HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE: PLANNED OUT-OF-HOSPITAL BIRTH

Approved 11/12/15

HERC COVERAGE GUIDANCE

Planned out-of-hospital (OOH) birth is recommended for coverage for women who do not have high-risk coverage exclusion criteria as outlined below *(weak recommendation)*. This coverage recommendation is based on the performance of appropriate risk assessments[1] and the OOH birth attendant's compliance with the consultation and transfer criteria as outlined below.

Planned OOH birth is not recommended for coverage for women who have high risk coverage exclusion criteria as outlined below, or when appropriate risk assessments are not performed, or where the attendant does not comply with the consultation and transfer criteria as outlined below *(strong recommendation)*.

High-risk coverage exclusion criteria:

Complications in a previous pregnancy:

Maternal surgical history

- Cesarean section or other hysterotomy
- Uterine rupture
- Retained placenta requiring surgical removal
- Fourth-degree laceration without satisfactory functional recovery

Maternal medical history

- Pre-eclampsia requiring preterm birth
- Eclampsia
- HELLP syndrome

Fetal

- Unexplained stillbirth/neonatal death or previous death related to intrapartum difficulty
- Baby with neonatal encephalopathy
- Placental abruption with adverse outcome

Complications of current pregnancy:

Maternal

- Induction of labor
- Prelabor rupture of membranes > 24 hours

- Pre-existing chronic hypertension; Pregnancy-induced hypertension with diastolic blood pressure greater than or equal to 90 mmHg or systolic blood pressure greater than or equal to 140 mmHg on two consecutive readings taken at least 30 minutes apart
- Unknown group B strep carrier state
- Lack of informed consent on group B strep prophylaxis, if mother is Group B strep positive.
- Eclampsia or pre-eclampsia
- Anemia – hemoglobin less than 8.5 g/dL
- Thrombosis/thromboembolism/ thrombocytopenia (platelets <100,000), or other maternal bleeding disorder
- Drug or alcohol use with high risk for adverse effects to fetal or maternal health
- Maternal mental illness requiring inpatient care
- Unknown or positive HIV, syphilis or Hepatitis B status
- Current active infection of varicella at the time of labor; rubella infection anytime during pregnancy; active infection (outbreak) of genital herpes at the time of labor
- Refractory hyperemesis gravidarum
- Diabetes, type I or II, uncontrolled gestational diabetes, or gestational diabetes controlled with medication

Placental

- Low lying placenta within 2 cm or less of cervical os at term; placenta previa, vasa previa
- Placental abruption/abnormal bleeding
- Recurrent antepartum hemorrhage
- Uteroplacental insufficiency

Fetal

- Gestational age - preterm or postdates (defined as gestational age < 37 weeks + 0 days or > 41 weeks + 6 days)
- Multiple gestation
- Non-cephalic fetal presentation
- IUGR (defined as fetal weight less than fifth percentile using ethnically-appropriate growth tables, or concerning reduced growth velocity on ultrasound)
- Abnormal fetal heart rate/Doppler/surveillance studies
- Oligohydramnios or polyhydramnios
- Blood group incompatibility with atypical antibodies, or Rh sensitization
- Molar pregnancy

Transfer criteria:

If out-of-hospital birth is planned, certain intrapartum and postpartum complications may necessitate transfer to a hospital to meet coverage criteria. For these indications, an attempt should be made to transfer the mother and/or her newborn; however, imminent fetal delivery may delay or preclude actual transfer prior to birth.

Maternal

- Temperature ≥ 38.0 C
- Maternal infection requiring hospital treatment (e.g. endometritis or wound infection)
- Hemorrhage (hypovolemia, shock, need for transfusion)
- Retained placenta > 60 minutes
- Laceration requiring hospital repair (e.g., extensive vaginal, cervical or third- or fourth-degree trauma)
- Enlarging hematoma
- Bladder or rectal dysfunction

Fetal and uteroplacental

- Repetitive or persistent abnormal fetal heart rate pattern
- Thick meconium staining of amniotic fluid
- Prolapsed umbilical cord
- Failure to progress/failure of head to engage in active labor
- Chorioamnionitis or other serious infection (including toxoplasmosis, rubella, CMV, HIV, etc.)
- Uterine rupture, inversion or prolapse

If the infant is delivered out-of-hospital, the following complications require transfer to a hospital for the out-of-hospital birth to meet coverage criteria:

- Low Apgar score (< 5 at 5 minutes, < 7 at 10 minutes)
- Weight less than 5th percentile for gestational age
- Unexpected significant or life-threatening congenital anomalies
- Respiratory or cardiac irregularities, cyanosis, pallor
- Temperature instability, fever, suspected infection or dehydration
- Hyperglycemia/hypoglycemia unresponsive to treatment
- Hypotonia, tremors, seizures, hyperirritability
- Excessive bruising, enlarging cephalohematoma, significant birth trauma
- Vomiting/diarrhea

Consultation criteria:

Certain high risk conditions require consultation (by a provider of maternity care who is credentialed to admit and manage pregnancies in a hospital) for coverage of a planned out-of-hospital birth to be recommended. These complications include (but are not limited to) patients with:

Complications in a previous pregnancy:

Maternal

- More than three first trimester spontaneous abortions, or more than one second trimester spontaneous abortion
- More than one preterm birth, or preterm birth less than 34 weeks 0 days in most recent pregnancy

- Pre-eclampsia, not requiring preterm birth
- Cervical insufficiency/prior cerclage
- Third degree laceration; fourth-degree laceration with satisfactory functional recovery
- Postpartum hemorrhage requiring additional pharmacologic treatment or blood transfusion
- Retained placenta requiring manual removal

Fetal

- Child with congenital and/or hereditary disorder
- Baby > 4.5 kg or 9 lbs 14 oz
- Shoulder dystocia, with or without fetal clavicular fracture
- Unexplained stillbirth/neonatal death or previous death unrelated to intrapartum difficulty
- Unresolved intrauterine growth restriction (IUGR) or small for gestational age (defined as fetal or birth weight less than fifth percentile using ethnically-appropriate growth tables)
- Blood group incompatibility, and/or Rh sensitization

Complications of current pregnancy:

Maternal

- Inadequate prenatal care (defined as less than five prenatal visits or care began in the third trimester)
- Body mass index at first prenatal visit of greater than 35 kg/m^2
- History of maternal seizure disorder (excluding eclampsia)
- Gestational diabetes, diet-controlled
- Maternal mental illness under outpatient psychiatric care with suspicion for psychosis or potential harm to self or infant
- Maternal anemia with hemoglobin < 10.5 g/dL, unresponsive to treatment
- Third-degree laceration not requiring hospital repair
- Laparotomy during pregnancy

Fetal

- Fetal macrosomia (estimated weight >4.5 kg or 9 lbs 14 oz)
- Confirmed intrauterine death
- Life-threatening congenital anomalies (unless non rescucitation planned)
- Family history of genetic/heritable disorders that would impact labor, delivery or newborn care

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

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

RATIONALE FOR GUIDANCE DEVELOPMENT

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

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

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

EVIDENCE SOURCES

[Note: an additional source search was done at the request of the Evidence-based Guidelines Subcommittee (EbGS) at their April 2, 2015 meeting. A narrative and tabular description of this additional evidence follows that of the initial evidence sources description. A complete listing of the sources included from the new search immediately follows those identified in the initial search below. A full evidence table for these new sources is included in Appendix C.]

Initial search – trusted sources

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

National Institute for Clinical Excellence (2014). *Intrapartum care: care of healthy women and their babies during childbirth. Clinical Guideline 190,* December 2014*.* Retrieved from https://www.nice.org.uk/guidance/cg190/resources/guidance-intrapartum-care-care-of-healthy-women-and-their-babies-during-childbirth-pdf

Initial search – additional sources

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

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

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

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

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

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

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

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

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

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

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

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

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

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

New search (requested by EbGS at April 2, 2015 meeting) – included studies

Birthplace in England Collaborative Group; Brocklehurst, P., Hardy, P., Hollowell, J., Linsell, L., Macfarlane, A., McCourt, C. … Stewart, M. (2011). Perinatal and maternal outcomes by planned place of birth for healthy women with low risk pregnancies: The Birthplace in England national prospective cohort study. *British Medical Journal, 343*, d7400. Retrieved from http://www.bmj.com/content/343/bmj.d7400.full.pdf+html

Catling-Paull, C., Coddington, R. L., Foureur, M. J., Homer, C. S.; Birthplace in Australia Study; National Publically-funded Homebirth Consortium. (2013). Publically funded homebirth in Australia: A review of maternal and neonatal outcomes over 6 years. *Medical Journal of Australia, 198*(11), 616-20. Retrieved from https://www.mja.com.au/system/files/issues/198_11_170613/cat11665_fm.pdf

Cheng, Y. W., Snowden, J. M., King, T. L., & Caughey, A. B. (2013). Selected perinatal outcomes associated with planned home births in the United States. *American Journal of Obstetrics & Gynecology, 209*(4), 325.e1-8. Retrieved from http://www.ajog.org/article/S0002-9378(13)00630-3/pdf

Cheyney, M., Bovbjerg, M., Everson, C., Gordon, W., Hannibal , D., & Verdam, S. (2014). Outcomes of care for 16,924 planned home births in the United States: the Midwives Alliance of North America Statistics Project, 2004-2009. *Journal of Midwifery & Women's Health, 59*(1), 17-27. Retrieved from http://onlinelibrary.wiley.com/doi/10.1111/jmwh.12172/epdf

Davis, D., Baddock, S., Paiman, S., Hunter, M., Benn, C., Anderson, J. … Herbison, P. (2012). Risk of severe postpartum hemorrhage in low-risk childbearing women in New Zealand: Exploring the effect of place of birth and comparing third stage management of labor. *Birth, 39*(2), 98-105. DOI: 10.1111/j.1523-536X.2012.00531.x.

Janssen, P. A., Saxell, L., Page, L. A., Klein, M. C., Liston, R. M., & Lee, S. K. (2009). Outcomes of planned home birth with registered midwife versus planned hospital birth with midwife for physician. *Canadian Medical Association Journal, 181*(6-7), 377-83. Retrieved from http://www.cmaj.ca/content/181/6-7/377.full.pdf+html

de Jonge, A., Geerts, C. C., van der Goes, B. Y., Mol, B. W., Buitendijk, S. E., & Nijuhuis, J. G. (2015). Perinatal mortality and morbidity up to 28 days after birth among 743,070 low-risk planned home and hospital births: A cohort study based on three merged national perinatal databases. *British Journal of Obstetrics and Gynecology, 122*(5), 720-728. Retrieved from http://onlinelibrary.wiley.com/doi/10.1111/1471-0528.13084/epdf

de Jonge, A., Mesman, J. A., Mannien, J., Zwart, J. J., van Dillen, J., & van Roosmalen, J. (2013). Severe adverse maternal outcomes among low risk women with planned home versus hospital births in the Netherlands: Nationwide cohort study. *British Medical Journal, 346*, f3263. Retrieved from http://www.bmj.com/content/346/bmj.f3263.full.pdf+html

de Jonge, A., van der Goes, B. Y., Ravelli, A. C., Amelink-Verburg, M. P., Bol, B. W., Nijhuis, J. G. … Buitendijk, S. E. (2009). Perinatal mortality and morbidity in a nationwide cohort of 529,688 low-

risk planned home and hospital births. *British Journal of Obstetrics and Gynecology, 116*(9), 1177-84. Retrieved from http://onlinelibrary.wiley.com/doi/10.1111/j.1471-0528.2009.02175.x/epdf

Hutton, E. K., Reitsma, A. H., & Kaufman, K. (2009). Outcomes associated with planned home and hospital births in low-risk women attended by midwives in Ontario, CA, 2003-2006: A retrospective cohort study. *Birth, 36*(3), 180-9. Retrieved from http://www.aom.on.ca/files/Communications/Reports_and_Studies/Birth_Ontario_Home_Birth_Hutton_Sept_09.pdf

Johnson, K. C., & Daviss, B. A. (2005). Outcomes of planned home births with certified professional midwives: Large prospective study in North America. *British Medical Journal, 330*(7505), 1416. Retrieved from http://www.bmj.com/content/330/7505/1416.full.pdf+html

Kennare, R. M., Keirse, M. J., Tucker, G. R., & Chan, A. C. (2010). Planned home and hospital births in South Australia, 1991-2006: Differences in outcomes. *Medical Journal of Australia, 192*(2), 76-80. Retrieved from https://www.mja.com.au/system/files/issues/192_02_180110/ken10465_fm.pdf

Nove, A., Berrington, A., & Matthews, Z. (2012). Comparing the odds of postpartum haemorrhage in planned home birth against planned hospital birth: Results of an observational study of over 500,000 maternities in the UK. *BMC Pregnancy & Childbirth, 12*, 130. Retrieved from http://www.biomedcentral.com/content/pdf/1471-2393-12-130.pdf

Stapleton, S. R., Osborne, C., & Illuzzi, J. (2013). Outcomes of care in birth centers: Demonstration of a durable model. *Journal of Midwifery & Women's Health, 58*(1), 3-14. Retrieved from http://onlinelibrary.wiley.com/doi/10.1111/jmwh.12003/epdf

van der Kooy, J., Poeran, J., de Graaf, J. P., Bimie, E., Denklass, S., Steegers, E. A., & Bonsel, G. J. (2011). Planned home compared with planned hospital births in the Netherlands: Intrapartum and early neonatal death in low-risk pregnancies. *Obstetrics & Gynecology, 118*(5), 1037-46. DOI: 10.1097/AOG.0b013e3182319737.

TOPIC BACKGROUND

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

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

EVIDENCE OVERVIEW

Clinical background

From Cochrane 2012

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

A range of interventions continue to be used routinely in relation to births at many hospitals despite the fact that for a long time they have been proven to have harmful effects, or only marginal or no beneficial effect (e.g., fetal monitoring, episiotomy and early cord clamping). Even though the use of a few specific interventions have been reduced (e.g., placental function tests), in general "routine medical interventions have [...] increased steadily over time despite the efforts of the Cochrane Pregnancy and Childbirth Group, its predecessors, and other researchers carrying out systematic reviews" (Hodnett 2009).

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

Initial evidence review

Cochrane 2012

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

women was willing to be randomized, the others having all decided where they wanted to deliver before being recruited into the study.

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

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

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

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

Wax 2010

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

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

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

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

de Jonge 2009

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

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

Hutton 2009

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

- Twins
- Breech

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

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

Janssen 2009

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

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

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

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

to require resuscitation or oxygen therapy for more than 24 hours when compared to either hospital group.

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

April 2015 New Evidence Search Results

(References listed on pages 7-8.)

Background

At the April 2, 2015 meeting, the EbGS asked for a full evidence search on OOH birth literature due to concerns raised in public comment and testimony about the completeness of evidence identified in the initial trusted source search published to the OHA website in August 2014. Public comments and testimony raised the issue of risk of perinatal mortality, particularly for primiparous women, in planned OOH birth. It also raised the issue of assuring that the evidence spoke to planned OOH birth compared to planned hospital birth, with the recognition that unplanned OOH birth was outside the topical area and that mixing evidence from these two populations would be misleading. Staff were also concerned that the initial search did not explicitly include birth centers. Amending the coverage guidance to encompass this site, staff determined that a broader, new evidence search was warranted. The new evidence search focused on perinatal mortality and mode of birth because those outcomes appeared to encompass both the greatest potential harm and benefit of OOH birth. In addition, the new search explicitly included terms related to birth centers since the initial search was focused on home birth. Appendix C includes details about the search, inclusion criteria, review methodology, and a full evidence table with the 15 included studies.

New Evidence Search

The new evidence search (MEDLINE®) conducted on April 22, 2015 yielded 596 citations and a final search on May 20, 2015 identified an additional 21 citations. The MEDLINE® search was limited to the past 10 years and not limited by study design.These 617 citations were subject to dual review for possible inclusion. See Appendix C for details on the search strategy and inclusion criteria. Inclusion criteria specified study size, relevant fetal/neonatal and maternal outcomes, and location of study. At least one study arm had to include subjects with planned OOH birth, either at home or in a birth center. Two staff epidemiologists reviewed 40 full text articles and found 15 that met inclusion criteria. All included studies were dual rated for quality of evidence for key oucomes, based on the GRADE system. No study was excluded based on quality in accord with accepted practice for systematic reviews (SRs). See Appendix C for GRADE quality ratings.

The new search located two SRs and no randomized controlled trials (RCTs). The first SR (Olsen, 2012) was the Cochrane Review discussed in the prior evidence summary. It included two RCTs, one with a single patient and another with 11 subjects. Neither of these individual trials met the new evidence search inclusion criteria based on study date and sample size. The second SR identified (Wax, 2010) was also identified in the trusted sources and is discussed in the initial evidence summary above. It was excluded from the new evidence summary because, on closer examination, it was clear that it incorporated studies including women who had unplanned births at home rather than restricting inclusion to studies reporting planned home birth exclusively. Three of 12 studies included in the Wax (2010) SR are also included in this new evidence search and summary. Nine of 12 of the individual studies captured in the Wax SR (2010) were excluded from the new evidence search on the basis of date (published more than 10 years ago). It appears that the new search strategy was more comprehensive than that used by Wax (2010), yielding 617 citations as compared with 237 for Wax (2010). The 15 studies meeting final inclusion criteria are included in the evidence table in Appendix C.

Results

Context

To contextualize the results it is important to understand baseline risks of perinatal mortality and other harms among women experiencing hospital births. For the U.S. as a whole, perinatal mortality has remained relatively stable over recent years.[1] Perinatal mortality is defined and reported in the U.S. in two ways: first, as the number of fetal and early neonatal deaths (0 to 7 days of life) per 1000 live births and eligible fetal deaths (over 20 weeks of gestation); and second, with the addition of late neonatal deaths (those taking place between 7 and 28 days of life).[2] Some countries and studies use alternate definitions, such as reporting only neonatal deaths during the first week of life (early neonatal death) or only including gestations above 24 weeks, making international comparison difficult. However, there are still clear differences across countries and among populations, even with these definitional issues. For example, the World Health Organization reported a 2000 perinatal mortality rate of 6 in Australia, Belgium, Finland, and Canada; 7 for the U.S.; 8 for the U.K. and rising to rates well above 80 in many countries of the developing world.[3] The U.S. National Center for Health Statistics (NCHS) reported a U.S. rate (first definition, using stillbirths and early neonatal deaths) of 6.51 in 2006 with a slight decline to 6.26 in 2011,[1] but did not report perinatal mortality by parity. However, the risk of perinatal death varies by gestational age and co-existing maternal and fetal/neonatal factors. For example, infant mortality rates for low-risk pregnancies at term vary from a high of 0.66 at 37 weeks to a nadir of 0.33 at 39 weeks and an intermediate level of 0.40 at 41 weeks.[4] Similarly, the fetal mortality rate varies from 1.40 at 37

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[1] Gregory, E.C., MacDorman, M.F., & Martin, J.A. (2014). Trends in fetal and perinatal mortality in the United States, 2006-2012. *NCHS Data Brief*, Nov(169), 1-8. Retrieved from http://www.cdc.gov/nchs/data/databriefs/db169.pdf

[2] MacDorman, M. F., Kirmeyer, & S. E., & Wilson, E. C. (2012). Fetal and perinatal mortality. United States, 2006. *National vital statistics reports, 60*(8). Retrieved from http://www.cdc.gov/nchs/data/nvsr/nvsr60/nvsr60_08.pdf

[3] World Health Organization (WHO). (2006). Neonatal and Perinatal Mortality. Country, Regional and Global Estimates. Geneva: WHO Press. Retrieved from http://whqlibdoc.who.int/publications/2006/9241563206_eng.pdf

[4] Zhang X., & Kramer, M. S. (2009). Variations in mortality and morbidity by gestational age among infants born at term. *Journal of Pediatratrics, 154*(3), 358-62. Retrieved from http://www.jpeds.com/article/S0022-3476(08)00781-6/abstract

to 39 weeks, to 0.88 at 40 weeks and increases late in pregnancy to 1.76 at 42 or more weeks of gestation.[2]

In 2006, the overall perinatal mortality rate in Oregon was 5.27.[2] During 2012, there were 92 reported term fetal deaths and early neonatal deaths in the state. Of these 92 deaths, 84 occurred in planned hospital births and 8 occurred in planned OOH births.[5] These rates were not reported by parity. Chart review of the eight cases of intrapartum and early neonatal death found that six of the eight did not meet low-risk criteria. The total term perinatal mortality rate for planned OOH births in Oregon in 2012 was 4.0 and for planned in-hospital births was 2.1.[5]

The perinatal mortality rate, and perinatal morbidity more generally, is higher among women having a first birth (primiparous women) than those having a subsequent birth (multiparous women), regardless of birth setting. For example, Cheng (2013) found that the risk of low Apgar score was nearly twice as high among low risk primiparous women having a hospital birth in the U.S. than among multiparous women in that setting. The Birthplace study, conducted in the U.K., reported that the incidence of stillbirth among low risk multiparous women giving birth in hospital obstetric units was half of what it was for primiparous women in the same types of hospital settings (Birthplace, 2011). They also reported that the incidence of neonatal death within the first week of life was four times as common among primiparas (Birthplace, 2011). Similarly, de Jonge (2009) reported that the adjusted relative risk of stillbirth or death within the first week of life was 1.68 for primiparous women compared to multiparous women in a study from the Netherlands. While the absolute risk of these outcomes is low, it is important to note the relative baseline differences among first and subsequent births.

Summary of Results – New Search

A summary table of included studies and results for our primary outcomes of interest is presented in Table 1 below. Four of the 15 studies were conducted in the U.S. and the remainder were based in Australia, Canada, England, the Netherlands, and New Zealand. Two studies provided low quality evidence for the primary outcomes of interest and 13 studies yielded very low quality evidence. This is largely because all studies were observational and most (11 of 15) were conducted outside the U.S., thus introducing indirectness and potential for non-comparability to the U.S. setting. Ten studies reported measures of perinatal mortality with definitions ranging from intrapartum fetal deaths plus neonatal deaths within the first 24 hours of life up to 28 days. These rates (per 1000 births) ranged from 0.87 to 2.06 for planned home birth among non-comparative studies. Among comparative studies, perinatal mortality (measured as stillbirths and neonatal deaths up to 28 days) ranged from a protective relative risk (RR) of 0.61 in the Canadian study by Janssen (2009) to an excess adjusted RR of 1.38 in the Australian study by Kennere (2009). No confidence interval (CI) was statistically significant and the CIs of these studies were overlapping. Cesarean delivery rates were low overall, but statistically lower in the planned OOH birth group among comparative studies. Two studies contributed data only on postpartum

[5] Oregon Public Health Division. (2013). Oregon Birth Outcomes, by Planned Birth Place and Attendant. Persuant to: HB 2380. Prepared by Oregon Public Health Division, August 30, 2013. Retrieved from http://public.health.oregon.gov/BirthDeathCertificates/VitalStatistics/birth/Documents/PlannedBirthPlaceandAttendant.pdf

hemorrhage (Davis, 2011; Nove, 2012). Both found a decreased risk of postpartum hemorrhage with home birth, but only one of these findings was statistically significant.

Table 1. Summary of Included Studies from New Search, Primary Outcomes of Interest Reported, and Study Quality

Citation	Study Description • Country • Study design • Number of planned OOH births included	Primary Fetal & Neonatal Outcome Reported	Primary Maternal Outcome Reported	Study Quality (GRADE)
Birthplace, 2011	• England • Prospective comparative cohort comparing planned home (n=16,840), freestanding midwifery unit (FMU) (11,282), alongside midwifery unit (AMU) (n=16,710), and obstetric unit (OU) (n=19,706) sites	Composite outcome (CO) (stillbirth, neonatal death 0-7d, neonatal encephalopathy, meconium aspiration, brachial plexus injury, fractured humerus or clavicle) CO incidence (95% CI), by site Home 4.2 (3.2-5.4) FMU 3.5 (2.5-4.9) AMU 3.6 (2.6-5.9) OU 4.4 (3.2-5.9)	Cesarean delivery Cesarean incidence/1000 (99% CI), by site Home 2.8 (2.3-3.4) FMU 3.5 (2.8-4.2) AMU 4.4 (3.5-5.5) OU 11.1 (9.5-13.0)	Very low (OOO+)
Catling-Paull, 2013	• Australia • Retrospective, non-comparative cohort of planned home birth • 1807	Perinatal mortality (fetal to 7d) Home 1.7/1000	Cesarean delivery Home 5.4%	Very low (OOO+)
Cheng, 2013	• U.S. • Retrospective cohort comparing planned home birth to hospital birth using vital statistics data (27 states) • 12,039	5 minute Apgar score < 4 Home v. Hospital adjOR 1.87 (95% CI 1.36-2.58)	Operative vaginal delivery Home v. Hospital adjOR 0.12 (95% CI 0.08-0.17)	Very low (OOO+)

Citation	Study Description • Country • Study design • Number of planned OOH births included	Primary Fetal & Neonatal Outcome Reported	Primary Maternal Outcome Reported	Study Quality (GRADE)
Cheyney, 2014	• U.S. • Prospective, non-comparative cohort of planned home birth • 16,924	Perinatal mortality (intrapartum to 28d) Home (non-anomalous) 2.06/1000	Cesarean delivery Home 5.2%	Low (OO++)
Davis, 2011	• New Zealand • Retrospective, comparative cohort of planned home birth and planned hospital (primary, secondary, tertiary) birth • 1830	*None*	Postpartum hemorrhage (>1000mL) Home v.Primary hospital adjOR 0.93 (95% CI 0.49-1.74)	Very low (OOO+)
de Jonge, 2009	• Netherlands • Retrospective cohort study of planned home and planned hospital birth • 466,041	Perinatal mortality (intraparum to 7d) Home v. Hospital adjRR 1.00 (95%CI 0.78-1.27)	*None*	Very low (OOO+)
de Jonge, 2013	• Netherlands • Retrospective cohort study of planned home and planned hospital birth • 92,333	*None*	Composite outcome (ICU admission, uterine rupture, eclampsia/preeclampsia, transfusion) incidence Home v. Hospital 1.5/1000 v. 2.7/1000	Very low (OOO+)

Citation	Study Description • Country • Study design • Number of planned OOH births included	Primary Fetal & Neonatal Outcome Reported	Primary Maternal Outcome Reported	Study Quality (GRADE)
de Jonge, 2015	• Netherlands • Retrospective cohort study of planned home and planned hospital birth • 335,683	Perinatal mortality (intrapartum to 28d) Home v. Hospital (nulliparous) adjOR 0.99 (95% CI 0.79-1.24) Home v. Hospital (multiparous) adjOR 1.16 (95% CI 0.87-1.55)	*None*	Very low (OOO+)
Hutton, 2009	• Ontario, Canada • Retrospective matched cohort of planned home birth • 6692	Perinatal mortality (intrapartum to 28d) Home v. Hospital 9/6692 (0.13%) v. 8/6692 (0.12%)	Cesarean delivery Home v. Hospital RR 0.64 (95% CI 0.56-0.73)	Very low (OOO+)
Janssen, 2009	• British Columbia, Canada • Retrospective cohort of planned home and planned hospital births • 2889	Perinatal mortality (intrapartum to 28d) Home v. Hospital (both with registered midwife) RR 0.61 (95% CI 0.06-5.88)	Cesarean delivery Home v. Hospital (both with registered midwife) adjRR 0.76 (95% CI 0.64-0.91)	Very low (OOO+)
Johnson, 2005	• U.S. • Retrospective, non-comparative cohort of planned home births • 5418	Perinatal mortality (intrapartum to neonatal) Home (non-anomalous) 2.03/1000	Cesarean delivery Home 3.7%	Very low (OOO+)

Citation	Study Description • Country • Study design • Number of planned OOH births included	Primary Fetal & Neonatal Outcome Reported	Primary Maternal Outcome Reported	Study Quality (GRADE)
Kennere, 2009	• South Australia • Retrospective cohort of planned home and planned hospital births • 1141	Perinatal mortality (intrapartum to 28d) Home v. Hospital adjOR 1.38 (95% CI 0.56-3.41)	Cesarean delivery Home v. Hospital adjOR 0.27 (95% CI 0.22-0.34)	Very low (OOO+)
Nove, 2012	• North West Thames Region, England • Retrospective cohort of planned home and planned hospital births • 5598	*None*	Postpartum Hemorrhage (>1000mL) Home v. Hospital adjOR 0.40 (95% CI 0.26-0.59)	Very low (OOO+)
Stapleton, 2013	• US • Retrospective, non-comparative cohort of planned birth center birth • 15, 574	Perinatal mortality (intrapatum to 7d) Birth center (non-anomalous) 0.87/1000	Cesarean delivery Home 6.1%	Low (OO++)
van der Kooy, 2011	• Netherlands • Retrospective cohort of planned home and planned hospital births • 402,912	Perinatal mortality (intrapartum to 7d) Home v. Hospital adjRR 1.05 (95% CI 0.91-1.21)	*None*	Very low (OOO+)

Table Abbreviations: adjOR – adjusted odds ratio; AMU – planned alongside midwifery unit birth; CI – confidence interval; CO – composite outcome; d – days; FMU – planned freestanding midwifery unit birth; home – planned home birth; n – number of subjects in study or group; OOH – out of Hospital; OU – planned obstetric unit birth; RR – relative risk.

Note: Study quality: (OOO+) represents very low, (OO++) represents low.

While several studies presented data on the overall perinatal mortality rate for the entire study population of women having a first birth and women having subsequent birth, only four studies provided those data by parity. See Table 2 below for perinatal mortality outcomes reported by parity. Only one non-comparative U.S.-based study contributed information on the risk of perinatal mortality among primiparous women compared to multiparous women. Cheyney (2014) reported 18/3771 (0.48%) cases of perinatal death (intrapartum stillbirth through 28 days) among primiparas compared to

17/13,153 (0.13%) for multiparas. The unadjusted intrapartum stillbirth rate was 2.92 vs. 0.84 for primiparas compared to multiparas. Among primiparous women experiencing perinatal death, eight women had risk factors including breech presentation, gestational diabetes and preeclampsia. For the 10 cases of perinatal death among women who did not have these risk factors, the intrapartum stillbirth rate was 2.21; the early neonatal perinatal mortality rate was 0.28; and the late neonatal mortality rate was also 0.28, for a total perinatal mortality rate of 2.77 among low-risk primiparous women (Cheyney, personal communication, 2015).

Table 2. Perinatal Mortality, New Search, Among Studies Reporting by Parity

Citation, Year (Country) [Quality]	Perinatal Mortality (PM) – Primiparous Women (per 1000 births)	Perinatal Mortality (PM) – Multiparous Women (per 1000 births)	Total Deaths Reported (total N of study)
Cheyney, 2014 (U.S.) [OO++]	Crude PM (Home) Intrapartum: 2.92 Early neonatal: 0.41 Late neonatal: 0.80 Total crude PM, primiparas: 4.13 adjPM (Home), parimiparas 2.77 (after excluding high risk)	Crude PM (Home) Intrapartum: 0.84 Early neonatal: 0.27 Late neonatal: 0.23 Total crude PM: 1.34 (*adjPM not reported*)	35 (N=16,924)
Birthplace, 2011 (England) [OOO+]	Intrapartum Stillbirth (n (95% CI) Home 0.9 (0.2-3.3) FMU 0.3 (0.0-3.5) AMU 0.1 (0.0-1.6) OU 0.1 (0.0-1.5) Early Neonatal Death (n (95% CI) Home 0.4 (0.1-2.4) FMU 0.5 (0.1-1.7) AMU 0.1 (0.0-1.7) OU 0.4 (0.1-1.3)	Intrapartum Stillbirth (n (95% CI) Home 0.1 (0.0-0.9) FMU 0.5 (0.1-2.2) AMU 0 events OU 0.2 (0.0-1.2) Early Neonatal Death (n (95% CI) Home 0.3 (0.1-1.3) FMU 0.3 (0.1-2.2) AMU 0.1 (0.0-1.4) OU 0.1 (0.0-1.8)	32 (N=44,434)
Hutton, 2009 (Canada) [OOO+]	PM (fetal death to neonatal 28d) Home: 2.18 Hospital: 1.74	PM (fetal death to neonatal 28d) Home: 0.91 Hospital: 0.91	18 (N=13,384)

Citation, Year (Country) [Quality]	Perinatal Mortality (PM) – Primiparous Women (per 1000 births)	Perinatal Mortality (PM) – Multiparous Women (per 1000 births)	Total Deaths Reported (total N of study)
de Jonge, 2015 (Netherlands) [OOO+]	PM (fetal death to neonatal 28d) Home: 1.02 Hospital: 1.09	PM (fetal death to neonatal 28d) Home: 0.59 Hospital: 0.58	592 (N=743,070)

Table Abbreviations: adj – adjusted; AMU – planned alongside midwifery unit birth; CI – confidence interval; d – days; FMU – planned freestanding midwifery unit birth; home – planned home birth; N – number of subjects in study; OU – planned obstetric unit birth; PM – perinatal mortality. -number of subjects in study.

Note: Study quality (OOO+) represents very low , (OO++) represents low.

U.S.-based Studies Reporting Perinatal Mortality and Cesarean Delivery Rate

There were four U.S.-based studies with two presenting low quality evidence (Cheyney, 2014; Stapleton, 2013) and two with very low quality evidence (Cheng, 2013; Johnson, 2005). Neither of the low quality evidence studies was comparative, but both were large and well-conducted (Cheyney, 2014; Stapleton, 2013). Cheyney (2014) presented data on home birth and the Stapleton (2013) studied birth center outcomes. Cheng (2013) did not report perinatal mortality and is discussed in a separate section below. Johnson (2005) used data collected by midwives registered by the North American Registry of Midwives (NARM) as a requirement of recertification. It is smaller and older than Cheyney (2014), but similar in that it was conducted by a midwifery registration organization.

For home birth in the U.S., Cheyney (2014) found a non-anomalous perinatal mortality rate (stillbirth to neonatal death within 28 days) of 2.06. Johnson (2005) reported a similar finding with a non-anomolous perinatal mortality rate (intrapartum stillbirth to 28 days) of 2.03. Stapleton (2013) reported a non-anomalous perinatal mortality rate (stillbirth to neonatal death within 7 days) of 0.87. The reported cesarean delivery rates were similar across the U.S.-based studies, ranging from 3.7% (Johnson, 2005) to 5.2% (Cheyney, 2014) to 6.1% (Stapleton, 2013).

U.S.-based Study Reporting Low Apgar Score Outcome

The fourth U.S.-based study did not report perinatal mortality, but instead reported the surrogate outcome of low Apgar score (5-minute Apgar score less than 4) (Cheng, 2013). Cheng (2013) reported lower odds (but not statistically different) of low Apgar score for home births attended by certified nurse midwives (CNMs) compared to hospital births for either primiparous or multiparous women (adjusted odds ratio [adjOR] 0.47 [95% CI 0.55-3.22]; adjOR 0.83 [95% CI 0.27-2.60]). When the comparison was for home birth attended by other types of midwives compared with hospital birth, Cheng and colleagues (2013) found the odds of low Apgar score to be elevated in both parity groups (not statistically significant for primiparous women, but statistically significant for multiparous women), with the adjOR of 1.34 (95%CI 0.55-3.22) for primiparas and an adjOR of 1.84 (95% CI 1.04-3.26) for multiparas. Based on other research, the association between a low 5-minute Apgar and the live born infant dying when this occurs is moderate, with about 20 neonatal deaths out of every 1000 (2%)

births.[6,7] Other methodologic limitations also exist for this type of birth certificate-based study[8,9] and contributed to the rating of very low quality evidence for this study.

Non-U.S.-based Studies Reporting Perinatal Mortlity by Parity

Among non-U.S. studies, three provided information on perinatal mortality by parity and compared planned home and hospital birth (Birthplace, 2011; de Jonge, 2015; Hutton, 2009). The information from the prospective Birthplace study (2011) for stillbirth and neonatal death in the first week of life should be interpreted cautiously as these items were not the primary outcome (which was a composite outcome including both items, but also including items such as humeral and clavicular fracture). Total event rates were small, confidence intervals (CI) are wide, and only unadjusted figures are available from the online appendices to the article. For primiparous women, the rate of stillbirth with planned home birth was 0.9 (95% CI 0.2-3.3), while the rate for multiparous women was 0.1 (95% CI 0.0-0.9) (Birthplace, 2011). The rate of early neonatal death was 0.4 (95% CI 0.1-2.4) among primiparas and 0.3 (95% CI 0.1-1.3) for multiparas (Birthplace, 2011). Hutton (2009) conducted a retrospective matched cohort study of planned home birth in Ontario, Canada. They reported that the proportion of non-anomalous perinatal deaths (stillbirth to 28 days) for primiparous (0.2%) vs. multiparous women (0.1%) was the same for both planned home and hospital birth (Hutton, 2009). The total number of non-anomalous perinatal deaths was small, with nine among primiparous women and six among multiparas (Hutton, 2009). A large retrospective, national study from the Netherlands by de Jonge and colleagues (de Jonge, 2015) found that for primiparous women planning home birth, 1.02% experienced perinatal death (stillbirths and neonatal deaths up to 28 days) compared to 1.09% planning a hospital birth, with an adjOR of 0.99 (95% CI 0.79-1.24). Among multiparous women the comparable figures were 0.59% vs. 0.58%, with an adjOR of 1.16 (95% CI 0.87-1.55) (de Jonge, 2015).

Summary – New Evidence Search

In summary, the additional literature review found that rates of cesarean delivery are lower for both primiparous and multiparous women planning a home birth compared to a hospital birth. Neonatal risks varied across studies. Among comparative studies, two reported a slightly higher perinatal mortality risk for nulliparous women planning a home birth compared to a hospital birth and one reported a slightly lower risk at home compared to hospital. These three comparative studies were from three different countries and the only U.S. study to report perinatal mortality by parity was not comparative. Estimates of perinatal mortality are unstable because of small numbers of this fortunately rare outcome. Among the four studies in Table 2 there were 677 occurrences of perinatal death among 817,812 total births

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[6] Casey, B. M., McIntire, D. D., & Leveno, K. J. (2001). The continuing value of the Apgar score for the assessment of newborn infants. *New England Journal of Medicine, 344*(7), 467-471.

[7] Moster, D., Lie, R. T., Irgens, L. M., Bjerkedal, T., & Markestad, T. (2001). The association of Apgar score with subsequent death and cerebral palsy: A population-based study in term infants. *Journal of Pediatrics, 138*(6), 798-803.

[8] Martin, J. A., Wilson, E. C., Osterman, M. J. K., Saadi, E. W., Sutton, S. R., & Hamilton, B. E. (2013). Assessing the quality of medical and health data from the 2003 birth certificate revision: Results from two states. *National Vital Statistics Reports, 62*(2). Retrieved from http://www.cdc.gov/nchs/data/nvsr/nvsr62/nvsr62_02.pdf

[9] Reichman, N. E., & Hade, E. M. (2001). Validation of birth certificate data: A study of women in New Jersey's HealthStart Program. *Annals of Epidemiology, 11*(3), 186-193.

(0.82%). Comparisons are limited by differences in outcome and population definitions, differences among OOH birth provider training and regulation, differences among risk status of women planning home birth, and differences among health systems. Because of all these factors and the low quality of available evidence, we cannot exclude a small increase in perinatal risk, particularly for nulliparous women who choose to plan a home birth rather than a hospital birth. However, available evidence indicates that the absolute risk is small, particularly among low-risk women and in situations where there are well-trained OOH birth attendants and functioning systems for consultation and transfer to higher levels of care when the need arises.

Guidelines

The NICE guideline on intrapartum care in healthy women was published in December 2014. The guideline recommends the following regarding place of birth:

Women at low risk of complications

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

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

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

1.1.3 Using Tables 3 and 4, explain to low-risk multiparous women

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

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

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

Table 4. Outcomes for the baby for each planned place of birth: low-risk multiparous women

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

1.1.4 Using Tables 5 and 6, explain to low-risk nulliparous women that:

- Planning birth at home or in a freestanding midwifery unit is associated with a higher rate of spontaneous vaginal birth than planning birth in an alongside midwifery unit, and these 3 settings are associated with higher rates of spontaneous vaginal birth than planning birth in an obstetric unit
- Planning birth in an obstetric unit is associated with a higher rate of interventions, such as instrumental vaginal birth, caesarean section and episiotomy, compared with planning birth in other settings
- There are no differences in outcomes for the baby associated with planning birth in an alongside midwifery unit, a freestanding midwifery unit or an obstetric unit
- Planning birth at home is associated with an overall small increase (about 4 more per 1,000 births) in the risk of a baby having a serious medical problem compared with planning birth in other settings.

Table 5. Rates of spontaneous vaginal birth, transfer to an obstetric unit, and obstetric interventions for each planned place of birth: low-risk nulliparous women

	Number of incidences per 1,000 nulliparous women giving birth			
	Home	**Freestanding midwifery unit**	**Alongside midwifery unit**	**Obstetric unit**
Spontaneous vaginal birth	794	813	765	688
Transfer to an obstetric unit	450	363	402	10
Epidural	218	200	240	349
Episiotomy	165	165	216	242
Cesarean birth	80	69	76	121
Instrumental birth (forceps or ventouse)	126	118	159	191
Blood transfusion	12	8	11	16

Table 6. Outcomes for the baby for each planned place of birth: low-risk nulliparous women

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

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

1.1.10 Use tables 7, 8, 9 and 10 as part of an assessment for a woman choosing her planned place of birth:

- Tables 7 and 8 show medical conditions or situations in which there is increased risk for the woman or baby during or shortly after labour, where care in an obstetric unit would be expected to reduce this risk.
- The factors listed in tables 9 and 10 are not reasons in themselves for advising birth within an obstetric unit, but indicate that further consideration of birth setting may be required.
- Discuss these risks and the additional care that can be provided in the obstetric unit with the woman so that she can make an informed choice about planned place of birth. [2007, amended 2014]

Table 7. Medical conditions indicating increased risk suggesting planned birth at an obstetric unit

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

Table 8. Other factors indicating increased risk suggesting planned birth at an obstetric unit

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

Table 9. Medical conditions indicating individual assessment when planning place of birth

Disease Area	Medical Condition
Cardiovascular	• Cardiac disease without intrapartum implications
Haematological	• Sickle-cell trait • Thalassaemia trait • Atypical antibodies not putting the baby at risk of haemolytic disease • Anemia – haemoglobin 8.5-10.5 g/dl at onset of labor
Infective	• Hepatitis B/C with normal liver function tests
Immune	• Nonspecific connective tissue disorders
Endocrine	• Unstable hypothyroidism such that a change in treatment is required
Skeletal/Neurological	• Spinal abnormalities • Previous fractured pelvis • Neurologic deficits
Gastrointestinal	• Liver disease without current abnormal liver function • Crohn's disease • Ulcerative colitis

Table 10. Other factors indicating individual assessment when planning place of birth

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

Factor	Additional Information
	• Age over 35 at booking
Fetal indications	• Fetal abnormality
Previous gynaecological history	• Major gynaecological surgery • Cone biopsy or large loop excision of the transformation zone • Fibroids

Service organization and clinical governance

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

1.1.16 Ensure that there are

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

Risk criteria for planned home birth

The 2014 NICE draft guideline for antepartum care clearly outlines conditions that make a woman high-risk. In addition, the Oregon Public Health Division referenced a report from the American College of Obstetrics and Gynecology (ACOG) on Planned Home Birth[10] as their published criteria for being low-risk. This includes the following requirements:

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

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

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

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

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

Current Oregon law[11] outlines risk criteria which birthing centers must follow. A proposed rule would apply those same criteria to home births. Those criteria can be found in Appendix A.

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

Midwifery certification

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

The Netherlands[12]

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

British Columbia[13]

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

Ontario[14]

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

- A baccalaureate degree in health sciences (midwifery) from a university in Ontario.
- A degree, diploma or certificate from a program listed in Schedule 1.

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[11] http://arcweb.sos.state.or.us/pages/rules/oars_300/oar_333/333_076.html
[12] http://www.nurse.or.jp/nursing/international/icm/report/data/2012/icm-dutch.pdf
[13] http://www.cmbc.bc.ca/pdf.shtml?Exploring-Midwifery-as-a-Career
[14] http://www.e-laws.gov.on.ca/html/source/regs/english/2011/elaws_src_regs_r11168_e.htm

- Qualifications that are equivalent to the degree referred to in subparagraph i, as determined by the Council or by a body or bodies designated by the Council.

2. The applicant must:

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

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

United Kingdom[15]

Midwifery degree

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

Oregon[16]

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

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

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[15] http://www.nhscareers.nhs.uk/explore-by-career/midwifery/training-to-be-a-midwife/
[16] http://www.oregon.gov/OHLA/DEM/Pages/Midwifery_How_to_Get_Licensed.aspx

North American Registry of Midwives (NARM)[17]

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

Phase 1: Births as an Observer

- Ten births in any setting, in any capacity

Phase 2: Clinicals as Assistant under Supervision

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

Phase 3: Clinicals as Primary under Supervision

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

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

Oregon data on planned out-of-hospital birth

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

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

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

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

- Sixty-two term (≥ 37 weeks' gestation) fetal deaths occurred in Oregon during 2012; 4 (6.5%) of these occurred among planned out-of-hospital births.
- Thirty term early neonatal deaths (during the first 6 days of life) occurred in Oregon during 2012; 4 (13.3%) of these occurred among planned out-of-hospital births.

[17] http://narm.org/entry-level-applicants/

- In total, 92 term fetal and early neonatal deaths occurred in Oregon during 2012; 8 (8.7%) occurred among planned out-of-hospital births. These 8 deaths underwent a fetal and neonatal mortality case review per published national guidelines.

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

- Four term fetal and four early neonatal deaths occurred during 2012 among women who planned to deliver out-of-hospital
- Planned birth attendants: Certified Nurse Midwife (1), Licensed Direct-Entry Midwives (4), Unlicensed Midwife (1), Undetermined Licensure Midwife (1), and Naturopathic Physician (1)
- Median birth weight (3515 grams)
- Maternal characteristics were similar to the larger group of planned out-of-hospital births
- Two pregnancies had inadequate or no prenatal care
- Chart review noted that, among perinatal deaths:
    - Two pregnancies were twin gestations
    - Four mothers declined prenatal ultrasound (to confirm gestation and identify pathology)
    - Five mothers declined Group B streptococcal testing (to identify women who are carriers of GBS; treatment during labor is recommended to decrease the risk of early GBS neonatal sepsis)
    - Two mothers declined prophylaxis during labor for Group B streptococcal positive tests
- Six of eight transferred to the hospital during labor:
    - Indications for transfer to a hospital from home or birthing center included (multiple causes may apply): loss of fetal heart tones (3), prolonged labor (2), decreased fetal movement (2), and malpresentation (2)
    - One mother initially declined transfer during labor despite recommendation by birth attendant
- Six of eight pregnancies did not meet published low-risk criteria for out-of-hospital birth*:
    - More than 41 weeks gestation (4)
    - Twin gestation (2)
    - Morbid obesity (> 40 BMI) (1)
    - Planned attendants among these 6: Certified Nurse Midwife (1), Licensed Direct-Entry Midwives (3), Unlicensed Midwife (1), and Naturopathic Physician (1)
- Causes of death and major contributing factors (more than one may apply):
    - Hypoxic ischemic encephalopathy or cardiorespiratory failure (lack of blood flow) (3)
    - Chorioamnionitis (infection in the womb) (3)
    - Pre-existing or pregnancy-related maternal disease (2)
    - Respiratory failure (1)

- Undetermined, umbilical cord wrapped around neck, large baby (1)
- Undetermined, twin gestation, small baby (2)

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

EVIDENCE SUMMARY

The evidence pertaining to home birth from randomized trials is extremely sparse, limited to just 12 participants, and hence an insufficient evidence base from which to draw conclusions. The largest observational studies suggest that home birth results in significantly fewer obstetrical interventions and maternal adverse outcomes. The evidence pertaining to neonatal outcomes is less clear; while one meta-analysis found an elevated risk of neonatal death, this was not true when the analysis was limited to studies in which the attendant was either a certified midwife or certified nurse midwife. Observational studies conducted in settings where there are clear criteria for appropriateness of home birth, differing regulatory and training requirements, and systems of care (e.g., Canada, the Netherlands) do not find an elevated neonatal death rate. The NICE guideline's evidence review (based on the Birthplace study) found that there is a slightly increased risk of adverse neonatal events for primiparous women, but the NICE panel still suggesteds that these women be eligible for planned home birth after participating in informed decision-making using risk tables.

The new search and evidence summary done at the request of the EbGS at the April 2, 2015 meeting found that the absolute risk of perinatal mortality is very low overall, but that there are few U.S.-based studies, that evidence quality is low at best, and that available studies provide conflicting estimates of perinatal mortality risk. However,an elevated risk of perinatal mortality, particularly among primiparous women, cannot be ruled out by current research. This is in alignment with the findings of the Birthplace study (2011) on which the NICE guideline was based and generally supports that guideline's conclusions of offering home birth to low-risk women who have participated in informed decision-making.

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

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

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

Consideration of distance and time from a hospital able to provide emergency obstetric and neonatal services is important in managing intrapartum complications and in providing fully informed consent. Another characteristic is written agreements that cover consultation/referral/transfer and a well-defined and practiced system of transfer. Out-of-hospital birth attendants in these systems are appropriately trained and experienced in the identification and management of obstetric and neonatal emergencies, and are also licensed and certified. These providers should be capable of initiating appropriate newborn resuscitation, and be able to provide standard newborn care in addition to the routine postpartum care of women. Certification requirements for the practice of midwifery can vary significantly between the U.S. and other countries, with U.S. requirements for midwives, other than CNM/CMs, generally being less rigorous with regard to both years of formal education and experience.

GRADE-INFORMED FRAMEWORK

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

Indication/ Intervention	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Variability in values and preferences	Coverage recommendation	Rationale
Planned out-of-hospital birth for low-risk pregnancies	Include fewer intrapartum interventions and cesarean births (common outcome). Mixed results on neonatal outcomes, including potential increased risk of fetal/neonatal death (very rare outcome), particularly for primiparous women.	Very low to low based on 15 observational studies. Risk of bias generally acceptable, but some studies had marked limitations. Many studies downgraded because of indirectness due to different country and context of study.	Low. (favors out of hospital birth)	Low (women planning out-of-hospital birth prefer a non-hospital setting)	Recommended for coverage (*weak recommendation)*	There is low quality, but consistent evidence of benefit and lower quality evidence of significant, rare harms, including increased perinatal mortality. Women choosing out-of hospital birth have strong values and preferences toward this choice, despite the potential risk of significant harm. Additional evidence search and summary results in no change in weak recommendation for coverage.

Indication/ Intervention	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Variability in values and preferences	Coverage recommendation	Rationale
Planned out-of-hospital birth for unselected pregnancies (including those with unknown or known high risk factors)	Possible lower maternal morbidity, increased fetal/neonatal mortality	Very low based on one systematic review of 12 studies (downgraded to very low because of internal and external validity concerns). Additional evidence search and summary also found very low-quality evidence suggesting increased risk for pregnancy complicated by maternal diseases, breech, multiple gestation and TOLAC.	Moderate. Increased risk of poor outcomes leading to increased medical and societal costs.	Low (women planning out-of-hospital birth prefer a non-hospital setting)	Not recommended for coverage *(strong recommendation)*	Based on very low evidence that suggests increased fetal/neonatal mortality, increased resources (for associated harms), and rapidity of evolution of complications (e.g. uterine rupture). This leads to a strong recommendation against coverage, despite values and preferences that lead some women to choose this despite potential harms.

*The Quality of Evidence rating was assigned by the primary evidence source for initial literature search (not the HERC Subcommittee), and determined for critical and important outcomes for each individual study included in the new evidence search.

Note: GRADE framework elements are described in Appendix B.

POLICY LANDSCAPE

Quality measures

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

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

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

APPENDIX A. RISK CRITERIA FOR PLANNED HOME BIRTH

Oregon birth center absolute risk criteria

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

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

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

- Need for Caesarean delivery this birth
- Multiple gestation without reassuring bio-physical profile of greater than or equal to 8 out of 10
- No previous prenatal care or written prenatal records available
- Abnormal fetal surveillance studies
- Fetal presentation other than vertex, when known
- Rising antibody titre -types known to affect fetal well-being; significant Rh sensitization
- Amniotic fluid index >30 at term
- Amniotic fluid index <5 without reassuring labor progress, without reassuring fetal heart tones and/or abnormal non- stress test
- Abnormal bleeding

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

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

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

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

Mother

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

Other

- Hypertension >150/100 on at least two occasions
- Shock, unresponsive to treatment
- Laceration requiring repair in a hospital
- Enlarging hematoma

- Development of preeclampsia or eclampsia
- Signs or symptoms of serious infection

Infant

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

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

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

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

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

Explanation of the codes used for the care providers

Code	Description	Care provider
A Primary obstetric care	The responsibility for obstetric care in the situation described is with the primary obstetric care provider.	Midwife/G.P.
B Consultation situation	This is a case of evaluation involving both primary and secondary care. Under the item concerned, the individual situation of the pregnant woman will be evaluated and agreements will be made about the responsibility for obstetric care (see Section 4.5).	Depending on Agreements

Code	Description	Care provider
C Secondary obstetric care	This is a situation requiring obstetric care by an obstetrician at secondary level for as long as the disorder continues to exist.	Obstetrician
D Transferred primary obstetric care	Obstetric responsibility remains with the primary care provider, but in this situation it is necessary that birth takes place in a hospital in order to avoid possible transport risk during birth.	Midwife/G.P.

1. Pre-existing disorders – non-gynaecological

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

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

1.1	Epilepsy, without medication	A
1.2	Epilepsy, with medication Prenatal diagnostics are recommended in connection with the disorder and its medication. Optimal care requires consultation between all care providers concerned (midwife, G.P, obstetrician, neurologist).	B
1.3	Subarachnoid haemorrhage, aneurysms Care during puerperium can be at primary level.	C
1.4	Multiple sclerosis Depending upon the neurological condition, a complicated delivery and the possibility of urine retention should be taken into account. For optimal care, consultation between all care providers concerned is indicated.	B
1.5	Hernia nuclei pulposi This represents a C-situation in cases of a recently suffered HNP or where there are still neurogenic symptoms. It is an A-situation after treated hernia, especially if a previous pregnancy was normal. Both the medical history and the current clinical condition are relevant.	A/ C
1.6	Lung function disorder The opinion of the lung specialist should be taken into account during evaluation.	B

1.7	Asthma Care during pregnancy, birth and puerperium can only take place at a primary level when the asthma involves lengthy symptom-free intervals, whether or not use is made of inhalation therapy. Consultation with the GP/specialist involved is recommended.	A/ C
1.8	Tuberculosis, active Tuberculosis, non-active In cases of an active tuberculoses process and subsequent treatment, consultation should take place with the physician involved and the obstetrician regarding the clinical condition and care during pregnancy and birth. In cases of non-active tuberculosis, care during pregnancy and birth can take place at a primary level.	C A
1.9	HIV-infection As a result of the current possibilities of medical therapy for preventing vertical transmission, these patients should be cared for during pregnancy and birth in a hospital equipped for the treatment of HIV and AIDS.	C
1.10	Hepatitis B with positive serology (Hbs-AG+) Since 1988 it is important that a screening programme for this serology is carried out on pregnant women.	A
1.11	Hepatitis C Consultation with the obstetrician and follow-up by the pediatrician is recommended.	B
1.12	A heart condition with haemodynamic consequences Pregnancy and birth will have an effect on the pre-existing haemodynamic relationships. A cardiac evaluation is important.	C
1.13	Thrombo-embolic process Of importance are the underlying pathology and the presence of a positive family medical history. Pre-conceptual counselling is important.	B
1.14	Coagulation disorders	C
1.15	Renal function disorders When there is a disorder in renal function, with or without dialysis, referral to secondary care is recommended.	C

1.16	Hypertension Pre-existing hypertension, with or without medication therapy, will require referral to secondary care. Hypertension has been defined by the ISSHP as: A single event of diastolic blood pressure of 110 mm Hg or more (Korotkoff IV). Diastolic blood pressure of 90 mm Hg or more at two subsequent blood pressure measurements with an interval of at least 4 hours between the two measurements. A distinction should be drawn between a diastolic blood pressure under 95 mm and a pressure of 95 mm and higher. Extra attention should be paid to a pregnant woman with a diastolic pressure between 90 and 95 mm; from 95 mm, referral to secondary care should take place.	A/ C
1.17	Diabetes mellitus	C
1.18	Hyperthyroidism	C
1.19	Hypothyroidism In cases of biochemical euthyroid, without antibodies and without medication, or stable on levothyroxine medication, care can take place at a primary level. Where levothyroxine medication is given, specific tests are recommended due to the frequent increase in medication required during pregnancy.	B
1.20	Anemia, due to a lack of iron Anemia is defined as Hb<6.0 mmol that has existed for some time.	B
1.21	Anemia, other This includes the haemoglobinopathies.	B
1.22	Inflammatory Bowel Disease This includes ulcerative colitis and Crohn's disease.	C
1.23	System diseases and rare diseases These include rare maternal disorders such as Addison's disease and Cushing's disease. Also included are systemic lupus erythematosus (SLE), anti-phospholipid syndrome (APS), scleroderma, rheumatoid arthritis, periarteritis nodosa, Marfan's syndrome, Raynaud's disease and other systemic and rare disorders.	C
1.24	Use of hard drugs (heroin, methadone, cocaine, XTC, etc.) Attention should be paid to actual use. A urine test can be useful even in cases of past use in the medical history. The involvement of the pediatrician is indicated during the follow-up postpartum.	C
1.25	Alcohol abuse The fetal alcohol syndrome is important. The involvement of the pediatrician is indicated during the follow-up postpartum.	C

1.26	Psychiatric disorders Care during pregnancy and birth will depend on the severity and extent of the psychiatric disorder. Consultation with the physician in charge is indicated.	B

2. Pre-existing gynaecological disorders

2.1	Pelvic floor reconstruction This refers to colpo-suspension following prolapse, fistula and previous rupture. Depending on the cause, the operation technique used and the results achieved, the obstetrician will determine policy regarding the birth. A primary caesarean section or an early primary episiotomy can be considered, to be repaired by the obstetrician. If the chosen policy requires no special measures and no specific operating skill, then care during birth can be at primary level.	C
2.2	Cervical amputation	C
	Cervical cone biopsy	B
	Cryo- and lis-treatment The practical application of obstetric policy in this field can be worked out in local mutual agreements. If an uncomplicated pregnancy and birth have taken place following cone biopsy then a subsequent pregnancy and birth can take place at primary level.	A
2.3	Myomectomy (serous, mucous) Depending on the anatomical relationship, the possibility of a disturbance in the progress of the pregnancy or birth should be taken into account.	B
2.4	Abnormalities in cervix cytology (diagnostics, follow-up) There should be differentiation according to obstetric versus gynaecological policy. Gynaecological consultation can be indicated even without obstetric consequences. Participation in national cervical cancer screenings program is not provided pregnant women. The gynaecological follow-up is not an impediment to obstetric care at primary level.	B/A
2.5	DES-daughter (untreated and under supervision) There should be a differentiation according to obstetric versus gynecological policy. Gynaecological care related to the problems surrounding DES may be necessary, while obstetric care can take place at primary level.	B
2.6	IUD in situ	B
	Status following removal of the IUD	A

2.7	Status following infertility treatment In practice, the wish of the patient to be cared for at secondary level plays a role here, even though the pregnancy and birth are otherwise normal. There is no question of an increased obstetric risk.	A
2.8	Pelvic deformities (trauma, symphysis rupture, rachitis) Consultation should take place at the start of the last trimester. It should be pointed out that care at secondary level has not been shown to have any added value in cases of pelvic instability and symphysis pubis dysfunction.	B
2.9	Female circumcision/Female genital mutilation Circumcision as such can require extra psychosocial care. Where there are serious anatomical deformities, consultation should take place in the third trimester.	A/B

3. Obstetric medical history

3.1	Active blood group incompatibility (Rh, Kell, Duffy, Kidd)	C
	ABO-incompatibility Pregnancy and birth can take place at primary care level in cases of ABO-antagonism, but one should be on the alert for neonatal problems. Consultation is indicated.	B
3.2	Pregnancy induced hypertension in the previous pregnancy	A
	Pre-eclampsia in the previous pregnancy	B
	HELLP-syndrome in the previous pregnancy	C
3.3	Habitual abortion (3 times) If an abortion should occur again, the need to carry out pathological study of fetal material should be discussed. Genetic counselling prior to pregnancy is also advised.	A
3.4	Pre-term birth (<37 weeks) in a previous pregnancy If a normal pregnancy has taken place subsequent to the premature birth, then a further pregnancy can be conducted at primary care level.	B
3.5	Cervix insufficiency (and/or Shirodkar-procedure) Secondary level care during pregnancy is indicated up to 37 weeks; with a full term pregnancy, home birth is allowed. If a subsequent pregnancy was normal, then future pregnancies and deliveries can be conducted at primary care level.	C/A
3.6	Placental abruption	C

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

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

4. Developed/discovered during pregnancy

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

4.1	Uncertain duration of pregnancy by amenorrhoea >20 weeks Consultation is required when the duration of pregnancy is uncertain after 20 weeks amenorrhoea. The primary care provider has access to sufficient additional diagnostic tools in the first 20 weeks.	B
4.2	Anemia (Hb<6.0 mmol/l) It is important that the nature and the severity of the anemia are analysed during consultation.	B

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

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

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

	disorder and a decrease in the number of platelets.	
4.31	Blood group incompatibility	C
4.32	Thrombosis	C
4.33	Coagulation disorders	C
4.34	Recurring blood loss prior to 16 weeks	B
4.35	Blood loss after 16 weeks After the blood loss has stopped, care can take place at primary care level if no incriminating causes were found.	C
4.36	Placental abruption	C
4.37	(Evaluation of) negative size-date discrepancy A negative size-date discrepancy exists if the growth of the uterus remains 2 to 4 weeks behind the normal size for the duration of the pregnancy.	B
4.38	(Evaluation of) positive size-date discrepancy	B
4.39	Post-term pregnancy This refers to amenorrhoea lasting longer than 294 days.	C
4.40	Threat of or actual pre-term birth As soon as there is no longer a threat of pre-term birth, care during the pregnancy and birth can be continued at primary care level.	B
4.41	Insufficient cervix Once the pregnancy has lasted 37 weeks, further care can take place at primary care level.	C
4.42	Symphysis pubis dysfunction (pelvic instability) This refers to complaints that started during the present pregnancy	A
4.43	Multiple pregnancy	C
4.44	Abnormal presentation at full term (including breech presentation)	C
4.45	Failure of head to engage at full term If at full term there is a suspected cephalo-pelvic disproportion, placenta praevia or comparable pathology, consultation is indicated.	B
4.46	No prior prenatal care (full term) Attention should be paid to the home situation. The lack of prenatal care can suggest psychosocial problems. This can lead to further consultation and a hospital delivery.	A
4.47	Baby up for adoption The prospective adoption often goes hand-in-hand with psychosocial problems. This can lead to further consultation and a hospital delivery.	A

4.48	Dead fetus If the mother prefers to give birth at home, the care she receives should be the same as if the birth were to take place in a hospital. Attention should be paid to postmortem examination study and evaluation according to protocol.	C
4.49	Obstetrically relevant fibroids (myoma) Depending on the anatomical proportions, the possibility of a disturbance in the progress of pregnancy or birth should be taken into account.	B

5. Occurring during birth

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

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

5.9	Umbilical cord prolapse	C
5.10	(Partial) retained placenta It is not always possible to be sure of the retention of part of the placenta. If there is reasonable cause to doubt, then referral to secondary care should take place	C
5.11	Fourth degree perineal laceration	C
5.12	Meconium stained amniotic fluid	C
5.13	Fever It is obviously important to find out the cause of the fever. In particular, the possibility of an intrauterine infection should be taken into account and the administration of antibiotics intrapartum should be considered.	C
5.14	Analgesia It is important to be aware of the effects on dilatation and respiratory depression. The use of painkillers during birth is a subject that can be covered during local discussions with the aid of guidelines. One should attempt to achieve well-founded consensus.	B
5.15	Vulva haematoma Treatment policy is determined according to the complaints intrapartum and in the early puerperium.	C
5.16	Symphyiolysis This refers to rupturing of the symphyseal rupture. It should be distinguished from pelvic instability. The added value of consultation in cases of pelvic instability has not been proven.	B
5.17	Birth with no prior prenatal care A lack of prenatal care can be a sign of psychosocial problems and in particular addiction. Intrapartum monitoring, serological screening and immunisation are of utmost importance.	C

6. Occurring during the puerperium

6.1	Puerperal fever It is important to know the underlying cause. In cases of reasonable doubt, referral should be considered.	A/C
6.2	(Threat of) eclampsia, (suspected) HELLP-syndrome	C
6.3	Thrombosis	C
6.4	Psychosis It is important to involve (non-obstetrically) the GP and the psychiatrist in treating the psychiatric disorder.	B

6.5	Postpartum haemorrhage	C
6.6	Hospitalisation of child It is obviously important here to involve (non-obstetrically) the GP and the pediatrician. The bonding between mother and child are important in the period following birth.	C

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

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

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

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

Definitions

Consultation with a Physician, or other appropriate health care provider

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

Transfer of Care to a Physician

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

- If the condition for which the transfer of care was initiated is resolved, the midwife may resume primary responsibility for the care of the mother and/or newborn.

Midwife's Responsibilities

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

Indications: Initial History and Physical Examination

Consultation

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

- History of more than one preterm birth, or preterm birth less than 34+ 0 weeks in most recent pregnancy
- History of more than one small for gestational age infant
- History of severe hypertension or pre-eclampsia, eclampsia or HELLP syndrome
- Previous neonatal mortality or stillbirth which likely impacts current pregnancy

Transfer of care

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

Indications: Prenatal Care

Consultation

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

Transfer of care

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

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

Indications: Labor, Birth, and Immediate Post-Partum

Consultation

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

Transfer of care

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

Indications: Post-partum (Maternal)

Consultation

- Breast or urinary tract infection unresponsive to pharmacologic therapy
- Suspected endometritis
- Abdominal or perineal wound infection unresponsive to non-pharmacologic treatment
- Persistent or new onset hypertension
- Significant post-anesthesia complication
- Thrombophlebitis or suspected thromboembolism
- Significant mental health concerns including postpartum depression and signs or symptoms of postpartum psychosis

- Persistent bladder or rectal dysfunction
- Secondary postpartum hemorrhage
- Uterine prolapse
- Abnormal cervical cytology requiring treatment

Transfer of care

- Postpartum eclampsia
- Postpartum psychosis

Indications: Post-partum (Infant)

Consultation

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

Transfer of care

- Major congenital anomaly requiring immediate intervention

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

As a primary caregiver, the midwife is fully responsible for decision-making, together with the client. The midwife is responsible for writing orders and carrying them out or delegating them

to an appropriate regulated health professional in accordance with the standards of the College of Midwives.

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

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

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

Definitions

Discussion with a midwife, a physician, or nurse practitioner

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

Consultation with a physician or a nurse practitioner

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

The midwife should expect the consultant to address the problem described in the consultation request, conduct an in-person assessment(s) of the client, and promptly communicate findings and recommendations to the client and to the referring midwife. Discussion will then normally occur between the midwife and the consultant regarding the future plan of care for the client.

Where urgency, distance or climatic conditions do not allow the client to see a physician or nurse practitioner for an in-person consultation visit, the midwife should seek advice from the consultant by

phone or other similar means. The consultant may use alternative means of communication (e.g., via telehealth) to assess the client as available and appropriate. The midwife should document such requests for advice in client records, in accordance with the standards of the College of Midwives, and discuss the advice received with the client.

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

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

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

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

Shared primary care

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

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

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

Transfer to a physician for primary care

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

Indications: Initial History and Physical Examination

Discussion

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

Consultation

- Current medical conditions, for example: cardiovascular disease, pulmonary disease, endocrine disorders, hepatic disease, neurologic disorders, severe gastrointestinal disease
- Family history of genetic disorders, hereditary disease or significant congenital anomalies
- History of cervical cerclage or incompetent cervix
- History of repeated spontaneous abortions
- History of more than one late miscarriage or pre-term birth
- History of more than one low-birth-weight infant
- History of eclampsia
- History of significant medical illness
- Previous myomectomy, hysterotomy or cesarean section other than one
- Documented previous low-segment cesarean section
- Previous neonatal mortality or stillbirth
- Rubella during first trimester of pregnancy
- Significant use of drugs, alcohol or other toxic substances
- Age less than 14 years
- History of postpartum hemorrhage requiring transfusion

Transfer

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

Indications: Prenatal Care

Discussion

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

Consultation

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

Transfer

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

Indications: During Labor and Delivery

Discussion

- No prenatal care
- Thin, non-particulate meconium

Consultation

- Breech presentation
- Pre-term labor (34 – 36 + 6 weeks)
- Prolonged active phase
- Prolonged rupture of membranes
- Prolonged second stage
- Suspected placenta abruption and/or previa

- Retained placenta
- Third or fourth degree tear
- Twins
- Unengaged head in active labor in primipara
- Thick or particulate meconium
- Temperature of 38°c or greater on more than one occasion

Transfer

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

Indications: Post-partum (Maternal)

Consultation

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

Transfer

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

Indications: Post-partum (Infant)

Discussion

- Feeding problems
- Excessive moulding
- Cephalohaematoma

Consultation

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

Transfer

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

APPENDIX B. GRADE ELEMENT DESCRIPTIONS

Element	Description
Balance between desirable and undesirable effects	The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. The narrower the gradient, the higher the likelihood that a weak recommendation is warranted
Quality of evidence	The higher the quality of evidence, the higher the likelihood that a strong recommendation is warranted
Resource allocation	The higher the costs of an intervention—that is, the greater the resources consumed—the lower the likelihood that a strong recommendation is warranted
Values and preferences	The more values and preferences vary, or the greater the uncertainty in values and preferences, the higher the likelihood that a weak recommendation is warranted

Strong recommendation

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

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

Weak recommendation

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

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

Quality or strength of evidence rating across studies for the treatment/outcome[18]

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

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

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

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

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

APPENDIX C. METHODOLOGY, NEW EVIDENCE SEARCH, AND SUMMARY PROCESS DESCRIPTION

1) Conduct MEDLINE® search to update and expand on trusted source review conducted in 2014 at initiation of the topic for HERC. Search strategy attached below was developed by an Research Associate for the Center for Evidence-based Policy (Center) and an experienced health care librarian at Oregon Health & Science University with extensive experience working on systematic reviews (SRs). The search was conducted with the following parameters:
    a. 10-year search (January 2005-April 2015) to capture sources that Wax 2010 SR, which was included from initial trusted source search, may have missed or excluded. Search also limited to 10-year time frame to avoid including studies that were conducted in time periods that now would be considered to be outdated obstetric practice.
    b. MEDLINE® search for both SRs (with or without meta-analyses), randomized trials and cohort studies
    c. Broad search terms encompassing out-of-hospital birth, home birth, and birthing center locations with a variety of outcomes, both in the U.S. and abroad
    d. Review of included study reference lists and public comments to the HERC to identify any additional studies

2) Dual review by Center epidemiology staff for inclusions & exclusions
    a. Inclusion criteria:
        i. Population-based study of relevant patient populations in countries with developed health care systems similar to the U.S.;
        ii. N > 1000 in OOH birth group;
        iii. Exclusion or control or reporting of patients deemed a priori high-risk by HERC (multiple birth, breech, prior Cesarean birth, non-vertex);
        iv. Inclusion and analysis by planned birth setting;
        v. Reporting of relevant maternal or fetal/neonatal outcomes;
        vi. Abstractable data; or
        vii. Not a narrative review, opinion, comment or letter to the editor.

3) Evidence summary and addendum to HERC Coverage Guidance document based on additional studies meeting inclusion criteria, with quality rating of evidence

4) EbGS to update coverage guidance language, as appropriate, based on updated evidence search and additional discussion

Table C1. MEDLINE® Search Strategy

Database: Ovid MEDLINE® without Revisions <1996 to April Week 3 2015>

1	exp Home Childbirth/	2152
2	((plan or plans or plann$) adj3 (birth$ or born or deliver$) adj7 (house$ or home or homes or ((away or outsid$) adj3 (hospital$ or facilit$)))).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	191
3	exp Birthing Centers/	567
4	(birth$ adj center$).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	831
5	(birth$ adj2 setting$).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	235
6	(midwi$ adj3 (home or homes or hous$)).mp.	186
7	1 or 2 or 3 or 4 or 5 or 6	3216
8	exp Mortality/	291819
9	mo.fs.	436286
10	advers$.mp.	327767
11	exp "Outcome and Process Assessment (Health Care)"/	765349
12	exp Economics/	503207
13	ec.fs.	345974
14	exp Pregnancy Complications/	349245
15	exp Risk/	874947
16	8 or 9 or 10 or 11 or 12 or 13 or 14 or 15	2976033
17	7 and 16	1360
18	limit 17 to yr="2005 -Current"	721
19	limit 18 to english language	677
20	limit 19 to journal article	593

21	limit 19 to (comment or editorial or letter or news)	92
22	19 not 21	585
23	20 or 22	596

Center staff excluded 558 citations of the 596 identified by the MEDLINE® search based on not meeting inclusion criteria for this review and reviewed 38 full text articles for possible final inclusion.

During full text review of the MEDLINE® search results, two studies were excluded as duplicates, four studies did not have abstractable data, two were excluded because of country setting and five on the basis of the included population.

An additional 20 sources were identified from references in included studies, a final MEDLINE® update conducted on May 20, 2015 (21 citations were identified; two were selected for full text review, and one was included), and/or from public comment and testimony to the HERC. Twelve of these were peer reviewed publications. Of these 12, three were identified in the initial MEDLINE® search on April 22, 2015 and two were identified in the final MEDLINE® search on May 20, 2015. The remaining nine articles were not specifically on the topic of OOH birth and were submitted as part of public comment related to risk criteria.

After full text review of a total of 40 studies, 15 met inclusion criteria and were abstracted into Table C1.

The authors of two studies (Cheyney, 2014; Janssen, 2009) which had not reported all perinatal mortality outcomes by parity, and which were relevant to Oregon, were contacted for additional data.

References Suggested Through Public Comment And Testimony Process

Suggested references that were also identified in MEDLINE® search and are included in evidence summary

Birthplace in England Collaborative Group; Brocklehurst, P., Hardy, P., Hollowell, J., Linsell, L., Macfarlane, A., McCourt, C., … Stewart, M. (2011). Perinatal and maternal outcomes by planned place of birth for healthy women with low risk pregnancies: The Birthplace in England national prospective cohort study. *British Medical Journal, 343*, d7400. Retrieved from http://www.bmj.com/content/343/bmj.d7400.full.pdf+html

Cheyney, M., Bovbjerg, M., Everson, C., Gordon, W., Hannibal , D., & Verdam, S. (2014). Outcomes of care for 16,924 planned home births in the United States: the Midwives Alliance of North America Statistics Project, 2004-2009. *Journal of Midwifery & Women's Health, 59*(1), 17-27. Retrieved from http://onlinelibrary.wiley.com/doi/10.1111/jmwh.12172/epdf

Stapleton, S. R., Osborne, C., & Illuzzi, J. (2013). Outcomes of care in birth centers: Demonstration of a durable model. *Journal of Midwifery & Women's Health, 58*(1), 3-14. Retrieved from http://onlinelibrary.wiley.com/doi/10.1111/jmwh.12003/epdf

Suggested references which were not included in evidence summary because they did not meet inclusion criteria (but which were included in public comment disposition)

American Congress of Obstetricians and Gynecologists (ACOG). (2013, November 14). *Ob-gyns issue task force report on hypertension in pregnancy: Preeclampsia diagnosis no longer requires presence of proteinuria*. Retrieved from http://www.acog.org/About-ACOG/News-Room/News-Releases/2013/Ob-Gyns-Issue-Task-Force-Report-on-Hypertension-in-Pregnancy

American College of Nurse-Midwives. (2010). Intermittent auscultation for intrapartum fetal heart rate surveillance (replaces ACNM Clinical Bulletin #9, March 2007). *Journal of Midwifery and Womens Health, 55*(4), 397-403.

American College of Obstetricians and Gynecologists.. (2014). Safe prevention of the primary cesarean delivery. *American Journal of Obstetrics & Gynecology, 123*, 693-711.

Fretts. R. C. (2005). Etiology and prevention of stillbirth. *American Journal of Obstetrics and Gynecology, 193*(6),1923-35.

International Confederation of Midwives (ICM). (2011). *International definition of the midwife. Revised and adopted by ICM Council June 15, 2011.* Retrieved from http://www.internationalmidwives.org/assets/uploads/documents/Definition%20of%20the%20Midwife%20-%202011.pdf

International Confederation of Midwives (ICM). (2013) *Global standards for basic midwifery education (2010, amended in 2013).* Retrieved from http://www.internationalmidwives.org/assets/uploads/documents/CoreDocuments/ICM%20Standards%20Guidelines_ammended2013.pdf

Kramer, M. S., Liu, S., Luo, Z., Yuan, H., Platt, R. W., & Joseph, K. S. (2002). Fetal and infant health study group of the Canadian perinatal surveillance system. Analysis of perinatal mortality and its components: Time for a change? *American Journal of Epidemology, 156*(6), 493-7.

Leveno, K. J., Cunningham, F. G., Nelson, S., Roark, M., Williams, M. L., Guzick, D. … Buckley, A. (1986). A prospective comparison of selective and universal electronic fetal monitoring in 34,995 pregnancies. *New Engalnd Journal of Medicine, 315*(10), 615-9.

Magee, L., Pels, A., Helewa, M., Rey, E., & von Dadelszen, P. (2014). Diagnosis, evaluation, and management of the hypertensive disorders of pregnancy: Executive summary. *Journal of Obstetrics and Gynecology Canada, 36*(5), 416-438.

National College of Naturopathic Medicine. (2014). *Course catalogue 2013-2014*. Portland, Oregon. Retrieved from http://www.ncnm.edu/images/Publications/coursecatalog/2013-2014_Course_Catalog_FINAL_web.pdf

North American Registry of Midwives (NARM). (2009, April 20). *10 things you should know about PEP*. Retrieved from http://narm.org/forum/viewtopic.php?f=3&t=3#p3

North American Registry of Midwives, Midwifery Education Accreditation Council, National Association of Certified Professional Midwives, Midwives Alliance of North America. (2008). Certified

professional midwives in the United States. Retrieved from https://www.google.com/search?q=Issue+Brief%E2%80%94Certifi+ed+Professional+Midwives+in+the+United+States&oq=Issue+Brief%E2%80%94Certifi+ed+Professional+Midwives+in+the+United+States&aqs=chrome..69i57.3411j0j7&sourceid=chrome&es_sm=91&ie=UTF-8

Oregon Licenses, Permits and Registrations, Detailed Information for Natural Childbirth Certificate (Naturopathic). Retrieved from http://licenseinfo.oregon.gov/index.cfm?fuseaction=license_seng&link_item_id=14456

Oregon Health Authority. (2013). *Oregon birth outcomes by planned birth place and attendant, Pursuant to: HB 2380 (2011).* Retrieved from https://public.health.oregon.gov/BirthDeathCertificates/VitalStatistics/birth/Documents/PlannedBirthPlaceandAttendant.pdf

Prata, N., Hamza, S., Bell, S., Karasek, D., Vahidnia, F., & Holston, M. (2011). Inability to predict postpartum emorrhage: Insights from Egyptian intervention data. *BMC Pregnancy and Childbirth*, 11, 97. Retrieved from http://www.biomedcentral.com/content/pdf/1471-2393-11-97.pdf

Rosenstein, M. G., Snowden, J. M., Cheng, Y. W., & Caughey, A. B. (2014). The mortality risk of expectant management compared with delivery stratified by gestational age and race and ethnicity. *American Journal of Obstetrics and Gynecology, 211*(6), 660.e1-8. Retrieved from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3719843/

Rowe, T. (2007). Fetal health surveillance: Antepartum and intrapartum consensus guideline. *Journal of Obstetrics and Gynecology Canada, 29*(9), S3-S50.

Table C2: Evidence Table for Out-of-Hospital Birth Studies, New Search

Citation	Study Description	Fetal & Neonatal Outcomes#, +	Maternal Outcomes#	Study Quality* (GRADE) Comments
Studies with Outcomes Reported by Parity				
U.S.-based Studies				
Cheng, 2013	U.S. Retrospective cohort study U.S. birth certificates from 27 states using 2003 modification noting planned and actual place of birth. N=12,039 planned home births of 2,081,753 births meeting study criteria, out of 4,247,694 total U.S. births in 2008. Exclusion criteria included <37, >=43 wk EGA; breech; multifetal; birth at freestanding birth cntr; accidental home birth; unclear planned location of birth. Included multips with history of prior CS. 21.0% Nulliparas in home birth group. Significant differences (p<0.001) among planned home and hospital groups for all reported characteristics,	Results below are for planned site of birth and also by attendant, abbreviations as follows: Hospital (Hosp) Home CNM-CM (Home-CNM) Home-Other Midwife (Home-OMW) **Primary outcome--5 min Apgar <4** [# (%)], by parity, by site/provider Nulliparas Hosp: 2843 (0.34%) Home-CNM: 3 (0.42%) Home-OMW: 5 (0.37%) Multiparas Hosp: 2185 (0.18%) Home-CNM: 3 (0.12%) Home-OMW: 12 (0.25%) adjOR 5 min Apgar<4 [crudeOR not reported, adjOR adjusted for parity, maternal age, race/ethnicity,	CS not reported For mode of delivery, only **operative vaginal delivery** was reported: adjOR (planned home v. hospital) 0.12 (0.08-0.42) (Very small data cell for planned home birth where only 10 cases reported among 12,039 births) Other maternal outcomes reported: Induction of Labor Augmentation of Labor Antibiotic use in labor	**Very low (OOO+)** Sample included fewer than 50% of U.S. births during 2008. No linkage to fetal/neonatal death files for mortality outcomes. All outcomes are surrogates/short term outcomes with most relevant outcome being 5 min Apgar <4 which is associated with poor perinatal outcome. Two studies were cited with 5 min Apgar score of 0-3 associated with neonatal mortality rate of 20-21/1000 among term births. Some birth certificate items very poor sensitivity. Large state variation in 2003 revised birth certificate sensitivity compared to medical records has also been reported for some items (such as NICU admission, neonatal assisted ventilation, antibiotics for suspected neonatal sepsis and meconium staining) by the National Center for Health Statistics. Planned place of birth a relatively new data item on birth certificates and no validation offered for this key variable. The 2003 birth certificate revision asks “Place where birth

Citation	Study Description	Fetal & Neonatal Outcomes#, +	Maternal Outcomes#	Study Quality* (GRADE) Comments
	including parity, age, race/ethnicity, marital status, years of education, month of initiation of prenatal care and gestational age a birth. Multivariable logistic regression model adjusted for parity, maternal age, race/ethnicity, educational attainment, marital status, EGA at delivery, cigarette use during pregnancy, prenatal visits, medical conditions (prepregnancy htn or DM, gestational htn or GDM and/or preeclampsia, eclampsia. Total Nulliparas, N=840,641 Total Multiparas, N=1,227,272	education, GA, number of PN care visits, cigarette smoking, medical/obstetric conditions] *Home-CNM v. Hospital* Nullip adjOR 0.47 (0.07-3.38) Multip adjOR 0.83 (0.27-2.6) *Home-OMW v. Hospital* Nullip adjOR 1.34 (0.55-3.22) Multip adjOR 1.84 (1.04-3.26) *Other outcomes reported* 5 min Apgar <7 Ventilator support >6 hrs NICU admission Neonatal seizures (very small cells—2 each among nullips and multips at home with other midwife and 1 among multip at home with CNM)		occurred (Check one)" and gives options of Hospital, Freestanding birthing center, Home Birth, Clinic/Doctor's Office, or Other (Specify). Only the home birth selection asks the additional question of "Planned to delivery at home?" (2003 Revisions of the U.S. Standard Certificates of Live Birth: http://www.cdc.gov/nchs/data/dvs/birth11-03final-ACC.pdf) No way to attribute intention to treat analysis factors (planned home vs. transfer to hospital for actual place of birth). Transfer from hospital to home much less likely than home to hospital may give positive bias to home birth. Large sample size with use of U.S. data and analysis by parity and type of OOH birth attendant. adjOR may be overadjusted for risk factors and not present adequate impression of average case, but useful for assessment of lowest risk population estimate. Despite adjustment, likely residual confounding based on factors not captured on birth certificate.
Cheyney, 2014	U.S. Prospective, non-comparative cohort Data collected using MANA (Midwives Alliance of North America) web-based tool	**Perinatal mortality [#, rate per 1000, (95% CI)]** Overall PM (non-anomalous), all parities 35/16,980 or 2.06/1000	**CS birth** 887/16,984 (5.2%) Other maternal outcomes reported:	**Low (OO++)** Largest study of home births, primarily attended by CPMs, in the U.S.

Citation	Study Description	Fetal & Neonatal Outcomes#, +	Maternal Outcomes#	Study Quality* (GRADE) Comments
	(MANA Stats 2.0), 2004-2009 20-30% of active CPMs in North American participated (n=432), with ~95% of women consenting to participate. Over 79% of birth attendants were CPMs, with other types including CNMs, naturopaths, non-licensed midwives Prospective entry of subjects into database, usually early in pregnancy, before outcomes of interest known. Database variables cover first prenatal visit through 6 wks postpartum. Multiple data reviews after entry. Quality of data accuracy tested previously and found to be high. Final sample size, N=16,924 (Total dataset N=24,848. Excluded women transferred to care prior to labor, planned birth location other than home, women living outside the U.S.)	*By time of death* Intrapartum: 22/16,980 [1.30 (0.75-1.84)/1000] Early neonatal: 7/16,950 [0.41 (0.11-0.72)/1000] Late neonatal: 6/16,942 [0.35 (0.07-0.64)/1000] Total intrapartum mortality when higher-risk women removed from sample (multiple gestations, breech, TOLAC, GDM, preeclampsia): 0.85/1000 (95% CI 0.39-1.31) Intrapartum: 11/3771 [2.92 (1.20-4.64)] Early neonatal: 1/3757 [0.41 (0.11-0.72)] Late neonatal: 6/16,942 [0.35 (0.07-0.64)] Primiparous v. multiparous, intrapartum death 2.92/1000 v. 0.84/1000 (p<0.01) Primiparous v. multiparous, without risk factors 2.77/1000 v. 0.30/1000 [Author contacted for additional information since many perinatal deaths were associated with risk conditions that might preclude home birth. For primiparous women at low risk (with a non-breech presentation, no	Intrapartum transfer (and if transferred, use of epidural, oxytocin augmentation) Postpartum maternal transfer SVD, OVD Primary CS TOLAC Breech presentation	Prospective data collection with outcomes reported by parity. Good attention to data quality with prior validation study published. Not possible to assemble a comparable comparative group of CPM attended hospital births, but there were birth center births which were excluded from this sample (n=3895) and which may be reported in the future. Some additional data on nulliparity and perinatal mortality obtained from first author—see neonatal outcomes. Additional papers are in process or press from this dataset.

Citation	Study Description	Fetal & Neonatal Outcomes#, +	Maternal Outcomes#	Study Quality* (GRADE) Comments
	Nulliparas, 22.3% of sample	gestational diabetes and no preeclampsia) there were a total of 10 perinatal deaths (8 intrapartum, 1 early neonatal, and 1 late neonatal), for PM rates of 2.21/1000, 0.28/1000, and 0.28/1000, or a total low risk primiparous PM rate of 2.77/1000] # (out of total of 35) Perinatal deaths, by risk factor Breech: 5 TOLAC: 5 Multiple gestation: 1 GDM: 2 Preeclampsia: 1 Intrapartum fetal death rate by risk factor *Breech* 13.51/1000 v. 1.09/1000 vertex (p<0.01) *TOLAC* 2.85/1000 v. 0.66/1000 for multiparas without h/o prior CS (p=0.05) Other fetal/neonatal outcomes reported: Breech presentation (early and late neonatal death) GA (pre- v. post-term) Low BW, Macrosomia		

Citation	Study Description	Fetal & Neonatal Outcomes#, +	Maternal Outcomes#	Study Quality* (GRADE) Comments
		Neonatal transfer NICU admission		
Non-U.S.-based Studies				
Birthplace, 2011	England Prospective, comparative cohort Collected all planned home (home), freestanding midwifery unit (FMU), and alongside midwifery unit (AMU) births, and a stratified random sample of births in obstetric units (OU). Data from all NHS trusts providing home birth services between April 2008 and April 2010. Composite primary outcome used in study was combination of stillbirth after the start of care in labor, early neonatal death, neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured humerus, and fractured clavicle.	**Primary composite outcome (CO)** (stillbirth after the start of care in labor, early neonatal death, neonatal encephalopathy, meconium aspiration syndrome, brachial plexus injury, fractured humerus, and fractured clavicle for women with low risk status) Organization of presentation of CO outcome below: Incidence of events/1000 crudeOR (95% CI) weighted for duration of unit's participation in study, probability of being sampled, and clustering. adjOR adjusted for maternal age, ethnicity, understanding of English, marital/partner status, BMI, deprivation score, prior pregnancies, GA. Referent group for crudeOR and adjOR calculations are OU group. Overall CO incidence, all parities Home 4.2 (3.2-5.4) FMU 3.5 (2.5-4.9) AMU 3.6 (2.6-5.9) OU 4.4 (3.2-5.9)	**Intrapartum Cesarean Section** (events/1000) for women with low risk status Overall CS incidence (all parities) 9.9 (8.4-11.5) By planned location Home 2.8 (2.3-3.4) FMU 3.5 (2.8-4.2) AMU 4.4 (3.5-5.5) OU 11.1 (9.5-13.0) Crude and adjORs for Cesarean birth compared to referent OU category *crudeOR* Home 0.23 (0.17-0.30) FMU 0.28 (0.21-0.37) AMU 0.37 (0.28-0.49) *adjOR* Home 0.31 (0.23-0.41)	**Very Low (OOO+)** High quality, large, population-based prospective study with robust attention to data quality, design, conduct and appropriate statistical analysis. Study formed basis for 2014 NICE guideline recommendations on planned place of birth. English NHS health system, training, practice patterns, regulation of midwives and other professionals are different from U.S. systems, and may not be applicable to U.S. setting. Supplementary tables (online with study available at: http://www.bmj.com/content/343/bmj.d7400/related) Supplementary tables have event counts for stillbirth and neonatal death at 0-7d. for low risk women. These are secondary analyses and were not presented in main paper because number of events was small

Citation	Study Description	Fetal & Neonatal Outcomes#, +	Maternal Outcomes#	Study Quality* (GRADE) Comments
		crudeOR Home 0.96 (0.65—1.42) FMU 0.82 (0.52-1.28) AMU 0.84 (0.54-1.30) *adjOR* Home 1.16 (0.76-1.77) FMU 0.92 (0.58-1.46) AMU 0.92 (0.60-1.39) Nulliparas Home 9.3 (6.5-13.1) FMU 4.5 (2.8-7.1) AMU 4.7 (3.1-7.2) OU 5.3 (3.9-7.3) *crudeOR* Home 1.76 (1.10-2.82) FMU 0.85 (0.49-1.48) AMU 0.90 (0.53-1.54) *adjOR* Home 1.75 (1.07-2.86) FMU 0.91 (0.52-1.80) AMU 0.96 (0.58-1.61)	FMU 0.32 (0.24-0.42) AMU 0.39 (0.29-0.53) Other outcomes reported: Spontaneous vertex birth Vaginal breech birth Ventouse delivery Forceps delivery 3rd/4th degree perineal trauma Blood transfusion Admission to higher level of care Syntocinon augmentation Immersion in water for pain relief Epidural or spinal analgesia General anesthetic No active management of 3rd stage Episiotomy Transfer during labor Transfer immediately after birth	(total of 18 cases of stillbirth/early neonatal death among nullips and 14 among multips) and not statistically stable. The incidence figures (expressed as # (95% CI)/1000) below should be treated with caution: **Stillbirth** Nulliparas Home 0.9 (0.2-3.3) FMU 0.3 (0.0-3.5) AMU 0.1 (0.0-1.6) OU 0.1 (0.0-1.5) Multiparas Home 0.1 (0.0-0.9) FMU 0.5 (0.1-2.2) AMU 0 events OU 0.2 (0.0-1.2) **Early neonatal death (within 7d)** Nulliparas Home 0.4 (0.1-2.4) FMU 0.5 (0.1-1.7) AMU 0.1 (0.0-1.7) OU 0.4 (0.1-1.3)

Citation	Study Description	Fetal & Neonatal Outcomes#, +	Maternal Outcomes#	Study Quality* (GRADE) Comments
		Multiparas Home 2.3 (1.6-3.2) FMU 2.7 (1.6-4.6) AMU 2.4 (1.4-4.3) OU 3.3 (2.2-5.0) *crudeOR* Home 0.70 (0.40-1.21) FMU 0.86 (0.44-1.69) AMU 0.77 (0.38-1.57) *adjOR* Home 0.72 (0.41-1.27) FMU 0.91 (0.46-1.80) AMU 0.81 (0.40-1.62) Overall CO incidence, all parities, women without complicating conditions at start of labor (prolonged ROM >18h., meconium stained fluid, proteinuria >=1+, hypertension, abnormal vaginal bleeding, non-cephalic presentation, abnormal fetal heart rate, other-unspecified) Home 4.0 (3.0-5.3) FMU 3.2 (2.3-4.6) AMU 3.4 (2.4-4.9) OU 3.1 (2.2-4.2)		Multiparas Home 0.3 (0.1-1.3) FMU 0.3 (0.1-2.2) AMU 0.1 (0.0-1.4) OU 0.1 (0.0-1.8)

Citation	Study Description	Fetal & Neonatal Outcomes[#, +]	Maternal Outcomes[#]	Study Quality* (GRADE) Comments
		crudeOR Home 1.34 (0.88-2.05) FMU 1.11 (0.69-1.77) AMU 1.19 (0.74-1.91) *adjOR* Home 1.59 (1.01-2.52) FMU 1.22 (0.76-1.96) AMU 1.26 (0.80-1.99) Nulliparas Home 9.5 (6.6-13.7) FMU 4.5 (2.8-7.4) AMU 4.4 (2.7-7.0) OU 3.5 (2.4-5.1) *crudeOR* Home 2.81 (1.66-4.76) FMU 1.33 (0.72-2.46) AMU 1.31 (0.71-2.39) *adjOR* Home 2.80 (1.59-4.92) FMU 1.40 (0.74-2.65) AMU 1.38 (0.75-2.52)		

Citation	Study Description	Fetal & Neonatal Outcomes#, +	Maternal Outcomes#	Study Quality* (GRADE) Comments
		Multiparas Home 2.0 (1.4-2.9) FMU 2.2 (1.3-3.8) AMU 2.5 (1.4-4.5) OU 2.6 (1.5-4.4) *crudeOR* Home 0.80 (0.41-1.54) FMU 0.90 (0.42-1.94) AMU 1.04 (0.47-2.30) *adjOR* Home 0.83 (0.44-1.58) FMU 0.97 (0.46-2.04) AMU 1.09 (0.50-2.39)		
Hutton, 2009	Ontario, Canada Retrospective matched cohort Ontario Ministry of Health Database of planned home births during 2003 to 2006. Planned home (N=6692) v. Planned hospital (N=6692)	Planned home v. planned hospital birth **Intrapartum Stillbirth** 3 v. 4 **Neonatal mortality (0-28d)** 6 v. 4 **Neonatal death (28-42d)** 0 v. 1 **Total perinatal mortality (stillbirths and**	Planned home v. planned hospital birth **Cesarean birth** 348/6692 (5.2%) v. 544/ 6692 (8.1%) RR 0.64 (0.56-0.73) **CS, by parity**	**Very Low (OOO+)** Population-based retrospective matched cohort study of midwifery care. Subjects matched on parity and for multiparous women on h/o prior CS. Matching by parity would not eliminate unmeasured confounding (systematic differences between women desiring a home v. hospital birth), but both groups were registered with midwives who have

Citation	Study Description	Fetal & Neonatal Outcomes#, +	Maternal Outcomes#	Study Quality* (GRADE) Comments
	Nulliparas, 34.3% of both groups (groups matched on parity)	**neonatal deaths from 0-42d)** 9 v. 9 (denominator N= 6692 for each group) **Composite outcome (CO)** (perinatal/neonatal mortality or morbidity, including 5 min Apgar <4, neonatal resuscitation w/ PPV and cardiac compressions, admission to NICU w/ LOS>4d, BW<2500g) 159/6692 v. 190/6692 RR 0.84 (0.68-1.03) CO, Nulliparas v. Multiparas Home 80 (3.5%) v. 79 (1.8%) Hospital 85 (3.7%) v. 105 (2.4%) Perinatal/neonatal mortality, Nulliparas v. Multiparas Home 5 (0.2%) v. 4 (0.1%) Hospital 4 (0.2%) v. 2 (0.1%) Other outcomes reported: Breech presentation	Nulliparas 276/2293 (12%) v. 365/2298 (15.9%) Multiparas 71/4393 (1.3%) v. 179/4394 (2.6%) Other outcomes reported: Actual place of birth Ambulance transport from home during or after birth Intrapartum transfer of care Postpartum transfer of care Est. intrapartum blood loss Consultation or transfer of care for bleeding Genital tract laceration Episiotomy Induction of labor Labor augmentation Pharmaceutical pain relief	both home and hospital birth privileges which would make them more similar than a comparable group of low risk women not seeking midwifery care. Records required to be kept from entry to care, but no comment on when the "planned" place of birth was elected (early/late prenatal v. onset of labor). Records audited regularly by the College of Midwives of Ontario. Ontario midwives adhere to provincial standards for low-risk care and have education comparable to U.S. CPM or CNM. Indirectness due to non-U.S. setting as described above. Canadian practice likely most similar to U.S. compared to other non-U.S. studies, but there are differences in health care systems, as well as midwifery accreditation, licensure, and monitoring.

Citation	Study Description	Fetal & Neonatal Outcomes#, +	Maternal Outcomes#	Study Quality* (GRADE) Comments
		Gestational age Birthweight Apgar scores Infant resuscitation NICU admission Significant congenital anomalies Infant feeding at 1 wk, 6 wks		
de Jonge, 2015	Netherlands Retrospective cohort Nationwide national database of birth registration for 10 years from 2000-2009. (This study contains 7 years of overlapping data from de Jonge, 2009.) Data from women in primary midwifery care, eligible for home birth and planning either a home or hospital birth. Planned home birth Nulliparas, n=198,515 Multiparas, n=267,526 Planned hospital birth Nulliparas, n=137,168 Multiparas, n=139,740	**Perinatal Mortality (stillbirths and neonatal deaths up to 28d)** (certain and uncertain time of death) Nulliparas Planned home birth 203/198,515 (1.02%) Planned hospital birth 150/137,168 (1.09%) Nulliparas--Home v. Hospital crudeOR 0.94 (0.76-1.16) adjOR 0.99 (0.79-1.24) (adjusted for GA, maternal age, SES, ethnicity) Multiparas Planned home birth 158/267,526 (0.59%)	No maternal outcomes reported.	**Very Low (OOO+)** Netherlands has national primary care midwifery, and home birth criteria, integrated system of home and hospital care with clear lines of responsibility for transfer and consultation. This is a high quality set of cohort studies from the Netherlands and this study represents largest database analyzed for these outcomes. Quality rating is related to the fact that these are non-randomized studies and have some indirectness as practice situation may not be applicable to U.S. settings.

Citation	Study Description	Fetal & Neonatal Outcomes#, +	Maternal Outcomes#	Study Quality* (GRADE) Comments
		Planned hospital birth 81/139,740 (0.58%) Multiparas--Home v. Hospital crudeOR 1.02 (0.78-1.33) adjOR 1.16 (0.87-1.55) Other outcomes reported: Perinatal mortality, certain time of death Intrapartum death Neonatal death, 0-7d Neonatal death, 0-28d 5 min Apgar <4, <7 Admission to NICU Admission to NICU within 7d, 28d Severe adverse perinatal outcome (PM or NICU admission, to 28d)		
de Jonge, 2013	Netherlands Retrospective cohort Data for singleton, term (37-42 wks) births among women in primary midwifery care at onset of spontaneous labor, planning either a home or hospital birth, using national	No neonatal outcomes reported.	Planned home v. Planned hospital birth **Severe acute maternal morbidity** (composite outcome, including admission to ICU, uterine rupture, eclampsia/HELLP, transfusion of >=4 units PRBCs, or other severe morbidity as diagnosed	**Very Low (OOO+)** Netherlands has national primary care midwifery, and home birth criteria, integrated system of home and hospital care with clear lines of responsibility for transfer and consultation. Study setting may not be applicable to U.S.

Citation	Study Description	Fetal & Neonatal Outcomes#, +	Maternal Outcomes#	Study Quality* (GRADE) Comments
	registration database, 2004-2006. National database was merged with that from the LEMMon database (database of severe maternal morbidity) to give more full information on maternal morbidity among planned home births compared to planned hospital births. Study sample size Home: N=92,333 Hospital: N=54,419 Nulliparas, n=65,227 (44.4% of sample) Multiparas, N=81,521 (55.6% of sample)		by attending clinician) [adjOR adjusted for parity, GA, maternal age, ethnicity, SES] Nulliparas crudeOR 0.74 (0.55-1.00) adjOR 0.77 (0.56-1.06) Multparas crudeOR 0.42 (0.29-0.60) adjOR 0.43 (0.29-0.63) Other outcomes reported: Admission to ICU Eclampsia or severe HELLP syndrome Transfusion of >=4 units PRBCs PPH>1000mL Manual removal of placenta	settings.
Studies with Outcomes NOT Reported by Parity				
U.S.-based Studies				
Johnson, 2005	U.S. Retrospective cohort Database of births attended by CPMs and with participating made mandatory	**Perinatal Mortality (PM)** 14/5418 (0.26%) Crude PM = 2.58/1000 adjPM (adjusted for lethal congenital anomalies [11/5415]) = 2.03/1000	**Cesarean Birth** 200/5418 (3.7%) Other outcomes reported: Timing, urgency and indication for maternal transfer to	**Very Low (OOO+)** Over 4% of CPMs did not fully participate and were excluded after agreeing to take part in study. This could have introduced selection bias or outcome assessment bias if these CPMs had poor outcomes and

Citation	Study Description	Fetal & Neonatal Outcomes#, +	Maternal Outcomes#	Study Quality* (GRADE) Comments
	by NARM CPM recertification during 2000. 409 practicing CPMs agreed to participate in study and 18 excluded for non-participation as they decided over the year not to re-certify. 0.8% of clients declined to participate. CPM clients logged prospectively and data collected prospectively using paper forms at start of care. Care entry logs collected every 3 months and verified against data forms received. Data collected through 6 wks postpartum. Stratified random sample of CPM patients contacted as data validity check and satisfaction. Additional data collection done for cases of perinatal mortality. Final N=5418 women planning a home birth in the U.S. with a CPM. Nulliparas, 31.2% of study sample	PM among low risk women (removing breech/twins) = 1.7/1000 Intrapartum deaths = 5 (1 cord prolapse after AROM in hospital [note that this should have been classed as a neonatal death as Apgars were 1/0]; 1 cord accident [true knot], 2 complications of breech delivery, 1 subgaleal/subdural/subarachnoid hemorrhage) Neonatal deaths = 9 (3 lethal congenital anomalies; 2 with low 5 min Apgar scores died in neonatal period; 2 with high 5 min Apgar scores died suddenly at 15 and 26 hours of age; 1 post-CS for vasa previa; 1 with late onset GBS) Sample included 80 breech births (2 cases of perinatal death); and 13 twin gestations (no deaths) Other outcomes reported: Timing, urgency and indication for neonatal transfer to hospital Admission to NICU 5 min Apgar < 7 Health problems in first 6 wks Breastfeeding	hospital Use of electronic fetal monitoring Intravenous fluids/medications Artificial rupture of membranes Epidural Induction of labor Stimulation of labor Episiotomy Forceps Vacuum extraction Health problems in first 6 wks Breastfeeding Client satisfaction	elected to stop re-certification because of this. Appears to be some potential misclassification of type of death (one early neonatal classed as an intrapartum death). Limited information available for cause/location of some perinatal deaths. Data not presented by parity. Included all births, with some at <37 wks (1.4%), some at >42 wks (6.7%). 6% of study population had maternal age >=40y. Although a PM rate adjusted for lethal congenital anomalies, and breech/twin births was provided, no information given about contribution of other high risk conditions such as these or TOLAC. However, this study likely represents average CPM practice in the U.S. in 2000, where practice is regulated differently across states and not integrated into systems of care. The PM rate is also comparable to that found in other studies.

Citation	Study Description	Fetal & Neonatal Outcomes#, +	Maternal Outcomes#	Study Quality* (GRADE) Comments
Stapleton, 2013	U.S. Retrospective registry-based outcomes study. Data collected for women planning birth center birth in a participating center from 2007 through 2010. Prenatal data collected prospectively using the American Association of Birth Centers (AABC) Uniform Data Set (UDS). Intrapartum, postpartum and neonatal data entered during and after birth. The UDS has been previously validated for data quality and there is ongoing audit for data quality. Seventy-nine (78%) of AABC member birth centers use the UDS registry and approximately 40% of known U.S. birth centers are members of AABC. Most AABC centers have midwifery-led care (both CNM and RM or CPM providers) in collaboration with physicians.	**Perinatal mortality** (stillbirths and neonatal death within 7d.) Fetal deaths 14/15,574 (0.09%) (7 fetal deaths occurred prior to admission in labor and 7 were intrapartum deaths. 4 intrapartum deaths occurred after auscultation of abnormal heart tones and transfer. 3 occurred to women who labored and had unexpected stillbirths.) Neonatal deaths 9/15,560 (0.058%) (2 neonatal deaths were due to known lethal congenital anomalies. 1 was due to a congenital diaphragmatic hernia not detected on 2nd trimester anatomy ultrasound scan. 2 deaths occurred among infants of women who were transferred emergently in labor for non-reassuring fetal heart tones and 1 with rupture of a velamentous cord insertion. 2 births occurred in infants who were transferred emergently after birth and had respiratory distress syndrome and 1 in an infant with hypoxic ischemic encephalopathy attributed to a prenatal insult.) Perinatal mortality rate for women admitted	**Cesarean birth** Overall CS incidence, all parities 949/15,574 (6.1%) Other maternal outcomes reported: Intrapartum transfer Postpartum transfer Incidence and indication for emergency transfer Spontaneous vaginal birth Vaginal breech birth VBAC Assisted vaginal birth Repeat CS, with and without TOLAC	**Low (OO++)** This is the only included study of U.S. birth centers meeting inclusion criteria. It has a large sample size and collected data from a geographically diverse group of centers, including the only AABC accredited birth center in Oregon, over a 4 year period. Birth centers contributing data to the UDS registry may not be similar to those who do not support AABC membership standards and thus the findings may not be generalizable to all birth centers in the U.S. The care providers make the coding determination for intrapartum data elements such as the urgency of transfer. However, chart audit indicated that some providers coded a transport as emergent when it was not. Outcomes are not reported by parity. Although TOLAC and breech birth do not meet AABC risk criteria for accredited birth centers there were several women who experienced both in this study. It is not clear where these births took place, but all were admitted in labor to a birth center.

Citation	Study Description	Fetal & Neonatal Outcomes#, +	Maternal Outcomes#	Study Quality* (GRADE) Comments
	Women are entered into the UDS at first prenatal visit and data is collected through a postpartum visit which generally occurs at 4 to 6 weeks postpartum. AABC eligibility for care criteria for low risk pregnancy include singleton, vertex presentation, term gestation and no precluding medical or obstetric risks. Planned birth center birth, N=15,574 Nulliparas, N=7355, 47.2% of sample	in labor (excluding lethal anomalies) 0.87/1000 Other neonatal outcomes reported: Neonatal transfer Incidence and indication for emergency neonatal transfer		
Non-U.S.-based Studies				
Catling-Paull, 2013	Australia Retrospective cohort Non-comparative analysis of routinely collected data for 2005-2010 from the 12 publically-funded home birth programs in Australia at that	**Perinatal Mortality** (stillbirth and early neonatal death within 7d. for planned home birth group) 6/1807 (0.33%) Perinatal mortality excluding expected deaths of infants with lethal anomalies	**Cesarean Section** (for planned home birth group) Other outcomes reported: Place of birth Normal vaginal birth Assisted vaginal birth Vaginal breech birth Transfer to hospital before	**Very Low (OOO+)** 9 of 12 programs participated in study, raising possibility of underreporting of poor outcomes. Australian health system, training, practice patterns, regulation of midwives and other professionals are different from U.S.

Citation	Study Description	Fetal & Neonatal Outcomes#, +	Maternal Outcomes#	Study Quality* (GRADE) Comments
	time. Data was collected and stored by hospitals in which the home birth program was based. 3 smaller programs did not contribute data (55/1862 births). Publically funded home birth programs have strict low-risk criteria, including singleton gestation, 37-42 wks EGA, no medical, surgical, or obstetric/fetal risk factors. Despite these criteria, there were Nulliparas, N=575, 31.8% of study sample	1.7/1000 (0.17%) Other outcomes reported: 5 min Apgar score <7 BW Admission to special care nursery Neonatal morbidity (respiratory distress, hypoxic-ischemic encephalopathy) Breastfeeding initiation Breastfeeding at 6 weeks	birth Transfer to hospital after birth Perineal trauma Episiotomy Management of 3rd stage	systems, and results may not be applicable to U.S. settings. Prior studies had raised questions about the safety of home birth in Australia and in 2001 the provision of home birth services by private midwives was in marked decline due to the collapse of international indemnity insurance. In a 2009 governmental national Maternity Services Review, the majority of public submissions related to homebirth, most of these from women who wanted access to the service. In response, the government established publically funded home birth in all states/territories with the exception of Queensland. The services operate within the public hospital system. Midwives are accredited, their cases subject to peer review and they engage in emergency training.
Davis, 2012	New Zealand Retrospective cohort Data from New Zealand College of Midwives research database for low-risk women giving birth in 2006 & 2007. Database included data for 32% of all NZ births and is	No neonatal outcomes reported.	**Postpartum Hemorrhage** (PPH) (greater than 1000mL) Planned primary unit birth is referent category for each RR calculation (PPH in primary unit, 23/2904 [1.1%]) Planned home birth	**Very Low (OOO+)** No analysis by parity. No report of neonatal outcomes. Limited to outcomes related to PPH. Did not report any critical outcomes.

Citation	Study Description	Fetal & Neonatal Outcomes#, +	Maternal Outcomes#	Study Quality* (GRADE) Comments
	subject to regular audit and validation. Midwives in NZ are the primary caregivers for most women and care for women at home, in primary units (or birth centers), secondary- and tertiary-level hospitals. There is a nationally agreed set of consultation and referral criteria Low-risk births, N=16,453 (mean parity only reported as descriptive variable with home birth cohort having mean parity of 1.4)		19/1830 (1.0%) crudeRR 0.93 (0.53-1.65) adjRR 0.93 (0.49-1.74) (adjusted for smoking, age, parity, ethnicity, augmentation, length of labor, mode of birth, episiotomy, perineal trauma, BW>4kg, and mode of third stage management) Planned secondary hospital 96/7359 (1.3%) crudeRR 1.2 (0.08-1.79) adjRR 1.07 (0.68-1.69) Planned tertiary hospital 67/4107 (1.6%) crudeRR 1.47 (0.96-2.24) adjRR 1.10 (0.67-1.79) No other relevant outcomes reported.	Indirectness present due to non-U.S. setting.
de Jonge, 2009	Netherlands Retrospective cohort National database of birth registrations	Planned home v. Planned hospital birth **Intrapartum and neonatal death (0-7 days)** [adjOR adjusted for parity, gestational age,	No maternal outcomes reported.	**Very Low (OOO+)** Very large, 7 year, population-based national registry study.

Citation	Study Description	Fetal & Neonatal Outcomes#, +	Maternal Outcomes#	Study Quality* (GRADE) Comments
	Data for singleton, term (37-42 wks) births among low-risk women in primary midwifery care at onset of labor, planning either a home or hospital birth, using national registration database, for 7 years from 2000-2006. Planned home birth, N=312,307 Primiparous, 40.9% of study sample Planned hospital birth, N=163,261 Primiparous, 46.7% of study sample	maternal age, SES, ethnicity] adjRR 1.00 (0.78-1.27) Other outcomes reported: Intrapartum and neonatal death within 1d. NICU admission		Netherlands has national primary care midwifery, and home birth criteria, integrated system of home and hospital care with clear lines of responsibility for transfer and consultation. Study setting may not be applicable to U.S. settings.
Janssen, 2009	British Columbia, Canada Retrospective cohort Prospectively collected data of all planned home births attended by registered midwives (RM) compared to planned hospital births meeting eligibility requirements for home birth and attended by the same group of registered midwives from 2000 through 2004. A	**Perinatal mortality rate** (intrapartum stillbirth or death in first 28 days of life) RM-Home: 0.35 (0.00-1.03)/1000 RM-Hosp: 0.57 (0.00-1.43)/1000 Phys-Hosp: 0.64 (0.00-1.56)/1000 Overall RR Perinatal Mortality (all parities) RM-Home v. RM-Hosp	**Cesarean delivery** CS-Nulliparous RM-Home: 158/1215 (13%) RM-Hosp: 453/2428 (18.7%) Phys-Hosp: 481/2204 (21.8%) CS-Multiparous RM-Home: 50/1684 (3.0%) RM-Hosp: 45/2324 (1.9%) Phys-Hosp: 107/3127 (3.4%)	**Very Low (OOO+)** No analysis of perinatal mortality outcomes by parity. (Authors have been contacted to see if additional information available for outcomes by parity.) Perinatal mortality reported in text and tables as stillbirth and death within 7d., but group followed longer and no deaths occurred from days 7 through 28 in any group so we have reported this as the more

Citation	Study Description	Fetal & Neonatal Outcomes#, +	Maternal Outcomes#	Study Quality* (GRADE) Comments
	second comparison group of planned, home birth eligible, hospital births attended by physicians was included. RMs are required to offer women choice of planned delivery in home or hospital for those meeting College of Midwives of British Columbia eligibility requirements. These allow 1 prior CS, and require woman to be term (37-42 wks), singleton fetus, spontaneous labor or with outpatient induction method only, and absence of significant pre-existing or pregnancy-related disease. Provincial standards require RM to have baccalaureate degree in midwifery from a Canadian university. If trained outside of Canada they are required to pass written, oral and practice-based exams. Planned home—RM (RM-Home), n=2889 (41.9% nulliparous) Planned hospital—RM (RM-Hosp), n=4752 (51.1% nulliparous) Planned hospital—Physician	RR 0.61 (0.06-5.88) RM-Home v. Phys-Hosp RR 0.55 (0.06-5.25) Other outcomes reported: 1 and 5 min Apgar<7 Meconium aspiration Asphyxia at birth Birth trauma Resuscitation at birth BW<2500g Seizures Oxygen therapy >24h. Assisted ventilation>24h. Admission to hospital after birth or readmission if hospital birth	Overall RR for CS (all parities and adj for parity) RM-Home v. RM-Hosp adjRR 0.76 (0.64-0.91) RM-Home v. Phys-Hosp adjRR 0.65 (0.56-0.76) Other outcomes reported: Electronic fetal monitoring Augmentation of labor Narcotic analgesia Epidural analgesia Assisted vaginal delivery Episiotomy 3rd or 4th degree perineal tear Postpartum hemorrhage Infection Pyrexia	conventional measure of PM. This study has the strength of controlling for birth attendant by use of the same group of midwives in both home and hospital settings. Quality rating is due to study being conducted outside of the U.S., but to the extent that there are similarities to situation in Oregon the results may be more applicable than for some other non-U.S. studies.

Citation	Study Description	Fetal & Neonatal Outcomes#, +	Maternal Outcomes#	Study Quality* (GRADE) Comments
	(Phys-Hosp), n=5331 (41.3% nulliparous)			
Kennere, 2010	South Australia (SA) region of Australia Retrospective cohort Analysis of perinatal database of all births in SA, 2001-2006, plus additional information on perinatal deaths from expert committee reviews of all deaths in SA. Planned home birth, N=1141, 31.2%, nulliparas Planned hospital birth, N=297,192, 41.0% nulliparas All GA included, but proportions not specified.	**Perinatal Mortality, rate per 1000 births** (stillbirths and neonatal deaths up to 28d.): Planned home births 8.2/1000 Planned hospital births 7.9/1000 adjOR 1.38 (0.56-3.41) (Adjusted for maternal age, parity, occupational status, smoking, plurality, medical and obstetric complications, GA, SGA, congenital anomalies, type of hospital, mode of delivery.) Perinatal mortality standardized by GA 2.18 (0.87-4.50)/1000 Perinatal mortality standardized by BW groups 2.36 (0.95-4.86)/1000 Total perinatal deaths Home: 9/1141 Hospital: 2440/297,192	**Cesarean birth:** Planned home birth 104/1136 (9.2%) Planned hospital birth 79,238/292,469 (27.1%) adjOR 0.27 (0.22-0.34) Other outcomes reported: Instrumental delivery Episiotomy 3rd or 4th degree perineal tear Postpartum hemorrhage	**Very Low (OOO+)** No information on types of home birth attendants or training and other systems of referral/transfer. Included all gestational ages >20 wks EGA and with BW >=400g, but little information about the population included in study, including proportions of women with risk factors such as breech, multiple gestation, or prior CS.

Citation	Study Description	Fetal & Neonatal Outcomes#, +	Maternal Outcomes#	Study Quality* (GRADE) Comments
		Attributed causes of 9 perinatal deaths--2 lethal congenital anomaly; 1 in context of waterbirth with limited monitoring at home; 1 second twin from intrapartum asphyxia; 1 hydropic fetus with non-lethal congenital anomaly; 1 growth restricted with suspected karyotype abnormality; 1 unexplained, but with tight nuchal cord x 4; 1 early gestation ROM resulting in pulmonary hypoplasia; 1 "seriously post-term" with refusal of all intervention. Other neonatal outcomes reported: Intrapartum deaths Deaths attributed to intrapartum asphixia 5 min Apgar <7 Specialized neonatal care		
Nove, 2012	UK, North West Thames Regional Health Authority Retrospective cohort 15 NHS hospitals in region, all using the computerized St. Mary's Infirmary Information System. Data from 1988-2000 for low risk pregnancies planning a	No neonatal outcomes reported.	(Only outcome reported) **Postpartum Hemorrhage (PPH) of >=1000ml** Risk of PPH, Hospital v. Home crudeOR 2.7 (no CI, p<0.001) adjOR 2.5 (1.7-3.8) Risk of PPH, Hospital v. Home Primiparas:	**Very Low (OOO+)** Database included "most" hospitals in region, but how many not included not specified. Sample may not be considered low risk by current standards (no upper limit on GA, no specification on what meant by high-risk pregnancy) which may have introduced selection bias. Data from time period as late as 1988 and up to 2000, in system different from U.S., thus contributing to indirectness.

Citation	Study Description	Fetal & Neonatal Outcomes#, +	Maternal Outcomes#	Study Quality* (GRADE) Comments
	home or hospital birth, and that did not have medical induction of labor, elective cesarean, GA<37 wks, unplanned home birth, and which resulted in live births or stillbirths. Planned home birth, N=5998 Planned hospital birth, N=7874		crudeOR 1.7 (no CI, p<0.001) adjOR 2.0 (1.9-2.2) [model adjusted for pregnancy risk status, suspected macrosomia, prior BW <4500g, BMI, borderline anemia, parity, age, ethnicity, BW, infant sex, # ultrasound scans in pregnancy, yr of birth, hospital providing care, time of day of delivery]	No critical outcome reported.
van der Kooy, 2011	Netherlands Retrospective cohort Data from the Netherlands Perinatal Registry for planned home and hospital births, attended by a community midwife, taking place from 2000-2007. Subjects met low-risk national criteria and were eligible for planned birth in either location. Note that this study overlaps with the series of studies by de Jonge. Planned home birth: Total (all parities) N=402,912	**Perinatal Mortality** (stillbirth and neonatal death within 7d.) Planned home birth 594/402,912 (0.15%) Planned hospital birth 403/219,105 (0.18%) Planned home v. planned hospital birth, risk of PM *crudeRR* 0.80 (0.71-0.91) *adjRR* 1.05 (0.91-1.21) (adjusted for intended place of birth, parity, age, ethnicity, neighborhood, GA, SGA, prematurity, low Apgar score, congenital	No maternal outcomes reported.	**Very Low (OOO+)** Outcomes not reported by parity. Perinatal mortality outcome includes neonatal deaths to 7d. rather than to 28d. The Netherlands has national primary care midwifery, and home birth criteria, integrated system of home and hospital care with clear lines of responsibility for transfer and consultation. Study setting may not be applicable to U.S. settings.

Citation	Study Description	Fetal & Neonatal Outcomes#, +	Maternal Outcomes#	Study Quality* (GRADE) Comments
	Primiparas, N=171,986 Multiparas, N=230,926 Planned hospital birth: Total (all parities) N=219,105 Primiparas, N=104,249 Multiparas, N=114,856	abnormality.) [note: RR for primiparas v. multiparas was presented in Table 2, but mixed intended place of birth such that abstractable data by parity not available.] Other outcomes reported: GA at birth Proportions in categories of SGA, prematurity, low Apgar score, and congenital abnormality, for each planned birth location.		

Evidence table presents outcomes of fetal/neonatal death under neonatal outcomes and data on incidence of Cesarean delivery under maternal outcomes when it was reported by the study. If those data not available then next most relevant outcome abstracted for table. Additional outcomes reported by study are listed in each column. Primary available outcome indicated in bold text. Specific and subgroup analyses are indicated by underlining outcome.

+ Measures of effect presented when possible with 96% Confidence Interval (CI) when available, the CI is indicated by placing it in parentheses after the measure of effect.

*Study quality based on most relevant/critical perinatal/neonatal mortality/morbidity outcome reported in study unless otherwise indicated

Table Abbreviations: adjOR-adjusted OR; adjPM-adjusted perinatal mortality; adjRR-adjusted relative risk; AMU-planned alongside midwifery unit birth; BW-birth weight; CI-confidence interval; CNM-certified nurse midwife; CO-composite outcome; CPM-certified professional midwife; crudeOR-basic OR without any adjustment; CS-cesareean section; d-days; DM-diabetes; EGA-estimated gestational age; FMU-planned freestanding midwifery unit birth; GA-gestational age; GDM-gestational diabetes; GRADE- Grading of Recommendations Assessment, Development and Evaluation HELLP-hemolysis, elevated liver enzymes, low platelets; Home-planned home birth; htn-hypertension; ICU-intensive care unit; OOH-out of Hospital; OR-odds ratio; p-p-value; PPH-postpartum hemorrhage; PN-prenatal; PRBCs-packed red blood cells; N-number of subjects in study or group; NHS-National Health Service (UK); NICU-neonatal intensive care unit; OR-odds ratio; OU-planned obstetric unit birth; OVD-operative vaginal delivery; PM-perinatal mortality; RM-registered midwife; ROM-rupture of membranes; RR-relative risk; SGA-small for gestational age; SVD-spontaneous vaginal delivery;

Study Quality (OOO+) represents very low, (OO++) represents low.

Table C3. GRADE Evidence Profile (Quality Assessment) for Primary Outcomes, New Search, by Study

Quality Assessment							
Design	**Risk of Bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other Considerations**	**Quality Rating**	**Outcome Importance**
5 min Apgar score <4 (Cheng, 2013; US, vital stats)							
observational studies	serious[1]	no serious inconsistency	serious[2, 3]	no serious imprecision	increased effect for RR ~1[2]	OOO+ VERY LOW	IMPORTANT
Perinatal Mortality (intrapartum stillbirth to 28d.) (Cheyney, 2014; US, MANA registry)							
observational studies[4]	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	OO++ LOW	CRITICAL
Fetal/Neonatal Composite Outcome (Birthplace, 2011; UK)							
observational studies[5]	no serious risk of bias	no serious inconsistency	serious[6]	no serious imprecision	none	OOO+ VERY LOW	CRITICAL
Perinatal/Neonatal (intrapartum stillbirth to 28 d) Mortality (Hutton, 2009; Ontario, Canada)							
observational studies	no serious risk of bias	no serious inconsistency	serious[6]	no serious imprecision	none	OOO+ VERY LOW	CRITICAL
Perinatal Mortality (intrapartum stillbirth to 28d) (de Jonge, 2015; Netherlands)							
observational studies	no serious risk of bias	no serious inconsistency	serious[6]	no serious imprecision	none	OOO+ VERY LOW	CRITICAL
Severe Combined Maternal Morbidity (de Jonge, 2013; Netherlands)							
observational studies	no serious risk of bias	no serious inconsistency	serious[6]	no serious imprecision	none	OOO+ VERY LOW	IMPORTANT
Perinatal Mortality (intrapartum stillbirth and neonatal deaths) (Johnson, 2005; US, NARM CPM study)							
observational studies	serious[7]	no serious inconsistency	serious	no serious imprecision	none	OOO+ VERY LOW	CRITICAL

Quality Assessment							
Perinatal Mortality (intrapartum stillbirth to 7d) (Stapleton, 2013; US, birth center)							
observational studies[8]	no serious risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	none	OO++ LOW	CRITICAL
Perinatal Mortality (intrapartum stillbirth to 7d) (Catling-Paull, 2013; Australian publically-funded home birth programs)							
observational studies[9]	serious[10]	no serious inconsistency	serious[6]	no serious imprecision	none	OOO+ VERY LOW	CRITICAL
Postpartum Hemorrhage (>=1000mL) (Davis, 2012; New Zealand)							
observational studies	no serious risk of bias	no serious inconsistency	serious[6]	no serious imprecision	none	OOO+ VERY LOW	IMPORTANT
Perinatal Mortality (intrapartum stillbirth to 7d) (de Jonge, 2009; Netherlands)							
observational studies	no serious risk of bias	no serious inconsistency	serious[6]	no serious imprecision	none	OOO+ VERY LOW	CRITICAL
Perinatal Mortality (intrapartum stillbirth to 28d.) (Janssen, 2009; British Columbia, Canada)							
observational studies[11]	no serious risk of bias	no serious inconsistency	serious[6]	no serious imprecision	none	OOO+ VERY LOW	CRITICAL
Perinatal Mortality (stillbirth to 28 days) (Kennare, 2009; South Australia)							
observational studies	serious[12]	no serious inconsistency	serious[6]	no serious imprecision	none	OOO+ VERY LOW	CRITICAL
Postpartum Hemorrhage (>=1000mL) (Nove, 2012; North West Thames, England)							
observational studies	serious[13]	no serious inconsistency	serious[6]	no serious imprecision	none	OOO+ VERY LOW	IMPORTANT
Perinatal Mortality (intrapartum stillbirth to 7d) (van der Kooy, 2011; Netherlands)							
observational studies[14]	no serious risk of bias	no serious inconsistency	serious[6]	no serious imprecision	none	OOO+ VERY LOW	CRITICAL

Table Footnotes:

[1] Vital statistics--US birth certificates--substantial differences among OOH and hospital birth cohorts--although logistic regression to attempt control of residual confounding was undertaken may still be substantial unmeasured confounding. No info on validity of measure by each group of providers/site of birth.

[2] If planned home birth mother or infant transferred to hospital then outcome attributed to hospital. This could have created bias against hospital and positively for home. However, the outcome numbers for home setting are small and all ORs are highly overlapping such that determination of plausible confounding effect for this surrogate outcome is uncertain.

[3] Surrogate outcome used

[4] Large, prospective data collection, non-comparative, registry study

[5] Large prospective study of planned home, planned midwifery units and planned obstetric unit births with high quality control and sophisticated analysis

[6] Non-US based study, closely regulated midwifery, with defined system of consultation and transfer.

[7] 4% of CPMs did not participate after registering in study. If these stopped study/CPM re-certification process because of poor outcomes could have introduced a negative bias on measures of effect.

[8] Large, prospective data collection, non-comparative study of planned birth center birth

[9] Small, non-comparative study

[10] 3 of 12 programs did not participate in study. Represented small numbers of births, but if poor outcome and participation linked then could introduce confounding.

[11] Provincial BC perinatal databases used to compare same midwives attending low-risk, home birth eligible women for planned home or hospital birth, and second comparison group of women receiving physician care in hospital.

[12] Included all births over 20 wks EGA and BW 400g, which could contribute bias to either group depending on care patterns and referral. There was robust inquiry into perinatal deaths.

[13] Data from time older time period, as late as 1988 and up to 2000. Database included "most" hospitals in region, but how many not included not specified. Sample may not be considered low risk by current standards (no upper limit on GA, no specification on what meant by high-risk pregnancy) which may have introduced selection bias.

[14] Data may overlap with de Jonge, 2009 and de Jonge, 2015.

APPENDIX D. APPLICABLE CODES

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

Note: Inclusion on this list does not guarantee coverage.