: 12 (4.14%) vs. 45 (1.72%) |
| | | | <u>Diabetes</u> : 1 (0.27%) vs. 89 (3.62%) |
| | | | Epilepsy: 3 (0.67%) vs. 60 (2.27%) |
| | | | 'Other' medical: 20 (7.84%) vs. 78 (3.10%) |
| | | | Any medical: 108 (37.93%) vs. 1102 (43.29%) |
| | | | <u>Current pregnancy</u> |
| | | | Pre-eclampsia or pregnancy-induced hypertension: 6 (2.37%) vs. 369 (14.60%) |
| | | | <u>Gestational diabetes</u> : 8 (2.63%) vs. 119 (4.68%) |
| | | | BMI at booking >35 kg/m ² : 70 (24.60%) vs. 557 (22.24%) |
| | | | Post-term (42+1–44 weeks): 78 (26.80%) vs. 198 (8.20%) |
| | | | Small for gestational age: 5 (1.67%) vs. 107 (4.11%) |
| | | | <u>'Other' obstetric/fetal</u> : 15 (4.62%) vs. 120 (4.84%) |
| | | | Any obstetric/fetal: 187 (64.36%) vs. 1570 (62.64%) |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|---|----------------------|--|---|
| Dates, Quality rissessificate | | | Current pregnancy |
| | | | Pre-eclampsia or pregnancy-induced hypertension: 16 (1.20%) vs. 176 (4.13%) |
| | | | <u>Gestational diabetes</u> : 175 (4.33%) vs. 33 (3.14%) |
| | | | BMI at booking >35 kg/m ² : 828 (19.48%) vs. 314 (26.23%) |
| | | | Post-term (42+1–44 weeks): 132 (3.11%) vs. 114 (8.92%) |
| | | | Small for gestational age: 136 (2.96%) vs. 18 (1.58%) |
| | | | 'Other' obstetric/fetal: 143 (3.55%) vs. 78 (6.56%) |
| | | | Any obstetric/fetal: 3213 (77.44%) vs. 936 (78.93%) |
| | | | Medical and obstetric/fetal risk factors per women |
| | | | 1: 1,079 (90.23%) vs. 3,415 (82.00%) 2+: 122 (9.77%) vs. 752 (18.00%) |
| Li et al., 2014 | N = 63,371 | Inclusion criteria: | Previously described in Birthplace, 2011 |
| United Kingdom | 16 to 19 n = 3354 | Age 16 year and older, 37 and 0 weeks to | |
| Birthplace | 20 to 24 n = 11,395 | 42 and 0 weeks gestation, parity less than | |
| April 2008 to April 2010 | 25 to 29 n = 18,091 | 6, "low-risk" | |
| Good quality | 30 to 34 n = 18,453 | Exclusion criteria: | |
| | 35 to 39 n = 10,397 | elective cesarean delivery or cesarean | |
| | 40 and over n =1,681 | delivery before onset of labor, presented in preterm labor (<37 weeks' gestation), | |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|--|---|---|--|
| | | multiple pregnancy, unplanned home birth, received no antenatal care | |
| MacDorman & Declercq, 2016 U.S. Birth certificates in 47 states and DC 2004 to 2014 Poor quality | Planned Home n = 29,021 Planned Birthing Center n = 18,047 Planned Hospital n = 3,773,115 | Inclusion criteria: Births in states that had implemented the revised birth certificate Exclusion criteria: NR | Planned Home (n = 29,021) vs. Planned Birthing Center (n = 18,047) vs. Planned Hospital (n = 3,773,115) Not all states report on every population characteristic Pre-pregnancy BMI < 18.5: 4.3% vs. 4.4% vs. 3.8% 18.5 to 24.9: 62.9% vs. 61.9% vs. 45.6% 25.0 to 29.9: 21.2% vs. 21.9% vs. 25.6% 30+: 11.6% vs. 11.8% vs. 25.0% Smoked during pregnancy: 0.9% vs. 1.3% vs. 8.5% First live birth: 20.5% vs. 36.1% vs. 39.2% Percent VBAC: 4.6% vs. 1.6% vs. 1.6% Maternal education Less than high school diploma: 22.8% vs. 13.8 vs. 15.1% High school diploma: 13.0% vs. 11.9% vs. 25.3% Some college: 26.5% vs. 27.8% vs. 29.6% Bachelor's degree: 26.4% vs. 31.2% vs. 19.0% Master's degree or higher: 11.2% vs. 15.3% vs. 11.0% |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|---|---|--|--|
| | | | Prenatal care: |
| | | | Began during first trimester: 54.3% vs. 66.9% vs. 76.9% |
| | | | Began during second trimester: 34.4% vs. 27.0% vs. 17.2% |
| | | | Late or no prenatal care: 11.4% vs. 6.0% vs. 5.9% |
| | | | Receipt of WIC food: 8.2% vs. 11.8% vs. 44.2% |
| | | | Method of payment for this delivery: Medicaid: 8.5% vs. 18.4% vs. 44.2% Private insurance: 19.7% vs. 47.0% vs. 48.0% Self-pay: 67.1% vs. 31.9% vs. 3.4% |
| | | | Other: 4.7% vs. 2.6% vs. 4.4% |
| | | | Attendant at birth: Physician: 0.9% vs. 3.1% vs. 91.5% CNM/CM: 28.1% vs. 53.6% vs. 8.0% Other midwife: 49.6% vs. 39.0% vs. 0.2% Other: 21.5% vs. 4.3% vs. 0.4% |
| Monk et al., 2014 Australia | N = 3,651 Planned Birth Center n | Inclusion criteria: All women booked to give birth at the | Planned Birth Center (n = 494) vs. Planned Tertiary Maternity Unit (n = 3,157) |
| ObstetriX surveillance system of | | freestanding midwifery units were | Mean age: 29.6 vs. 28.5 |
| point-of-care maternity data collection across the antenatal, | i idiliica icitialy | considered low risk and were included in the study, regardless of their specific | Median parity: 1 (0.9) vs. 1 (1.0) |
| intrapartum, and immediate | , | ACM risk classification | Nulliparous: 208 (42.1%) vs. 1,364 (43.2%) |
| postnatal periods 2005 to 2006 | | Exclusion criteria: NR | Ethnicity African: 5 (1.0%) vs. 40 (1.3%) |
| Fair quality | | | |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|---|---|--|---|
| | | | Asian: 100 (20.2%) vs. 140 (4.4%) European: 27 (5.5%) vs. 92 (2.9%) Oceania: 350 (70.9%) vs. 2,856 (90.5%) Aboriginal/Torres Strait Islander: 12 (3.4%) vs. 165 (5.8%) South American: 4 (0.8%) vs. 5 (0.2%) North American: 7 (1.4%) vs. 20 (0.6%) Smoker: 27 (5.5%) vs. 546 (17.3%) Risk level at booking B/C or C: 27 (5.5) vs. 0 (0%) Risk level at labor B/C or C: 65 (13.2%) vs. 598 (18.9%) Previous cesarean delivery: 2 (0.4%) vs. 430 (13.6%) |
| Nove et al., 2012 United Kingdom St Mary's Maternity Information System 1988 to 2000 Fair quality | N = 273,872 Planned Home n = 5,998 Planned Hospital n = 267,874 | Inclusion criteria: Pregnancy ended in live birth or stillbirth Exclusion criteria: Elective Cesarean delivery, medical induction, gestation < 37 weeks, high-risk pregnancy, unplanned home birth, unattended in labor, baby of indeterminate sex | Combined N = 273,872 Pregnancy risk status Medium: 73,862 (27%) Low: 200,010 (73%) Parity Primipara: 125,963 (46%) Multipara: 147,909 (54%) Mother's age at delivery <20: 13,881 (5%) 20 to 24: 51,640 (20%) 25 to 29: 93,757 (34%) |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|---|---|--|--|
| | | | 30 to 34: 81,332 (30%) 35 to 39: 29,031 (11%) 40+: 4,231 (2%) |
| | | | Mother's ethnic group Black African: 7,516 (3%) Black Caribbean: 6,587 (2%) Mediterranean: 6,808 (3%) Asian: 39,024 (14%) White European: 195,498 (71%) Other: 11,064 (4%) |
| | | | Pregnancy risk status based on a 2007 clinical guideline from the National Institute for Health and Clinical Excellence |
| Øian et al., 2018 Norway Medical Birth Registry with supplementary data collection January 2008 to December 2010 Poor quality | Births in Midwife-led Birth Units, Planned n = 2,298 Births Planned for Midwife-led Birth | Inclusion Criteria: Planned Birth Center Births - Planned births in midwife-led birth units between 2008 and 2010 Planned Low-Risk Hospital Births - Infants born after 36 weeks gestation Exclusion Criteria: | Births in Midwife-Led Birth Centers, Planned (n = 2,298) vs. Births Planned for a Midwife-led Birth Unit, Took Place Elsewhere (n = 220) vs. Births in Hospital, Low Risk (n = 105,358) Parity Nulliparous: 225 (14.5%) vs. 90 (50.6%) vs. 45,700 (43.4%) |
| | Births in Hospital, Low Risk n = 105,358 | Planned Birth Center Births - NR Planned Low-Risk Hospital Births - planned cesarean deliveries, deliveries that were induced, women with chronic diseases such as hypertension, kidney disease, rheumatoid arthritis or heart disease; had suffered pregnancy | Multiparous: 1,332 (85.5%) vs. 88 (49.4%) vs. 59,658 (56.6%) Presentation Normal, Vertex: 1,470 (94.4%) vs. 150 (84.3%) vs. 98,182 (93.2%) Breech: 19 (1.2%) vs. 6 (3.4%) vs. 1,929 (1.8%) |

| Citation, Location,Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|---|---|--|---|
| | | complications such as gestational diabetes and hypertensive complaints | Other: 67 (4.3%) vs. 22 (12.4%) vs. 5,229 (5.0%) Missing Data: 1 (.0%) vs. 0 vs. 18 (0%) |
| Quigley et al., 2016 Ireland and United Kingdom Growing Up in Ireland study, 2008 to 2009 United Kingdom Millennium Cohort Study, 2001 to 2002 Fair quality | N = 28,125 Ireland: n = 10,604, Planned Home (n = 157), Planned Hospital (n = 10,447) United Kingdom: n = 17,521, Planned Home (n = 340), Planned Hospital (n = 17,181) | Inclusion criteria: Ireland: Mother-infant pairs, born between December 2007 and May 2008 United Kingdom: Mother-infant pairs, born between 2000 and 2001 Exclusion criteria: NR | Ireland (n = 10,604) vs. United Kingdom (n = 17,521) Place of birth Home: 157 (1.0%) vs. 340 (2.0%) Hospital: 10,447 (99%) vs. 17,181 (98%) Parity Primiparous: 4,312 (41%) vs. 8,596 (49%) Multiparous: 6,292 (59%) vs. 8,975 (51%) Maternal age < 30 years: 3,453 (33%) vs. 9,762 (56%) 30 to 35 years: 3,662 (35%) vs. 5,042 (27%) ≥ 35 years: 3,489 (33%) vs. 2,764 (16%) Socioeconomic status Never worked: 1,193 (11%) vs. 2,114 (12%) Manager/Professional: 5,172 (49%) vs. 4,556 (26%) BMI < 25: 5,496 (52%) vs. 9,303 (53%) 25 to 30: 2,967 (28%) vs. 3,920 (22%) ≥30: 1,634 (15%) vs. 1,982 (11%) Missing: 534 (5.0%) vs. 2,316 (13%) |
| Rowe et al., 2016 England | N = 1,436 | Inclusion criteria: | Planned Home (n = 209) vs. Planned Obstetric Unit (n = 1,227) |

| Citation, Location,Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|---|--|--|--|
| Birthplace in England national prospective cohort study April 2008 to April 2010 Good quality | n = 209 Planned Obstetric Unit n = 1,227 | Women planning vaginal birth after cesarean delivery Exclusion criteria: Elective cesarean delivery before the onset of labor, presented in preterm labor (<37 weeks' gestation), multiple pregnancy, unplanned home birth, received no antenatal care | Parity Para 1: 87 (6.1%) vs. 787 (55%) Para 2+: 122 (8.5%) vs. 440 (30.6%) Maternal age < 20 years: 0 vs. 10 (0.8%) 20 to 24 years: 12 (5.4%) vs. 140 (11.1%) 25 to 29 years: 27 (13.6%) vs. 340 (27%) 30 to 34 years: 72 (36%) vs. 382 (31.1%) 35 to 39 years: 74 (34%) vs. 296 (25%) 40+ years: 24 (11%) vs. 58 (5.1%) Ethnicity White: 191 (92.4%) vs. 877 (68.6%) Non-white: 18 (7.6%) vs. 347 (31.4%) BMI Not recorded: 45 (20.4%) vs. 191 (16.6%) < 18.5: 4 (1.7%) vs. 24 (2.0%) 18.5 to 24.9: 81 (42.1%) vs. 431 (34.3%) 25.0 to 29.9: 56 (25.7%) vs. 326 (26.6%) 30.0 to 34.9: 17 (7.4%) vs. 165 (13.6%) 35.0 to 39.9: 1 (0.5%) vs. 54 (4.3%) 40.0+: 5 (2.2%) vs. 33 (2.7%) IMD quintiles 1st least deprived: 43 (21.4%) vs. 206 (15.6%) 2nd: 45 (20.8%) vs. 206 (15.9%) 3rd: 39 (18.5%) vs. 216 (17%) 4th: 38 (19%) vs. 222 (18.5%) |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|---|---|--|---|
| | | | 5th most deprived: 44 (20.3%) vs. 365 (33%) |
| Schroeder et al., 2017 England Interviews and medical records from Barkantine Birth Centre and Royal London Hospital's obstetric unit in Tower Hamlets, a low-income borough in east London 2008 to 2009 Poor quality | N = 333 Planned Birth Center n = 167 Planned Hospital n = 166 | Inclusion criteria: Resident of Tower Hamlets, low risk of obstetric complications, satisfied criteria to use the birth center Exclusion criteria: NR | Planned Birth Center vs. Planned Hospital Marital status Living with partner/married: 123/141 (87.2%) vs. 90/104 (86.5%) Partner living away from home: 8/141 (5.7%) vs. 7/104 (6.7%) Single/no partner: 1/141 (0.7%) vs. 0/104 (0.0%) Other marital statuses: 9/141 (6.4%) vs. 7/104 (6.7%) Mother's ethnic group White British: 72/215 (33.5%) vs. 10 (5.7%) All white non-British ethnic groups: 21/215 (9.8%) vs. (10 5.7%) White European: 18/215 (8.4%) vs. 6 (3.4%) White other: 3/215 (1.4%) vs. 4 (2.3%) Black: 10/215 (4.7%) vs. 5 (2.9%) South Asian (Indian/Pakistani/Bangladeshi): 33/215 (15.3%) vs. 127 (73.0%) All other ethnic groups: 29/215 (13.5%) vs. 6 (3.4%) Interpreter needed: Yes: 5/160 (3.1%) vs. 43/104 (41.3%) |
| Snowden, et al., 2015 Oregon, U.S. State vital statistics | N = 79,727 | Inclusion criteria: Cephalic, singleton, term, non-anomalous deliveries | Planned Out-of-Hospital birth (n = 3,804) vs. Planned Hospital Birth (n = 75,923) |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|--|--|--|--|
| January 2012 to December 2013 Good quality | Hospital Birth n = 3,804 | Exclusion criteria: Unplanned home births, unknown intended place of birth, other location of birth (e.g., clinic or doctor's office) | Race or ethnic group White: 3,317 (87.2%) vs. 51,238 (67.5%) Black: 34 (0.9%) vs. 1,945 (2.6%) Hispanic: 192 (5%) vs. 14,882 (19.6%) Asian: 97 (2.5%) vs. 4,896 (6.4%) American Indian or Alaskan native: 87 (2.3%) vs. 1,940 (2.6%) Other: 77 (2.0%) vs. 1,022 (1.3%) Parity 0: 1,514 (39.8%) vs. 30,758 (40.5%) 1: 1,219 (32.0) vs. 24,739 (32.6%) 2: 548 (14.4% vs. 12,136 (16.0%) ≥3: 523 (13.7%) vs. 8,290 (10.9%) Insurance status (n = 3,710 vs. n = 75,523) Public: 872 (23.5%) vs. 35,243 (46.7%) Private: 1,718 (46.3%) vs. 39,507 (52.3%) Self-pay: 1,120 (30.2%) of vs. 773 (1.0%) Maternal age <20: 47 (1.2%) vs. 4,887 (6.4) 20 to 34: 2,932 (77.1%) vs. 59,383 (78.2) ≥35: 825 (21.7%) vs. 11,653 (15.3) |
| Sprague et al., 2018 Ontario, Canada Better Outcomes Registry & Network, Canadian Institute of Health Information Discharge Abstracts Database, Statistics | Planned Birth Center: n = 495 Planned Hospital: n = 1,980 | All birth center births matched on 1:4 basis to singleton pregnancies in spontaneous labor in hospital midwifery care, additional matching based on gestational age at birth (within 2 weeks), parity and maternal age (<30, 30 to 34, | Planned Birthing Center (n = 495) vs. Planned Hospital (n = 1,980) <u>Age (years)</u> <20: 10 (2.0%) vs. 25 (1.3%) 20 to 24: 38 (7.7%) vs. 151 (7.6%) |

| Citation, Location,Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|--|---|--|--|
| Canada census data, birth center records January 2014 to February 2015 Poor quality | | 35+), location of residence, and pregnancy complications (gestational diabetes and hypertension) | 25 to 29: 113 (22.8%) vs. 468 (23.6%) 30 to 34: 209 (42.2%) vs. 836 (42.0%) 35 to39: 115 (23.2%) vs. 452 (22.8%) ≥40: 10 (2.0%) vs. 48 (2.4%) |
| | | | Parity Nulliparous: 292 (59.0%) vs. 1,168 (59.0%) Multiparous: 201 (41.0%) vs. 812 (41.0%) |
| | | | Previous cesarean delivery: 8 (1.6%) vs. 108 (5.5%) |
| | | | BMI category <21: 192 (38.8%) vs. 533 (26.9%) 21 to 25: 217 (43.8%) vs. 928 (46.9%) 26 to 30: 64 (12.9%) vs. 337 (17.0%) 31 to 35: 14 (2.8%) vs. 110 (5.6%) 36 to 40: 4 (0.8%) vs. 44 (2.2%) ≥41: 4 (0.8%) vs. 28 (1.4%) Spontaneous labor: 486 (98.2%) vs. 1,973 (99.6%) Women giving birth in the birth center: 373 (75.4%) vs. 0 (0.0%) |
| | | | Intermittent auscultation use: 487 (98.4%) vs. 839 (42.4%) |
| Thornton et al., 2017 U.S. Uniform Data Set from American Association of Birth | N = 11,303 Planned Birth Center n = 8,776 | Inclusion criteria: Received prenatal care in birth center, reached 37 weeks' gestation, admitted in | Planned Birth Center (n = 8,776) vs. Planned Hospital (n = 2,527) Parous: 4,698 (53.53%) vs. 1,521 (60.19%), p < 0.001 |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|---|----------------------------|---|---|
| Centers at 79 U.S. birth centers in 43 states 2006 to 2011 Poor quality | Planned Hospital n = 2,527 | spontaneous labor to birth center or affiliated hospital Exclusion criteria: Twin gestation, labor was pharmacologically induced, nonvertex presentations, history of cesarean delivery, anomalous fetuses, neonates weighing < 2500 grams or > 6000 grams at birth, BMI less than 20 or greater than 27, hypertension, diabetes, renal disease, asthma, seizure history, treated psychiatric disorders including depression, tobacco or other substance abuse, sexual or other physical victimization, gestational diabetes or hypertension, preeclampsia, anemia (hematocrit 30), infection, preterm labor or rupture of membranes, placental abruption or previa, nonreassuring antepartum fetal testing | Mean age: 28.96 ± 5.17 vs. 26.81 ± 5.89 , p < 0.001 Payment, p < 0.001 Private: $4,685$ (53.38%) vs. 953 (37.71%) Medicaid: $2,192$ (24.98%) vs. $1,174$ (46.46%) Military: 240 (2.73%) vs. 25 (0.99%) Self-pay: $1,337$ (15.23%) vs. 282 (11.16%) Race, p < 0.001 White: $7,490$ (85.35%) vs. $1,871$ (74.04%) Black: 428 (4.88%) vs. 275 (10.88%) Asian Pacific Islander: 220 (2.51%) vs. 131 (5.18%) Native American: 48 (0.55%) vs. 14 (0.55%) Lives with partner: $7,907$ (90.10%) vs. $1,888$ (74.71%); p < 0.001 Mean gestational age at birth: 39.90 ± 1.05 vs. 39.73 ± 1.09 , p < 0.001 Trimester care began, p < 0.001 First trimester: (1 to 13 weeks): $6,581$ (74.99%) vs. $1,674$ (66.24%) Second trimester: (14 to 27 weeks) $1,643$ (18.72%) vs. 637 (25.21%) Third trimester: (28+ weeks) 163 (1.86%) vs. 69 (2.73%) Missing: 389 (4.43%) vs. 147 (5.82%) |

| Citation, Location,Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|---|--|---|--|
| Tilden et al., 2017 U.S. Birth and death certificates 2007 to 2010 Fair quality | N = 109,970 Planned Home n = 2,352 Planned Birth Center n = 795 Planned Hospital n = 106,823 | Inclusion criteria: Women with singleton, term, vertex, nonanomolous, liveborn neonates who were delivered by VBAC in or out-of-hospital between 2007 and 2010 in the U.S. Exclusion criteria: No prior cesarean delivery, delivered by repeat cesarean delivery, multiple gestation, delivered preterm (<37 weeks) or extremely postterm (>43 weeks), breech fetus, fetus with congenital anomalies, stillbirth, obvious data miscoding | Planned Home and Birth Center (n = 3,147) vs. Planned Hospital (n = 106,823) Race/ethnicity White: 2,728 (86.69%) vs. 53,226 (49.83%) Black: 94 (2.99%) vs. 15,396 (14.41%) Hispanic: 273 (8.67%) vs. 31,030 (29.05%) Asian: 42 (1.33%) vs. 6,106 (5.72%) American Indian/Alaska Native: 10 (0.32%) vs. 1,065 (1.00%) Parity 1: 648 (20.59%) vs. 33,813 (31.65%) 2: 660 (20.97%) vs. 28,423 (26.61%) ≥ 3: 1785 (56.72%) vs. 43,237 (40.48%) Tobacco use: 25 (0.79%) vs. 7,842 (7.34%) Maternal age ≤20: 5 (0.16%) vs. 2,302 (2.15%) 21 to 34: 2,192 (69.65%) vs. 81,386 (76.19%) ≥35: 950 (30.19%) vs. 23,135 (21.66%) Education Not completed high school: 673 (21.39%) vs. 9,044 (8.47%) High school: 585 (18.59%) vs. 41,668 (39.01%) College: 1,587 (50.43%) vs. 45,093 (42.21%) |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|--|------------------|---|--|
| | | | Graduate school: 283 (8.99%) vs. 9,744 (9.12%) |
| | | | Previous cesarean deliveries 1: 2,791 (88.69%) vs. 94,478 (88.44%) 2: 232 (7.37%) vs. 7,916 (7.41%) ≥3: 42 (1.33%) vs. 1,676 (1.57%) |
| | | | <u>History of vaginal birth</u> : 2,392 (76.01%) vs. 67,217 (62.92%) |
| | | | Prenatal care initiation after 1st trimester: 1,584 (50.33%) vs. 31,415 (29.41%) |
| | | | Kotelchuck Index Adequate Plus: 208 (6.61%) vs. 21,011 (19.67%) |
| | | | Adequate: 998 (31.71%) vs. 35,629 (33.35%) Intermediate: 722 (22.94%) vs. 20,748 (19.42%) |
| | | | Inadequate: 1,131 (35.94%) vs. 22,486 (21.05%) |
| | | | Weight gain >40 pounds: 569 (18.08%) vs. 20,477 (19.17%) |
| van der Kooy et al., 2017 The Netherlands | • | Inclusion criteria: Low-risk women in midwife-led care at | Planned Home (n = 402,912) vs. Planned Hospital (n = 219,105) |
| Netherlands Perinatal Registry 2000 to 2007 Good quality | Planned Hospital | the onset of labor, single pregnancy, spontaneous labor <u>Exclusion criteria</u> : | Parity Primiparous: 171,986 (42.7%) vs. 104,249 (47.6%) |
| | | | Multiparous: 230,926 (57.3%) vs. 114,856 (52.4%) |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|--|-----------------------------|---|---|
| | | Medium-risk women, defined by Dutch guidelines (e.g., women with a history of postpartum hemorrhage or obesity) | Maternal age < 19 years: 4,036 (1.0%) vs. 6,713 (3.1%) 20 to 25 years: 34,661 (8.6%) vs. 32,617 (14.9%) 25 to 34 years: 296,128 (73.5%) vs. 142,597 (65.1%) > 35 years: 68,087 (16.9%) vs. 37,178 (17.0%) Ethnicity Dutch: 370,647 (96.3%) vs. 196,659 (89.8%) Non-Dutch: 32,265 (8.0%) vs. 65,533 (29.9%) Socioeconomic status Privileged neighborhood: 388,089 (96.3%) vs. 196,659 (89.8%) Underprivileged neighborhood: 14,823 (3.7%) vs. 22,446 (10.2%) |
| van der Kooy et al., 2011 The Netherlands Netherlands Perinatal Registry 2000 to 2007 Fair quality | Planned Home n = 402,912 | Inclusion criteria: Singleton pregnancy, under the supervision of a community midwife at the onset of labor Exclusion criteria: Medium-risk women (e.g., a history of postpartum hemorrhage, BMI > 30) | Planned Home (n = 402,912) vs. Planned Hospital-Midwife (n = 219,105) Parity Primiparous: 171,986 (42.69%) vs. 104,249 (47.58%) Multiparous: 230,926 (57.31%) vs. 114,856 (52.42%) Maternal age Younger than 19: 4,036 (1.00%) vs. 6,713 (3.06%) 20 to 25: 34,661 (8.60%) vs. 32,617 (14.89%) |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|---|---|--|--|
| | | | 25 to 34: 296,128 (73.50%) 267 vs. 142,597 (65.08%) Older than 35: 68,087 (16.90%) vs. 37,178 (16.97%) |
| | | | Ethnic background Western: 364,796 (90.54%) vs. 143,677 (65.57%) Non-Western: 38,116 (9.46%) vs. 75,428 (34.43%) Neighborhood Privileged neighborhood: 388,089 (96.32%) vs. 196,659 (89.76%) |
| | | | Underprivileged neighborhood: 14,823 (3.68%) vs. 22,446 (10.24%) |
| | | | Gestational age (weeks) Less than 34: 2,409 (0.60%) vs. 1,702 (0.78%) 35 to 36: 6,510 (1.62%) vs. 4,064 (1.85%) 37: 15,203 (3.77%) vs. 9,603 (4.38%) 38 to 41: 368,926 (91.56%) vs. 193,816 (88.46%) More than 41: 9,864 (2.45%) vs. 9,920 (4.53%) |
| 2015 The Netherlands | Planned Home n = 226 Planned Hospital- Midwife n = 168 | Low-risk nulliparous women who started their pregnancy in midwife-led care or in | Planned Home (n = 226) vs. Planned Hospital-Midwife (n = 168) vs. Planned Hospital-Obstetrician (n = 182) Mean age: 28.8 (3.9) vs. 29.1 (3.8) vs. 30.9 (4.8), p < 0.01 |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|---|---|--|--|
| 2007 to 2011 Poor quality | Planned Hospital- Obstetrician n = 182 | Exclusion criteria: Women with an obstetric or medical indication according to the List of Obstetric Indications (high risk), women who had previously given birth, women who miscarried, women who began prenatal care at 20 weeks gestation or later, women who did not report a preferred place of birth, women whose deliveries did not result in a birth registration form | BMI <18.5: 10 (4.5%) vs. 5 (3.1%) vs. 7 (3.9%) 18.5 to 24.99: 139 (63.2%) vs. 115 (71.4%) vs. 121 (68.0%) 25.00 to 29.99: 55 (25.0%) vs. 33 (20.5%) vs. 40 (22.5%) ≥30.0: 16 (7.3%) vs. 8 (5.0%) vs. 10 (5.6%) Ethnic background Dutch: 225 (99.6%) vs. 160 (95.2%) vs. 174 (95.6%) Non-Dutch: 1 (0.4%) vs. 8 (4.8%) vs. 8 (4.4%) Highest completed level of education Low: 19 (8.4%) vs. 18 (10.7%) vs. 19 (10.4%) Middle: 86 (38.1%) vs. 56 (33.3%) vs. 71 (39.0%) High: 121 (53.5%) vs. 94 (56.0%) vs. 92 (50.5%) Distance to hospital 0 to 15 minutes: 170 (75.6%) vs. 135 (80.8%) vs. 135 (74.6%) >15 minutes: 55 (24.4%) vs. 32 (19.2%) vs. 46 (25.4%) First pregnancy Yes: 181 (80.1%) vs. 142 (84.5%) vs. 112 (61.9%), p < 0.01 No: 45 (19.9%) vs. 26 (15.5%) vs. 69 (38.1%) |

| Citation, Location,Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|---|---|---|---|
| | | | Mean gestation (days) at birth: 278 (15) vs. 278 (13) vs. 274 (15), p < 0.01 |
| Wiegerinck et al., 2018 The Netherlands National Perinatal Register 2005 to 2008 Poor quality | N = 57,396 Midwife-led care n = 46,764 Obstetrician-led care n = 10,632 | acatily mon ventex position of the retus, a | Midwife-led care (n = 46,764) vs. Obstetrician-led care (n = 10,632) Maternal age <25: 6,060 (13.0%) vs. 1,305 (12.3%) 25 to 29: 12,995 (27.8%) vs. 2,361 (22.2%) 30 to 34: 17,562 (37.5%) vs. 3,719 (35.0%) ≥35: 10,147 (21.7%) vs. 3,247 (30.5%) Parity Nulliparous: 21,074 (45.1%) vs. 4,376 (41.2%) Multiparous: 25,690 (54.9%) vs. 6,256 (58.8%) Ethnicity Western: 35,358 (75.6%) vs. 7,406 (69.7%) Non-Western: 11,406 (24.4%) vs. 3,226 (30.3%) Socioeconomic status Low: 11,752 (25.1%) vs. 3,079 (29.0%) Mid: 22,973 (49.1%) vs. 4,785 (45.0%) High: 12,039 (25.8%) vs. 2,768 (26.0%) Mean birth weight (grams): 3,552 ± 458 vs. 3,474 ± 500 Gestational age, median (range): 40 (37 to 41) vs. 40 (37 to 41) |

| Citation, Location,Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|--|---|----------------------------------|--|
| | | | Propensity Score Matched Cohort† Home (n = 10,632) vs. Hospital (n = 10,632) |
| | | | Maternal age <25: 1,308 (12.3%) vs. 1,305 (12.3%) 25 to 29: 2,454 (23.1%) vs. 2,361 (22.2%) 30 to 34: 3,611 (34.0%) vs. 3,719 (35.0%) ≥35: 3,259 (30.7%) vs. 3,247 (30.5%) |
| | | | <u>Parity</u> Nulliparous: 4,344 (40.9%) vs. 4,376 (41.2%) Multiparous: 6,288 (59.1%) vs. 6,256 (58.8%) |
| | | | Ethnicity Western: 7,379 (69.4%) vs. 7,406 (69.7%) Non-Western: 3,253 (30.6%) vs. 3,226 (30.3%) |
| | | | Socioeconomic status Low: 3,023 (28.4%) vs. 3,079 (29.0%) Mid: 4,796 (45.1%) vs. 4,785 (45.0%) High: 2,813 (26.5%) vs. 2,768 (26.0%) Mean birthweight: 3,483 ± 463 vs. 3,474 ± 500 Median gestational age (range): 40 (37 to 41) vs. 40 (37 to 41) |
| | | | †Matched on maternal age, birth weight, parity, ethnicity, gestational age, socioeconomic status and gender of the child |

| Citation, Location,Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|--|--|---|--|
| Wiegerinck et al., 2015 The Netherlands Netherlands Perinatal Register with additionally retrieved data from hospitals and midwife practices 2005 to 2008 Poor quality | N = 47,490 Planned Home n = 26,128 Planned Hospital n = 21,362 | Inclusion criteria: In the perinatal region of Amsterdam, singleton pregnancy, gave birth beyond 37+0 weeks gestation, in primary care (led by midwives or general practitioners) at onset of labor Exclusion criteria: Preplanned cesarean delivery, pregnancy complicated by congenital anomalies or antepartum fetal death (antenatal testing showed significant chromosomal anomaly, multiple anomalies were established at physical examination suggesting an underlying syndrome, or underlying syndrome was documented in the autopsy report) | Primiparous: 11,214 (43%) vs. 11,022 (52%), p < 0.001 Mean gestational age: 40 (range, 37 to 42) vs. 40 (range, 37 to 42), p = 0.81 Ethnicity, p < 0.001 Non-Western: 4,278 (16%) vs. 7,282 (34%) Western 21,850 84% vs. 14,080 (66%) Socioeconomic status, p < 0.001 |

Appendix F. Outcome Data from Comparative Observational Studies

Table F1. Outcome Data from Comparative Studies: Delivery Mode

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|--|---|-------------|-------------|
| U.S. Studies | | | |
| Snowden, et al., 2015 Oregon, U.S. State vital statistics January 2012 to | Planned Out-of-Hospital birth (n = 3,804) vs. Planned Hospital Birth (n = 75,923) Absolute difference in risk percentage | NR | NR |
| December 2013 Good quality | points Unassisted vaginal delivery: 27.5, 95% CI 24.9 to 30.2, p < 0.001 | | |
| | Operative vaginal delivery: -4.7 , 95% CI -5.8 to -3.5 , p < 0.001 Cesarean delivery: -24.0 , 95% CI -26.6 to -21.4 , p < 0.001 | | |
| Thornton et al., 2017 U.S. | Planned Birth Center (n = 8,776) vs. Planned Hospital (n = 2,527) | NR | NR |
| Uniform Data Set from American Association of Birth Centers at 79 U.S. birth centers in 43 states | Cesarean delivery: 363 (4.14%) vs. 126 (4.99%), aOR 0.63, 95% CI 0.50 to 0.79, p = NR Propensity weight adjustment using | | |
| 2006 to 2011 Poor quality | maternal age, parity, race, payment method, cohabitation status, trimester prenatal care began, gestational age at birth, newborn weight | | |

Appendix F. Outcome Data from Comparative Observational Studies

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|--|--|-------------|-------------|
| Non-U.S. Studies | | | |
| Birthplace in England Collaborative, 2011 England Birthplace study April 2008 to April 2010 Good quality | Planned Home (n = 16,825) vs. Planned Hospital (n = 19,688) Spontaneous vertex: 15,590 (92.8%) vs. 14,645 (73.8%), aOR 3.61, 95% CI 2.97 to 4.38 Cesarean delivery 458 (2.8%) vs. 2158 (11.1%), aOR 0.31, 95% CI 0.23 to 0.41 Forceps: 372 (2.1%) vs. 1307 (6.8%), aOR 0.43, 95% CI 0.32 to 0.57 Vaginal breech: 63 (0.4%) vs. 43 (0.2%), aOR 2.13, 95% CI 1.15 to 3.96 Planned Freestanding Midwifery Unit (n = 11,280) vs. Planned Hospital (n = 19,688) Spontaneous vertex: 10,150 (90.7%) vs. 14,645 (73.8%), aOR 3.38, 95% CI 2.70 to 4.25 Cesarean delivery: 405(3.5%) vs. 2158 (11.1%), aOR 0.32, 95% CI 0.24 to 0.42 Forceps: 365 (2.9%) vs. 1307 (6.8%), aOR 0.45, 95% CI 0.32 to 0.63 Vaginal breech: 39 (0.4%) vs. 43 (0.2%), aOR 2.00, 95% CI 1.00 to 3.99 Adjusted for maternal age, ethnic group, understanding of English, marital or partner status, BMI, deprivation score quintile, previous pregnancies, weeks of gestation | | NR |

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|--|--|--|---|
| Davies-Tuck et al., 2018 Australia Victorian Perinatal Data | Low risk, Planned Home (n = 3,202) vs. Planned Hospital (n = 701,058) | NR | NR |
| Collection 2000 to 2015 Poor quality | Unplanned cesarean delivery: 81 (2.5%) vs. 87,716 (12.5%), p < 0.001 Instrumental delivery: 79 (2.5%) vs. 122,517 (17.5%), p < 0.001 Spontaneous vaginal: 3,038 (94.9%) vs. 490,748 (70.0%), p < 0.001 | | |
| Halfdansdottir et al., 2018 Iceland Maternity notes review 2005 to 2009 Poor quality | No home birth contraindication Planned Home (n = 278) vs. Planned Hospital (n = 851) Operative: 12 (4.3%) vs. 60 (7.1%) Home birth contraindication present Planned Home (n = 29) vs. Planned Hospital (n = 70) Operative: 7 (24.1%) vs. 9 (12.9%) | NR | NR |
| Halfdansdottir et al., 2015 Iceland Review of midwives' and | Planned Home (n = 307) vs. Planned Hospital or Midwifery Alongside Unit (n = 921) | Planned Home (n = 64) vs. Planned Hospital or Midwifery Alongside Unit (n = 192) | Planned Home (n = 243) vs. Planned Hospital or Midwifery Alongside Unit (n = 729) |
| doctors' original hand- written maternity notes 2005 to 2009 Poor quality | Spontaneous vaginal birth: 288 (93.8%) vs. 852 (92.5%) Instrumental birth: 12 (3.9%) vs. 42 (4.6%) Cesarean delivery: 7 (2.3%) vs. 27 (2.9%) | vs. 154 (80.2%) Instrumental birth: 7 (10.9%) vs. 24 | Spontaneous vaginal birth: 236 (97.1%) vs. 698 (95.7%) Instrumental birth: 5 (2.1%) vs. 18 (2.5%) Cesarean delivery: 2 (0.8%) vs. 13 (1.8%) |
| Hermus et al., 2017 The Netherlands | NR | Planned Home (n = 348) vs. Planned Birth Center (n = 939) vs. Planned | Planned Home (n = 687) vs. Planned Birth Center (n = 729) vs. Planned |

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|---|--|---|---|
| July to December 2013 Good quality | | Hospital (n = 399) (Birth Center reference group) | Hospital (n = 353) (Birth center reference group) |
| | | Vaginal (non-instrumental): 314 (78.7%) vs. 730 (77.7%) vs. 279 (80.2%) Vaginal (spontaneous or instrumental): 377 (94.5%) vs. 864 (92.0%) vs. 330 (94.8%) | Vaginal (non-instrumental): 674 (98.1%) vs. 709 (97.3%) vs. 337 (95.5%) Vaginal (spontaneous or instrumental): 684 (99.6%) vs. 722 (99.0%) vs. 347 (98.3%) |
| - | Planned home (n = 11,493) vs. Planned hospital (n = 11,493) | Planned Home (n = 4,027) vs. Planned Hospital (n = 4,027) | Planned Home (n = 7,466) vs. Planned Hospital (n = 7,466) |
| | Assisted vaginal: 370 (3.2%) vs. 591 (5.1%), RR 0.61, 95% CI 0.54–0.70 Cesarean delivery: 672 (5.8%) vs. 903 (7.9%), RR 0.74, 95% CI 0.67–0.82 | Assisted vaginal: 313 (8.9%) vs. 452 (13.2%), RR 0.68, 95% CI 0.59 to 0.78 Cesarean delivery: 531 (13.2%) vs. 611 (15.2%), RR 0.87, 95% CI 0.78 to 0.97 | Assisted vaginal: 57 (0.8%) vs. 139 (1.9%), RR 0.40, 95% CI 0.30 to 0.55 Cesarean delivery: 141 (1.9%) vs. 292 (3.9%), RR 0.48, 95% CI 0.40 to 0.59 |
| • | Planned Home (n = 6,692) vs. Planned Hospital-Midwife (n = 6,692) | Planned Home (n = 2,293) vs. Planned Hospital-Midwife (n = 2,298) | Planned Home (n = 4,393) vs. Planned Hospital-Midwife (n = 4,394) |
| | Spontaneous vaginal: 6,146 (91.8%) vs. 5,852 (87.4%) | | Assisted vaginal delivery: 28 (0.6%) vs. 72 (1.6%) |
| 2003 to 2006 Poor quality | Assisted vaginal: 195 (2.9%) vs. 293 (4.4%); RR 0.67, 95% CI 0.56 to 0.80 Cesarean delivery: 348 (5.2%) vs. 544 (8.1%), RR 0.64, 95% CI 0.56 to 0.73 | Cesarean delivery: 276 (12.0%) vs. 365 (15.9%) | Cesarean delivery: 71 (1.6%) vs. 179 (4.1%) |
| British Columbia, Canada | Planned Home vs. Planned Hospital- Midwife vs. Matched Sample of Physician-Attended Hospital Births | Planned Home vs. Planned Hospital- Midwife vs. Matched Sample of Physician-Attended Hospital Births | Planned Home vs. Planned Hospital- Midwife vs. Matched Sample of Physician-Attended Hospital Births |
| 2000 to 2004 | Cesarean delivery: 208 /2899 (7.2%) vs. 498/4,752 (10.5%) vs. 588/5,331 (11.0%) | , , , , , | Cesarean delivery: 50/1,684 (3.0%) vs. 45/2,324 (1.9%) vs. 107/3,127 (3.4%) |

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|---|---|-------------|-------------|
| | Spontaneous vaginal: 2,605/2,899 (89.9%) vs. 3910/4752 (82.3%) vs. 4,007/5,331 (75.2%) | | |
| Katoaka et al., 2018 Japan Review of medical records Birth centers: 2001 to 2006, one hospital: 2004 to 2006, other hospital: 2008 Poor quality | Planned Birth center (n = 5,379) vs. Planned Hospital (n = 4,209) Spontaneous vaginal delivery: 5,379 (100%) vs. 4,011 (95.3%) Vacuum extraction: 0 (0%) vs. 178 (4.2%) Forceps delivery: 0 (0%) vs. 20 (0.5%) | NR | NR |
| Kennare et al., 2010 Australia Pregnancy Outcome Unit of South Australia Health perinatal data 1991 to 2006 Poor quality | Cesarean delivery: 104/1136 (9.2%) vs. 79,238/292,469 (27.1%), aOR 0.27, 95% CI 0.22 to 0.34, p < 0.001 Instrumental delivery: 50/1136 (4.4%) vs. 37,386/292,469 (12.8%), aOR 0.33, 95% CI 0.25 to 0.44, p < 0.001 Adjusted for maternal age, parity, occupational status, smoking, plurality, medical and obstetric complications (e.g., antepartum hemorrhage, diabetes, hypertension), gestational age, small for gestational age, congenital anomalies, city or | NR | NR |
| Laws et al., 2014 Australia | country hospital, mode of delivery Planned Birth Center (n = 14,707) vs. Planned Hospital (n = 29,414) | NR | NR |

Appendix F. Outcome Data from Comparative Observational Studies

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|---|--|-------------|-------------|
| | Assisted vaginal: 980 (6.7%) vs. 4,137 (14.1%), aOR 0.32, 95% CI 0.29 to 0.35 Emergency cesarean delivery: 575 (3.9%) vs. 3,702 (12.6), aOR 0.23, 95% CI 0.20 to 0.25 Adjusted for maternal age, Australian/overseas-born, socioeconomic disadvantage, smoking during pregnancy, parity, preexisting medical conditions, admitted patient insurance status, obstetric complications, level of hospital, day of the week, and holidays. | | |
| Monk et al., 2014 Australia ObstetriX surveillance system of point-of-care maternity data collection across the antenatal, intrapartum, and immediate postnatal periods 2005 to 2006 Fair quality | Planned Birth Center (n = 494) vs. Planned Tertiary Maternity Unit (n = 3,157) Spontaneous vaginal: 400 (81.0%) vs. 2,044 (64.7%), aOR 1.57, 95% CI 1.20 to 2.06, p = 0.001 Instrumental: 34 (6.9%) vs. 331 (10.5%), aOR 0.79, 95% CI 0.53 to 1.17, p = 0.237 Elective cesarean delivery: 20 (4.0%) vs. 369 (11.7%), aOR 0.50, 95% CI 0.29 to 0.88, p = 0.02 Intrapartum cesarean delivery: 40 (8.1%) vs. 413 (13.1%), aOR 0.76, 95% CI 0.53 to 1.10, p = 0.151 Adjusted for maternal age, smoking status, parity, risk at the onset of | NR | NR |

Appendix F. Outcome Data from Comparative Observational Studies

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|---|--|-------------|-------------|
| | labor, previous cesarean delivery and gestation at the time of birth | | |
| Øian et al., 2018 Norway Medical Birth Registry with supplementary data collection | Births in Midwife-Led Birth Centers, Planned (n = 2,298) vs. Births Planned for a Midwife-led Birth Unit, Took Place Elsewhere (n = 220) vs. Births in Hospital, Low Risk (n = 105,358) | NR | NR |
| January 2008 to December 2010 | Vacuum: 7 (.4%) vs. 25 (14.0%) vs. 9,218 (8.7%) | | |
| Poor quality | Forceps: 0 vs. 1 (.6%) vs. 1,761 (1.7%) Cesarean, Elective: 0 vs. 0 vs. 0 Cesarean, Acute: 1 (.1%) vs. 21 (11.8%) vs. 6,564 (6.2%) Unspecified: 1 (.1%) vs. 0 vs. 8 (0%) | | |
| Schroeder et al., 2017 England Interviews and medical | Planned Hospital (n = 164) Spontaneous vaginal delivery: 142 | NR | NR |
| records from Barkantine Birth Centre and Royal London Hospital's obstetric unit in Tower Hamlets, a low-income borough in east London 2008 to 2009 Poor quality | (85%) vs. 120 (73%), p = 0.006 Assisted delivery with ventouse: 8 (5%) vs. 9 (6%), p = 0.78 Assisted delivery with forceps: 7 (4%) vs. 8 (5%), p = 0.57 Lower segment cesarean delivery: 12 (7%) vs. 28 (17%), p = 0.003 | | |

Appendix F. Outcome Data from Comparative Observational Studies

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|--|---|-------------|-------------|
| Sprague et al., 2018 Ontario, Canada Better Outcomes Registry & Network, Canadian Institute of Health Information Discharge Abstracts Database, Statistics Canada census data, birth center records January 2014 to February 2015 Poor quality | Mode of Delivery Spontaneous vaginal: 435 (87.9%) vs. 1567 (79.1%), aRR 1.0 Reference Assisted (vacuum or forceps): 22 (4.4%) vs. 174 (8.8%), aRR 1.9, 95% CI 1.3 to 3.0 Cesarean: 38 (7.7%) vs. 239 (12.1%) aRR 1.5, 95% CI 1.1 to 2.1 Adjusted for BMI (<30, >30) and prior Cesarean delivery (yes, no) | NR | NR |
| van der Kooy et al., 2017 The Netherlands Netherlands Perinatal Registry 2000 to 2007 Good quality | Planned Home (n = 402,912) vs. Planned Hospital (n = 219,105) Vaginal Delivery: 359,146 (89%) vs. 188,970 (86%) Operative vaginal delivery and cesarean section: 43,766 (10.9%) vs. 30,135 (13.8%), aOR 0.77, 95% CI 0.75 to 0.78, p = NR Adjusted for maternal factors, child factors, health care factors | | NR |
| Wiegerinck et al., 2015 The Netherlands Netherlands Perinatal Register with additionally retrieved data from hospitals and midwife practices | Planned Home (n = 26,128) vs. Planned Hospital (n = 21,362) Mode of delivery Spontaneous: 23,055 (88%) vs. 18,166 (85%), OR 1.32, 95% CI 1.25 to 1.39, p < 0.001 | | NR |

| Combined Parity | Nulliparous | Multiparous |
|--|--|--|
| Cesarean delivery: 988 (4%) vs. 1,131 5%), OR 0.70, 95% CI 0.64 to 0.77, 0 < 0.001 nstrumental vaginal delivery: 2,085 8%) vs. 2,065 (10%), OR 0.81, 95% CI 0.76 to 0.86, p < 0.001 | | |
| only | | |
| | I | Planned Birth Center (n = 7,010) vs. Planned Hospital (n = 25,018) |
| | 1981 (16.6%), aOR 0.47, 95% CI 0.41 to 0.53 Cesarean delivery: 247 (7.2%) vs. 1500 (12.6%), aOR 0.51, 95% CI 0.44 to 0.59 Adjusted for maternal age, ethnicity, | * |
| | Hospital (n = 717) Spontaneous: 651 (75.0%) vs. 498 (69.5%), aOR 1.38, 95% CI 1.08 to 1.76 Instrumental: 156 (18%) vs. 150 (20.9%), aOR 0.77, 95% CI 0.60 to 1.01 Unplanned cesarean delivery: 61 (7.0%) vs. 69 (9.6%), aOR 0.72, 95% CI 0.48 to 1.09 Adjusted for maternal age, gestational | Instrumental: 11 (0.9%) vs. 13 (1.8%), aOR 0.46, 95% CI 0.20 to 1.07 Unplanned cesarean delivery: 7 (0.6%) vs. 12 (1.7%), aOR 0.42, 95% CI 0.16 to 1.10 |
|) r 8 | esarean delivery: 988 (4%) vs. 1,131 5%), OR 0.70, 95% CI 0.64 to 0.77, < 0.001 Instrumental vaginal delivery: 2,085 3%) vs. 2,065 (10%), OR 0.81, 95% CI .76 to 0.86, p < 0.001 INSTRUMENTAL VARIANCE OF THE PROPERTY OF THE | esarean delivery: 988 (4%) vs. 1,131 (5%), OR 0.70, 95% CI 0.64 to 0.77, < 0.001 (nstrumental vaginal delivery: 2,085 (3%) vs. 2,065 (10%), OR 0.81, 95% CI (.76 to 0.86, p < 0.001 (nstrumental delivery: 2,085 (10%), oR 0.81, 95% CI (.76 to 0.86, p < 0.001 (nstrumental delivery: 495 (14.4%) vs. 1981 (16.6%), aOR 0.47, 95% CI 0.41 to 0.53 (nstrumental delivery: 247 (7.2%) vs. 1500 (12.6%), aOR 0.51, 95% CI 0.44 to 0.59 (12.6%), aOR 0.51, 95% CI 0.44 to 0.59 (12.6%), aOR 0.51, 95% CI 0.44 to 0.59 (12.6%), aOR 0.51, 95% CI 0.64 to 0.59 (12.6%), aOR 0.51, 95% CI 0.64 to 0.59 (12.6%), aOR 0.77, 95% CI 0.60 to 1.76 (185 trumental: 156 (18%) vs. 150 (188 trumental: 156 (18%) vs. 150 (188 trumental: 156 (188)) vs. 150 (188 trumental: 156 (188 trumental: 156 (188 trumental: 156 (188 trumental: 158 trumental: 1 |

Appendix F. Outcome Data from Comparative Observational Studies

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|--|-----------------|---|---|
| | | western background), BMI, socio- economic position | western background), BMI, socio- economic position |
| Christensen & Overgaard, 2017 | NR | Planned Birth Center (n = 215) vs. Planned Obstetric Unit (n = 215) | Planned Birth Center (n = 624) vs. Planned Obstetric Unit (n = 624) |
| Denmark Data collected on sociodemographic characteristics, present and previous pregnancies and births, neonatal outcomes and transfers March 2004 to October 2008 Poor quality | | Uncomplicated birth: OR 2.2, 95% CI 1.4 to 3.3 Cesarean delivery: OR 0.4, 95% CI 0.2 to 0.9 Instrumental delivery: OR 0.4, 95% CI 0.2 to 0.7 | Uncomplicated birth: OR 2.9, 95% CI 2.0 to 4.2 Cesarean delivery: OR 0.8, 95% CI 0.3 to 2.2 Instrumental delivery: OR 0.3, 95% CI 0.1 to 0.9 |
| Hollowell et al., 2017 England Birthplace in England national prospective cohort study April 2008 to April 2010 Fair quality | NR | Planned Hospital (n = 8.,350) SVD: 78.8% vs. 71.5%, aOR 1.47, 99% CI 1.17 to 1.85, p < 0.001 Instrumental delivery (ventouse or forceps): 10.8% vs. 16.3%, aOR 0.63, 99% CI 0.46 to 0.86, p < 0.001 Intrapartum cesarean delivery: 6.7% vs. 7.7%, aOR 0.84, 99% CI 0.63 to 1.14, p = 0.15 Adjusted for maternal characteristics | Planned Birthing Center (n = 6,078) vs. Planned Hospital (n = 8,323) SVD: 97.0% vs. 94.6%, aOR 1.86, 99% CI 1.35 to 2.57, p < 0.001 Instrumental delivery (ventouse or forceps): 1.1% vs. 2.5%, aOR 0.41, 99% CI 0.25 to 0.68, p < 0.001 Intrapartum cesarean delivery: 0.7% vs. 0.1%, aOR 0.75, 99% CI 0.41 to 1.38, p = 0.224 Adjusted for maternal characteristics |
| | | • | and complicating conditions identified at the start of care in labor |

Appendix F. Outcome Data from Comparative Observational Studies

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|--|-----------------|--|---|
| Li et al., 2015 England | NR | Planned Home (n = 201) vs. Planned Hospital (n = 2,504) | Planned Home (n = 1,189) vs. Planned Hospital (n = 4,138) |
| Birthplace national prospective cohort study April 2008 to April 2010 | | Straightforward vaginal birth: 201 (73.5%) vs. 1305 (51.7%), aRR 1.63, 95% CI 1.47 to 1.81 | Straightforward vaginal birth: 1101 (92.7%) vs. 3109 (74.7%), aRR 1.20, 95% CI 1.16 to 1.23 |
| Good quality | | · | Birth without intrapartum cesarean delivery, instrumental delivery, 3rd or 4th degree tear, blood transfusion. |
| | | deprivation score quintile, gestation at | Adjusted for maternal age, ethnic group, marital/partner status, BMI in pregnancy, index of multiple deprivation score quintile, gestation at delivery and parity where appropriate |
| van Haaren-ten Haken et al., 2015 The Netherlands Self-reported | NR | Planned Home with Midwife (n = 226) vs. Planned Hospital with Midwife (n = 168) vs. Planned Hospital with Obstetrician (n = 182) | NR (included nulliparous only) |
| questionnaires, medical records, and birth registration forms | | Spontaneous vaginal: 161 (74.5%) vs. 104 (66.2%) vs. 103 (63.6%) (reference) | |
| 2007 to 2011 Fair quality | | Assisted vaginal (VE/FE): 37 (17.1%) vs. 29 (18.5%) vs. 37 (22.8%) | |
| | | Midwife at Home vs. Midwife at Hospital: aOR 0.94, 95% CI 0.49 to 1.83, | |
| | | Midwife at Home vs. Obstetrician at Hospital: aOR 0.83, 95% CI 0.45 to 1.53 | |

Appendix F. Outcome Data from Comparative Observational Studies

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|---|-----------------|--|-------------|
| | | Cesarean delivery (unplanned): 18 (8.3%) vs. 24 (15.3%) vs. 22 (13.6%) Midwife at Home vs. Midwife at Hospital: aOR 0.48, 95% CI 0.23 to 1.02, | |
| | | Midwife at Home vs. Obstetrician at Hospital: aOR 0.75, 95% CI 0.35 to 1.59 | |
| | | Midwife at Hospital vs. Obstetrician at Hospital: aOR 1.55, 95% CI 0.76 to 3.17 | |

Table F2. Outcome Data from Comparative Studies: Perinatal Mortality

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|--|--|--|---|
| U.S. Studies | | | |
| Grunebaum, McCullough, Sapra et al., 2017 U.S. CDC-linked birth-infant death files 2009 to 2013 Fair quality | Planned home birth (all providers) (n = 96,815) vs. Planned Hospital-Midwife (n = 1,077,197) Neonatal death, 0 to 27 days: 118 (0.12%) vs. 334 (0.03%) Standardized mortality ratio, 4.13, 95% CI 3.38 to 4.88 Indirectly standardized for maternal age (<35 or ≥35, parity (nulliparous vs. parous), and gestational age (37 to 40 vs. ≥41 weeks) | Planned home birth (n = 20,125) vs. Hospital-Midwife (n = 424,060) 45 (0.22%) vs. 157 (0.04%) SMR 6.06, 95% CI 4.30 to 7.83 | Planned home birth (n = 75,809) vs. Hospital-Midwife (n = 641,625) 70 (0.09%) vs. 171 (0.03%) SMR 3.49, 95% CI 2.68 to 4.30 |
| Grunebaum, McCullough, Arabin et al., 2017 U.S. CDC-linked birth-infant death data set 2008 to 2012 Poor quality | midwife) vs. Planned Hospital-Midwife Neonatal mortality (birth through 27 days): 122/95,657 (0.127%) vs. 480/1,363,199 (0.035%) | Planned Home vs. Planned Hospital-Midwife Neonatal death, 0 to 27 days: 45/22,773 (0.198%) vs. 200/540,582 (0.037%) RR 5.34, 95% CI 3.9 to 7.4 | Planned home vs. Planned Hospital-Midwife Neonatal death, 0 to 27 days: 77/72,884 (0.106%) vs. (280/822,617 (0.034%) RR 3.1, 95% CI 2.4 to 4 |

Appendix F. Outcome Data from Comparative Observational Studies

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|---|--|-------------|-------------|
| Snowden, et al., 2015 Oregon, U.S. | Planned Home or Birth Center (n = 3,804) vs. Planned Hospital (n = 75,923) | NR | NR |
| State vital statistics January 2012 to December 2013 Good quality | Fetal death ≥20 weeks, intrapartum, or neonatal death, 0 to 27 days: 15 (0.39%) vs. 137 (0.18%) Absolute difference in risk (percentage points), propensity score adjusted 0.158, 95% CI 0.055 to 0.261, p = 0.003 | | |
| | Fetal death ≥20 weeks: 9 (0.24%) vs. 91 (0.12%) Absolute difference in risk (percentage points), propensity score adjusted 0.088, 95% CI 0.005 to 0.171, p = 0.04 Neonatal death, 0 to 27 days: 6 (0.16%) vs. 46 (0.06%) Absolute difference in risk (percentage points), propensity score adjusted | | |
| Thornton et al., 2017 U.S. Uniform Data Set from American Association of Birth Centers at 79 US | 0.077, 95% CI 0.013 to 0.140, p = 0.02 Planned Birth Center (n = 8,776) vs. Planned Hospital (n = 2,527) Intrapartum or newborn death, days of life not reported: 3 (0.03%) vs. 1 (0.04%), OR 0.86, 95% CI 0.09 to 8.3, p = 0.99 RR calculated, 0.96, 95% CI 0.54 to 1.70 | NR | NR |
| Non-U.S. Studies | | | |

Appendix F. Outcome Data from Comparative Observational Studies

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|--|---|---|---|
| Collaborative, 2011 England | Planned Home vs. Planned Birth Center vs. Planned Hospital Intrapartum death | Center vs. Planned Hospital Intrapartum death | Planned Home vs. Planned Birth Center vs. Planned Hospital Intrapartum death |
| I | 3/19,706 (0.02%) | 4/4,568 (0.09%) vs. 1/5,187 (0.02%) vs. 1/10,626 (0.01%) | 2/12,255 (0.02%) vs. 3/6,078 (0.05%) vs. 2/9,049 (0.02%) |
| Jose quanty | Neonatal death (0 to 7 days) 5/16,759 (0.03%) vs. 5/11,263 (0.04%) vs. 5/19,637 (0.03%) | Neonatal death (0 to 7 days) 2/4,544 (0.04%) vs. 3/5,180 (0.06%) vs. 4/10,593 (0.04%) | Neonatal death (0 to 7 days) 3/12,199 (0.02%) vs. 2/6,066 (0.03%) vs. 1/9,013 (0.01%) |
| | No statistical analysis provided, data from Appendix 8, table 8.4 | No statistical analysis provided, data from Appendix 8, table 8.5 | No statistical analysis provided, data from Appendix 8, table 8.5 |
| Davies-Tuck et al., 2018 Australia | Low risk, Planned Home (n = 3,202) vs. Planned Hospital (n = 701,058) | NR | NR |
| 0 11 | Stillbirth: 2 (0.062%) vs. 906 (0.129%), p = 0.29 | | |
| 2000 to 2015 Poor quality | Neonatal death: 3 (0.094%) vs. 262 (0.037%), p = 0.10 | | |
| | Still birth or neonatal death: 5 (0.16%) vs. 1,168 (0.17%), p = 0.90 | | |
| | Timing of stillbirth nor neonatal death reported. | | |

Appendix F. Outcome Data from Comparative Observational Studies

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|--|---|--|---|
| Grigg et al., 2017 New Zealand Maternity and Midwifery | Planned Hospital (n = 285) Intrauterine or intrapartum death: 2 (0.5%) | NR | NR |
| Provider Organization data 2010 to 2011 Poor quality | vs. 0 (0.0%) Neonatal death, 0 to 27 days: 1 (0.26%) vs. 0 (0.0%) | | |
| | Intrauterine demise identified at 38 weeks during antenatal care visit. Freestanding Primary Level Midwife-led Maternity Units (PMUs) vs. Tertiary-level Obstetric-led Maternity Hospital (TMH) | | |
| Halfdansdottir et al., 2015 Iceland Review of midwives' and | Hospital or Midwifery Alongside Unit | Planned Home (n = 64) vs. Planned Hospital or Midwifery Alongside Unit (n = 192) | Planned Home (n = 243) vs. Planned Hospital or Midwifery Alongside Unit (n = 729) |
| doctors' original hand- written maternity notes 2005 to 2009 Poor quality | , , , , , , | Neonatal mortality: 0 (0.0%) vs. 0 (0.0%) | Neonatal mortality: 0 (0.0%) vs. 0 (0.0%) |
| Hermus et al., 2017 The Netherlands July to December 2013 Good quality | | Planned Home (n = 348) vs. Planned Birth Center (n = 939) vs. Planned Hospital (n = 399) (Birth Center reference group) | Planned Home (n = 687) vs. Planned Birth Center (n = 729) vs. Planned Hospital (n = 353) (Birth Center reference group) |
| , | | Perinatal mortality in 24 hours: 0 (0%) vs. 0 (0%) vs. 1 (0.3%) | Perinatal mortality in 24 hours: 0 (0%) vs. 0 (0%) vs. 0 (0%) |

Appendix F. Outcome Data from Comparative Observational Studies

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|---|---|---|--|
| · · | Planned Home vs. Planned Birth Center vs. Planned Hospital | Planned Home vs. Planned Birth Center vs. Planned Hospital | Planned Home vs. Planned Birth Center vs. Planned Hospital |
| Admitted Patient Data Collection, Register of | Intrapartum or neonatal death, 0 to 7 days: 1/693 (0.14%) vs. 10/14,476 (0.06%) vs. 255/242,665 (0.01%) | Intrapartum or neonatal death, 0 to 7 days: 1/304 (0.329%) vs. 10/9,145 (0.109%) vs. 158/149,417 (0.106%) | Intrapartum and neonatal death, 0 to 7 days: 0/392 (0%) vs. 0/5,332 (0%) vs. 96/93,298 (0.103%) |
| and Marriages, and the Australian Bureau of | Planned Home vs. Planned Hospital: aOR 1.29, 95% CI 0.18 to 9.23 Planned Birth Center vs. Planned Hospital: aOR 0.66, 95% CI 0.35 to 1.24 | Planned Home vs. Planned Hospital: aOR 2.48, 95% CI 0.34 to 18.02 Birth center vs. Hospital: aOR 0.99, 95% CI 0.52 to 1.88 | Planned Home vs. Planned Hospital: Unable to calculate due to zero events Planned Birth center vs. Planned |
| | Adjusted for maternal age, gestational age in weeks at delivery and parity. Any case with missing data was excluded from the regression. | Adjusted for maternal age, gestational age in weeks at delivery and parity. Any case with missing data was excluded from the regression. | Hospital: Unable to calculate due to zero events |
| • | Planned Home (n = 11,493) vs. Planned Hospital (n = 11,493) | Planned Home (n = 4,027) vs. Planned Hospital (n = 4,027) | Planned Home (n = 7,466) vs. Planned Hospital (n = 7,466) |
| March 2016 to April 2009 | Intrapartum or neonatal death, 0 to 27 days: 9 (0.1%) vs. 9 (0.1%), RR 1.00, 95% CI 0.40 to 2.52 | • | Intrapartum or neonatal death, 0 to 27 days: 2 (0.03%) vs. 3 (0.04%), RR 0.67, 95% CI 0.11 to 3.99 |
| Canada | Planned Home (n = 6,692) vs. Planned Hospital-Midwife (n = 6,692) | Planned Home (n = 2,293) vs. Planned Hospital-Midwife (n = 2,298) | Matched, Planned Hospital- |
| database | Intrapartum or neonatal death, 0 to 27 days: 9 (0.1%) vs. 6 (0.1%); RR 1.50, 95% CI 0.53 to 4.21 | Intrapartum or neonatal death, 0 to 27 days: 5 (0.2%) vs. 4 (0.2%), no additional analysis reported | Midwife (n = 4,394) Intrapartum or neonatal death, 0 to 27 days: 4 (0.1%) vs. 2 (0.1%) |

Appendix F. Outcome Data from Comparative Observational Studies

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|--|---|-------------|-------------|
| British Columbia, Canada Perinatal Database Registry and vital statistics 2000 to 2004 | Planned Home (n = 2,889) vs. Planned Hospital-Midwife (n = 4,752) vs. Matched Sample of Physician-attended Hospital Births (n = 5,331) Fetal death ≥ 20 weeks, intrapartum, or neonatal death, 0 to 7 days: 1 (0.035%) vs. 3 (0.057%) vs. 3 (0.064%) | NR | NR |
| | Planned Home vs. Planned Hospital-Midwife RR 0.61, 95% CI 0.06 to 5.88, p = NR Planned Home vs. Matched Hospital-Physician RR 0.55, 95% CI 0.06 to 5.25, p = NR | | |
| Review of medical records | Planned Birth Center (n = 5,379) vs. Planned Hospital (n = 4,209) Fetal death ≥22 weeks or intrapartum death: 0 (0%) vs. 11 (0.3%) | NR | NR |

Appendix F. Outcome Data from Comparative Observational Studies

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|---|---|-------------|-------------|
| Australia | Planned Home (n = 1,141) vs. Planned Hospital (n = 297,192) | NR | NR |
| of South Australia Health perinatal data for all births and data on | Fetal death ≥ 20 weeks, intrapartum, or neonatal deaths, 0 to 28 days: 9 (0.079%) vs. 2,440 (0.082%), aOR 1.38, 95% CI 0.56 to 3.41, p = 0.48 | | |
| perinatal deaths 1991 to 2006 Poor quality | Adjusted for maternal age, parity, occupational status, smoking, plurality, medical and obstetric complications (e.g., antepartum hemorrhage, diabetes, hypertension), gestational age, small for gestational age, congenital anomalies, city or country hospital, mode of delivery | | |
| van der Kooy et al., 2011 The Netherlands | Planned Home (n = 402,912) vs. Planned Hospital-Midwife (n = 219,105) | NR | NR |
| Registry | Intrapartum or neonatal deaths, 0 to 7 days: 594 (0.15%) vs. 403 (0.18%), aOR 1.05, 95% Cl 0.91 to 1.21 | | |
| Fair quality | Adjusted for parity, age, ethnic background, and neighborhood, gestational age, congenital abnormalities, preterm birth, low Apgar score, small for gestational age | | |

Appendix F. Outcome Data from Comparative Observational Studies

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|--|--|--|---|
| | Planned Home (n = 26,128) vs. Planned Hospital (n = 21,362) | NR | NR |
| Register with additionally retrieved data from hospitals and midwife | Intrapartum or neonatal death, 0 to 27 days: 19 (0.073%) vs. 12 (0.056%), OR 1.30, 95% CI 0.63 to 2.67, p = 0.61 RR calculated: 1.11, 95% CI 0.84 to 1.47 | | |
| 2005 to 2008 | | | |
| Poor quality | | | |
| Non-U.S. Studies, by parit | y only | | |
| New Zealand Routinely collected maternity outcome data compiled from Counties- Manukau District Health Board (CMDHB) maternity facilities 2003 to 2010 | | Planned Hospital (n = 11,195) Hypoxic peripartum mortality: 6 (0.17%) vs. 14 (0.12%), OR 1.30, 95% | Planned Birth Center (n = 7,010) vs. Planned Hospital (n = 25,018) Hypoxic peripartum mortality: 4 (0.06%) vs. 8 (0.03%), OR 1.79, 95% CI 0.47 to 5.90 Unadjusted OR because of small numbers |
| Poor quality | | | RR calculated, 1.52, 95% CI 0.68 to 3.39 |

Appendix F. Outcome Data from Comparative Observational Studies

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|---|------------------------|---|--|
| de Jonge et al., 2015 The Netherlands | NR | Planned Home vs. Planned Hospital- Midwife | Planned Home vs. Planned Hospital-Midwife |
| Netherlands Perinatal Registry 2000 to 2009 Fair quality | | 1.02, 95% CI 0.76 to 1.37 Neonatal death, 0 to 7 days: 95/198,412 (0.05%) vs. 67/137,088 (0.05%), aOR 0.98, 95% CI 0.70 to 1.36 Neonatal death, 0 to 28 days: 100/198,412 (0.05%) vs. 70/137,088 (0.05%), aOR 0.97, 95% CI 0.70 to 1.34 Adjusted for gestational age, maternal | 95% CI 0.70 to 1.65 Neonatal death, 0 to 28 days: |
| van Haaren-ten Haken et al., 2015 The Netherlands Self-reported questionnaires, medical records, and birth registration forms 2007 to 2011 Poor quality | NR | Planned Home (n = 226) vs. Planned Hospital-Midwife (n = 168) vs. Planned Hospital-Obstetrician (n = 182) Intrapartum or neonatal death, 0 to 7 days: 0 (0%) vs. 0 (0%) vs. 0 (0%) | NR (included only nulliparous) |

Table F3. Outcome Data from Comparative Studies: Neonatal Morbidity

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|--|--|-------------|-------------|
| U.S. Studies | | | |
| Li et al., 2017 South Carolina Birth certificates 1996 to 2013 Poor quality | 2004 to 2013 birth certificate data, Medicaid claims, or discharge abstracts Planned Home (n = 661) vs. Planned Birth Center (n = 1,233) vs. Planned Clinic (n = 9) vs. Planned Hospital (n = 547,523) Neonatal seizures: 1 (0.15%) vs. 0 (0.0%) vs. 0 (0.0%) vs. 131 (0.02%) Neonatal convulsions: 4 (0.61%) vs. 3 (0.24%) vs. 0 vs. 1,290 (0.24%) | NR | NR |
| Snowden, et al., 2015 Oregon, U.S. State vital statistics January 2012 to December 2013 Good quality | Absolute difference in risk percentage points 5-Minute Apgar score < 7: 0.50, 95% CI 0.07 to 0.93, p = 0.02 5-Minute Apgar < 4: 0.18, 95% CI 0.00 to 0.37, p = 0.05 Neonatal seizures: 0.07, 95% CI 0.02 to 0.13, p = 0.007 Ventilator support: 1.05, 95% CI 0.48 to 1.62, p < 0.001 NICU admission: -0.85, 95% CI -1.57 to -0.14, p = 0.02 Propensity score adjusted result | | NR |
| Thornton et al., 2017 U.S. Uniform Data Set from American Association of | Planned Birth Center (n = 8,776) vs. Planned Hospital (n = 2,527) | NR | NR |

Appendix F. Outcome Data from Comparative Observational Studies

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|---|--|-------------|-------------|
| birth centers in 43 states | 5-minute Apgar score 3 to 7: 70 (0.80%) vs. 13 (0.51%), aOR 1.60, 95% CI 0.82 to 3.16, p = NR | | |
| Poor quality | Newborn septic workup: 62 (0.71%) vs. 35 (1.39%), aOR 0.51, 95% CI 0.32 to 0.81, p = NR | | |
| | Positive pressure ventilation < 10 minutes: 268 (3.05%) vs. 57 (2.26%), aOR 1.31, 95% CI 0.95 to 1.82, p = NR | | |
| | Neonatal composite: 39 (0.44%) vs. 11 (0.44%), aOR 1.44, 95% CI 0.66 to 3.14 | | |
| | Composite definition: intrapartum and newborn mortality, hypoxic neurologic injury, Apgar score less than 4 at 5 minutes, seizures, persistent pulmonary hypertension, positive pressure ventilation greater than 10 minutes, and meconium aspiration syndrome | | |
| | Propensity score adjustment with a covariate considering maternal age, parity, race, payment method, cohabitation status, trimester prenatal care began, gestational age at birth, and newborn weight | | |

Appendix F. Outcome Data from Comparative Observational Studies

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|--|---|---|---|
| Non-U.S. Studies | | | |
| Birthplace in England Collaborative, 2011 England Birthplace study April 2008 to April 2010 Good quality | Planned Home (n = 16,553) vs. Planned Hospital (n = 19,551) Birthplace composite: 70 (4.2%) vs. 81 (4.4%), aOR 1.16, 95 % CI 0.76 to 1.77 Planned Freestanding Midwifery Unit (n = 11,199) vs. Planned Hospital (n = 19,551) Birthplace composite: 41 (3.5%) vs. 81 (4.4%), aOR 0.92, 95 % CI 0.58 to 1.46 Adjusted for maternal age, ethnic group, understanding of English, marital or partner status, BMI, deprivation score quintile, previous pregnancies, weeks of gestation Birthplace composite definition: stillbirth after the start of care in labor, early neonatal death, neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured humerus or clavicle | Planned Home (n = 4,488) vs. Planned Hospital (n = 10,541) Birthplace composite: 39 (9.3%) vs. 52 (5.3%), aOR 1.75, 95 % Cl 1.07 to 2.86 Planned Freestanding Midwifery Unit (n = 5,158) vs. Planned Hospital (n = 10,541) Birthplace composite: 24 (4.5%) vs. 52 (5.3%), aOR 0.91, 95 % Cl 0.52 to 1.60 Adjusted for maternal age, ethnic group, understanding of English, marital or partner status, BMI, deprivation score quintile, previous pregnancies, weeks of gestation. | Planned Home (n = 12,050) vs. Planned Hospital (n = 8,980) Birthplace composite: 31 (2.3%) vs. 29 (3.3%), aOR 0.72, 95% CI 0.41 to 1.27 Planned Freestanding Midwifery Unit (n = 6,025) vs. Planned Hospital (n = 8,980) Birthplace composite: 17 (2.7%) vs. 29 (3.3%), aOR 0.91, 95% CI 0.46 to 1.80 Adjusted for maternal age, ethnic group, understanding of English, marital or partner status, BMI, deprivation score quintile, previous pregnancies, weeks of gestation |

Appendix F. Outcome Data from Comparative Observational Studies

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|--|--|-------------|-------------|
| Source, Dates Davies-Tuck et al., 2018 Australia Victorian Perinatal Data Collection 2000 to 2015 Poor quality | Low risk, Planned Home (n = 3,202) vs. Planned Hospital (n = 701,058) Admission to SCN: 58 (1.8%) vs. 58,303 (8.3%), p < 0.001 NICU admission: 14 (0.4%) vs. 1,721 (0.2%), p = 0.03 5-minute Apgar < 7: 29 (0.9%) vs. 8,739 (1.2%), p = 0.08 | NR | NR |
| | HIE: 0 (0%) 133 vs. (0.2%), p = 0.44 Birth trauma: 46 (1.4%) vs. 46,502 (6.6%), p < 0.001 Intrauterine hypoxia: 47 (1.5%) vs. 40,760 (5.8%), p < 0.001 Other perinatal morbidity: 8 (0.3%) vs. 1,113 (0.2%), p = 0.20 | | |
| | Composite morbidity: 115 (3.6%) vs. 94,094 (13.4%), p < 0.001 Birth trauma: brachial plexus injury, fractured clavicle or humerus Other perinatal morbidity: meconium aspiration syndrome, congenital pneumonia or respiratory distress syndrome | | |

Appendix F. Outcome Data from Comparative Observational Studies

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|---|---|-------------|-------------|
| , | Planned Birthing Center (n = 407) vs. Planned Hospital (n = 285) | NR | NR |
| Provider Organization data | 5-minute Apgar score < 7: 8 (2.0%) vs. 6 (2.1%), aOR 0.82, 95% CI 0.27 to 2.52 | | |
| Door guality | Resuscitation not needed: 345 (84.8%) vs. 234 (82.1%), aOR 0.97, 95% CI 0.63 to 1.50‡ | | |
| | Admission to NNU: 24 (5.9%) vs. 14 (4.9%), aOR 1.44, 95% CI 0.70 to 2.96, p > 0.05 | | |
| | Freestanding Primary Level Midwife-led Maternity Units (PMUs) vs. Tertiary-level Obstetric-led Maternity Hospital (TMH) | | |
| | ‡Refers to a dichotomous outcome of "resuscitation or not" adjusted for maternal age, smoking status, parity, augmentation, induction, term | | |

Appendix F. Outcome Data from Comparative Observational Studies

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|---|--|--|---|
| Halfdansdottir et al., 2018 Iceland Maternity notes review 2005 to 2009 Poor quality | No home birth contraindication Planned Home (n = 278) vs. Planned Hospital (n = 851) NICU admission: 16 (5.8%) vs. 57 (6.7%) 5-minute Apgar < 7: 2 (0.7%) vs. 14 (1.6%) Neonatal resuscitation: 6 (2.2%) vs. 15 (1.8%) Neonatal morbidity, 7 days: 28 (10.1%) vs. 116 (13.6%) Home birth contraindication present Planned Home (n = 29) vs. Planned Hospital (n = 70) NICU admission: 6 (20.7%) vs. 6 (8.6%) 5-minute Apgar < 7: 3 (10.3%) vs. 1 (1.4%) Neonatal resuscitation: 2 (6.9%) vs. 2 (2.9%) Neonatal morbidity, 7 days: 7 (24.1%) vs. 10 (14.3%) | NR | NR |
| Halfdansdottir et al., 2015 Iceland Review of midwives' and doctors' original hand- written maternity notes 2005 to 2009 Poor quality | aOR 0.98, 95% CI 0.30 to 3.19 | Hospital or Midwifery Alongside Unit (n = 192) NICU admission: 12 (18.8%) vs. 23 (12.0%); aOR 1.88, 95% Ci 0.81 to 4.36 5 minute Apgar < 7: 4 (6.3%) vs. 6 (3.1%), aOR 1.24, 95% Ci 0.25 to 6.28 Neonatal resuscitation: 4 (6.3%) | Planned Hospital or Midwifery Alongside Unit (n = 729) |

Appendix F. Outcome Data from Comparative Observational Studies

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|--|--|-------------|-------------|
| Hitzert et al., 2016 The Netherlands Dutch Birth Centre Study August to December 2013 Poor quality | Planned Home (n = 350) vs. Planned Birth Center (n = 263) vs. Planned Hospital-Midwife (n = 262) vs. Planned Hospital-Obstetrician (n = 115) Hospital admission of the child after birth No: 304 (87.4%) vs. 188 (72.3%) vs. 196 (74.8%) vs. 58 (50.9%) Yes, at the maternity ward: 38 (10.9%) vs. 63 (24.2%) vs. 58 (22.1%) vs. 41 (36.0%) Yes, high care: 6 (1.7%) vs. 9 (3.5%) vs. 8 (3.1%) vs. 15 (13.2%) Experienced health baby after birth Healthy: 318 (91.4%) vs. 229 (87.4%) vs. 229 (87.4%) vs. 93 (80.9%) Small problems: 22 (6.3%) vs. 29 (11.1%) vs. 25 (9.5%) vs. 20 (17.4%) Big problems/problems with impact unclear: | | NR |
| | 8 (2.3%) vs. 4 (1.6%) vs. 8 (3.1%) vs. 2 (1.8%) | | |

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|--|--|--|---|
| Homer et al., 2014 Australia Perinatal Data Collection, Admitted Patient Data Collection, Register of Congenital Conditions, Registry of Birth Deaths and Marriages, and the Australian Bureau of Statistics 2000 to 2008 Fair quality | stillbirth, early neonatal death (<7 days), | 4/304 (1.32%) vs. 65/9,145 (0.71%) vs. 949/149,417 (0.64%) Home vs. Hospital: aOR 1.72, 95% CI 0.64 to 4.63 | CI 0.07 to 3.38 Birth center vs. Hospital: aOR 0.45, 95% CI 0.26 to 0.81 Composite represented any of the |
| | neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured clavicle, fractured humerus. Adjusted for maternal age, gestational age in weeks at delivery and parity | encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured clavicle, | encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured clavicle, fractured humerus Adjusted for maternal age, gestational age in weeks at delivery, parity |
| Hutton et al., 2016 Ontario, Canada | Planned Home (n = 11,493) vs. Planned Hospital (n = 11,493) | Planned Home (n = 4,027) vs. Planned Hospital (n = 4,027) | Planned Home (n = 7,466) vs. Planned Hospital (n = 7,466) |
| Chart review March 2016 to April 2009 Poor quality | Neonatal morbidity: 38 (0.3%) vs. 40 (0.3%), RR 0.95, 95% CI 0.6 to 1.48 5 minute Apgar < 4, positive pressure ventilation, or chest compressions | * * * | Neonatal morbidity: 11 (0.2%) vs. 14 (0.2%), RR 0.79, 95% CI 0.36 to 1.73 5 minute Apgar < 4, positive pressure ventilation, or chest compressions |

Appendix F. Outcome Data from Comparative Observational Studies

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|--|---|--|---|
| Hutton et al., 2009 Canada Ontario Ministry of Health database 2003 to 2006 Poor quality | Planned Home (n = 6,692) vs. Planned Hospital-Midwife (n = 6,692) Neonatal morbidity: 155 (2.3%) vs. 189 (2.8%), RR 0.82, 95% CI 0.66 to 1.01 Birthweight <2,500: 38 (0.6%) vs. 56 (0.8%) 5-minutes Apgar < 4: 10 (0.1%) vs. 8 (0.1%) positive pressure ventilation and cardiac compressions: 21 (0.3%) vs. 23 (0.3%) NICU >4 days: 102 (1.5%) vs. 115 (1.7%) | Planned Home (n = 2,293) vs. Planned Hospital-Midwife (n = 2,298) Neonatal morbidity: 78 (3.4%) vs. 84 (3.7%) | Planned Home (n = 4,393) vs. Planned Hospital-Midwife (n = 4,394) Neonatal morbidity: 77 (1.8%) vs. 105 (2.4%) |
| and vital statistics 2000 to 2004 Poor quality | Planned Home (n = 2,889) vs. Planned Hospital-Midwife (n = 4,752) RR - Planned Home vs. Hospital with Midwife 1-minute Apgar score < 7: RR 0.76, 95% CI 0.66 to 0.88 5-minute Apgar score < 7: RR 0.92, 95% CI 0.58 to 1.47 Meconium aspiration: RR 0.83, 95% CI 0.38 to 1.81 Asphyxia at birth: RR 0.79, 95% CI 0.30 to 2.05 Birth trauma: RR 0.26, 95% CI 0.11 to 0.58 Resuscitation at birth: RR 0.23, 95% CI 0.14 to 0.37 Birth weight < 2500 g: RR 0.44, 95% CI 0.25 to 0.78 Seizures: RR 0.61, 95% CI 0.12 to 3.03 | NR | NR |

Appendix F. Outcome Data from Comparative Observational Studies

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|---|---|-------------|-------------|
| | Assisted ventilation > 24 h: RR 1.02, 95% CI 0.34 to 3.04 Birth trauma: subdural or cerebral hemorrhage, fracture of clavicle, long bones or skull, facial nerve injury, Erb palsy, or unspecified birth trauma | | |
| Katoaka et al., 2018 Japan Review of medical records Birth centers: 2001 to 2006, one hospital: 2004 to 2006, other hospital: 2008 Poor quality | Planned Birth Center (n = 5,379) vs. Planned Hospital (n = 4,209) Birth weight (grams) <2,500: 171 (3.2%) vs. 234 (5.6%), aOR 0.67, 95% CI 0.55 to 0.82 2,500 to 3,999: 5,120 (95.3%) vs. 3,896 (92.7%), aOR = Reference >4,000: 82 (1.5%) vs. 72 (1.7%), aOR 0.65, 95% CI 0.46 to 0.92 Apgar score <7 at 1 minute: 20 (0.4%) vs. 115 (2.7%), aOR 0.17, 95% CI 0.10 to 0.28 <7 at 5 minutes: 5 (0.1%) vs. 26 (0.6%), aOR 0.23, 95% CI 0.10 to 0.63 Adjusted for age, parity, mode of delivery, and gestational weeks | | NR |

Appendix F. Outcome Data from Comparative Observational Studies

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|---|---|-------------|-------------|
| · | Planned Home (n = 1,136) vs. Planned Hospital (n = 295,568) | NR | NR |
| South Australia Health perinatal data for all births and data on perinatal deaths | 5-minute Apgar score < 7: 12 (1.1%) vs. 4,243 (1.4%), aOR 1.43, 95% CI 0.66 to 3.07, p = 0.36 Specialized neonatal care: 88 (7.7%) vs. 44,410 (15.0%), aOR 0.80, 95% CI 0.62 to 1.03), p = 0.08 | | |
| | Adjusted for maternal age, parity, occupational status, smoking, plurality, medical and obstetric complications (e.g., antepartum hemorrhage, diabetes, hypertension), gestational age, small for gestational age, congenital anomalies, city or country hospital, mode of delivery | | |

Appendix F. Outcome Data from Comparative Observational Studies

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|--|---|-------------|-------------|
| Monk et al., 2014 Australia | Planned Birth Center (n = 494) vs. Planned Tertiary Maternity Unit (n = 3,157) | NR | NR |
| system of point-of-care | 5-minute Apgar < 7: 6 (1.2%) vs. 88 (2.8%), aOR 0.57, 95% CI 0.25 to 1.35, p = 0.203 | | |
| maternity data collection across the antenatal, intrapartum, and immediate postnatal | Admitted to SCN/NICU: 33 (6.7%) vs. 432 (13.7%), aOR 0.60, 95% CI 0.39 to 0.91, p = 0.017 | | |
| periods | Birth weight | | |
| 2005 to 2006 Fair quality | <2,500: 9 (1.8) vs. 176 (5.6), aOR 0.38, 95% CI 0.16 to 0.89, p = 0.026 | | |
| | 2,500 to 4,500: 472 (96.3) vs. 2,899 (92.2%), aOR 1.74, 95% CI 1.00 to 3.03, p = 0.050 | | |
| | >4500: 9 (1.8%) vs. 70 (2.2%), aOR 0.77, 95% CI 0.37 to 1.58, p = 0.473 | | |
| | Adjusted for maternal age, smoking status, parity, augmentation, induction, previous cesarean delivery and risk at the onset of labor | | |
| Øian et al., 2018 Norway Medical Birth Registry with supplementary data collection | Births in Midwife-Led Birth Centers, Planned (n = 2,298) vs. Births Planned for a Midwife-led Birth Unit, Took Place Elsewhere (n = 220) vs. Births in Hospital, Low Risk (n = 105,358) | NR | NR |
| January 2008 to December 2010 | 5-minute Apgar Score < 7: 1 (.1%) vs. 2 (1.1%) vs. 1,029 (1.0%) | | |
| Poor quality | | | |

Appendix F. Outcome Data from Comparative Observational Studies

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|---|--|-------------|-------------|
| England Interviews and medical | Hospital (n = 164) Mean Days in NICU: 0.00 ± 0.0 vs. 0.01 ± 0.1, p = NR | | NR |
| Sprague et al., 2018 | Planned birth center (n = 495) vs. Matched Planned Midwifery (n = 1980) | NR | NR |
| 10 | NICU admission: 27 (5.5%) vs. 141 (7.1%), aRR 1.3, 95% CI 0.9 to 2.0 | | |

Appendix F. Outcome Data from Comparative Observational Studies

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|--|--|---|--|
| Wiegerinck et al., 2015 The Netherlands | Hospital (n = 21,362) | NR | NR |
| Register with additionally retrieved data from hospitals and midwife practices | 5-minute Apgar score: < 7: 181 (0.693%) vs. 159 (0.744%), OR 0.93, 95% CI 0.75 to 1.15, p = 0.54 NICU admittance >24 hours: 43 (0.165%) vs. 55 (0.258%), OR 0.64, 95% CI 0.43 to 0.95, p = 0.03 | | |
| Non- U.S., by parity only | | | |
| Bailey, 2017 New Zealand | | Planned Birth Center (n = 3,438) vs. Planned Hospital (n = 11,195) | Planned Birthing Center (n = 7,010) vs. Planned Hospital (n = 25,018) |
| Routinely collected maternity outcome data compiled from Counties- Manukau District Health Board (CMDHB) maternity facilities | | Neonatal unit admission: 155 (4.5%) vs. 226 (6.4%), aOR 0.70, 95% CI 0.58 to 0.86 Adjusted for maternal age, ethnicity, and deprivation score | Neonatal unit admission 168 (2.4%) vs. 718 (2.9%), aOR 0.85, 95% CI 0.71 to 1.01 Adjusted for maternal age, ethnicity, deprivation score |
| 2003 to 2010 Poor quality | | | |

Appendix F. Outcome Data from Comparative Observational Studies

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|--|-----------------|--|--|
| 2017 Denmark | | , | Planned Birth Center (n = 624) vs. Planned Obstetric Unit (n = 624) 5-minutes Apgar score < 9: OR 0.8, |
| Data collected on sociodemographic characteristics, present and previous pregnancies and births, neonatal outcomes and transfers | | NICU admission <24 h: 0.8, 95% CI 0.4 to 1.9 Infant readmission: 0.4, 95% CI 0.1 | 95% CI 0.4 to 1.9 NICU admission <24 h: OR 0.7, 95% CI 0.3 to 1.8 Infant readmission: OR 0.7, 95% CI 0.4 to 1.3 |
| March 2004 to October 2008 Poor quality | | | |

Appendix F. Outcome Data from Comparative Observational Studies

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|---|-----------------|---|---|
| de Jonge et al., 2015 The Netherlands | NR | Planned Home vs. Planned Hospital-Midwife | Planned Home vs. Planned Hospital-Midwife |
| Netherlands Perinatal Registry 2000 to 2009 Fair quality | | 1,568/198,372 (0.80%) vs. 1,213/137,054 (0.90%), aOR 0.95, | 5-minute Apgar score < 7: 855/267,371 (0.32%) vs. 638/139,656 (0.46%), aOR 0.77, 95% CI 0.69 to 0.86 |
| | | | 5-minute Apgar score < 4: 167/267,371 (0.06%) vs. 100/139,656 (0.07%), aOR 0.92, 95% CI 0.70 to 1.20 |
| | | 644/198,412 (0.03%) vs. 476/137,088 (0.03%), aOR 1.04, | Admission to NICU within 7 days: 327/267,444 (0.12%) vs. 232/139,697 (0.17%), aOR 0.84, 95% CI 0.70 to 1.01 |
| | | 677/198,412 (0.03%) vs. 495/137,088 (0.04%), aOR 1.05, | Admission to NICU within 28 days: 363/267,444 (0.14%) vs. 272/139,697 (0.20%), aOR 0.79, 95% CI 0.66 to 0.93 |
| | | maternal age, socioeconomic | Adjusted for gestational age, maternal age, socioeconomic status, and ethnicity |

Appendix F. Outcome Data from Comparative Observational Studies

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|--|-----------------|--|--|
| Hollowell et al., 2017 England Birthplace in England national prospective cohort study April 2008 to April 2010 Fair quality | | care in labor, early neonatal death, neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured humerus or clavicle Adjusted for maternal characteristics and complicating conditions identified at the start of | Planned Birthing Center (n = 6,078) vs. Planned Hospital (n = 8,323) Birthplace primary perinatal outcome: 0.047% vs. 0.024%, aOR 1.14, 95% CI 0.52 to 2.50, p = 0.745 Composite measure defined as any of: stillbirth after the start of care in labor, early neonatal death, neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured humerus or clavicle Adjusted for maternal characteristics and complicating conditions identified at the start of care in labor |

Appendix F. Outcome Data from Comparative Observational Studies

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|--|-----------------|--|--|
| Li et al., 2015 United Kingdom | NR | Planned Home (n = 283) vs. Planned Hospital (n = 2,503) | Planned Home (n = 1,186) vs. Planned Hospital (n = 4,133) |
| Birthplace national prospective cohort study April 2008 to April 2010 Good quality | | group, marital/partner status, BMI in pregnancy, index of multiple | Adverse perinatal outcomes (main composite): 16 (12.3%) vs. 108 (26.8%), aRR 0.47, 95% CI 0.25 to 0.88 Composite consisting of the birthplace intrapartum and admission to a neonatal unit within 48 hours of birth for more than 48 hours Adjusted for maternal age, ethnic group, marital/partner status, BMI in pregnancy, index of multiple deprivation score quintile, gestation at delivery and parity where appropriate |
| van Haaren-ten Haken et al., 2015 The Netherlands Self-reported questionnaires, medical records, and birth registration forms 2007 to 2011 | NR | Planned Home (n = 226) vs. Planned Hospital-Midwife (n = 168) vs. Planned Hospital-Obstetrician (n = 182) 5-minute Apgar score < 7: 4 (1.8%) vs. 3 (1.8%) vs. 4 (2.2%) Resuscitation: 1 (0.4%) vs. 0 (0%) vs. 0 (0%) | NR (included only nulliparous) |
| Poor quality | | Birth weight M (SD): 3,365 (543) vs. 3,401 (575) vs. 3210 (555) | |

Appendix F. Outcome Data from Comparative Observational Studies

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|---|-----------------|--|-------------|
| | | 2500 to 3999 gram: 195 (86.3%) vs. 135 (80.4%) vs. 155 (85.2%) (reference) | |
| | | <2500 grams: 11 (4.9%) vs. 10 (6.0%) vs. 15 (8.2) | |
| | | Midwife at Home vs. Midwife at Hospital: aOR 0.68, 95% CI 0.16 to 2.84 | |
| | | Midwife at Home vs. Obstetrician at Hospital: aOR 0.83, 95% CI 0.22 to 3.12 | |
| | | ≥4000 grams: 20 (8.8) 23 (13.7) 12 (6.6) Midwife at Home vs. Midwife at Hospital: aOR 0.69, CI 0.32 to 1.52 | |
| | | Midwife at Home vs. Obstetrician at Hospital: aOR 1.02, 95% CI 0.44 to 2.40 | |
| | | Adjusted for maternal age, method of conception, first pregnancy (previous miscarriage or ectopic pregnancy), gestational | |
| | | age at birth, medical indications pregnancy | |

Table F4. Outcome Data from Comparative Studies: Maternal Morbidity

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous | |
|--|---|-------------|-------------|--|
| U.S. Studies | | | | |
| Snowden, et al., 2015 Oregon, U.S. State vital statistics January 2012 to December 2013 Good quality | Absolute difference in risk percentage points Maternal ICU admission: -0.04, 95% CI -0.18 to 0.10, p = 0.58 Maternal blood transfusion: 0.27, 95% CI 0.08 to 0.46, p = 0.006 Severe perineal lacerations: -0.54, 95% CI -0.98 to -0.11, p = 0.02 Propensity score adjusted result | NR | NR | |
| Thornton et al., 2017 U.S. Uniform Data Set from American Association of Birth Centers at 79 U.S. birth centers in 43 states 2006 to 2011 Poor quality | Planned Birth Center (n = 8,776) vs. Planned Hospital (n = 2,527) Postpartum hemorrhage: 542 (6.18%) vs. 117 (4.63%), aOR 1.25, 95% CI 0.99 to 1.58, p = NR Propensity score adjustment with a covariate considering maternal age, parity, race, payment method, cohabitation status, trimester prenatal care began, gestational age at birth, newborn weight | NR | NR | |
| Non-U.S. Studies | Non-U.S. Studies | | | |

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|--|--|-------------|-------------|
| Birthplace in England Collaborative, 2011 United Kingdom Birthplace April 2008 to April 2010 Good quality | Planned Home (n = 16,800) vs. Planned Hospital (n = 19,638) Third or fourth degree perineal: 318 (1.9%) vs. 625 (3.2%), aOR 0.77, 95% CI 0.57 to 1.05 Planned Freestanding Midwifery Unit (n = 11,262) vs. Planned Hospital (n = 19,638) Third or fourth degree perineal: 259 (2.3%) vs. 625 (3.2%), aOR 0.78, 95% CI 0.58 to 1.05 Planned Home (n = 16,687) vs. Planned Hospital (n = 19,579) Blood transfusion: 101 (0.6%) vs. 241 (1.2%), aOR 0.72, 95% CI 0.47 to 1.12 Planned Freestanding Midwifery Unit (n = 11,230) vs. Planned Hospital (n = 19,579) Blood transfusion:67 (0.5%) vs. 241 (1.2%), aOR 0.48, 95% CI 0.32 to 0.73 | | NR |
| Davis et al., 2012 New Zealand New Zealand College of Midwives research database, managed by the Midwifery Maternity Provider Organisation 2006 to 2007 Fair quality | Planned Home (n = 1,830) vs. Planned Primary Unit (n = 2,877) vs. Planned Secondary Hospital (n = 7,380) vs. Planned Tertiary Hospital (n = 4,123) Planned Incomplete | NR | NR |

| Citation, Location, Data | Combined Parity | Nulliparous | Multiparous |
|--|--|--|--|
| Source, Dates | | | |
| | Secondary Hospital: 96 (1.3%), aRR 1.07, 95% CI 0.68 to 1.69, p = 0.45 Tertiary Hospital: 67 (1.6%), aRR 1.10, 95% CI 0.67 to 1.79, p = 0.23 Adjusted for smoking, maternal age, parity, ethnicity, augmentation, length of labor, mode of birth, episiotomy, perineal trauma, newborn birthweight > 4,000 g, mode of third stage management | | |
| Davies-Tuck et al., 2018 Australia | Low risk, Planned Home (n = 3,202) vs. Planned Hospital (n = 701,058) | NR | NR |
| Victorian Perinatal Data Collection 2000 to 2015 Poor quality | Postpartum hemorrhage: 291 (9.1%) vs. 90,603 (12.9%), $p < 0.001$ Mother admitted to HDU/ICU: 6 (0.2%) vs. 4,217 (0.6%), $p = 0.002$ 3rd/4th degree tear, 31 (1.0%) vs. 14,000 (2.0%), $p < 0.001$ | | |
| de Jonge, et al., 2013 The Netherlands | Planned Home (n = 92,333) vs. Planned Hospital (n = 54, 419) | Planned Home (n = 38,728) vs. Planned Hospital (n = 26,499) | Planned Home (n = 53,602) vs. Planned Hospital (n = 27,919) |
| LEMMoN study merged with Netherlands Perinatal Registry August 2004 to August 2006 Fair quality | Severe acute maternal morbidity: 141 (1.5%) vs. 147 (2.7%) Admission to intensive care unit: 32 (0.3%) vs. 38 (0.7%) Blood transfusion ≥4 packed cells: 134 (1.5%) vs. 122 (2.2%) Postpartum hemorrhage (>1,000 mL): 2,699 (29.2%) vs. 2172 (39.9%) | Severe acute maternal morbidity: 89 (0.23%) vs. 82 (0.31%), aOR 0.77, 95% CI 0.56 to 1.06, RRR 25.7%, 95% CI −0.1% to 53.5% Blood transfusion ≥4 packed cells: 85 (0.22%) vs. 68 (0.26%), aOR 0.90, 95% CI 0.65 to 1.27, RRR 14.5%, 95% CI −14.7% to 45.8% | Severe acute maternal morbidity: 52 (0.10%) vs. 65 (0.23%), aOR 0.43, 95% CI 0.29 to 0.63, RRR 58.3%, 95% CI 33.2% to 87.5% Blood transfusion ≥4 packed cells: 49 (0.09%) vs. 54 (0.19%), aOR 0.45, 0.30 to 0.68, RRR 52.7, 95% CI 24.9 to 85.3 Postpartum hemorrhage: 1,044 |

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|---|--|---|--|
| | (16.8%) vs. 1315 (24.2%) No statistical analysis reported. | Postpartum hemorrhage: 1,655 (4.31%) 1,134 (4.33%), aOR 0.92, 95% CI 0.85 to 1.00, RRR 0.5%, 95% CI -6.8% to 7.9% Manual removal of placenta: 1,099 (2.90%) vs. 773 (2.98%), aOR 0.91, 95% CI 0.83 to 1.00, RRR 2.8%, 95% CI -6.1% to 11.8% Severe acute maternal morbidity includes admission to ICU, eclampsia/HELLP, blood transfusion of 4 or more packed calls, or other serious event Adjusted for parity, gestational age, maternal age, ethnicity, socioeconomic position | 95% CI 0.46 to 0.55, RRR 47.9%, 95% CI 41.2% to 54.7% Manual removal of placenta: 451 (0.85%) vs. 542 (1.96%), aOR 0.41, 95% CI 0.36 to 0.47, RRR 56.9%, 95% CI 47.9% to 66.3% Severe acute maternal morbidity includes admission to ICU, eclampsia, blood transfusion of 4 or more packed cells, or other serious event Adjusted for parity, gestational age, maternal age, ethnicity, socioeconomic position |
| Grigg et al., 2017 New Zealand Maternity and Midwifery Provider Organization data 2010 to 2011 Poor quality | Planned Birthing Center (n = 407) vs. Planned Hospital (n = 285) Postpartum hemorrhage >1,000 ml: 24 (5.9%) vs. 13 (4.6%), aOR 1.74, 95% CI 0.85 to 3.59, p > 0.05 Perineal trauma Third/fourth: 9 (2.2%) vs. 5 (1.8%), aOR 1.43, 95% CI 0.46 to 4.42, p > 0.05 Adjusted for maternal age, smoking status, parity, term, augmentation, induction | | NR |

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|---|---|---|--|
| | No home birth contraindication Planned Home (n = 278) vs. Planned Hospital (n = 851) Postpartum hemorrhage ≥1,000 mL: 6 (2.2%) vs. 31 (3.7%) OASI: 7 (2.5%) vs. 26 (3.1%) Home birth contraindication present Planned Home (n = 29) vs. Planned Hospital (n = 70) Postpartum hemorrhage ≥1,000 mL: 3 (10.7%) vs. 3 (4.3%) OASI: 1 (3.4%) vs. 2 (2.9%) | NR | NR |
| Halfdansdottir et al., 2015 Iceland Review of midwives' and doctors' original hand- written maternity notes 2005 to 2009 Poor quality | Planned Home (n = 307) vs. Planned Hospital or Midwifery Alongside Unit (n = 921) Maternal blood transfusion: 1 (0.3) vs. 19 (2.1%), aOR 0.91, 95% Ci 0.41 to 2.05 OASI: 8 (2.6%) vs. 28 (3.0%), aOR 0.97, 95% CI 0.41 to 2.27 Adjusted for maternal age, gestational age, presentation, water birth, birth weight, gender | Planned Home (n = 64) vs. Planned Hospital or Midwifery Alongside Unit (n = 192) Postpartum hemorrhage ≥1,000 mL: 4 (6.3%) vs. 19 (2.6%); aOR 0.71, 95% CI 0.20 to 2.58 OASI: 4 (6.3%) vs. 12 (6.3%), aOR 1.37, 95% CI 0.40 to 4.63 | (2.1%) vs. 19 (2.6%), aOR 1.02, 95% CI 0.34 to 3.02 |
| | Planned Home (n = 11,493) vs. Planned Hospital (n = 11,493) 3rd or 4th degree perineal laceration: 151 (1.3%) vs. 266 (2.3%), RR 0.57, 95% CI 0.47 to 0.69 | Hospital (n = 4,027) | Planned Home (n = 7,466) vs. Planned Hospital (n = 7,466) 3rd or 4th degree perineal laceration: 25 (0.3%) vs. 77 (1.0%), RR 0.33, 95% CI 0.21 to 0.51 |

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|---|---|--|--|
| | | Postpartum hemorrhage: 130 (3.2%) vs. 146 (3.6%), RR 0.89, 95% CI 0.71 to 1.12 | Postpartum hemorrhage: 156 (2.1%) vs. 202 (2.7%), RR 0.77, 95% CI 0.63 to 0.95 |
| Hutton et al., 2009 Canada Ontario Ministry of Health database 2003 to 2006 Poor quality | Planned Home (n = 6,692) vs. Planned Hospital-Midwife (n = 6,692) Estimated intrapartum blood loss >1,000 mL: 56 (0.8%) vs. 82 (1.2%), RR 0.68, 95% CI 0.49 to 0.96 | Hospital-Midwife(n = 2,298) Estimated intrapartum blood loss | Planned Home (n = 4,393) vs. Planned Hospital-Midwife (n = 4,394) Estimated intrapartum blood loss >1,000 mL: 27 (0.6%) vs. 51 (1.2%) |
| Janssen et al., 2009 British Columbia, Canada Perinatal Database Registry and vital statistics | Hospital-Midwife (n = 4,752) vs. Matched Sample of Physician- | NR | NR |
| 2000 to 2004 Poor quality | Prolapsed cord: 2 (0.1%%) vs. 6 (0.1%%) vs. 9 (0.2%) Uterine rupture: 0 (0.0%) vs. 0 (0.0%) vs. 2 (0.04%) Postpartum hemorrhage: 110 (3.8%) vs. 285 (6.0%) vs. 357 (6.7%) Blood transfusion: 2 (0.1%) vs. 10 (0.2%) vs. 15 (0.3%) Obstetric shock: 1 (0.03%) vs. 1 (0.02%) vs. 1 (0.02%) Manual removal of placenta: 28 (1.0%) vs. 85 (1.8%) vs. 90 (1.7%) Uterine prolapse: 1 (0.03%) vs. 1 (0.02%) vs. 2 (0.04%) Puerperal fever: 1 (0.03%) vs. 4 (1.0%) vs. 7 (0.1%) | | |

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|---|--|-------------|-------------|
| | Third- or fourth-degree perineal tear: 34 (1.2%) vs. 137 (2.9%) vs. 183 (3.4%) Cervical tear: 2 (0.1%) vs. 5 (0.1%) vs. 4 (0.1%) | | |
| | Third- or fourth-degree perineal tear*: RR 0.43, 95% CI 0.29 to 0.63 Postpartum hemorrhage: RR 0.62, 95% CI 0.49 to 0.77 Infection: RR 0.39, 95% CI 0.13 to 1.14 *Adjusted for parity | | |
| Katoaka et al., 2018 Japan | Planned Birth Center (n = 5,379) vs. Planned Hospital (n = 4,209) | NR | NR |
| Review of medical records Birth centers: 2001 to 2006, one hospital: 2004 to 2006, other hospital: 2008 Poor quality | Total blood loss (mL) ≥1,000: 193 (3.6%) vs. 101 (2.4%), aOR 1.77, 95% CI 1.35 to 2.32 Perineal laceration: 2,085 (40.9%) vs. 2,773 (66.1%), aOR 0.38, 95% CI 0.35 to 0.42 | | |
| | Adjusted for age, parity, mode of delivery and gestational weeks | | |
| Kennare et al., 2010 Australia Pregnancy Outcome Unit of South Australia Health perinatal data for all births and data on perinatal deaths 1991 to 2006 | Planned Home vs. Planned Hospital Third or fourth degree perineal tears: 6/577 (1%) vs. 2,030/112,737 (1.8%), aOR 0.77, 95% CI 0.34 to 1.74, p = 0.53 Postpartum hemorrhage: Planned home births 50/1,136 (4.4%) vs. | NR | NR |

Appendix F. Outcome Data from Comparative Observational Studies

| Citation, Location, Data | Combined Parity | Nulliparous | Multiparous |
|--|---|-------------|-------------|
| Source, Dates | | | |
| Poor quality | 16,200/292,469 (5.5%), aOR 0.72, 95% CI 0.47 to 1.11, p = 0.14 | | |
| | Adjusted for maternal age, parity, occupational status, smoking, plurality, medical and obstetric complications (e.g., antepartum hemorrhage, diabetes, hypertension), gestational age, small for gestational age, congenital anomalies, city or country hospital, mode of delivery | | |
| Laws et al., 2014 Australia | Planned Birth Center (n = 14,707) vs. Planned Hospital (n = 29,414) | NR | NR |
| Registry of Births, Deaths, and Marriages, Midwives Data Collection, Admitted Patient Data Collection 2001 to 2009 | Uterine rupture: 4 (0.03%) vs. 24 (0.08%), aOR 0.17, 95% CI 0.04 to 0.73 Third/fourth degree tears: 360 (2.5%) vs. 779 (3.0%), aOR 0.85, 95% CI 0.74 to 0.99 | | |
| Poor quality | Postpartum hemorrhage: 1,270 (8.6%) vs. 3,128 (10.6%), aOR 0.79, 95% CI 0.73 to 0.86 | | |
| | Postpartum infection: 153 (1.0%) vs. 421 (1.4%), aOR 0.74, 95% CI 0.59 to 0.92 | | |
| | Hysterectomy: 0 (0.0%) vs. 15 (0.1%) Admitted to intensive care: 3 (0.02%) vs. 23 (0.08%), aOR 0.12, 95% CI 0.02 to 0.89 | | |

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|--|---|-------------|-------------|
| | Hospital readmission within 42 days: 691 (4.7%) vs. 1,235 (4.2%), aOR 1.08, 95% CI 0.97 to 1.21 | | |
| | Adjusted for maternal age, Australian/overseas-born, socioeconomic disadvantage, smoking during pregnancy, parity, preexisting medical conditions, admitted patient insurance status, obstetric complications, level of hospital, day of the week, and holidays | | |
| Monk et al., 2014 Australia ObstetriX surveillance | Planned Birth Center (n = 494) vs. Planned Tertiary Maternity Unit (n = 3,157) | NR | NR |
| system of point-of-care maternity data collection across the antenatal, | Blood loss (mL) >1,000: 18 (3.6%) vs. 139 (4.4%), aOR 0.88, 95% CI 0.52 to 1.47, p = 0.618 | | |
| intrapartum, and immediate postnatal periods 2005 to 2006 | 3rd/4th degree tear: 24 (4.9%) vs. 132 (4.2%), aOR 0.90, 95% CI 0.56 to 1.45, p = 0.671 | | |
| Fair quality | Adjusted for maternal age, smoking status, parity, augmentation, induction, previous cesarean delivery and risk at the onset of labor | | |
| Nove et al., 2012 United Kingdom St Mary's Maternity Information System | Planned Home (n = 5,998) vs. Planned Hospital (n = 267,874) | NR | NR |

| Citation, Location, Data | Combined Parity | Nulliparous | Multiparous |
|--|--|-------------|-------------|
| Source, Dates | | | |
| 1988 to 2000 Fair quality | Postpartum hemorrhage: 23 (0.38%) vs. 2,785 (1.04%), aOR 0.4, 95% CI 0.3 to 0.6, p < 0.001 | | |
| | Adjusted for macrosomia, previous baby with birthweight > 4,500 g, BMI, borderline anemia, parity, mother's age, ethnicity, birthweight, sex of baby, year of delivery, number of ultrasounds, hospital providing care, time of delivery | | |
| Øian et al., 2018 Norway Medical Birth Registry with supplementary data collection | Births in Midwife-Led Birth Centers, Planned (n = 2,298) vs. Births Planned for a Midwife-led Birth Unit, Took Place Elsewhere (n = 220) vs. Births in Hospital, Low Risk (n = 105,358) | NR | NR |
| January 2008 to December 2010 | Sphincter Injury, Grade 3/4: 13 (.8%) vs. 2 (1.1%) vs. 2,410 (2.3%) | | |
| Poor quality | Hemorrhage > 500 mL 500 to 1,500 mL: 58 (3.7%) vs. 15 (8.4%) vs. 12,378 (11.7%) > 1,500 mL, Transfusion: 10 (.6%) vs. 5 (2.8%) vs. 1,604 (1.5%) > 500 mL, No Further Details: 15 (1.0%) vs. 5 (2.8%) vs. 264 (.3%) | | |
| Schroeder et al., 2017 England | Planned Birth Center (n = 167) vs. Planned Hospital (n = 164) | NR | NR |
| Interviews and medical records from Barkantine Birth Centre and Royal | Mean Days in ICU: 0.00 ± 0.0 vs. 1.00 ± 0.0, p = NR | | |

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|--|---|--|--|
| London Hospital's obstetric unit in Tower Hamlets, a low-income borough in east London 2008 to 2009 Poor quality | | | |
| Register with additionally | Planned Home (n = 26,128) vs. Planned Hospital (n = 21,362) Postpartum hemorrhage: 928 (4%) vs. 1,096 (5%), OR 0.68, 95% CI 0.62 to 0.74, p < 0.001 | NR | NR |
| Non-US, by parity only | | | |
| Bailey, 2017 New Zealand Routinely collected maternity outcome data compiled from Counties- Manukau District Health Board (CMDHB) maternity facilities 2003 to 2010 Poor quality | | Hospital 2005 to 2010 data Blood transfusion: 24/2,710 (0.9%) vs. 219/9,260 (2.4%), aOR 0.40, 95% CI 0.25 to 0.62 | Planned Birth Center vs. Planned Hospital 2005 to 2010 data Blood transfusion: 0.4% vs. 1.0%, aOR 0.54, 95% CI 0.35 to 0.83 Adjusted for maternal age, ethnicity, and deprivation score |
| Bolten et al., 2016 The Netherlands | NR | I | Planned Home (n = 1,182) vs. Planned Hospital (n = 728) |

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|--|-----------------|---|---|
| DELIVER (Data EersteLljns VERloskunde) Study 2009 to 2010 | | , | Anal sphincter damage (third-or fourth degree): 17 (1.4%) vs. 14 (1.9%), aOR 0.73, 95% CI 0.34 to 1.58 |
| Poor quality | | CI 0.67 to 1.59 | Hemorrhage postpartum >1,000 ml: 28 (2.4%) vs. 24 (3.3%), aOR 0.68, 95% CI 0.38 to 1.23 Adjusted for maternal age, gestational age, ethnic background (Dutch/western background/non-western background), BMI, socio-economic position |
| Christensen & Overgaard, 2017 | NR | Planned Birth Center (n = 215) vs. Planned Obstetric Unit (n = 215) | Planned Birth Center (n = 624) vs. Planned Obstetric Unit (n = 624) |
| Denmark Data collected on sociodemographic characteristics, present and previous pregnancies and births, neonatal outcomes and transfers March 2004 to October 2008 Poor quality | | 3rd-4th degree tear: OR 0.9, 95% CI 0.4 to 2.0 Maternal readmission: OR 0.3, 95% CI 0.1 to 0.9 | 3rd-4th degree tear: OR 0.6, 95% CI 0.2 to 1.7 Maternal readmission: OR 0.4, 95% CI 0.1 to 1.3 |
| Hollowell et al., 2017 England Birthplace in England national prospective cohort study April 2008 to April 2010 | NR | Planned Birthing Center (n = 5,187) vs. Planned Hospital (n = 8.,350) Third or fourth degree perineal trauma: 4.0% vs. 4.9%, aOR 0.82, 99% CI 0.59 to 1.15, p = 0.13 | Planned Birthing Center (n = 6,078) vs. Planned Hospital n = 8,323) Third or fourth degree perineal trauma: 0.9% vs. 1.6%, aOR 0.60, 99% CI 0.36 to 1.00, p = 0.010 |

Appendix F. Outcome Data from Comparative Observational Studies

| Citation, Location, Data Source, Dates | Combined Parity | Nulliparous | Multiparous |
|---|-----------------|--|---|
| Fair quality | | Blood transfusion: 0.8% vs. 1.3%, aOR 0.71, 99% CI 0.44 to 1.14, p = 0.063 Maternal admission for higher level care: 0.2% vs. 1.0%, aOR 0.28, 99% CI 0.07 to 1.20, p = 0.025 Adjusted for maternal characteristics and complicating conditions identified at the start of care in labor | Blood transfusion: 0.3% vs. 0.6%, aOR 0.56, 99% CI 0.26 to 1.21, p = 0.052 Maternal admission for higher level care: 0.1% vs. 0.4%, aOR 0.30, 99% CI 0.07 to 1.10, p = 0.016 Adjusted for maternal characteristics and complicating conditions identified at the start of care in labor |
| van Haaren-ten Haken et al., 2015 The Netherlands Self-reported questionnaires, medical records, and birth registration forms 2007 to 2011 Poor quality | NR | Planned Home (n = 221) vs. Planned Hospital-Midwife (n = 160) vs. Planned Hospital-Obstetrician (n = 176) Postpartum hemorrhage ≥1000: 13 (5.9%) vs. 10 (6.3%) vs. 19 (10.8%), aOR 0.70, 95% CI 0.30 to 1.63 Adjusted for maternal age, method of conception, first pregnancy (previous miscarriage or ectopic pregnancy), gestational age at birth, medical indications pregnancy | |

Table F5. Outcome Data from Comparative Studies: Breastfeeding

| Citation, Location, Data Source, Dates , Quality Assessment | Combined Parity | Nulliparous | Multiparous |
|--|--|-------------|-------------|
| U.S. Studies | | | |
| MacDorman & Declercq, 2016 United States | Planned Home (n = 29,021) vs. Planned Birthing Center (n = 18,047) vs. Planned Hospital (n = 3,773,115) | | NR |
| Birth certificates in 47 states and DC 2004 to 2014 Poor quality | Breastfeeding initiation: 97.9% vs. 98.1% vs. 80.8% Excludes births in California and Michigan that did not report breastfeeding | | |
| Thornton et al., 2017 U.S. Uniform Data Set from American Association of Birth Centers at 79 US birth centers in 43 states 2006 to 2011 Poor quality | Planned Hospital (n = 2,527) Breastfeeding at discharge: 8,294 (94.51%) vs. 1,839 (72.77%), aOR 9.12, | NR | NR |
| Non-U.S. Studies | | | |
| de Cock et al., 2015 The Netherlands Survey data, DELIVER study | Planned Home (n = 547) vs. Planned Hospital-Midwife (n = 165) | NR | NR |

| Citation, Location, Data Source, Dates , Quality Assessment | Combined Parity | Nulliparous | Multiparous |
|---|--|--|---|
| September 2009 to April 2011 Poor quality | Exclusive breastfeeding at median 5 weeks postpartum: 410 (75.0%) vs. 113 (68.5%), aOR 0.79, 95% CI 0.53 to 1.19 Adjusted for parity, age, education level, education level partner, ethnicity, smoking, birth weight aOR 0.80, 95% CI 0.53 to 1.18 Adjusted for characteristics listed above and early opportunity to breastfeed, early skin-to-skin contact, postnatal breastfeeding consult | | |
| Grigg et al., 2017 New Zealand Maternity and Midwifery Provider Organization data 2010 to 2011 Poor quality | Planned Birthing Center (n = 407) vs. Planned Hospital (n = 285) Exclusive or fully at 6 weeks: 328 (80.6%) 224 (78.6%), aOR 1.14, 95% CI 0.76 to 1.70, p > 0.05 Adjusted for maternal age, smoking status, parity, augmentation, induction, term | | NR |
| Hutton et al., 2016 Ontario, Canada Chart review March 2016 to April 2009 Poor quality | Planned Home (n = 11,493) vs. Planned Hospital (n = 11,493) At 10 days: 9,566 (87.8%) vs. 8,459 (78.9%), RR 1.11, 95% CI 1.10 to 1.13 | Hospital (n = 4,027) At 10 days: 3,220 (84.8%) vs. 2,825 | Planned Home (n = 7,466) vs. Planned Hospital (n = 7,466) At 10 days: 6,346 (89.6%) vs. 5,634 (81.2%), RR 1.10, 95% CI 1.09 to 1.12 |
| Hutton et al., 2009 Canada | Planned Home (n = 6,692) vs. Planned Hospital-Midwife (n = 6,692) Infant feeding at 6 weeks | Planned Home (n = 2,293) vs. Planned Hospital-Midwife (n = 2,298) | Planned Home (n = 4,393) vs. Planned Hospital-Midwife (n = 4,394) |

| Citation, Location, Data Source, Dates , Quality Assessment | Combined Parity | Nulliparous | Multiparous |
|---|---|--|--|
| Ontario Ministry of Health database 2003 to 2006 Poor quality | Exclusively breastfed: 5,853 (87.5%) vs. 5,140 (76.8%) | Infant feeding at 6 weeks exclusively breastfed: 1,962 (89.1%) vs. 1,680 (76.7%) | Infant feeding at 6 weeks exclusively breastfed: 3,887 (91.1%) vs. 3,460 (82.2%) |
| Laws et al., 2014 Australia Registry of Births, Deaths, | Planned Birth Center (n = 14,707) vs. Planned Hospital (n = 29,414) Breastfeeding on discharge: 4,951 | NR | NR |
| and Marriages, Midwives Data Collection, Admitted Patient Data Collection 2001 to 2009 Poor quality | (93.7%) vs. 9,129 (86.4%), aOR 2.32, 95% CI 2.04 to 2.65 Adjusted for maternal age, Australian/overseas-born, socioeconomic disadvantage, smoking during pregnancy, parity, preexisting medical conditions, admitted patient insurance status, obstetric complications, level of hospital, day of the week, and "holidays." | | |
| Monk et al., 2014 Australia ObstetriX surveillance system of point-of-care maternity data collection across the antenatal, intrapartum, and immediate postnatal periods 2005 to 2006 Fair quality | Planned Birth Center (n = 494) vs. Planned Tertiary Maternity Unit (n = 3,157) Exclusive on discharge: 447 (91.22%) vs. 2,586 (82.23%), aOR 1.59, 95% CI 1.14 to 2.24, p = 0.007 | NR | NR |

Appendix F. Outcome Data from Comparative Observational Studies

| Citation, Location, Data Source, Dates , Quality Assessment | Combined Parity | Nulliparous | Multiparous |
|---|---|-------------|-------------|
| Ireland and United Kingdom Growing Up in Ireland study, 2008 to 2009 United Kingdom Millennium Cohort Study, 2001 to 2002 Fair quality | Ireland Planned Home (n = 157) vs. Planned Hospital (n = 10,447) EBF at 6 months: 35 (22%) vs. 928 (9%), aOR 2.77, 95% CI 1.78 to 4.33, p = 0.007 United Kingdom Planned Home (n = 340) vs. Planned Hospital (n = 17,181) EBF at 6 months: 13 (4%) vs. 213 (1%), aOR 2.24, 95% CI 1.14 to 4.03, p < 0.001 | NR | NR |

Appendix G. Outcome Data by Subgroups for Comparative Observational Studies

Table G1. Outcome Data by Maternal Age

| Cite, Location, Data source, Dates, Quality Assessment | Findings |
|--|--|
| Grunebaum, McCullough, Arabin et al., 2017 U.S. CDC linked birth-infant death data set 2008 to 2012 | Planned home vs. Planned Hospital-Midwife vs. Planned Hospital-Physician Neonatal mortality (birth to 27 days) <35 years 92/74,850 (0.123%) vs. 429/1,216,860 (0.035%) vs. 7,527/12,359,811 (0.061%) Planned home vs. Planned Hospital-Midwife: RR 3.49, 95% CI 2.8 |
| Poor quality | to 4.4 ≥ 35 years 30/20,807 (0.144%) vs. 51/146,339 (0.035%) vs. 1168/2,087,544 (0.056%) Planned home vs. Planned hospital-Midwife: RR 4.1, 95% CI 2.6 to 6.5 |
| Grunebaum, McCullough, Sapra et al., 2017 U.S. CDC linked birth-infant death files 2009 to 2013 Fair quality | Planned Home Birth vs. Hospital-Midwife Neonatal deaths <35: 90/76,703 (0.12%) vs. 302/958,141 (0.03%), SMR 3.72, 95% CI 2.95 to 4.50 ≥ 35: 27/20,106 (0.13%) vs. 32/119,030 (0.03%), SMR 5.11, 95% CI 3.19 to 7.03 |
| Li et al., 2014 United Kingdom Birthplace April 2008 to April 2010 Good quality | Maternal composite outcome per 5- year increase in maternal age Non-Obstetric Unit: aRR 1.21, 95% CI 1.18 to 1.25 Obstetric Unit: aRR 1.12, 95% CI 1.10 to 1.15 Adjusted for ethnic group, understanding of English, marital/partner status, BMI in pregnancy, index of multiple deprivation score quintile, gestation at delivery Intrapartum cesarean section per 5 year increase in maternal age, controlling for birth setting Nulliparous: aRR 1.27, 95% CI 1.23 to 1.32 Multiparous: aRR 1.16, 95% CI 1.06 to 1.28 |
| | Instrument delivery by 5 year increase in maternal age, controlling for birth setting Nulliparous: aRR 1.18, 95% CI 1.12 to 1.25 |

| Cite, Location, Data source, Dates, Quality Assessment | Findings |
|---|--|
| | Multiparous: aRR 1.15, 95% CI 1.05 to 1.27 |
| | Third/fourth degree perineal tear, controlling for birth setting Nulliparous: aRR 1.12, 95% CI 1.02 to 1.23 Multiparous: aRR 1.01, 95% CI 0.89 to 1.15 |
| | Maternal blood transfusion, controlling for birth setting Nulliparous: aRR 1.13, 95% CI 0.95 to 1.34 Multiparous: aRR 1.24, 95% CI 0.94 to 1.62 |
| | Adjusted for ethnic group, understanding of English, marital/partner status, BMI in pregnancy, index of multiple deprivation score quintile, gestation at delivery and planned place of birth (Obstetric Unit vs. Alongside Midwifery Unit vs. Freestanding Midwifery Unit vs. home) |
| | Maternal composite outcome by age in nulliparous women, non- Obstetric Unit vs. Obstetric Unit |
| | 16 to 19: 252/1553 (17.5%) vs. 480/1239 (39.4%), aRR 0.45, 95% CI 0.38 to 0.54 |
| | 20 to 24: 886/3679 (24.2%) vs. 1229/2577 (47.9%), aRR 0.51, 95% CI 0.45 to 0.58 |
| | 25 to 29: 1680/5354 (32.3%) vs. 1670/3003 (55.6%), aRR 0.59, 95% CI 0.54 to 0.65 |
| | 30 to 34: 1730/4897 (36.6%) vs. 1402/2322 (61.1%), aRR 0.61, 95% CI 0.56 to 0.67 |
| | 35 to 39: 792/1995 (39.9%) vs. 622/957 (65.5%), aRR 0.62, 95% CI 0.56 to 0.69 |
| | 40+: 83/196 4(4.8%) vs. 108/148 (71.9%), aRR 0.66, 95% CI 0.51 to 0.87 |
| | Adjusted for ethnic group, understanding of English, marital/partner status, BMI in pregnancy, index of multiple deprivation score quintile, gestation at delivery |
| | Maternal composite outcome by age in nulliparous women, also adjusted for complicating conditions at start of labor |
| | 16 to 19: aRR 0.49, 95% CI 0.42 to 0.58 20 to 24: aRR 0.55, 95% CI 0.49 to 0.62 |
| | 25 to 29: aRR 0.63, 95% CI 0.57 to 0.70 |
| | 30 to 34: aRR 0.66, 95% CI 0.60 to 0.73 |
| | 35 to 39: aRR 0.68, 95% CI 0.61 to 0.76 |
| | 40+: aRR 0.70, 95% CI 0.53 to 0.93 |

| Cite, Location, Data source, Dates, Quality Assessment | Findings |
|---|---|
| | Adjusted for ethnic group, understanding of English, marital/partner status, BMI in pregnancy, index of multiple deprivation score quintile, gestation at delivery, complicating conditions identified at the start of care in labor |
| | Maternal composite: augmentation, instrument delivery, intrapartum cesarean delivery, general anesthesia, blood transfusion, 3rd or 4th degree tear, or admission to higher level of care |
| | Perinatal composite outcome, nulliparous women, controlling for place of birth 40+ vs. 25 to 29 years: aRR 2.29, 95% CI 1.28 to 4.09 |
| | Perinatal composite outcome, multiparous women, controlling for place of birth 40+ vs. 25 to 29 years: aRR 1.21, 95% CI 0.60 to 2.43 |
| | Adjusted for ethnic group, understanding of English, marital/partner status, BMI in pregnancy, index of multiple deprivation score quintile, gestation at delivery, and planned place of birth (Obstetric Unit vs. Alongside Midwifery Unit vs. Freestanding Midwifery Unit vs. home) |
| | Perinatal composite: stillbirth after start of care in labor, early neonatal death, neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured humerus or clavicle, neonatal unit admission within 48 hours of birth for at least 48 hours |

Table G2. Outcome Data by Gestational Age

| Cite, Location, Data source, Dates, Quality Assessment | Findings |
|--|--|
| Grunebaum, McCullough, Arabin et al., 2017 U.S. CDC linked birth-infant death data set 2008 to 2012 Poor quality | Planned home vs. Planned Hospital-Midwife vs. Planned Hospital-Physician Neonatal mortality (birth to 27 days): ≥ 37 to < 41 weeks: 77/67,832 (0.114%) vs. 378/1,083,665 (0.035%) vs. 7,487/12,194,578 (0.061%), Planned home vs. Planned Hospital-Midwife: RR 3.25, 95% CI 2.6 to 4.2 ≥ 41 weeks: 45/27,825 (0.162%) vs. 102/279,534 (0.037%) vs. 1,208/2,252,777 (0.054%), Planned home vs. Planned Hospital-Midwife: RR 4.43, 95% CI 3.1 to 6.3 |
| Grunebaum, McCullough, Sapra et al., 2017 U.S. CDC linked birth-infant death data set 2009 to 2013 Fair quality | Planned home vs. Planned Hospital-Midwife Neonatal mortality (birth to 27 days) ≥ 37 to < 41 weeks 0.0994% vs. 0.0295%, SMR 3.37, 95% CI 2.57 to 4.17 ≥41 weeks 0.1717% vs. 0.0359%, SMR 4.78, 95% CI 3.43 to 6.12 |

Table G3. Outcome Data by Race/Ethnicity

| Cite, Location, Data source, Dates, Quality Assessment | Findings |
|---|--|
| Grunebaum, McCullough, Arabin et al., 2017 | Planned home vs. Planned Hospital-Midwife vs. Planned Hospital-Physician |
| U.S. | Neonatal Mortality (birth to 27 days) White non-Hispanic: 112/84,759 (0.132%) vs. 260/728,918 |
| CDC linked birth-infant death data set | (0.036%) vs. 4,663/7,779,467 (0.06%), Planned home vs. Planned Hospital-Midwife: RR 3.71, 95% CI 3 to |
| 2008 to 2012 | 4.6 |
| Poor quality | Others: 10/10,898 (0.918%) vs. 220/634,281 (0.035%) vs. 4,032/6,667,888 (0.061%), |
| | Planned home vs. Planned Hospital-Midwife: RR 2.65, 95% CI 1.4 to 5 |

Table G4. Outcome Data by Composite Risk Scores

| Cite, Location, Data source, Dates, Findings | | |
|--|--|--|
| Quality Assessment | | |
| Birthplace in England | Without complicating condition at start of labor | |
| Collaborative, 2011 United Kingdom | Nulliparous women Planned Home (n = 4,063) vs. Planned Hospital (n = 8,018) Birthplace composite: 36 (9.5%) vs. 28 (3.5%), aOR 2.80, 95% CI | |
| Birthplace | 1.59 to 4.92 | |
| April 2008 to April 2010 Good quality | Planned Freestanding Midwifery Unit (n = 4,785) vs. Planned Hospital (n = 8,018) Birthplace composite: 22 (4.5%) vs. 28 (3.5%), aOR 1.40, 95% CI 0.74 to 2.65 | |
| | Multiparous women Planned Home (n = 11,461) vs. Planned Hospital (7,637) Birthplace composite:26 (2.0%) vs. 20 (2.6%), aOR 0.83, 95% CI 0.44 to 1.58 | |
| | Planned Freestanding Midwifery Unit (n = 5,772) vs. Planned Hospital (7,637) Birthplace composite: 13 (2.2%) vs. 20 (2.6%), aOR 0.97, 95% CI 0.46 to 2.04 | |
| | Adjusted for maternal age, ethnic group, understanding of English, marital or partner status, body mass index, deprivation score quintile, previous pregnancies, weeks of gestation | |
| | Test for statistical interaction between planned place of birth and parity. P values for parity adjusted regression tests of heterogeneity: overall 0.03, pairwise (vs. obstetric unit) for home 0.006, freestanding midwifery unit 0.47, and alongside midwifery unit 0.66. | |
| | All women without complicating condition at start of labor (n = 55,849) | |
| | Planned Home (n = 15,675) vs. Planned Hospital (n = 15,689) Normal births: 13,902 (89.0%) vs. 9840 (62.2%), aOR 4.12, 95% CI 3.37 to 5.04 | |
| | Planned Freestanding Midwifery Unit (n = 10,620) vs. Planned Hospital (n = 15,689) Normal births: 8892 (84.1%) vs. 9849 (62.2%), aOR 3.42, 95% CI 2.74 to 4.27 | |

| Cite, Location, Data source, Dates, Quality Assessment | Findings |
|--|--|
| | Normal birth: birth without induction of labor, epidural or spinal analgesia, general anesthesia, forceps or ventouse delivery, cesarean section, or episiotomy |
| Davies-Tuck et al., 2018 Australia | High risk, Planned Home (n = 755) vs. Planned Hospital (n = 131,726) |
| Victorian Perinatal Data Collection 2000 to 2015 Poor quality | Unplanned cesarean: 66 (8.9%) vs. 41,530 (32.4%) < 0.001 Instrumental delivery: 34 (46%) vs. 18,407 (14.4%) < 0.001 Spontaneous vaginal: 640 (86.1%) vs. 68,219 (53.2%) < 0.001 Admission to special care nursery: 33 (4.4%) vs. 17,995 (13.7%), p < 0.001 NICU admission: 12 (1.6%) vs. 555 (0.4%), p < 0.001 5-minute Apgar < 7: 18 (2.4%) vs. 2,390 (1.8%), p = 0.24 HIE: 1 (0.13%) vs. 42 (0.03%), p = 0.13 Birth trauma: 23 (3.1%) vs. 10,056 (7.6%), p < 0.001 Intrauterine hypoxia: 24 (3.2%) vs. 8,714 (6.6%), p < 0.001 Other perinatal morbidity: 3 (0.4%) vs. 287 (0.2%), p = 0.29 Composite morbidity: 59 (7.8%) vs. 22,223 (16.9%), p < 0.001 Postpartum hemorrhage: 108 (14.5%) vs. 25,079 (19.6%), p < 0.001 Mother admitted to high dependency or intensive care unit: 4 (0.5%) vs. 1,459 (1.1%), p = 0.06 3rd/4th degree tear: 12 (1.6%) vs. 2,443 (1.9%), p = 0.58 |
| | High risk defined as any of the following: multiple pregnancy, post-term (> 41 and 6 weeks), non-cephalic presentation in labor, obesity (BMI Class 2 or greater), a prior cesarean, previous uterine surgery, grand multiparity (≥5 previous births), any significant maternal medical condition such as pre-existing diabetes, hypertension, renal, cardiac, liver, respiratory, endocrine, immunological, renal, or gastrointestinal disease as determined by individual ICD-10 codes. Birth trauma: brachial plexus injury, fractured clavicle or humerus Other perinatal morbidity: meconium aspiration syndrome, congenital pneumonia or respiratory distress syndrome |
| Homer et al., 2014 | Planned Home vs. Planned Birth Center vs. Planned Hospital |
| Australia Perinatal Data Collection, Admitted Patient Data Collection, | Women without complications at the start of care in labor Stillbirth during labor and early neonatal death: 0/688 (0%) vs. 8/13,718 (0.058%) vs. 198/221,056 (0.089%) |

| Cite, Location, Data source, Dates, Quality Assessment | Findings |
|---|--|
| Register of Congenital Conditions, | Birth center vs. Hospital: aOR 0.63, 95% CI 0.31 to 1.28 |
| Registry of Birth Deaths and Marriages, and the Australian Bureau of Statistics | Composite morbidity or mortality: 4/695 (0.58%) vs. 66/13,723 (0.48%) vs. 1,221/221,193 (0.552%) Home vs. Hospital: aOR 0.87, 95% CI 0.33 to 2.35 |
| 2000 to 2008 | Birth center vs. Hospital: aOR 0.82, 95% CI 0.64 to 1.05 |
| Fair quality | Composite: stillbirth, early neonatal death (<7 days), neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured clavicle, fractured humerus |
| | Adjusted for maternal age, gestational age in weeks at delivery, parity |
| Li et al., 2015 | Higher risk without complicating factor at start of labor |
| United Kingdom | Nulliparous - Planned Home (n = 247) vs. Planned Hospital (n = |
| Birthplace national prospective cohort study | 1,523) Straightforward vaginal birth: 180 (75.9%) vs. 906 (59.0%), aRR 1.43, 95% CI 1.29 to 1.58 |
| April 2008 to April 2010 Good quality | Interventions and adverse maternal outcomes: 85 (31.4%) vs. 841 (56.6%), aRR 0.50, 95% CI 0.40 to 0.63 |
| | Nulliparous- Planned Home (n = 248) vs. Planned Hospital (n = 1,528) |
| | Adverse perinatal outcomes (main composite): 6 (21.1%) vs. 64 (44.7%), aRR 0.43, 95% CI 0.16 to 1.16 |
| | Multiparous- Planned Home (n = 1,065) vs. Planned hospital (n = 3,181) |
| | Straightforward vaginal birth: 992. (93.4%) vs. 2,484 (77.7%), aRR 1.17, 95% CI 1.13 to 1.20 |
| | Interventions and adverse maternal outcomes: 86 (7.9%) vs. 969 (30.7%), aRR 0.26, 95% CI 0.21 to 0.34 |
| | Multiparous- Planned Home (n = 1,062) vs. Planned Hospital (n = 3,183) |
| | Adverse perinatal outcomes (main composite): 12 (10.5) vs. 75 (24.6%), aRR 0.41, 95% CI 0.18 to 0.89 |
| | Straightforward: birth without intrapartum CS, instrumental delivery, 3rd or 4th degree tear, blood transfusion. Adverse perinatal outcomes (main composite): stillbirth after the start of care in labor, early neonatal death, neonatal encephalopathy, meconium aspiration syndrome, brachial plexus |

Appendix G. Outcome Data by Subgroups for Comparative Observational Studies

| Cite, Location, Data source, Dates, Quality Assessment | Findings |
|---|---|
| | injury, fractured humerus or clavicle) or admission to a neonatal unit within 48 hours of birth for more than 48 hours. Adverse maternal outcomes: augmentation, instrumental delivery, intrapartum CS, general anesthesia, maternal blood transfusion, 3rd/4th degree perineal tear, maternal admission for higher level care |

Table G5. Outcome Data by TOLAC

| Cite, Location, Data source, Dates, Quality Assessment | Findings |
|---|---|
| Grunebaum, McCullough, Sapra et al., 2017 U.S. CDC linked birth-infant death files 2009 to 2013 Fair quality | Planned Home Birth vs. Hospital-Midwife Previous cesarean delivery No: SMR 3.72, 95% CI 3.01 to 4.43 Yes: SMR 8.33, 95% CI 2.59 to 14.07 |
| Rowe et al., 2016 England Birthplace in England national prospective cohort study April 2008 to April 2010 Good quality | Planned Home vs. Planned Hospital Study inclusion criteria of prior cesarean delivery Any vaginal birth: 182/209 (87.6%) vs. 853/1227 (69.1%), aRR 1.15, 95% CI 1.06 to 1.24 Any vaginal birth includes, spontaneous vertex birth, spontaneous breech birth, assisted by vacuum or forceps. Adjusted for maternal age, ethnic group, understanding of English, marital/partner status, BMI in pregnancy, index of multiple deprivation score quintile, gestation at delivery, parity where appropriate, complicating conditions identified at the start of care in labor Unadjusted analyses Stillbirth OR Apgar < 7 at 5 minutes: 4/206 (1.87%) vs. 20/1225 (1.57%), RR 1.19, 95% CI 0.41 to 3.44 Neonatal unit admission: 8/205 (3.71%) vs. 40/1223 (3.04%), RR 1.22, 95% CI 0.57 to 2.59 Maternal blood transfusion or maternal admission for higher level care: 7/209 (2.99%) vs. 36/1218 (2.85%), RR 1.05, 95% CI 0.49 to 2.26 |
| Tilden et al., 2017 U.S. Birth and death certificates 2007 to 2010 Fair quality | TOLAC: Planned Home and Freestanding Birth Center (n = 3,147) vs. Planned Hospital (n = 106,823) Neonatal death: 4 (0.13%) vs. 84 (0.08%), aOR 2.10, 95% CI 0.73 to 6.05, p > 0.05 Apgar score < 7: 139 (4.42%) vs. 2859 (2.68%), aOR 1.62, 95% CI 1.35 to 1.96, p < 0.001 Apgar score < 4: 23 (0.73%) vs. 431 (0.40%), aOR 1.77, 95% CI 1.12 to 2.79, p = 0.016 Neonatal seizures: 6 (0.19%) vs. 23 (0.02%), aOR 8.53, 95% CI 2.87 to 25.4, p = 0.003 |

| Cite, Location, Data source, Dates, Quality Assessment | Findings |
|---|--|
| | Ventilator support: 12 (0.38%) vs. 309 (0.29%), aOR 1.36, 95% CI 0.75 to 2.46, p = 0.31 |
| | NICU: 35 (1.11%) vs. 3,292 (3.10%), aOR 0.40, 95% CI 0.29 to 0.57, p < 0.001 |
| | Birth injury: 1 (0.03%) vs. 109 (0.10%), aOR 0.78, 95% CI 0.58 to 1.04, p = 0.089 |
| | Adjusted for maternal race, maternal age, maternal education (high school education as referent), Kotelchuck Index (adequate plus as referent), parity, number of previous Cesarean deliveries, maternal weight gain 40 pounds |

Table G6. Outcome Data by Breech

| Cite, Location, Data source, Dates, Quality Assessment | Findings |
|---|---|
| Grunebaum, McCullough, Sapra et | Planned Home Birth vs. Hospital-Midwife |
| al., 2017 | Cephalic: SMR 3.61, 95% CI 2.92 to 4.31 |
| U.S. | Breech: SMR 8.14, 95% CI 2.17 to 14.11 |
| CDC linked birth-infant death files | |
| 2009 to 2013 | |
| Fair quality | |

Table G7. Outcome Data by Other Factors

| Cite, Location, Data source, Dates, Quality Assessment | Findings |
|---|---|
| Grunebaum, McCullough, Sapra et | Planned Home Birth (n = NR) vs. Planned Hospital-Midwife (n = NR) |
| al., 2017 | Nulliparous & ≥35 Y: 0.523% vs. 0.042%, SMR 12.41, 95% CI 4.33 to |
| 11.6 | 20.49 |
| U.S. | Nulliparous & ≥41 weeks: 0.403% vs. 0.041%, SMR 9.57, 95% CI |
| CDC linked birth-infant death files | 5.84 to 13.30 |
| 2009 to 2013 | Nulliparous <35 Y: 0.197% vs. 0.036%, SMR 5.35, 95% CI 3.61 to |
| 2003 to 2013 | 7.09 |
| Fair quality | ≥41 weeks & ≥35 Y: 0.199% vs. 0.041%, SMR 4.87, 95% CI 2.00 to |
| | 7.73 |
| | 37 to 40 weeks & ≥35 Y: 0.112% vs. 0.024%, SMR 4.71, 95% CI 2.41 |
| | to 7.01 |

| Cite, Location, Data source, Dates, Quality Assessment | Findings |
|---|---|
| | ≥41 weeks & <35 Y: 0.165% vs. 0.035%, SMR 4.66, 95% CI 3.16 to 6.15 Nulliparous & 37 to 40 weeks: 0.145% vs. 0.036%, SMR 4.07, 95% CI 2.29 to 5.84 ≥41 Weeks & Parous: 0.106% vs. 0.031%, SMR 3.45, 95% CI 2.04 to 4.85 Parous & 35 Y: 0.099% vs. 0.023%, SMR 4.30, 95% CI 2.32 to 6.28 37 to 40 weeks & <35 Y: 0.096% vs. 0.030%, SMR 3.18, 95% CI 2.31 to 4.04 Parous & <35 Y: 0.091% vs. 0.027%, SMR 3.34, 95% CI 2.43 to 4.24 37 to 40 weeks & Parous: 0.088% vs. 0.026%, SMR 3.41, 95% CI 2.44 to 4.38 |
| Halfdansdottir et al., 2018 Iceland Maternity notes review 2005 to 2009 Poor quality | Within Planned Home Births Contraindication present (n = 29) vs. no home birth contraindication present (n = 274) Maternal Operative birth: OR 5.42, 95% CI 0.60 to 48.99 Postpartum hemorrhage ≥500 mL: OR 3.14, 95% CI 1.05 to 9.37 Postpartum hemorrhage ≥800 mL: OR 7.96, 95% CI 1.70 to 37.36 Postpartum hemorrhage ≥1000 mL: OR 7.29, 95% CI 1.16 to 45.88 OASI: OR 0.44, 95% CI 0.02 to 11.97 Maternal morbidity, 7 days: OR 2.50, 95% CI 0.74 to 8.49 Neonatal NICU admission: OR 1.88, 95% CI 0.41 to 8.64 5-minute Apgar < 7: OR 8.37, 95% CI 0.37 to 189.36 Neonatal resuscitation: OR 1.89, 95% CI 0.14 to 9.68 Neonatal morbidity, 7 days: OR 1.16, 95% CI 0.65 to 5.51 |
| Li et al., 2015 United Kingdom Birthplace national prospective cohort study April 2008 to April 2010 Good quality | All Planned Home Births Nulliparous - Higher risk planned home (n = 283) vs. Low risk planned home (n = 4,399) Adverse perinatal outcomes (main composite): 9 (27.7%) vs. 84 (19.3%), aRR 1.82, 95% CI 0.89 to 3.72 Multiparous - Higher risk planned home (n = 1,186) vs. Low risk planned home (n = 11,910) Adverse perinatal outcomes (main composite): 16 (12.3%) vs. 93 (7.5%), aRR 1.92, 95% CI 1.02 to 3.64 Planned home, without complicating condition at start of labor |

Appendix G. Outcome Data by Subgroups for Comparative Observational Studies

| Cite, Location, Data source, Dates, Quality Assessment | Findings |
|---|--|
| | Nulliparous - Higher risk planned home (n = 248) vs. Low risk planned home (n = 3,983) Adverse perinatal outcomes (main composite): 6 (21.1%) vs. 69 (17.8%), aRR 1.69, 95% CI 0.73 to 3.89 |
| | Multiparous - Higher risk planned home (n = 1,062) vs. Low risk planned home (n = 11,335) Adverse perinatal outcomes (main composite): 12 (10.5%) vs. 82 (7.1%), aRR 1.69, 95% CI 0.79 to 3.6 |
| | Low risk planned home birth from original birthplace cohort Adverse perinatal outcomes (main composite): stillbirth after the start of care in labor, early neonatal death, neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured humerus or clavicle) or admission to a neonatal unit within 48 hours of birth for more than 48 hours |

Appendix H. Characteristics of Noncomparative Observational Studies

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|---|---|--|---|
| Bachilova et al., 2018 U.S. Period Linked Birth/Infant Death databases from the National Center for Health Statistics at the Centers for Disease Control and Prevention (CDC) 2011 to 2013 Poor quality | N = 71,704 | Exclusion criteria: Births occurring in hospitals, freestanding birth centers, doctors' offices, clinics, other locations, or at an unknown location, home births that were accidental or not planned, planned home births that occurred ≤ 34 weeks gestation, infants born with congenital or chromosomal anomalies including anencephaly, Down syndrome, congenital diaphragmatic hernia, congenital heart disease, omphalocele, gastroschisis, cleft lip and/or palate, and limb defects. | Maternal race White: 64,323 (89.7%) Black: 1,436 (2.0%) Hispanic: 3,327 (4.6%) Other: 1,190 (1.7) Maternal education < 12 Grades: 18,896 (26.4%) High School: 21,612 (30.1%) University: 30,381 (42.4%) Unknown: 815 (1.1%) Maternal age < 25 Years: 11,092 (15.5%) 25 to 34 Years: 45,621 (63.6%) ≥ 35 Years: 14,991 (20.9%) Parity Nulliparous: 57,864 (82.7%) Unknown: 1,737 (2.4%) Fetal presentation Vertex: 47,158 (65.8%) Non-Vertex: 652 (.9%) Unknown: 23,894 (33.3%) Previous cesarean delivery: 3,140 (4.4%) Plurality Single: 71,145 (99.2%) Twins or greater: 559 (.8%) |
| Blix et al., 2015 Norway, Denmark, Sweden, Iceland Midwives attending planned home births | N = 3,068 Norway n = 482 Sweden n = 445 | Inclusion criteria: Planned home births in Norway, Denmark, Sweden, and Iceland between 2008 and 2013 | Home Birth (N = 3,068) Age < 20 Years: 10 (.3%) 20 to 24 Years: 201 (6.6%) 25 to 29 Years: 767 (25.0%) |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|--|-------------|-------------------------------------|---|
| Source, Dates, Quality | Denmark n = | Criteria Exclusion criteria: NR | 30 to 34 Years: 1,199 (39.1%) 35 to 39 Years: 736 (24.0%) ≥ 40 Tears: 138 (4.4%) Missing Data: 17 (.6%) Marital status Married/Cohabit: 2,992 (97.5%) Not Married/Cohabit: 48 (1.6%) Missing Data: 28 (.9%) Smokers Yes: 204 (6.7%) No: 2,805 (91.4%) Missing Data: 59 (1.9%) Parity Nulliparous: 572 (18.6%) Multiparous: 2,446 (81.4%) Missing Data: 50 Previous cesarean delivery (Total) No: 2,923 (95.3%) Yes: 144 (4.7%) Missing Data: 1 (0.0%) Previous cesarean (multiparous women) No: 2,301 (94.1%) Yes: 144 (5.9%) Missing Data: 1 (0.0%) Gestational age < 37 Weeks: 8 (0.3%) |
| | | | 37 to 42 Weeks: 2,956 (96.3%) > 42 Weeks: 22 (0.7%) Missing Data: 82 (2.7%) Fetal presentation Oscipito Apterior: 3,887 (04.1%) |
| | | | Occipito-Anterior: 2,887 (94.1%) Abnormal Cephalic: 126 (4.1%) Breech: 7 (.2%) Missing Data: 48 (1.6%) |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|--|---|--|--|
| U.S. | N = 47,394 MANA Stats 2.0 (2004 to 2009) | Inclusion criteria: Planned home or birth center births, primiparous, multiparous without a history | BMI < 18.5: 103 (3.4%) 18.5 to 24.9: 1,994 (65.0%) 25.0 to 29.9: 535 (17.4%) > 30: 199 (6.5%) Missing: 237 (7.7%) Planned Out-of-Hospital Birth (N = 47,394) Maternal Race/Ethnicity White, non-Hispanic: 41,626 |
| Project (MANA Stats) 2.0 and 4.0 2004 to 2009, 2012 to 2014 | n = 20,887 MANA Stats 4.0 (2012 to 2014) n = 26,507 | of cesarean delivery, multiparous with a history of cesarean delivery and also a history of vaginal birth, or multiparous with a history of cesarean delivery but without a history of vaginal birth Exclusion criteria: NR | (88.3%) Other: 5,513 (11.7) Expected Source of Payment Medicaid: 5,344 (11.3%) Not Medicaid: 42,042 (88.7%) Obstetric History Primiparous: 14,591 (30.8%) Multiparous, No History of Cesarean: 30,107 (63.6%) Multiparous, History of Both Cesarean and Vaginal Birth: 1,571 (3.3%) Multiparous, History of |
| | | | Cesarean Only: 1,086 (2.3%) BMI < 25: 30,578 (70.1%) 25 ≤ 30: 8,480 (19.4%) 30 ≤ 35: 2,954 (6.8%) 35+: 1,613 (3.7%) Maternal Age 35 Years or Older: 8,805 (18.8%) Maternal Education (fewer than 4 years of college): 20,988 (46.5%) Twin Pregnancy: 138 (0.3%) |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|---|------------|---|---|
| | | | Postterm Pregnancy (more than 42 completed weeks): 3,160 (6.7%) |
| | | | Pregnancy Complications Gestational Diabetes: 516 (1.1%) Preeclampsia: 63 (0.1%) Breech Presentation at Birth: 539 (1.2%) |
| Catling-Paull et al., 2013 | N = 1,807 | Inclusion criteria: | Home Birth (N = 1,807) |
| Australia 12 publicly funded home birth programs 2005 to 2010 Poor quality | | Planned to have a home birth at the onset of labor Exclusion criteria: Women who had planned a homebirth but were transferred to hospital-based care during pregnancy (i.e., before the onset of labor) | Maternal Age (n = 1,805) ≤ 25 Years: 219 (12.1%) 26 to 35 Years: 1,210 (67.0%) 36 to 40 Years: 337 (18.6%) > 40 Years: 39 (2.2%) Gestational Age at Birth (n = 1,807) < 37 Weeks: 19 (1.1%) 37 to 42 Weeks: 1,754 (97.1%) > 42 Weeks: 34 (1.9%) Parity (n = 1,807) Nulliparous: 575 (31.8%) Multiparous: 1,232 (68.2%) Place of Birth (n = 1,807) Home: 1,521 (84.2%) Birth Center:26 (1.4%) Hospital Labor Ward: 163 (9.0%) Operating Theater: 97 (5.4%) |
| U.S. | N = 16,924 | Inclusion criteria: Planned home births | Planned Out-of-Hospital Birth (N = 16,924) |
| Midwives Alliance of North America Statistics Project (MANA Stats) 2.0 dataset 2004 to 2009 Poor quality | | Exclusion criteria: Women transferred care to another provider prior to the onset of labor, women who at the onset of labor had a planned birth location other than home, women who did not live in the U.S. | Race/Ethnicity White: 15,614 (92.3%) Black: 361 (2.1%) Latina: 714 (4.2%) Asian/Pacific Islander: 760 (4.5%) Native American: 163 (1.0%) Other 145 (.9%) |

| Citation, Location, Data | N | Inclusion and Exclusion | Population Characteristics |
|--|---|-------------------------|--|
| Source, Dates, Quality Assessment | | Criteria | |
| A LOS COSTITUTE OF THE PROPERTY OF THE PROPERT | | | Belongs to Amish, Mennonite, or Other Plain Church: 1,098 (6.5%) |
| | | | Age at First Prenatal Visit, Mean Years: 30.3 ± 5.3 |
| | | | Education High School Graduate: 15,283 (92.4%) Completed ≥ 4 Years of College: 8,300 (58.0%) |
| | | | Marital Status Married: 14,961 (88.4%) Unmarried With a Partner: 1,579 (9.3%) Single (Includes Separated, Divorced): 331 (2.0%) Other: 51 (.3%) |
| | | | MANA Region of Residence New England: 873 (5.2%) North Atlantic: 1,992 (11.8%) Southeast: 2,054 (12.2%) Midwest: 2,646 (15.6%) West: 3,949 (23.4%) Pacific: 5,364 (31.8) |
| | | | Method of Payment Self-Pay: 10,888 (64.4%) Private Insurance: 4,092 (24.2%) Government Insurance (Includes Medicaid, CHAMPUS): 1,361 (8.0%) Other: 576 (3.4%) |
| | | | Parity Nulliparous: 3,773 (22.3%) Multiparous: 13,150 (77.7%) Grand Multiparous (≥ 5 Pregnancies): 1,150 (9.2%) TOLAC: 1,052 (8.0%) BMI |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|--|---|--|--|
| | | | Normal BMI Prepregnancy (18.5 to 25 kg/m²): 11,144 (66.9%) Mother's Pregravid BMI (kg/m²), Median: 22.5 (IQR, 20.6 to 25.7) |
| | | | Complications/Comorbid Conditions Affecting This Pregnancy Chronic Hypertension: 59 (.3%) Pregnancy-Induced Hypertension: 243 (1.4%) Preeclampsia: 29 (.2%) Eclampsia: 10 (.1%) Gestational Diabetes: 132 (.8%) Persistent Anemia: 146 (.9%) Rh Sensitization: 41 (.2%) Multiple Gestation: 60 (.4%) Breech Presentation: 222 (1.3%) |
| | | | Gestational Age of Neonate Preterm: 423 (2.5%) Postterm: 862 (5.1%) |
| U.S. Midwives Alliance of North America Statistics | N = 13,144 TOLAC n = 1,052 Comparison Group: 12,092 | Inclusion criteria: Multiparous women without a history of cesarean delivery Exclusion criteria: Care transferred to another provider prior to the onset of labor, planned birth location other than home prior to the onset of labor, did not live in the U.S., Primiparous women, | Planned Out-of-Hospital Birth (N |
| | | | Median maternal age at first prenatal visit: 32 (IQR, 28 to 36) vs. 31 (IQR, 27 to 34), p ≤ 0.001 Median maternal pregravid BMI: 24.0 (IQR, 21.3 to 28.0) vs. 22.7 (IQR, 20.6 to 25.8), p ≤ 0.001 |
| | | previous cesarean status unknown | Race/ethnicity White: 970 (92.2%) vs. 11,172 (92.4%) Black: 21 (2.0%) vs. 253 (2.1%) Latina: 42 (4.0%) vs. 474 (4.0%) Asian: 46 (4.4%) vs. 487 (4.0%) Native American: 7 (.7%) vs. 120 (1.0%) |

| Citation, Location, Data | N | Inclusion and Exclusion | Population Characteristics |
|-----------------------------------|---|-------------------------|--|
| Source, Dates, Quality Assessment | | Criteria | |
| | | | Other: 11 (1.0%) vs. 237 (2.0%), p ≤ 0.05 Amish/Mennonite: 54 (5.1%) vs. 875 (7.2%), p ≤ 0.01 |
| | | | Education High School Graduate: 966 (91.8%) vs. 10,843 (89.7%), p ≤ 0.05 4 or More Years of College: 531 (50.5%) vs. 5,694 (47.1%) |
| | | | Partner status Married: 986 (93.7) vs. 10.923 (90.3%), p ≤ 0.001 Partnered: 49 (4.7%) vs. 942 (7.8%), p ≤ 0.001 Separated/Divorced, Single, or Other: 17 (1.6%) vs. 227 (1.9%), p ≤ 0.001 |
| | | | MANA region of residence New England: 54 (5.2%) vs. 614 (5.1%) North Atlantic: 131 (12.5%) vs. 1,384 (11.5%) |
| | | | Southeast: 187 (17.9%) vs. 1,456 (12.1%), $p \le 0.001$ Midwest: 182 (17.4%) vs. 1,940 (16.1%) West: 214 (20.4%) vs. 2,935 (24.3%), $p \le 0.01$ Pacific: 279 (26.6%) vs. 3,738 (31.0%), $p \le 0.01$ |
| | | | p ≤ 0.01 <u>Previous pregnancies</u> 1: 275 (26.1%) vs. 3,971 (32.8%), p ≤ 0.001 2: 247 (23.5%) vs. 3,002 (24.8%), p ≤ 0.001 |

| Citation, Location, Data | N | Inclusion and Exclusion | Population Characteristics |
|---|--|---|---|
| Source, Dates, Quality Assessment | | Criteria | |
| | | | 3 or 4: 287 (27.3%) vs. 3,145 (26.0%), p ≤ 0.001 Previous cesarean deliveries (TOLAC group only) 1: 943 (89.6%), p ≤ 0.001 2: 91 (8.7%), p ≤ 0.001 3 or More: 18 (1.7%), p ≤ 0.001 Previous vaginal births (TOLAC group only): 721 (68.7%), p ≤ 0.001 Previous VBAC (TOLAC group only): 454 (43.3%), p ≤ 0.001 Comorbid conditions Gestational diabetes: 17 (1.6%) vs. 93 (.8%), p ≤ 0.01 Pregnancy-induced hypertension: 20 (1.9%) vs. 140 (1.2%), p ≤ 0.05 Chronic hypertension: 8 (.8%) vs. 40 (.3%), p ≤ 0.05 Twin pregnancy: 5 (.5%) vs. 49 (.4%), p ≤ 0.05 |
| Edqvist et al., 2016 Norway, Denmark, Sweden, Iceland Midwives attending planned home births submitted data through a questionnaire 2008 to 2012 Poor quality | N = 2,992 (subpopulation of Blix et al., 2015) Norway n = 468 Sweden n = 438 Denmark n = 1,799 Iceland n = 287 | who had a cesarean delivery or instrumental delivery after transfer to hospital | Home Birth (N = 2,992) Age Groups < 25 Years: 202 (6.8%) 25 to 34 Years: 1,923 (64.3%) > 35 years: 850 (28.4%) Missing Data: 17 (.6%) Marital Status Married/Cohabit: 2,918 (97.5%) Not Married/Cohabit: 51 (1.7%) Missing Data: 23 (.8%) Tobacco Use Yes: 198 (6.6%) No: 2,735 (91.4%) |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|--|---|---|---|
| | | | Missing Data: 59 (2.0%) Number of Children* First Baby: 524 (17.5%) 1 Previous Child: 1,257 (42.0%) 2 Previous Children: 828 (27.7%) 3 or More Previous Children: 322 (10.8%) Missing Data: 61 (2.0%) * 141 women had 1 previous cesarean, 3 women had 2 previous cesareans BMI < 18.5: 101 (3.3%) 18.5 to 24.9: 1,943 (64.9%) 25.0 to 29.9: 516 (17.2%) > 30: 196 (6.6%) Missing Data: 236 (7.9%) |
| Eto et al., 2017 Japan Birth records from 9 Tokyo midwifery centers January 2001 to August 2006 Poor quality | | Inclusion criteria: Delivery at one of 9 birth centers during January 2001 to August 2006 Exclusion criteria: Need for medical treatment related to breach delivery, preterm premature rupture of membrane, weak contractions, weaker fetal heartbeat, or returning to parents' home for delivery, high risk situations (e.g., primary hemorrhage, placenta accrete, hematoma formation) | Planned Birth Center (N = 4,051) Mean maternal age (n = 4,033): 31.7 ± 4.2 Parity Nulliparous: 1,157 (28.6%) Multiparous: 2,893 (71.4%) Mean Gestational Period (n = 4,040): 39.9 ± 1.1 weeks |
| Johnson & Daviss, 2005 North America (U.S. and Canada) North American Registry of Midwives (planned home birth data), birth | | Inclusion criteria: Women who engaged the services of a certified professional midwife in Canada or the U.S. as their primary caregiver for a birth | Home Birth (N = 5,418) <u>Maternal Age</u> ≤ 19 Years: 130 (2.4%) 20 to 24 Years: 930 (17.2%) 25 to 29 Years: 1,554 (28.7%) |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|--|---|---|---|
| certificate data from the National Center for Health Statistics (used as proxy for a comparable low risk hospital group) 2000 Poor quality | | with the expected date of delivery in 2000 Exclusion criteria: Individuals who left care because of social reasons (e.g., chose hospital birth, moved, changed midwife) or medical reasons (e.g., referred for pregnancy complications, miscarried, preterm labor, stillbirths before labor, set of twins) | 30 to 34 Years: 1,423 (26.3%) 35 to 39 Years: 969 (17.9%) ≥ 40 Years: 327 (6.0%) Parity 0: 1,690 (31.2%) 1: 1,295 (23.9%) ≥ 2: 2,415 (44.6%) Mother's Formal Education High School or Less: 2,152 (39.2%) Any College: 1,272 (23.2%) College Graduate: 1,169 (21.3%) Postgraduate: 692 (12.7%) Partner Status at Time of Birth Has Partner: 5,169 (95.4%) No Partner: 164 (3.1%) Ethnicity White: 4,846 (89.4%) Hispanic: 216 (4.0%) African-American: 70 (1.3%) Other: 140 (2.6%) Other Special Groups Amish: 467 (8.7%) Mennonite: 194 (3.6%) Socioeconomic Status Low: 1,256 (23.2%) Middle: 3,244 (59.9%) Upper: 664 (12.3%) Location City: 1,891 (34.9%) Small Town: 1,506 (27.9%) Rural: 1,734 (32.0%) Time (Trimester) Prenatal Care Began 1st: 2,483 (45.8%) 2nd: 2,975 (38.2%) |

| Citation, Location, Data Source, Dates, Quality | N | Inclusion and Exclusion Criteria | Population Characteristics |
|---|----------|---|--|
| Assessment | | | |
| | | | 3rd: 803 (14.8%) |
| | | | 3rd: 803 (14.8%) Smoked During Pregnancy No: 5,099 (94.1%) Yes, 1 to 9 Cigarettes/Day: 164 (3.0%) Yes, ≥ 10 Cigarettes/Day: 78 (1.4%) Unknown or Not Stated: 155 (2.9%(Alcohol Intake (Drinks/Week) During Pregnancy Non: 5,162 (95.3%) Yes, Total: 136 (2.5%) Yes, < 2: 136 (2.5%) Yes, ≥ 2: 23 (.4%) Unknown or Not Stated: 120 (2.2%) |
| | | | Gestational Age < 37 Weeks: 77 (1.4%) 37 to 41 Weeks: 4,834 (89.2%) ≥ 42 Weeks: 361 (6.7%) |
| Nethery et al., 2017 U.S. Midwives Alliance of North America Statistics Project (MANA Stats) 2.0 dataset 2004 to 2009 Poor quality | Nonrural | Inclusion criteria: Planned community births (home or birth center), in midwife care at time of delivery Exclusion criteria: Multi-fetal pregnancies, breech, congenital anomalies, pre-existing maternal conditions (e.g., chronic anemia not resolved, chronic hypertension, eclampsia, preeclampsia, Rh sensitization, gestational diabetes), prior cesarean delivery | Planned Out-of-Hospital Birth (N = 18,724) Rural (n = 3,737) vs. Nonrural (n = 14,986) Race/Ethnicity (p ≤ 0.001) African or Caribbean: 18 (.5%) vs. 140 (.9%) Asian: 9 (.2%) vs. 133 (.9%) Caucasian: 3,422 (91.6%) vs. 13,266 (88.5%) Hispanic or Latina: 67 (1.8%) vs. 248 (1.7%) Native American: 18 (.5%) vs. 20 (.1%) Other: 25 (.7%) vs. 124 (.8%) More than 1 race indicated: 167 |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|--|---|-------------------------------------|---|
| | | | Education (p ≤ 0.001) Any High School or Completed: 1,832 (49.0%) vs. 3,868 (25.8%) |
| | | | Any Postsecondary up to 4 Years: 1,429 (38.2) vs. 7,607 (50.8%) More Than 4 Years of Postsecondary: 417 (11.2%) vs. 3,187 (21.3%) |
| | | | Belongs to Amish, Mennonite, or other Plain Church: 777 (20.8%) vs. 258 (1.7%0) (p ≤ 0.001) |
| | | | Any Medicaid, Primary or Secondary: 499 (13.4%) vs. 1,635 (10.9%) (p ≤ 0.001) |
| | | | Any Other Insurance (Non- Medicaid), Primary or Secondary: 745 (19.9%) vs. 6,408 (42.8%) (p ≤ 0.001) |
| | | | Marital Status: Married, Partnered, or Common-Law: 3,643 (97.5%) vs. 14,558 (97.1%) |
| | | | Age, in Years: 29 (IQR, 25 to 33) vs. 30 (IQR, 26 to 33) (p ≤ 0.001) |
| | | | BMI at Beginning of Pregnancy: 22.8 (IQR, 21 to 26) vs. 22.5 (IQR, 21 to 25) (p ≤ 0.001) |
| | | | Nulliparous: 1,182 (49.7%) vs. 5,801 (38.7%) (p ≤ 0.001) |
| | | | Grand Multiparity (> 4 Prior <u>Vaginal Deliveries)</u> : 446 (11.9%) vs. 611 (4.1%) (p ≤ 0.001) |
| | | | History of Home or Birth Center <u>Birth</u> : 1,858 (49.7%) vs. 5,596 (39.8%) (p ≤ 0.001) |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|--|--|--|--|
| Schuit et al., 2016 The Netherlands Netherlands Perinatal Registry | Secondary Care | Inclusion criteria: Singleton pregnancy, gestational age between 37 and 42 weeks, started labor in | Planned Birth Location at Onset of Labor (p ≤ 0.001): Freestanding Birth Center: 620 (16.6%) vs. 2,910 (19.4%) Home: 3,117 (83.4%) vs. 12,076 (80.6%) Number of Prenatal Care Visits With This Midwife: 10 (IQR, 7 to 12) vs. 11 (IQR, 9 to 12) (p ≤ 0.001) Weeks (From Last Menstrual Period) That Any Prenatal Care Began: 12 (IQR, 9 to 16) vs. 11 (IQR, 8 to 13) (p ≤ 0.001) Birth Location (Actual) (p ≤ 0.001) Freestanding Birth Center: 520 (13.9%) vs. 2,394 (16.0%) Home: 2,881 (77.1%) vs. 10,819 (72.2%) Hospital: 327 (8.8%) vs. 1,751 (11.7%) Other: 9 (.2%) vs. 21 (.1%) Planned Out-of-Hospital Birth (N = 746,642) Maternal Age > 25 Years: 96,060 (13%) |
| 2000 to 2007 Poor quality | n = 505,047 (68%) Referral to Secondary Care n = 241,595 (32%) | Exclusion criteria: Women with prolonged rupture of membranes without contractions | 25 to 35 Years: 563,724 (76%) > 35 Years: 86,858 (12%) Ethnicity Caucasian: 613,898 (82%) Creole: 15,079 (2%) Hindu: 7,050 (1%) Other Non-Western: 110,615 (15%) Degree of Urbanization Low: 148,462 (20%) |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|---|------------|---|---|
| | | | Average: 457,988 (61%) High: 140,192 (19%) |
| | | | Social Economic Status Low: 221,039 (30%) Average: 345,612 (46%) High: 179,991 (24%) |
| | | | Birth History Nulliparous: 332,854 (45%) Multiparous, Without Previous Instrumental Vaginal Delivery: 374,350 (50%) Multiparous, With Previous Instrumental Vaginal Delivery: 39,438 (5%) |
| | | | Intended Place of Delivery Home n = 466,662 (63%) Midwife-Led Birth Center n = 5,367 (1%) Hospital n = 274,613 (37%) Gestational Age 37+0 to 37+6 Weeks: 31,070 (4%) 38+0 to 40+6 Weeks: 549,026 (74%) |
| Stapleton et al., 2013 U.S. American Association of Birth Centers Uniform Data Set (online data | N = 15,574 | Inclusion criteria: Planned home center birth; estimated dates of birth during 2007 through 2010; singleton, full-term gestation | ≥ 41+0 Weeks: 166,546 (22%) Birth Center (N = 15,574) Maternal Age < 18 Years: 171 (1.1%) 18 to 34 Years: 13,218 (85.4%) |
| registry) 2007 to 2010 Poor quality | | in vertex presentation with no medical or obstetric risk factors precluding a normal vaginal birth or necessitating interventions such as continuous electronic fetal monitoring or induction of labor Exclusion criteria: | ≥ 35 Years: 2,093 (13.5%) Race Non-Hispanic White: 11,810 (77.4%) Hispanic: 1,711 (11.2%) Black: 840 (5.5%) Asian or Pacific Islander: 349 (2.3%) |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|---|-----------|---|--|
| | | NR | Native American or Native Alaskan: 101 (.7%) Unknown or Other: 440 (2.9%) Marital Status Married: 12,109 (80.1%) Unmarried: 3,015 (19.9%) Parity Nulliparous: 7,355 (47.2%) Multiparous: 8,219 (52.8%) Payment Method Private Insurance: 8,325 (53.5%) Medicaid: 3,701 (23.8%) Self-Pay: 2,261 (14.5%) Military Coverage: 411 (2.6%) Other Insurance/Grants: 406 (2.6%) Medicare: 374 (2.4%) Unknown: 96 (.6%) Education < 12 Years: 1,184 (8.7%) 12 Years: 2,669 (19.6%) 13 to 15 Years: 2,727 (20.0%) ≥ 16 Years: 7,067 (51.8%) |
| Stephenson-Famy et al., 2017 U.S. Washington State birth certificate data 2004 to 2011 Poor quality | N = 7,118 | singleton, vertex, live born infant at ≥ 37 weeks gestation Exclusion criteria: Preterm birth, previous | Planned Birth Center Birth (N = 7,118) Actual Birth Center Birth (n = 6,617) vs. Actual Hospital |

| Citation, Location, Data | N | Inclusion and Exclusion | Population Characteristics |
|-----------------------------------|---|-------------------------|--|
| Source, Dates, Quality Assessment | | Criteria | |
| | | | > 40 Years: 169 (2.6%) vs. 29 (5.8%) |
| | | | Race White: 6,139 (93.8%) vs. 446 (92.3%) African American: 114 (1.7%) vs. 10 (2.1%) American Indian/Alaska Native: 56 (.9%) vs. 6 (1.2%) Asian: 239 (3.6%) vs. 21 (4.4%) |
| | | | Ethnicity (p < 0.05) Non-Hispanic: 6,330 (96.1%) vs. 462 (94.1%) Hispanic: 261 (3.9%) vs. 29 (5.9%) |
| | | | Marital Status (p < 0.001) Married: 5,518 (83.6%) vs. 361 (72.2%) Not Married: 1,085 (16.4%) vs. 139 (27.8%) |
| | | | Maternal Education (p < 0.05) Less Than High School: 256 (3.9%) vs. 26 (5.2%) High School Graduate: 1,141 (17.3%) vs. 78 (15.7%) Some College: 2,311 (35.1%) vs. 151 (30.4%) College Graduate: 2,041 (31.0%) vs. 151 (30.4%) Graduate Level: 838 (12.7%) vs. |
| | | | 91 (18.3%) BMI (p < 0.001) < 18.5: 223 (3.5%) vs. 221 (52.6%) 18.5 to 25.9: 4,062 (64.2%) vs. 9 (2.1%) 25.0 to 29.9: 1,306 (20.6%) vs. 114 (27.1%) ≥ 30: 736 (11.6%) vs. 76 (18.1%) |

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|--|---|-------------------------------------|--|
| Assessment | | | |
| | | | <u>Residence</u> |
| | | | Urban: 5,777 (87.9%) vs. 450 (90.4%) |
| | | | Rural: 793 (12.1%) vs. 48 (9.6%) |
| | | | Insurance Status (p < 0.001) |
| | | | Self-Pay: 265 (4.0%) vs. 19 (3.0%) |
| | | | Medicaid: 1,958 (29.7%) vs. 115 (23.8%) |
| | | | Private Insurance: 4,316 (65.6%) vs. 322 (66.7%) |
| | | | Government Insurance: 49 (.7%) vs. 27 (5.6%) |
| | | | Prenatal Smoking |
| | | | No: 6,390 (96.6%) vs. 473 |
| | | | (95.0%) |
| | | | Yes: 227 (3.4%) vs. 25 (5.0%) |
| | | | Parity (p < 0.001) |
| | | | 0: 2,738 (42.3%) vs. 417 (83.7%) |
| | | | 1: 3,729 (57.7%) vs. 81 (16.3%) |
| | | | (p < 0.001) |
| | | | Gestational Age (p < 0.001) |
| | | | 37 Weeks: 266 (4.0%) vs. 30 (6.0%) |
| | | | 38 Weeks: 744 (11.2%) vs. 42 (8.6%) |
| | | | 39 Weeks: 1,368 (20.7%) vs. 104 (20.6) |
| | | | 40 Weeks: 3,085 (46.7%) vs. 162 (32.3%) |
| | | | 41 Weeks: 1,027 (15.5%) vs. 124 (24.9%) |
| | | | ≥ 42 Weeks: 127 (1.9%) vs. 38 (7.6%) |
| | | | Adequacy of Prenatal Care |
| | | | (Kotelchuck Index) (p < 0.001) |
| | | | Inadequate: 637 (9.9%) vs. 134 (28.9%) |

| Citation, Location, Data | N | Inclusion and Exclusion | Population Characteristics |
|--|---|--|---|
| Source, Dates, Quality Assessment | | Criteria | |
| | | | Intermediate: 561 (8.7%) vs. 75 (16.2%) Adequate: 4,480 (69.7%) vs. 199 (42.8%) |
| | | | Adequate Plus: 753 (11.7%) vs. 56 (12.1%) |
| | | | Prior Preterm Birth No: 6,544 (98.9%) vs. 496 (99.4%) Yes: 71 (1.1%) vs. 3 (.6%) |
| | | | Maternal Diabetes No: 6,538 (98.8%) vs. 496 (98.2%) Yes: 77 (1.2%) vs. 3 (.6%) Includes preexisting and |
| | | | gestation diabetes Maternal Hypertension (p < 0.001) No: 6,576 (99.4%) vs. 457 (91.6%) |
| | | | Yes: 39 (.6%) vs. 42 (8.4%) Includes chronic hypertension, gestational hypertension, preeclampsia, and eclampsia Group B Streptococcus Positive No: 5,156 (77.9%) vs. 393 (78.8%) |
| | | | Yes: 1,459 (22.1%) vs. 106 (21.2%) |
| Suto et al., 2015 Japan Data collected from 3 midwife-led birth centers in Tokyo January 2008 to June 2011 | N = 1,521 Nulliparous n = 422 Multiparous n = 1,099 | Inclusion criteria: Pregnant women who receive initial antenatal care at 1 of 3 birth centers between January 1, 2008 and June 30, 2011 Exclusion criteria: | Multiparous |
| Poor quality | | Women who changed childbirth facilities during pregnancy for personal reasons, referral to hospital | BMI 16.00 to 16.99: 0 (0%) vs. 1 (.1%) 17.00 to 18.49: 2 (.5%) vs. 3 (.3%) |

Appendix H. Characteristics of Noncomparative Observational Studies

| Citation, Location, Data Source, Dates, Quality Assessment | N | Inclusion and Exclusion Criteria | Population Characteristics |
|--|---|--|--|
| | | pregnancy-related complications, transfer to hospital from the onset of the end of the third stage of labor, gave birth at home unexpectedly, preterm birth, no record of perineal | 18.50 to 22.99: 180 (44.0%) vs. 316 (30.4%) 23.00 to 24.99: 116 (28.4%) vs. 364 (35.0%) 25.00 to 29.99: 111 (27.1%) vs. 356 (34.2%) Living With Partner: 421 (99.8%) vs. 1,099 (100%) |

Appendix I. Risk Criteria Matrix: Maternal/Fetal

| 3 | 2 | 1 | NA | |
|---|-----------------------|--|--|------------------------------------|
| High-risk condition requiring planned hospital birth or transfer to hospital | Consultation required | Eligible for planned out-of-hospital birth provided no other complicating conditions are present | Not applicable or superseded by a separate recommendation | No recommendation identified |

| Condition | Sub-condition | HERC 2015 CG | Other | 2020 Oregon DEM final rule | 2020 HER C CG prop osed | Footnotes | Description of EbGS change from 2015 |
|---------------------------------|--|-----------------|--------------------------|--|-------------------------------------|---|--------------------------------------|
| | Pre-labor rupture of membranes > 24 hours | 3 | NICE 3 WA (2) | | 2 | /* | Revised existing criterion |
| Amniotic membrane rupture | Rupture before 36 weeks | NA* | CMBC 2^ | 3 | | *superseded by gestational age recommendation | No change |
| | Rupture before 37 weeks 0 days | NA* | WA 3 | | 3 | ^34 + 0 to 36 and 6 weeks | Added new criterion |
| | Hemoglobin < 10 g/dL, unresponsive to treatment | 2* | CMBC 2 WA 2 | 2 | 2^ | *10.5 | Clarified existing criterion |
| Anemia | Hemoglobin < 9 g/dL unresponsive to treatment | | | 3 | | | No change |
| | Hemoglobin < 8.5 g/ dL (current pregnancy) | 3 | NICE 3* | ł | 3 | *at onset of labor | No change |
| Cancer | Cancer affecting site of delivery | | WA 3 | 3 | 3* | *Active gynecologic cancer | Added new criterion |
| Cardiovascular | Cardiovascular disease causing functional impairment | | ACNM 3* CMBC 3^ | 2~ | 3% | ^disease with failure ~cardiac condition | Added new criterion |

| Condition | Sub-condition | HERC 2015 CG | Other | 2020 Oregon DEM final rule | 2020 HER C CG prop osed | Footnotes | Descriptio n of EbGS change from 2015 |
|--|---|-----------------|------------|--|-------------------------------------|---|---|
| | | | NICE 3 | | | *cardiovascular disease with functional impairment | |
| | | | WA 3 | | | | |
| Cervical conditions | Insufficiency or cerclage | 2* | CMBC 2* | | - | *history of | Removed existing criterion |
| Collagen-vascular o | liseases | | WA 3 | | 2 | No specific disease listed | Added new criterion |
| | Prior child with congenital or hereditary disorder | | 1 | 1 | 1 | | Removed existing criterion |
| | Known fetal anomalies or conditions affected by site of birth | | WA 3 | 2* | | *that may require medical attention | No change (see below) |
| Congenital or hereditary anomaly | Evidence of congenital anomalies requiring immediate assessment and/or management by a neonatal specialists | | ACNM 3 | † | 2 | | Clarified existing criterion |
| | Suspected or diagnosed fetal anomaly that may require physician management during or immediately after delivery | | CMBC 2 | | | | No change |

| Condition | Sub-condition | HERC 2015 CG | Other | 2020 Oregon DEM final rule | 2020 HER C CG prop osed | Footnotes | Description of EbGS change from 2015 |
|------------------|--|-----------------|----------------------------------|--|-------------------------------------|-----------|--------------------------------------|
| | Life- threatening congenital anomalies (unless non- resuscitation planned) | 2 | 1 | 1 | 1 | | Removed existing criterion |
| | Less than 12 months from last delivery to present due date | | CMBC 2 | ł | -1 | | No change |
| | 1 Prior cesarean delivery | 3 | ACNM 3 NICE 3 ACOG 3 WA 3 CMBC 2 | 1 | 3 | | No change |
| Delivery history | 2 Prior cesarean deliveries | 3 | ACNM 3 NICE 3 ACOG 3 WA 3 CMBC 2 | 1 | 3 | | No change |
| | 3 Prior cesarean deliveries with a previous successful vaginal birth | 3 | ACNM 3 ACOG 3 NICE 3 WA 3 | 1 | 3 | | No change |
| | 3 Prior cesarean deliveries without a prior successful vaginal birth | 3 | ACNM 3 NICE 3 ACOG 3 WA 3 | 3 | 3 | | No change |
| | 4 or more cesarean deliveries | 3 | ACNM 3 ACOG 3 NICE 3 WA 3 | 3 | 3 | | No change |
| Diabetes | Туре 1 | 3 | WA 3 NICE 3 | 1 | 3 | | No change |

| Condition | Sub-condition | HERC 2015 CG | Other | 2020 Oregon DEM final rule | 2020 HER C CG prop osed | Footnotes | Descriptio n of EbGS change from 2015 |
|--|---|-----------------|------------------------------|--|-------------------------------------|--|---|
| | Type 2 | 3 | WA 3 | 2* | 3 | *blood glucose dysregulation well-controlled with diet and exercise | No change |
| | Gestational – diet controlled | 2 | NICE 3 | 2 | | | Remove existing criterion |
| | Gestational – on medication or uncontrolled | 3 | CMBC 2* NICE 3 WA 3 | | 3 | *insulin treated | No change |
| | Hyperthyroidis m | | | 2 | 2^ | ^listed as an example of a | |
| Endocrine conditions other than diabetes | Significant endocrine disorders | | WA 3 | | 2* | significant endocrine disorder *significant endocrine conditions other than diabetes (e.g. hyperthyroidism) | Added new criterion |
| | Fetal demise (current pregnancy) | 2 | CMBC 2 WA 2* | | | *after 12 completed weeks gestation | Removed existing criterion |
| Fetal demise or stillbirth | Prior unexplained stillbirth/neona tal death or death unrelated to intrapartum difficulty | 2 | CMBC 2 | | 2 | | No change |
| | History of unexplained stillbirth/neona tal death or previous death related to intrapartum difficulty | 3 | CMBC 2 | | 2 | | See above |

| Condition | Sub-condition | HERC 2015 CG | Other | 2020 Oregon DEM final rule | 2020 HER C CG prop osed | Footnotes | Description of EbGS change from 2015 |
|------------------------------|---|-----------------|---------|--|-------------------------------------|---|--------------------------------------|
| | Repetitive or | | WA 3 | | | | |
| | persistent abnormal fetal heart rate pattern during labor | 3 | ACNM 3 | 3 | 3 | | No change |
| | Abnormal fetal heart rate, | | CMBC 3 | 2* | | *abnormal fetal cardiac rate or rhythm | |
| | Doppler, or surveillance studies | 3 | NICE 3 | 3^ | 3 | ^abnormal fetal surveillance testing | No change |
| | | | | | | | |
| Fetal monitoring or movement | Rate below 110 or above 160 beat/minute, deceleration auscultated | | NICE 3 | | | | No change |
| | Inability to adequately follow an intermittent auscultation protocol | | | 3 | | | No change |
| | Abnormally decreased fetal movement antepartum | | | 2 | | | No change |
| | Abnormally decreased fetal movement at onset of labor | | NICE 3* | | | | No change |
| Fetal | Breech or non- cephalic presentation | 3 | AABC 3 | 1~ | 3 | *consult for breech, transfer for non-cephalic other than breech, greater clarification in guidance | No |
| presentation | | | ACNM 3 | | | ^2 at 37 weeks, 3 | change |
| | | | ACOG 3 | 2% | | if intrapartum Frank or complete breech and birth imminent | |

| Condition | Sub-condition | HERC 2015 CG | Other | 2020 Oregon DEM final rule | 2020 HER C CG prop osed | Footnotes | Descriptio n of EbGS change from 2015 |
|-----------------------------------|---|-----------------|------------------------|--|-------------------------------------|---|---|
| | | | CMBC 2/3* NICE 3 | 3 ^{&} | | *Frank or complete breech and birth not imminent | |
| | | | WA 2/3^ | Transve rse: 3 | | &Evidence or suspected footling or kneeling breech and birth not imminent | |
| | Excessive vomiting, dehydration, or exhaustion unresponsive to treatment | | | 3* | | | No change |
| Gastrointestinal or hepatological | Hepatic disorders including uncontrolled intrahepatic cholestasis of pregnancy and or abnormal liver function tests | | WA 3 | 2* | 2 | *abnormal hepatic test | Added new criterion |
| | Actively being treated with prescription medication for any ongoing or chronic medical condition | | | 2 | | | No change |
| General medical | Adverse socio- economic conditions | | CMBC 2 | | | | No change |
| conditions | Current medical conditions that may affect pregnancy or are exacerbated due to pregnancy | | CMBC 2 | | | | No change |

| Condition | Sub-condition | HERC 2015 CG | Other | 2020 Oregon DEM final rule | 2020 HER C CG prop osed | Footnotes | Descriptio n of EbGS change from 2015 |
|-----------|---|-----------------|---|--|-------------------------------------|--|---|
| | Current medical conditions that may affect pregnancy or are exacerbated by pregnancy that require specialized medical care (e.g., cardiac disease, renal disease, pre- existing insulin- dependent diabetes mellitus) | | CMBC 3 | 1 | 3 | (this is a modification from prior CMBC) | Clarified existing criterion |
| | Declining all blood products | | CMBC 2 | | | (this is a change from prior CMBC) | No change |
| | Family history of genetic/heritab le disorders that would impact labor, delivery or care of newborn | 2 | CMBC 2 | | | | Removed existing criterion |
| | History of trauma or sexual abuse | | CMBC 2 | | -1 | | No change |
| | Low-risk uncomplicated pregnancies | 1 | AABC 1 AAP 1 ACNM 1 ACOG 1 CMBC 1 NICE 1 SOGC 1 | 1 | 1 | | No change |

| Condition | Sub-condition | HERC 2015 CG | Other | 2020 Oregon DEM final rule | 2020 HER C CG prop osed | Footnotes | Descriptio n of EbGS change from 2015 |
|-----------|---|-----------------|-----------------|--|-------------------------------------|---|---|
| | Medical, obstetric, fetal and/or neonatal condition precluding a safe labor, birth and postpartum period in a birth center | | AABC 3 | 1 | | | No change |
| | Medical conditions arising during prenatal care, for example: endocrine disorders, renal disease, suspected or confirmed significant infection including H1N1, hyperemesis unresponsive to pharmacologic al therapy | | CMBC 2 | + | | | No change |
| | Pain which persists, worsens, or is unresponsive to therapy within the midwife's scope of practice | | CMBC 2 NICE 3* | | | *differs from pain normally associated with contractions | No change |
| | Poor nutrition | | CMBC 2 | | | | No change |
| | Significant medical illness history | | CMBC 2 | | | | No change |
| | Unstable health status | | ACNM 3 | | | | No change |

| Condition | Sub-condition | HERC 2015 CG | Other | 2020 Oregon DEM final rule | 2020 HER C CG prop osed | Footnotes | Description of EbGS change from 2015 |
|---|--|-----------------|----------------------------|--|-------------------------------------|--|--------------------------------------|
| | Other significant deviations from normal as assessed by the provider | 1 | WA 2 | 1 | -1 | | No change |
| | Development of any high risk condition | - | WA 3 NICE 3 | 1 | 3 | | Added new criterion |
| | Uncertain expected date of delivery | | CMBC 2 | | 2 | | Added new criterion |
| | 34 weeks or earlier | 3 | CMBC 3 | 1 | 3 | | No change |
| | 35 weeks, 0 to 6 days | 3 | CMBC 2* | 3 | 3 | *history of | No change |
| Gestational age including prior preterm birth | 36 weeks, 0 to 6 days | 3 | AABC 1 ACNM 3 CMBC 2* WA 3 | 1 | 3 | *history of or presenting in labor at | No change |
| | 37 weeks 0 days to 41 weeks, 6 days | 1 | AABC 1 ACNM 1 | | 1 | | No change |
| | 42 weeks, 0 to 6 days | 3 | ACNM 3 WA 2 | | 3* | *(unless already in active labor at 41 weeks 6 days) | Revised existing criterion |
| | 43 weeks or greater | 3 | CMBC 2 | 3 | 3 | . , | No change |
| | Unknown carrier state | 3 | | | | | Removed existing criterion |
| Group B streptococcus | Lack of informed consent on prophylaxis if mother is GBS positive and declines prophylaxis | 3 | | | | | Removed existing criterion |
| Hematological conditions other than anemia | Hemoglobinop athies | | ACNM 3 CMBC 2 NICE 3 | 2 | 2 | | Added new criterion |

| Condition | Sub-condition | HERC 2015 CG | Other | 2020 Oregon DEM final rule | 2020 HER C CG prop osed | Footnotes | Descriptio n of EbGS change from 2015 |
|--|--|-----------------|--------------------|--|-------------------------------------|--|---|
| | Thrombosis or thromboemboli sm (or history of) | 3 | ACNM 3 CMBC 2 | 2/3* | 2/3^ | *thromboembolic disease listed under both consult and transfer ^Consult for history of; transfer for current pregnancy | Revised existing criterion |
| | Thrombophlebi tis | | CMBC 2 | 2 | | | No change |
| | Suspected embolus | | CMBC 3 | 2 | 3 | | Added new criterion |
| | Family history of thrombophilia | | | 2 | | | No change |
| | Maternal bleeding disorder (or history of) | 3 | NICE 3 | 2 | 2 | | Revised existing criterion |
| | Thrombocytop enia (platelets <100,000) | 3 | NICE 3 | 2* | 3 | *platelets < 115,000 | No change |
| | Abnormal bleeding in pregnancy | 3 | WA 3 NICE 3* | 2 | 3 | *in labor | No change |
| | Antepartum hemorrhage, | 3 | NICE 3 | | 3 | | No |
| | recurrent | J | CMBC 2 | | , | | change |
| Hemorrhage or vaginal bleeding, including history of | Repeated vaginal bleeding other than transient spotting or uncomplicated spontaneous abortion less than 14 weeks | | CMBC 2 | | | | No change |
| | Hemorrhage (hypovolemia, shock, need for transfusion, | 3 | CMBC 3* WA 3 | 3 | 3 | *unresponsive to therapy, shock | No change |

| Condition | Sub-condition | HERC 2015 CG | Other | 2020 Oregon DEM final rule | 2020 HER C CG prop osed | Footnotes | Description of EbGS change from 2015 |
|------------------------|---|-----------------|--------------------------|--|-------------------------------------|---|--------------------------------------|
| | vital sign instability) | | | | | | |
| | History of postpartum hemorrhage or bleeding requiring additional procedures such as Bakri- balloon, dilation and curettage, transfusion, and manual removal of | | ACNM 3 | | 3* | * History of postpartum hemorrhage requiring transfusion or other advanced treatment (e.g. Bakri balloon) | Revised existing criterion |
| | placenta History of postpartum hemorrhage requiring intervention | 2 | CMBC 2 | | 2 | | No change |
| Hyperemesis gravio | darum | 3* | WA 2 | | 2* | *refractory | Revised existing criterion |
| | Eclampsia (or history of) | 3 | CMBC 2/3* | 3^ | 3 | *consult for history, transfer for current ^current | No change |
| | HELLP (or history of) | 3 | CMBC 2/3* | | 3 | *consult for history, transfer for current | No change |
| Hypertensive disorders | History of hypertensive disorders of pregnancy | 2* | CMBC 2 | | | *history of pre- eclampsia not requiring preterm birth. | Remove existing criterion |
| | Systolic ≥ 140 or diastolic ≥ 90, on 2 occasions 30 minutes apart in pregnancy (e.g. gestational | 3 | NICE 3* CMBC 2 WA 2/3^ | 3 (4 hours apart) | 3 | *any hypertensive disorder ^consult antenatally, transfer intrapartum | No change |

| Condition | Sub-condition | HERC 2015 CG | Other | 2020 Oregon DEM final rule | 2020 HER C CG prop osed | Footnotes | Description of EbGS change from 2015 |
|--|--|-----------------|-------------------------------|--|-------------------------------------|-----------------------------------|--------------------------------------|
| | hypertension or pregnancy- induced | | | | | | |
| | hypertension) | | | | | | |
| | Systolic ≥ 140 or diastolic ≥ 90, on 2 | | CMBC 3 | | | *any hypertensive disorder is a 3 | |
| | occasions 4 hours apart, and proteinuria (e.g., pre- eclampsia without severe features) | | NICE 3* | 3 | | | No change |
| | Systolic ≥ 160 or diastolic ≥ 110, on one | | CMBC 3 | | | | |
| | occasion, or systolic ≥ 140 or Diastolic ≥ 90 with severe features (e.g. pre-eclampsia with severe features) | | NICE 3 | 3 | 3 | | Clarified existing criterion |
| | Pre-eclampsia requiring preterm birth (or history of) | 3 | NICE 3 | 3 | 3 | | No change |
| | Pre-existing or chronic hypertension | 3 | ACNM 3 CMBC 2 NICE 3* WA 3 | 2 | 3 | *any hypertensive disorder | No change |
| Infectious Conditions (except for group B streptococcal related) | HIV/AIDS status | 3 | | 3 | 3 | | No change |
| | HIV (unknown or positive) | 3 | WA 3 CMBC 2 | 2 | 3* | *Positive | Revised existing criterion |
| | Chorioamnionit is | 3 | ACNM 3 | 3 | 3 | | No change |
| | Cytomegalovir us | 3 | -1 | -1 | 1 | | Removed existing criterion |
| | | 3 | CMBC 2 | 3* | 3 | | |

| Condition | Sub-condition | HERC 2015 CG | Other | 2020 Oregon DEM final rule | 2020 HER C CG prop osed | Footnotes | Descriptio n of EbGS change from 2015 |
|-----------|---|-----------------|-------------------------------|--|-------------------------------------|---|---|
| | Maternal temperature ≥ 38.0 C in labor/postpart um | | WA 2 | | | *two over 100.4 or one over 102.2 | No change |
| | Genital herpes at time of labor | 3 | ACNM 3* CMBC 2 WA 2^ | 3 | 3 | *or at rupture of membranes ^also for primary infection past 1st trimester | No change |
| | Hepatitis B (unknown or positive) | 3 | | 1 | 3* | *Hepatitis B Positive | Revised |
| | Hepatitis B or C with abnormal liver function tests | | ACNM 3 NICE 3 WA 3 | | | | existing criterion |
| | Maternal infection postpartum (e.g., endometritis, sepsis, wound) | 3* | WA 2 | 2~/3# | 3* | *requiring hospital treatment ~Evident or suspected maternal infection unresponsive to treatment #uterine infection | No change |
| | Rubella | 3 | ANCM 3 | | 3 | | No change |
| | Sexually transmitted infection requiring treatment | | CMBC 2 | | | | No change |
| | Syphilis (unknown or positive) | 3 | ACNM 3 WA 3 | 2 | 3* | *Positive | Revised existing critierion |
| | Tuberculosis | | ACNM 3 NICE 3 | | 3* | *other than latent | Added new criterion |
| | Toxoplasmosis | | NICE 3* | | 3 | *women receiving treatment | Clarified existing criterion |

| Condition | Sub-condition | HERC 2015 CG | Other | 2020 Oregon DEM final rule | 2020 HER C CG prop osed | Footnotes | Description of EbGS change from 2015 |
|------------------------|---|-----------------|------------------|--|-------------------------------------|--|--------------------------------------|
| | Urinary tract infection (complicated) | | CMBC 2 | | | | Added new criterion |
| | Varicella (active at labor) | 3 | | | 3 | | No change |
| | Any infection whose treatment is beyond the scope of the provider | | WA 2 | | | | No change |
| Intrauterine growth | IUGR (defined as fetal weight less than fifth percentile using ethnically-appropriate growth tables, or concerning reduced growth velocity on ultrasound) | 3 | ACNM 3 NICE 3 | | | | |
| | | | WA 3 | | 3 | | No change |
| | History of IUGR as defined above | 2 | | - | | | Removed existing criterion |
| | Inappropriate uterine growth (size-date discrepancy) | | CMBC 2 | | | *suspected growth restriction | |
| | | | NICE 3* | | 2~ | ^size/dates discrepancies ~an ultrasound | Added new |
| | | | WA 2^ | | | read by a qualified physician constitutes a consultation | criterion |
| | Prior small for gestational age infant | 2 | CMBC 2 | | | | Removed existing criterion |
| | Uteroplacental insufficiency | 3 | NICE 3 | | 3 | | No change |

| Condition | Sub-condition | HERC 2015 CG | Other | 2020 Oregon DEM final rule | 2020 HER C CG prop osed | Footnotes | Descriptio n of EbGS change from 2015 |
|---------------------|--|-----------------|----------------------------|--|-------------------------------------|---|---|
| Isoimmunization | Blood group incompatibility and/or Rh sensitization in current pregnancy | 3 | ACNM 3 CMBC 2 WA 3 NICE 3 | 2 | 3 | | No change |
| | Blood group incompatibility and/or Rh sensitization in a prior pregnancy | 2 | WA 3 | 2 | 2 | | No change |
| , | Induction | 3 | NICE 3 ACNM 3 | 1 | 3 | | No change |
| | Augmentation | | CMBC 2 | 1 | 1 | | No change |
| | Desire for pain management | | WA 3 | 1 | | | No change |
| | Failure to progress/failur e of head to engage in active labor | 3 | CMBC 2 WA 3* NICE 3* | 1 | 3 | *nullipara | No change |
| Labor management | Lack of adequate progress in 2 nd stage with cephalic presentation | 3 | | 3* | 3 | *no descent after 3 hours of pushing where the mother is fully dilated and has ruptured membranes; and active pushing | No change |
| | Lack of adequate progress in 2 nd stage with breech presentation | | | 2* | 1 | *no descent after 1 hour active pushing | No change |
| Macrosomia | Prior baby > 4.5 kg or 9 lbs 14 oz. | 2 | CMBC 2 | 1 | 1 | | Removed existing criterion |

| Condition | Sub-condition | HERC 2015 CG | Other | 2020 Oregon DEM final rule | 2020 HER C CG prop osed | Footnotes | Descriptio n of EbGS change from 2015 |
|----------------------------------|--|-----------------|---------------------------------------|--|-------------------------------------|---|---|
| | Suspected (estimated weight >4.5 kg or 9lbs 14 oz.) | 2 | NICE 3 | | | | Removed existing criterion |
| Maternal Age | <17 or > 40 years | | CMBC 2 | | | | No change |
| | Ectopic | | | 3 | | | Out of report scope |
| | Incomplete miscarriage | | | 3 | | | Out of report scope |
| | Molar | 3 | CMBC 3 WA 3 | | 3 | | No change |
| Miscarriage/nonv iable pregnancy | 3 or more 1st trimester spontaneous miscarriages | 2 | CMBC 2 | | | | Removed existing criterion |
| | 1 or more 2nd trimester spontaneous miscarriage | 2 | CMBC 2 | | | | Removed existing criterion |
| Meconium | Thick meconium staining of amniotic fluid | 3 | CMBC 2 any NICE 3 WA 3 | 3* | | *birth not imminent | Remove existing criterion |
| Multiple gestations | | 3 | AABC 3 ACNM 3 ACOG 3 CMBC 2/3* NICE 3 | 3~/2^ | 3 | *consult for twins, transfer for others with additional guidance in document ~Higher-order multiples (triplets or more) or monochorionic, monoamniotic twins, twin-to- twin transfusion or presenting twin transverse | No change |

| Condition | Sub-condition | HERC 2015 CG | Other | 2020 Oregon DEM final rule | 2020 HER C CG prop osed | Footnotes | Descriptio n of EbGS change from 2015 |
|--------------------------------------|--|-----------------|-----------------------|--|-------------------------------------|--|---|
| | | | | | | Adichorionic, diamniotic twins, monochorionic, diamniotic twins | |
| Neonatal encephal pregnancy | opathy in prior | 3 | NICE 3 | | 2 | | Revised existing criterion |
| | Significant maternal confusion or disorientation | | WA 2* | | | | No change |
| eclampsia | seizure | 2 | | | | | Removed existing criterion |
| | Neurological disorders or active seizure disorders that would impact | | ACNM 3* NICE 3^ | 1 | 3~ | *epilepsy, ^epilepsy, myasthenia gravis, previous cerebrovascular accident | Added new criterion |
| | maternal or neonatal health | | WA 3 | | | ~e.g. epilepsy, myasthenia gravis, previous cerebrovascular accident | |
| Obesity or overweight (prepregnancy) | Low or high BMI | | CMBC 2* | | -1 | *specifics not provided BMI At first prenatal visit | No change |
| | BMI 25 to 29.9 | | | | | | |

| Condition | Sub-condition | HERC 2015 CG | Other | 2020 Oregon DEM final rule | 2020 HER C CG prop osed | Footnotes | Descriptio n of EbGS change from 2015 |
|---|---|-----------------|---|--|-------------------------------------|---|---|
| | Class 1: BMI 30 to 34.9 | | | | | | |
| | Class 2 or 3: ≥ 35.0 | 2 | NICE 3 | | | | Removed existing criterion |
| Oligohydramnios or polyhydramnios | | 3 | ACNM 3 CMBC 2 NICE 3* WA 2 | 2 | 3 | *oligohydramnios with additional complicating factors, transfer if suspected in labor | No change |
| | Grand multipara (5 or more previous births) | | CMBC 2 | | | | No change |
| Parity | Nulliparity | | HERC draft Evidenc e Review | | | | No change |
| | 3 rd degree prior pregnancy | 2 | CMBC 2 | | | | |
| | 4 th degree prior pregnancy | 2*/3 | CMBC 2 | 3 | | *with satisfactory functional recovery | Removed |
| Perineal | 3 rd degree current pregnancy | 2*/3 | CMBC 2 | | 3^ | *not requiring hospital repair ^requiring hospital repair | existing criterion |
| laceration or obstetric anal sphincter injury | 4 th degree current pregnancy | 3 | CMBC 2 WA 3 | 3 | 3 | | |
| spnincter injury | History of obstetrical anal sphincter injury without satisfactory functional recovery | 3 | | | 3 | | No change |

| Condition | Sub-condition | HERC 2015 CG | Other | 2020 Oregon DEM final rule | 2020 HER C CG prop osed | Footnotes | Description of EbGS change from 2015 |
|----------------------|--|-----------------|---------------------------------|--|-------------------------------------|--|--------------------------------------|
| | Laceration requiring hospital repair or beyond expertise of attendant | 3 | ACNM 3 | 3 | 3 | | No change |
| | Bladder or Rectal dysfunction | 3 | CMBC 2 | 1 | | | Removed existing criterion |
| | Enlarging Hematoma | 3 | | 3 | 3 | | No change |
| | Low lying placenta within 2 cm or less of cervical os at 36 weeks or later | 3 | | 3 | 3* | *38 weeks or later | Revised existing criterion |
| | Placenta previa | 3 | ACNM 3 CMBC 2/3* NICE 3 WA 3 | 3 | 3 | *consult at third trimester if asymptomatic, transfer if symptomatic | No change |
| | Vasa previa | 3 | CMBC 2 | | 3 | | No change |
| Placental conditions | Evidence of or suspected placenta accreta | | | 3 | | | No change |
| | Abruption with adverse outcome | | | 2 | | | No change |
| | Abruption | 3 | CMBC 3* NICE 3 | 3/2^ | 3 | *if only suspected, consult ^past the first trimester | No change |
| | Retained placenta | | ACNM 2 CMBC 2 WA 3 | 3 | | | No change |

| Condition | Sub-condition | HERC 2015 CG | Other | 2020 Oregon DEM final rule | 2020 HER C CG prop osed | Footnotes | Descriptio n of EbGS change from 2015 |
|-------------------------------|---|-----------------|--------|--|-------------------------------------|--|---|
| | Retained placenta > 60 minutes | 3 | | | 3 | | No change |
| | History of retained placenta requiring surgical removal | 3 | ACNM 3 | 1 | 3 | | No change |
| | History of retained placenta requiring manual removal | NA | ACNM 3 | 1 | 1 | | No change |
| | No prenatal care until 3 rd | | CMBC 2 | | | | No |
| | trimester | | WA 2 | 1 | | | change |
| Prenatal care | Inadequate prenatal care* | 2* | 1 | | | *< 5 visits or care began in 3 rd trimester | Removed existing criterion |
| | Noncompliance with the plan of care (e.g., frequent missed prenatal visits) | | WA 3 | ł | 1 | | No change |
| | History of >1 preterm birth | 2 | CMBC 2 | | | | |
| Preterm birth (history of) | History of preterm birth (before 34 weeks) | 2 | CMBC 2 | | | | Removed existing criterion |
| Psychiatric disease | Severe psychiatric illness | | WA 3 | | | | No change |

| Condition | Sub-condition | HERC 2015 CG | Other | 2020 Oregon DEM final rule | 2020 HER C CG prop osed | Footnotes | Descriptio n of EbGS change from 2015 |
|-----------|--|-----------------|--------|--|-------------------------------------|---|---|
| | Maternal mental illness requiring inpatient care | 3* | | | | *history of | No change |
| | Mental health concerns presenting or worsening during pregnancy | | CMBC 2 | | | | No change |
| | Postpartum psychosis | | CMBC 3 | | | | No change |
| | Maternal mental illness under outpatient psychiatric care with suspicion for psychosis or potential harm to self or infant | 2 | | | 2^* | *maternal mental illness requiring psychological or psychiatric intervention or psychotropic medications history of postpartum mood disorder with high risk to the infant; schizophrenia, other psychotic disorders, bipolar I disorder or schizotypal disorder | Clarified existing criterion |
| | Psychiatric condition that may affect intrapartum care management or maternal or neonatal transition following birth | | ACNM 3 | | | | No change |

| Condition | Sub-condition | HERC 2015 CG | Other | 2020 Oregon DEM final rule | 2020 HER C CG prop osed | Footnotes | Descriptio n of EbGS change from 2015 |
|-----------|---|-----------------|-----------------------|--|-------------------------------------|---|---|
| | Postpartum depression or (postpartum) mood disorder with suspicion of possible endangerment to self or others | | 1- | 3 | 1 | | No change |
| | History of serious psychological problems | | CMBC 2 | | | | No change |
| | Psychiatric disorders with concern for maternal and fetal safety | | 1 | 2 | 1 | | No change |
| | Active respiratory distress | | WA 3* | | | *postpartum | No change |
| Pulmonary | Pulmonary disease | | WA 3 | 1 | 2^ | *asthma requiring an increase in treatment of hospital treatment, cystic fibrosis ^2 for history of chronic pulmonary disease | Added new criterion |
| | Acute pyelonephritis | | WA 2 | | 2 | | Added new criterion |
| Renal | Renal disease | | CMBC 3* NICE 3^ | 2~ | 3% | *with failure ^abnormal renal function, renal disease requiring supervision by a renal specialist" ~abnormal renal | Added new criterion |
| | | | WA 3 | | | function (consultation) | |

| Condition | Sub-condition | HERC 2015 CG | Other | 2020 Oregon DEM final rule | 2020 HER C CG prop osed | Footnotes | Description of EbGS change from 2015 |
|-------------------|--|-----------------|--------|--|-------------------------------------|---|--------------------------------------|
| | | | | | | [%] renal failure or requiring a specialist | |
| Rheumatological | Systemic lupus erythematosus | | NICE 3 | | 2 | | Added new criterion |
| Mieumatological | Scleroderma | | NICE 3 | | 2 | | Added new criterion |
| | History of, with | | NICE 2 | | | | Clauditia al |
| Shoulder dystocia | or without fetal clavicular fracture | 2 | ACNM 3 | - | 2 | | Clarified existing criterion |
| | Drug or alcohol use with high- risk for adverse effects to fetal or maternal health | 3 | | | 3* | *drug or alcohol misuse with high- risk for adverse effects to fetal or maternal health | Clarified existing criterion |
| | Substance use disorder | | | 2 | | | No change |
| | Cigarette and/or cannabis use | | CMBC 2 | | | | No change |
| Substance use | Significant use of drugs, alcohol or other toxic substances | | CMBC 2 | | | | No change |
| | Substance abuse/depende nce | | ACNM 3 | | | | No change |
| | Substance misuse, alcohol dependency requiring assessment or treatment | | NICE 3 | | | | No change |
| | Active substance abuse | | | 3 | | | No change |

| Condition | Sub-condition | HERC 2015 CG | Other | 2020 Oregon DEM final rule | 2020 HER C CG prop osed | Footnotes | Descriptio n of EbGS change from 2015 |
|-------------------|---|-----------------|-------------------|--|-------------------------------------|--|---|
| Surgical | Laparotomy during pregnancy | 2 | | | | | Removed existing criterion |
| Umbilical cord | Prolapse | 3 | CMBC 3 WA 3 | 3 | 3 | | No change |
| | Anatomic | | WA 2 | | | | |
| | anomaly (e.g. bicornuate, large fibroid impacting delivery) | | CMBC 2 | 2 | 2 | | Added new criterion |
| | Prior hysterotomy | 3 | CMBC 2 NICE 3 | | 3 | | No change |
| Uterine condition | Prior myomectomy | | CMBC 2 NICE 3 | 2 | 2 | | Added new criterion |
| | | | CMBC 2/3* | | | *Uterine prolapse is a consultation | |
| | | | NICE 3 | | | criterion; rupture and inversion | |
| | Uterine rupture, inversion or prolapse | 3 | WA 3 [%] | 3^ | 2*/3 | require transfer ^Rupture only *postpartum uterine prolapse or inversion only. | Revised existing criterion |

Appendix J. Risk Criteria Matrix: Newborn

| 3 | 2 | 1 | NA | |
|---|-----------------------|--|--|------------------------------------|
| High-risk condition requiring planned hospital birth or transfer to hospital | Consultation required | Eligible for planned out-of-hospital birth provided no other complicating conditions are present | Not applicable or superseded by a separate recommendation | No recommendation identified |

| Condition | Sub-condition | 2015 HERC CG | Other | 2020 Oregon DEM final rule | 2020 HERC CG proposed | Footnotes | Description of EbGS change from 2015 |
|-------------|--|--------------------|--------|-------------------------------------|-----------------------------|--|---|
| | Evidence of or suspected major congenital anomaly or abnormality | 3 | CMBC 2 | 3 | / | *unless no resuscitation planned | Removed existing criterion |
| | Fewer than 3 vessels in umbilical cord | | CMBC 2 | - | <i>/</i> | | No change |
| | Unexpected significant or life-threatening | 3 | | | | | Removed existing criterion |
| Anatomic | Major apparent abnormalities | | WA 3 | | | | No change |
| anomaly | Significant congenital anomaly requiring immediate medical intervention, for example omphalocele, myelomeningocele | <u></u> | CMBC 3 | | | | No change |
| | Any other abnormal findings on physical exam | | CMBC 2 | 1 | 1 | | No change |
| Angar score | < 5 at 5 minutes | 3 | | | | | Removed existing criterion |
| Apgar score | < 7 at 10 minutes | 3 | CMBC 3 | 3 | | | Removed existing criterion |
| | Excessive ruddiness | | | 2 | | | No change |
| Appearance | Not clinically well appearing | | AAP 3 | | | | No change |

| Condition | Sub-condition | 2015 HERC CG | Other | 2020 Oregon DEM final rule | 2020 HERC CG proposed | Footnotes | Description of EbGS change from 2015 |
|------------------|--|--------------------|----------------|-------------------------------------|-----------------------------|--------------------------------------|--------------------------------------|
| | Persistent poor suck, poor feeding, lethargy, hypotonia or abnormal cry | 1 | CMBC 2 | 2 | -1 | | No change |
| Blood sugar | Hyperglycemia/hypo glycemia unresponsive to treatment | 3 | AAP 3 | | | | Removed existing criterion |
| | Prolonged glycemic instability | | WA 3 | | | | No change |
| Dermatological | Abrasions, unusual pigmentation and/or lesions | | CMBC 2 | | | *severe abrasions | No change |
| | Any generalized rash at birth | | | 2 | | | No change |
| Gastrointestinal | Significant distended abdomen | | | 3 | | | No change |
| | Evident or suspected abnormally elevated bilirubin. | 1 | | 2 | - | | No change |
| | Vomiting, diarrhea | 3 | CMBC 2 | | | | Removed existing criterion |
| | Persistent projectile or bilious vomiting or emesis of fresh blood | | | 3 | | | No change |
| | Jaundice prior to 24 hours | | CMBC 2 WA 3 | | | | No change |
| | Failure to pass stool within 48 hours after birth | | | 2 | | | No change |
| General medical | In utero exposure to significant drugs, alcohol, or other substances with known or suspected teratogenicity | | CMBC 2 | | | | No change |
| Gestational age | 34 + 0 to 36 + 6 weeks | 1 | CMBC 2 | 2* | -1 | *less than 36 weeks and 0 days | No change |
| | Clinical evidence of prematurity (age < 35 weeks) | -1- | WA 3 | | | *e.g. Ballard | No change |
| | < 37 weeks | | AAP 3 | | | *obstetrically determined | No change |

| Condition | Sub-condition | 2015 HERC CG | Other | 2020 Oregon DEM final rule | 2020 HERC CG proposed | Footnotes | Description of EbGS change from 2015 |
|------------------------|--|--------------------|----------------|-------------------------------------|-----------------------------|---|---|
| Infectious | Infant born to an HIV positive mother | | | 2* | | *consult must be with a pediatrician | No change |
| | Evident or suspected infection | | | 3 | | | No change |
| disease/HIV | Infection of umbilical stump site | - | CMBC 2 | 1 | | | No change |
| | Maternal chorioamnionitis | 1 | AAP 3 | 1 | 1 | | No change |
| Musculoskeletal | Excessive bruising, enlarging cephalohematoma, significant birth trauma | 3 | CMBC 2 | | | | Removed existing criterion |
| | Birth injury such as facial or brachial plexy, suspected fracture or severe bruising | | CMBC 2* | 2 | | *birth injury requiring investigation | No change |
| | Birth injury requiring medical attention | | WA 3 | | | | No change |
| Neurological | Hypotonia, tremors, seizures, hyperirritability | 3 | CMBC 3 | -1 | | | Removed existing criterion |
| | Seizures | 3 | CMBC 3 WA 3 | 3 | 1 | | Removed existing criterion |
| | Evidence or suspected neonatal opioid withdrawal syndrome | 1 | | 2 | | | No change |
| Temperature | Instability, fever, suspected infection or dehydration | 3 | CMBC 2 | 3 | | | Removed existing criterion |
| | Persistent inability to maintain temperature between 97 to 100 degree Fahrenheit | | CMBC 2 | 3 | | | No change |
| | Prolonged temperature instability when intervention has failed | | WA 3 | | | | No change |
| Respiratory or cardiac | Irregularities, cyanosis, pallor | 3 | CMBC 2 WA 3 | | | | Removed existing criterion |

| Condition | Sub-condition | 2015 HERC CG | Other | 2020 Oregon DEM final rule | 2020 HERC CG proposed | Footnotes | Description of EbGS change from 2015 |
|-----------|---|--------------------|----------------|-------------------------------------|-----------------------------|-------------------|---|
| | Prolonged positive pressure ventilation or significant resuscitation | 1 | CMBC 3 | 1 | | | No change |
| | Abnormal heart rate pattern or persistent/symptom atic murmur | 1 | CMBC 3 | 2 | - | | No change |
| | Respiratory rate > 100 within 2 hours of birth and > 80 lasting more than 1 hours without improvement | 1 | 1 | 2 | ł | | No change |
| | Heart rate less than 80 or greater than 160 (at rest) without improvement | | | 2 | | | No change |
| | Pulse oximeter reading of less than 90 percent on right hand at greater than 24 hours | -1 | - | 2 | | | No change |
| | Apnea, central cyanosis, unresolved pallor at birth | | CMBC 2 | 3 | | | No change |
| Urinary | Failure to urinate within 24 hours after birth | - | CMBC 2* | 2 | | *36 hours of life | No change |
| Weight | < 5 th percentile for gestational age | 3 | CMBC 2 | 1 | | | Removed existing criterion |
| | <2000 grams | | WA 3 | - | | | Removed existing criterion |
| | <2,270 grams (5 lbs) | -1 | | 3 | - | | Removed existing criterion |
| | < 2500 grams | 1 | CMBC 2 | | | | Removed existing criterion |
| | Loss > 10% of birth weight/ failure to thrive | | CMBC 2 WA 3 | | | | No change |

| Condition | Sub-condition | 2015 HERC CG | Other | 2020 Oregon DEM final rule | 2020 HERC CG proposed | Footnotes | Description of EbGS change from 2015 |
|-----------|---|--------------------|--------|-------------------------------------|-----------------------------|-----------|---|
| | Weight loss in excess of 10% of birth weight that does not respond to treatment | | CMBC 2 | 2 | ł | | No change |

[†] Rules as of January, 2020