

Maternal and perinatal mortality and severe morbidity of midwife assisted births outside hospital compared with hospital births

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[Dödlighet och svår sjuklighet för mamma och barn vid förlossningar med barnmorska utanför sjukhus jämfört med sjukhusförlossningar]

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1 Abstract

Background Sweden has among the lowest maternal and perinatal mortality rates in the world, with approximately 0.05/1,000 for maternal mortality and 4.3/1,000 for perinatal mortality. The vast majority of births occur in hospital-based obstetric units. Planned home births do occur in several high-income countries, particularly in the Netherlands, Australia, and UK, up to 14%, but less in the Nordic countries, between 0.1 and 3.0%. Voices, for example through Birth Right Sweden, are raised for publicly funded, planned home births in Sweden, integrated into the national healthcare system, to promote autonomy and continuity of care. Even though internationally recommended exclusively for women with expected low-risk birth, the safety of planned home births and births in freestanding midwifery units remains uncertain. Although childbirth is a physiological process, risk levels vary depending on maternal health, fetal development, and access to timely medical interventions. Potential complications include fetal death, fetal distress, neonatal asphyxia, perineal trauma, postpartum haemorrhage, and the need for emergency interventions such as caesarean section or neonatal resuscitation.

Question at issue What are the differences concerning mortality and severe morbidity for mother and child in high-income countries when comparing planned birth outside hospital (planned home birth or birth at freestanding midwifery units) with planned birth at obstetric units in women with expected low-risk births?

Methods During May 2024, updated March 2025, two authors performed systematic searches in Medline, Embase, the Cochrane Library, and Cinahl. Websites of Scandinavian national and regional HTA-organisations were visited. Reference lists of relevant reports were also scrutinised for additional references. Two authors screened the obtained titles and abstracts and made the first selection of full-text reports. At least two authors read all full-text reports, independently of one another, and it was finally decided in a consensus meeting which reports should be included in the assessment. Included studies were critically appraised using checklists. The results of each study were summarised per outcome and, when possible, data were pooled in meta-analyses. Meta-analyses were conducted using the random effects model with odds ratio (OR) as point estimate with 95% CI. When available, adjusted OR (AOR) was used in meta-analyses. The certainty of evidence for each outcome was assessed using the GRADE approach for cohort studies. If only one study reported an outcome with AOR the certainty of evidence was based on OR.

Results Nine cohort studies with a total of 1,261,312 women were included. Further 18 case series and two case reports concerning the outcomes peri/neonatal mortality and transfer to hospital were included. The main problem with all cohort studies was risk of bias, particularly selection bias, with consistently healthier women giving birth at home/freestanding midwifery unit compared with birth at obstetric units. Further, outcome reporting might be affected by detection bias due to differences in clinical surveillance, documentation standards, and implications for care, such as the need for transfer. The precision was limited for maternal and peri/neonatal mortality. No maternal mortality was reported. Maternal admissions to intensive care unit were significantly fewer in planned home birth/freestanding midwifery unit births, compared with birth at obstetric units, adjusted OR 0.41 (95% confidence interval (CI) 0.19-0.89). A significantly higher risk for peri/neonatal and neonatal mortality was seen for planned home/freestanding

midwifery unit births compared with obstetric units, OR 1.70 (95% CI 1.05-2.74) and OR 2.65 (95% CI 1.45-4.86), respectively. Several critical outcomes for the children were not reported in any of the included articles. There were fewer neonatal intensive unit admissions from planned home/freestanding midwifery unit births, adjusted OR 0.67 (95% CI 0.56-0.81). Severe perineal tears were significantly fewer in planned home/freestanding midwifery unit births, adjusted OR 0.64 (95% CI 0.45-0.93). Further, there were fewer intrapartum caesarean sections, adjusted OR 0.29 (95% CI 0.26-0.33), and postpartum haemorrhage cases. There was no difference regarding the outcomes postpartum haemorrhage requiring transfusion and neonatal asphyxia. The certainty of evidence for conclusions was low for all outcomes (GRADE ⊕⊕○○), except maternal mortality where it was very low (GRADE ⊕○○○). The outcome postpartum depression was not reported in any of the included studies. Transfer from home/freestanding midwifery units to an obstetric unit was reported in 9.3%-33.3% (20.7% in the largest study).

Economic aspects Presently in Region Västra Götaland (VGR), care during childbirth is provided by obstetric units. Based on the need for care, jointly determined by level of complications and type of birth (vaginal or caesarean section), costs range between SEK 35,700 and SEK 155,500 per birth. Home births and births at birth-centres exist, however, outside the publicly funded health-care system. Home birth is currently not offered within the public health care in VGR but is provided in two other regions in Sweden and will be initiated in a third region in 2026. However, according to an initiative called *BB Gårda*, the first freestanding midwifery unit in Sweden, situated in Gothenburg, a "care package birth" costs SEK 65,000 for primiparous women and SEK 55,000 for multiparous women. Midwives offering home birth charge SEK 35,000/birth. A literature review observed that the costs of births at home and at freestanding midwifery units are generally lower, by varying proportions, than those at obstetric units. The included studies generally accounted for costs for birth, often ignoring costs for on-call services, and possible complications. Inclusion of such costs may increase the cost per home birth. Establishing home birth within the public health care system in VGR, with two midwives available 24/7 at each of the four obstetric units in the region, would require recruitment of additional midwives and thus a substantial increase in costs as well as a risk of displacement effect in healthcare.

Ethical aspects Priorities within healthcare are guided by the Ethical platform developed by the Parliament of Sweden, which involves the human dignity principle and states that those with the greatest needs should be given priority over those with fewer needs. The needs are normally associated with the severity of the condition. In addition, priorities within healthcare should consider benefit for the patient and take cost effectiveness into account. In this project the severity of the condition is low; healthy women with expected low-risk births. Further, results concerning benefits and especially risks for mother and child are not robust. In addition, allocating resources to low-risk out-of-hospital births may cause divert capacity from patients with greater medical needs. Healthcare should also support respectful maternity care which includes the right to make informed decisions about the place of birth. Women should be provided with accurate, comprehensive, and balanced information regarding the benefits and risks of home/freestanding midwifery unit births versus births at obstetric units, enabling them to make well-informed choices.

Conclusion All conclusions are based on low or very low certainty of evidence. Peri/neonatal mortality may be increased in planned midwifery-led home/freestanding midwifery unit births compared with planned obstetric unit births for women with expected low-risk births. However, the absolute risks are low. Reduced rates of some, mainly adverse maternal outcomes, including caesarean section, may occur in planned home/freestanding midwifery unit births. There are several ethical aspects to consider.

2 Populärvetenskaplig sammanfattning – Plain language summary in Swedish

Bakgrund Sverige har en av de lägsta siffrorna i världen för mödra- och barnadödlighet i samband med förlossning, 0,05/1 000 respektive 4,3/1 000. De flesta förlossningar i Sverige sker på förlossningsenheter på sjukhus med tillgång till förlossningsläkare. Planerad hemförlossning sker dock i höginkomstländer som Nederländerna, Australien och Storbritannien, i upp till 14%, men i de nordiska länderna bara i 0,1% till 3%. Vissa kvinnor föredrar hemförlossning av olika skäl och röster höjs, tex av den ideella föreningen Birth Rights Sweden, för att planerade hemförlossningar, stödda av och integrerade i den offentliga sjukvården, ska bli möjligt också i Sverige. Motiven är en önskan om högre autonomi, att få vara kvar hos familjen, få föda med en för modern känd barnmorska, en önskan om att undvika medicinska åtgärder, sjukhusrädsla eller förlossningsrädsla efter en tidigare förlossning. Övermedikalisering och onödiga ingrepp vid förlossning på sjukhus debatteras också idag. Planerad hemförlossning och förlossning på en fristående barnmorskeenheter rekommenderas internationellt endast för kvinnor med lågriskgraviditeter (enkelbörd, huvudbudning, fullgången graviditet) utan medicinska komplikationer. I Sverige kan enligt Socialstyrelsen, 2025, hemförlossning erbjudas till ovanstående grupper, om kvinnan tidigare genomgått en okomplicerad förlossning, men den verksamheten är lågt prioriterad. Det råder dock oklarhet angående den medicinska säkerheten för mamma och barn vid planerade hemförlossningar/ fristående barnmorskeenheter beroende på mammans och barnets hälsotillstånd, och på begränsade möjligheter till skyndsamt och avancerat medicinskt omhändertagande i risksituationer.

Frågeställning Vilka skillnader finns vad gäller död och svår sjuklighet för mamma och barn mellan planerad barnmorske-assisterad förlossning utanför sjukhus (hemförlossning eller förlossning på en barnmorskeledd enhet fristående från sjukhus) och sjukhusförlossning vid lågriskförlossning i höginkomstländer?

Metod Två författare genomförde sökningar i flera databaser i maj 2024 med uppdatering i mars 2025. Med hjälp av etablerade metoder identifierades de vetenskapliga artiklar som kunde bidra till att besvara den aktuella frågan. De enskilda studierna granskades, resultaten summerades och tillförlitligheten av de sammanlagda resultaten bedömdes.

Resultat Nio observationsstudier (åtta med hemförlossningar och en med förlossning på barnmorskeledd enhet fristående från sjukhus) med totalt 1 261 312 kvinnor inkluderades. Dessutom identifierades 18 fallserier och två fallrapporter angående mödradödlighet, dödlighet för barnet runt förlossningen och transport under eller efter förlossningen till sjukhus. De huvudsakliga bristerna berodde på risk för snedvridning av resultaten, med friskare kvinnor som födde hemma/på fristående barnmorskeenheter, då valet av hem- eller sjukhusförlossning gjordes av kvinnorna själva. Angående frekvensen mammor och barn som dog i samband med förlossningen beror osäkerheten främst på att resultaten vilar på få händelser. Inga mödradödsfall rapporterades. En lägre risk för mamman att överföras till intensivvård sågs hos gruppen kvinnor som fött sitt barn i hemmet eller på en barnmorskeledd enhet. En ökad dödlighet för barnet vid planerad hemförlossning eller förlossning på en barnmorskeledd enhet noterades jämfört med förlossning på sjukhus, denna skillnad sågs inte hos kvinnor som fött barn tidigare. Osäkerheten är dock stor på grund av få händelser. Flera kritiska barnutfall rapporterades inte i någon av de inkluderade studierna. Antalet komplikationer hos de födande kvinnorna, såsom bristningar i underlivet, kejsarsnitt och stora blödningar efter förlossningen var lägre efter hemförlossning, medan andelen blödningar som krävde blodtransfusion inte skilde sig åt. Även transport av barnet till neonatal intensivvård var

mindre vanligt vid hemförlossning. Utfallet postpartumdepression rapporterades inte i någon av de inkluderade studierna. Transport till sjukhus under eller efter hemförlossning av mamma eller barn rapporterades i 9%-33% av hemförlossningar och förlossning på barnmorskeledd enhet.

Ekonomiska aspekter Inom VGR sker förlossningar i dagsläget huvudsakligen på sjukhus. Kostnaden varierar mellan cirka 35 700 och 155 500 kronor per förlossning, beroende på graden av komplikationer och om förlossningen sker vaginalt eller via kejsarsnitt. Hemförlossning erbjuds för närvarande inte inom den offentliga hälso- och sjukvården i VGR eller i Sverige generellt. Som jämförelse kan nämnas att ett privat initiativ, en fristående barnmorskeenheter, erbjuder ett "förlossningspaket" där kostnaden uppgår till cirka 65 000 kronor för förstföderskor och 55 000 kronor för omföderskor. Privatpraktiserande barnmorskor i regionen tar 35 000 kronor för hemförlossning. En genomgång av litteraturen kring kostnader visar att kostnaden för hemförlossningar och förlossningar på en fristående barnmorskeenheter i regel är lägre än för sjukhusförlossningar, även om skillnaden i kostnadsnivå varierar. I dessa jämförelser ingår kostnader för genomförandet av vård såsom barnmorskans lön, kompetensutbildning, läkemedel och kostnader för barnmorskornas jourberedskap. Däremot är inte beredskap, inklusive jourberedskap, på sjukhus för att ta hand om eventuella komplikationer inkluderade. Om sådana kostnader inkluderas kan det innebära att kostnaderna för hemförlossning blir högre. En etablering av hemförlossning inom den offentliga vården i VGR, med två barnmorskor tillgängliga dygnet runt på vart och ett av regionens fyra sjukhus, skulle kräva nyrekrytering av personal och därmed medföra en betydande kostnadsökning samt risk för undanträngning.

Etiska aspekter Prioriteringar inom hälso- och sjukvården ska följa den Etiska plattformen, utformad av Sveriges riksdag, vilket inkluderar autonomiprincipen, samt att de med högst behov ska ges företräde framför de med lägre behov. Behov styrs vanligen av svårighetsgraden av sjukdomen i fråga. Dessutom ska prioriteringar inom sjukvården beakta fördelar för patienterna och kostnadseffektivitet. I detta projekt är svårighetsgraden av tillståndet låg; endast friska kvinnor med lågriskgraviditeter inkluderades, och resultaten avseende fördelar och framför allt risker för mamman och barnet innehåller olika grader av osäkerhet. Det kan också uppstå undanträngningseffekter om resurser allokeras till lågriskkvinnor som vill föda hemma i stället för att resurser går till patienter med större medicinska behov.

Hälso- och sjukvården ska stödja ett respektfullt omhändertagande av blivande mödrar och skydda deras rättigheter och individuella behov. Den gravida kvinnan har rätt till korrekt och fullständig information om för- och nackdelar med hemförlossning respektive förlossning på sjukhus, för att främja ett informerat val.

Konklusion Samtliga slutsatser baseras på låg- eller mycket låg tilltro till det vetenskapliga underlaget. Inga mödradödsfall förekom i studierna, men risken för mamman att överföras till intensivvården kan vara mindre vid förlossning hemma eller vid fristående barnmorskeenheter. Risken för att barnet dör i samband med förlossning kan vara ökad vid planerad barnmorskeledd hemförlossning och förlossning på fristående barnmorskeenheter jämfört med förlossning på sjukhus. De absoluta riskerna är dock låga. Lägre risker kan finnas för ett flertal mödrautfall, inkluderande kejsarsnitt, vid planerad hemförlossning. Det finns flera etiska aspekter i och med att både medicinsk säkerhet, prioriteringar och kvinnans autonomi ska beaktas.

The above summaries were written by representatives from HTA-centrum. The HTA report was approved by the regional board for quality assurance of activity-based HTA.

Ylva Carlsson

Head of HTA-centrum of Region Västra Götaland, Sweden, 2025-11-20

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MD Medical doctor

PhD Doctor of Philosophy

RN Registered Nurse

RNRM Registered Nurse Registered Midwife

3 Summary of findings

Outcomes in home birth/birth in freestanding midwifery units compared to birth in obstetric units

Outcomes	Number of studies per study design, Number of participants	Relative effect (95% CI)	Absolute effect* (%)	Certainty of evidence† GRADE
Outcomes critical for decision making*				
Maternal mortality	3 cohort studies n=18,125 3 case series n=3,929		Zero events	Very low ⊕○○○ ¹
Maternal admission to ICU	3 cohort studies n=700,708	AOR 0.41 (0.19 to 0.89), p=0.02	0.3 vs 0.4	Low ⊕⊕○○
Peri-/neonatal mortality (within 7 or 28 days)	5 cohort studies n=1,242,850 8 case series n=473,233 2 case reports	OR 1.70 (1.05 to 2.74) p=0.03	0.8 vs 0.7 per 1,000 In case series for home births between 0 to 5.2 per 1,000	Low ⊕⊕○○ ²
Neonatal mortality (within 7 or 28 days)	5 cohort studies n=891,614 7 case series n=472,738 2 case reports	OR 2.65 (1.45 to 4.86) p<0.01	0.5 vs 0.3 per 1,000 In case series for home births between 0 to 5.2 per 1,000	Low ⊕⊕○○ ²
Apgar score <7 at 1 and/or 5 min)	3 cohort studies n=41,001	AOR 0.65 (0.25 to 1.64) n.s.	0.8 vs 1.0	Low ⊕⊕○○ ²
Outcomes important for decision making*				
Postpartum haemorrhage requiring transfusion	3 cohort studies n=1,217,968	AOR 0.89 (0.60 to 1.32) n.s.	0.6 vs 0.5	Low ⊕⊕○○ ²
Perineal tear grade 3 or 4	4 cohort studies n=1,127,093	AOR 0.64 (0.45 to 0.93) p=0.02	1.6 vs 2.0	Low ⊕⊕○○
Admission to neonatal ward or NICU	4 cohort studies n=868,081	AOR 0.67 (0.56 to 0.81) p<0.01	1.4 vs 0.9	Low ⊕⊕○○

Outcomes less important for decision making [#]				
Postpartum haemorrhage (>500 ml or ≥/ >1000 ml)	4 cohort studies n=18,668	OR 0.72 (0.53 to 0.98) p=0.04	4.1 vs 4.0	Low ⊕⊕○○
Intrapartum caesarean section	4 cohort studies n=1,233,903	AOR 0.29 (0.26 to 0.33) p<0.01	2.6 vs 7.9	Low ⊕⊕○○

*Observe that the 'absolute effect' is calculated as the total number of events divided by the total over all included studies. This means that the results may differ from the weighted meta-analysis results and might even point in opposite directions.

[#] Conclusions were based on AOR when adjusted data were pooled from *more than one* study. If AOR was based on only one study, conclusions were based on OR (with several studies).

Maternal outcomes not reported in any study: postpartum depression; infant outcomes not reported: Apgar score <4 at 5 minutes, time at neonatal ward or neonatal intensive care unit (NICU) >72h, therapeutic hypothermia, neonatal seizures, mechanical ventilation, meconium aspiration, hypoxic-ischemic encephalopathy (HIE) grade 2-3, and resuscitation.

¹ Downgraded for very serious imprecision (zero events).

² Some problems with precision, but not enough to downgrade.

†Certainty of evidence

High certainty ⊕⊕⊕⊕: We are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty ⊕⊕⊕○: We are 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 to the estimate of the effect.

Low certainty ⊕⊕○○: Confidence in the effect estimate is limited. The true effect may be substantially different from the estimate of the effect.

Very low certainty ⊕○○○: We have very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of effect.

4 Abbreviations

AMU alongside midwifery unit

BMI body mass index

FMU freestanding midwifery unit

HB home birth

ICTRP WHO International Clinical Trials Registry Platform

ICU intensive care unit

LÖF Swedish patient insurance (landstingens ömsesidiga försäkringsbolag)

NBHW National Board of Health and Welfare

NICU neonatal intensive care unit

OECD Organisation for Economic Co-operation and Development

RCT randomised controlled trial

SBF The Swedish Association of Midwives

SBU Swedish Agency for Health Technology Assessment and Assessment of Social Services

SFOG Swedish Society of Obstetrics and Gynaecology

SR systematic review

VGR Region Västra Götaland

WHO World Health Organization

5 Background

Disease/disorder of interest and its degree of severity

Planned home birth is increasingly discussed as a care option for women with expected low-risk births, offering greater autonomy and birth supported by a known midwife, preferably in a continuity care model. In several high-income countries, this type of care is integrated into publicly funded healthcare under regulated conditions (Brocklehurst et al., 2011, Hermus et al., 2017). In Sweden, however, home birth remains rare and is mainly arranged privately. Whether home birth should be offered within routine care and be publicly funded remains a topic of ongoing debate due to concerns regarding safety, equity, and appropriate use of healthcare resources.

Sweden reports among the lowest maternal (approximately 0.05 maternal deaths per 1,000 births) and perinatal (4.3 perinatal deaths per 1,000 births) mortality rates globally, attributed to a universal, tax-funded healthcare system with strong midwifery competence and evidence-based care (Socialstyrelsen, 2024, WHO, 2023). However, perinatal mortality also includes intrauterine fetal deaths occurring before the onset of birth, which are not within the scope of this HTA report. The actual outcomes considered here — intrapartum and neonatal deaths — represent less than half of the total perinatal mortality (Socialstyrelsen, 2024, Skogsdal et al., 2025).

Although childbirth is a physiological process, it carries inherent risks that vary depending on maternal health, fetal condition, and access to timely medical interventions. Even in low-risk births, unforeseen complications may arise, making timely access to emergency care essential in any birth setting. At the same time, growing concerns over the medicalisation of childbirth have sparked a debate within medical and public health communities. Studies suggest that the decision for a home birth is often motivated by a desire for greater control, fewer interventions, and more individualised care (Hildingsson et al., 2003). Fear of not being seen or listened to, as well as fear of hospitals more generally, may also influence this decision. In some cases, previous negative experiences of hospital birth can further strengthen women's preference for giving birth at home (Gillen et al., 2023).

Structured models for planned home births and births in freestanding midwifery units (FMUs) — midwife-led birth centres located outside the hospital setting — are available in countries like the Netherlands, the UK, and Denmark. These are generally offered to women with expected low-risk births and attended by midwives but lack immediate access to specialist interventions (Farry et al., 2019, Hutton et al., 2016a Homer et al., 2019).

In Sweden, only few publicly funded regional initiatives exist, while most home births are organised and financed privately. The National Board of Health and Welfare (NBHW) in Sweden finds assisted home birth suitable for women with a previous uncomplicated vaginal birth. In 2025, NBHW assigned assisted home birth priority level 8 on a scale, where 1 is the highest and 10 is the lowest priority. No national framework currently regulates the integration of out-of-hospital assisted births into the publicly funded healthcare system (Socialstyrelsen, 2025).

In summary, interest in home and FMU births is growing in Sweden, reflecting increasing demands for autonomy and continuity of care with known midwives attending birth. This development continues to spark discussion on how to balance individual choice, safety of both mother and child, emergency preparedness, and equitable access to health care within a publicly funded healthcare system.

This health technology assessment (HTA) aims to evaluate the medical safety of planned home and FMU births in the Swedish context, with respect to maternal and neonatal outcomes, ethical, and economical aspects as well as implications for the healthcare system.

Prevalence and incidence

Planned home births remain rare in Sweden, approximately 1-2 per 1,000 births annually. One of the few national studies, based on voluntary reporting by midwives from 1992-2004, estimated the prevalence at 0.85 per 1,000 (Lindgren et al., 2008a). The low prevalence in Sweden reflects the strong emphasis within the national healthcare system on hospital-based births, alongside the limited integration of home and FMU births within the publicly funded framework.

Current data remain uncertain due to the historical lack of standardised national registration. In January 2023, NBHW introduced new procedure codes (KVÅ) to facilitate structured documentation of planned home births:

- **DMO32:** Planned and completed home birth.
- **DMO33:** Planned home birth transferred to hospital before birth.
- **DMO34:** Planned home birth transferred to hospital after birth.

The introduction of these codes marks a critical step toward more systematic data collection, enabling improved monitoring of the frequency and transfer of planned home births to the hospital. Preliminary data indicate that, from 1 January 2023 onwards, a total of 74 planned home births have been registered under these codes. Of these, in 51 (69%) births woman and children stayed at home, 13 (17.5%) involved transfers to hospital before birth, and 10 (13.5%) involved transfers after birth (Skogsdal et al., 2025). Most of these cases were reported from Region Stockholm, as part of the *Min Barnmorska* project, a continuity of care programme in which the same team of midwives provides antenatal care, attends the home birth, and offers postpartum follow-up.

Given the recent establishment of Sweden's first FMU *BB Gårda* in Gothenburg, it is anticipated that additional KVÅ codes will be introduced to enable structured documentation of births occurring in FMU settings. This would represent an important step toward improving national monitoring of all planned out-of-hospital births.

Present treatment

Swedish maternity care is highly centralised and predominantly hospital-based with access to advanced obstetric and neonatal care (Socialstyrelsen, 2022). In 2023, approximately 99,600 births were registered across 42 maternity clinics, ranging from large tertiary units (e.g. Sahlgrenska University Hospital, ~10, 000 births/year) to small clinics handling fewer than 500 births/year (Socialstyrelsen, 2023).

Hospital births for low-risk births are managed by a team including midwives, nurse assistants and obstetricians with midwives and nurse assistants primarily caring for the women, with obstetricians available on-site 24/7 for assessment of potential complications during labour, e.g. surgical interventions, including emergency/intrapartum caesarean section or repair of severe perineal tears. Swedish maternity care aims to follow the "one-to-one" model, with a midwife providing continuous support during active labour. This approach has been associated with increased patient safety, improved birth experience, and reduced intervention rates (Svenska Barnmorskeförbundet, 2022). However, due to regional variation in staffing and resource allocation, many units struggle to consistently meet this standard (Socialstyrelsen, 2022, Svenska Barnmorskeförbundet, 2022).

While most women give birth vaginally, approximately 18% give birth by caesarean section. Almost 30% of all births in Sweden occur after induction of labour (Skogsdal et al., 2025).

Neonatal care is closely integrated with obstetric care. Thirty-five hospitals offer neonatal care, including eight tertiary level Neonatal Intensive Care Units (NICUs) providing advanced therapies such as mechanical ventilation and therapeutic hypothermia. Specialised neonatal transport teams enable inter-hospital transfers when required (Svenskt Neonatalt Kvalitetsregister [SNQ], 2024).

Postpartum care includes observation of mother and newborn, breastfeeding support and screening for complications. Women with uncomplicated vaginal births are usually discharged within 6-24 hours, while those with caesarean sections or complications may require longer hospital stays (Socialstyrelsen, 2023). In some regions (e.g., Region Västra Götaland, VGR), continued postpartum care at home is available through early discharge programmes such as *Trygg hemgång* and *BB hemma* with follow-up visits by midwives. For example, *Trygg hemgång* includes discharge within 6-8 hours if medical controls are satisfactory, with a midwife conducting follow-up assessments using a checklist for early postpartum discharge. Meanwhile, *BB Hemma* comprises a mobile midwife and assistant team that visits families at home for examinations and support instead of extended hospital stays and has been described as a successful extension of hospital based postpartum care. All women are offered postpartum follow-up, including family planning, with the same midwife who provided their antenatal care (Sahlgrenska Universitetssjukhuset [SU], 2024, SU, 2023, Sahlgrenskaliv, 2025).

The normal pathway through the healthcare system and current wait time for medical assessment/treatment

In Sweden, all pregnant women are offered antenatal care (*Mödrahälsovård*) and free consultations and regular check-ups with their midwife throughout pregnancy and almost all pregnant women participate in the maternity care program. Midwives play a central role in monitoring maternal and fetal health, while obstetricians are available for managing high-risk pregnancies and pregnancy complications (Socialstyrelsen, 2022).

Upon arrival at the maternity ward, a midwife conducts an active risk assessment to ensure medical safety and allocate staff resources accordingly. Risk assessment should hereafter be conducted continuously throughout labour and documented in the medical

record whenever changes occur, and at a minimum once per work shift. A structured color-coded risk classification system is recommended to facilitate individualised risk assessment. The classification considers both maternal and fetal health, ensuring that care is provided at the appropriate level (Löf, 2020). A green (low-risk) birth is defined by the following criteria, indicating an expected low-risk birth (Löf, 2020).

- Gestational age between 37+0 and 41+6 weeks
- Singleton pregnancy (no multiple fetuses)
- Cephalic presentation (head-first position)
- Spontaneous onset of labour
- Clear amniotic fluid with spontaneous contractions following membrane rupture
- Normal fetal heart rate
- Blood pressure below 140/90 mmHg
- No known maternal or fetal disease or complications likely to affect the course of labour (e.g. previous caesarean section)

During labour, midwives, obstetricians, and nurse assistants work collaboratively in hospital maternity wards. Midwives manage uncomplicated births, while obstetricians intervene if complications arise (Socialstyrelsen, 2022).

Number of patients per year who undergo current treatment regimen

In the Gothenburg area, planned home or FMU births are not systematically registered. Only very few women choose this option. At Sahlgrenska University Hospital, approximately 3,522 births (30%) out of 11,855 births in 2024 met the criteria for low-risk births potentially eligible for planned home or FMU birth according to the criteria above. This includes 1,679 nulliparous and 1,843 multiparous women with spontaneous labour, no previous caesarean section, and without complicating medical conditions (data according to Obstetrix, the electronic medical record system used for maternity care at Sahlgrenska University Hospital). While this number represents a theoretical upper limit of eligible women, actual interest in home or FMU birth options would likely be much lower due to individual preferences, geographical access, and availability of midwives.

Present recommendations from medical societies or health authorities

Recommendation and guidelines for planned home births differ between Swedish health care authorities and professional organisations, reflecting different emphases on safety, autonomy, and healthcare resource allocation.

The NBHW in Sweden acknowledges that midwife assisted home births may be a viable option in specific cases, but with low priority, and particularly for low-risk multiparous women who reside close to maternity hospitals. They also state that planned home births should be conducted with two assisting midwives and in collaboration with hospital-based care to ensure medical safety. However, NBHW also raises concerns from a cost and equity perspective, cautioning that it is more important to secure resources for patient groups with more severe health conditions (Socialstyrelsen, 2023, 2025).

The Swedish Association of Midwives (SBF) advocates for the integration of publicly funded, midwife-assisted home births into Sweden's healthcare system for healthy women with expected low-risk births. They also emphasise that planned home births can be a safe alternative when appropriate risk assessments are conducted, two qualified midwives are present, and collaboration with hospital-based care is ensured. The association highlights the importance of respecting women's autonomy in choosing their place of birth and calls for the development of organisational structures that supports planned home births within the public healthcare framework (Svenska Barnmorskeförbundet, 2020). In its updated statement from October 2025, SBF further stresses that all regions should consider establishing clear and well-functioning organisational structures for home births as an integrated part of publicly funded maternity care (Svenska Barnmorskeförbundet, 2025).

In contrast, the Swedish Society of Obstetrics and Gynaecology (SFOG) has articulated a cautious stance regarding the integration of publicly funded, midwife-assisted home births into Sweden's healthcare system. Their concerns centre on potential medical risks associated with home births. SFOG emphasises that Sweden's hospital-based maternity care has contributed to some of the world's lowest perinatal and maternal mortality rates, and reallocating resources to support home births could strain staffing and compromise care for high-risk patients. SFOG cautions against extrapolating findings from countries with different healthcare systems, such as the Netherlands, where home births are more common, but perinatal mortality rates are higher (SFOG, 2024). SFOG advocates for improvements within hospital based maternity care to benefit all pregnant women, and to consider home birth within the framework of research and development (FoU) projects to allow for structured evaluation of safety and outcomes before a potential broader implementation (Borgfeldt et al., 2024, SFOG, 2024).

As part of a collaborative initiative, *SBF* and *SFOG* have jointly developed information materials intended to provide women with balanced, evidence-based guidance on planned home births (SFOG, 2025).

The Swedish Neonatal Society (Svenska Neonatalföreningen) has not issued an official position on planned home births. However, The Swedish Neonatal Society underscores the right for all newborns to have access to resuscitation and other emergency interventions following the National Guidelines for Neonatal Resuscitation published on the website of the Swedish Neonatal society (Dahlström et al., 2022). "The Swedish Neonatal Society recommends that trained personnel and material resources to perform neonatal cardiopulmonary resuscitation in accordance with national guidelines should always be available if the newborn requires it. We recommend that births be planned in such a way that these resources are accessible." (Svenska Neonatalföreningen, 2025). These national guidelines for neonatal resuscitation highlight that: "Effective neonatal resuscitation necessitates a well-composed, multidisciplinary team with advanced training in team-based resuscitation protocols."

Optimal execution of neonatal resuscitation requires thorough preparation and established readiness, both at the organisational level and for each individual clinical scenario. Neonatologists have underscored the importance of strict eligibility criteria, comprehensive risk assessment, regular emergency training for midwives, and clearly defined protocols for transfer to hospital-based care (Eriksson, 2023).

6 Health Technology at issue: Planned home birth or birth in freestanding midwifery units

Planned home and FMU births constitute a small component of maternity care in Sweden. While legally permitted, home births are not formally integrated into the public healthcare system and are typically attended by midwives operating privately outside the publicly funded sector. In recent years, interest in these alternative birth settings has increased, highlighting the need for healthcare providers and policymakers to critically evaluate their role within the Swedish maternity care framework.

In some regions, initiatives have been launched to offer publicly funded home births to eligible women. In Region Stockholm, the *Min Barnmorska* project provides publicly funded home births for multiparous women with low-risk pregnancies who live within a 40-minute driving distance from the hospital. Within the *Vårdval Förlossning* framework, this model offers continuity of care, with the same midwives involved throughout pregnancy, birth, and postpartum care. Karolinska University Hospital Huddinge was the first hospital to implement this model (Moderaterna i Region Stockholm, 2021). In Umeå, a similar model offers partial public funding for planned home births, but midwife availability is limited as the midwives are only allowed to provide home birth services outside their working hours at the hospital (Toss, 2021). In Uppsala, a publicly funded home birth programme and a midwifery-led unit are planned for implementation by 2026, with a midwifery-led unit providing care in a dedicated facility and in close collaboration with hospital-based maternity care (Lindblom, 2024).

Internationally, the prevalence of planned home/FMU births varies considerably across high income countries. In the Netherlands, a well-established midwife-led home birth system accounts for approximately 14% of births (StatLine, 2025). In the United Kingdom, home birth is integrated into the National Health Service (NHS) and about 1.9% of births in England and 2.3% in Wales occur at home (Office for National Statistics [ONS], 2024, NHS, 2024). Denmark offers publicly funded home births, with midwives obligated to attend during home birth even if women do not consent to transfer to the hospital in case of complications. Around 3% of births occur at home (eSundhed, 2023). In Norway, planned home births account for 0.2-0.3% of births and are mostly attended by independent midwives as they are not fully publicly funded (Helsedirektoratet, 2024, Helsenorge, 2025). Home birth rates in Finland and Iceland are approximately 0.15% and 1-2%, respectively. These differences reflect varying interest among pregnant women as well as different degrees of public funding and infrastructure across healthcare systems.

This health technology assessment (HTA) evaluates the medical safety and risks of planned home and FMU births compared with obstetric unit (hospital) birth in women with expected low-risk births. Further ethical and economical aspects as well as organisational implications are discussed. The aim is to offer a scientific knowledge base and provide an evidence-based report on maternal and child mortality and severe morbidity to support policy and decision-making for women and their caregivers.

7 Focused question

Question at issue	
What are the differences concerning mortality and severe morbidity for mother and child in high-income countries when comparing planned birth outside hospital (home birth or birth at FMU) with planned birth at hospital (obstetric unit) in low-risk birth?	
PICO	
P	<p>Healthy women with normal pregnancy and expected low-risk birth (as defined by the authors) in high income countries (according to OECD definition) with ICM-certified midwife education or similar (before 2011).</p> <p><i>Low-risk birth=singletons, cephalic position, spontaneous onset of labour, normal blood pressure, no previous caesarean section, full term (w 37+0 – 41+6)¹</i></p>
I	Planned birth outside hospital, led by midwife at home (home birth) or in a free-standing midwifery unit (FMU birth)
C	Planned birth at hospital, where both obstetricians and midwives work in a team, and with ability to perform emergency interventions, including surgery (obstetric unit birth)
O	<p><u>Outcomes critical for decision-making:</u></p> <p><i>Maternal:</i> Maternal mortality (within 42 days) Admission to intensive care unit</p> <p><i>Infant:</i> Peri/neonatal mortality (the fetus alive at first assessment at the unit in association with birth). Includes intrapartum mortality, neonatal mortality within 7 days after birth or neonatal mortality up to 28 days after birth</p> <p>Neonatal mortality. Includes neonatal mortality within 7 days after birth or neonatal mortality up to 28 days after birth</p> <p>Adverse infant events (short term), defined as: Therapeutic hypothermia Apgar score <4 at 5 min² Neonatal seizures Mechanical ventilation Meconium aspiration syndrome Hypoxic Ischemic Encephalopathy (HIE) 2-3 Resuscitation</p> <p>Length of stay at neonatal ward/NICU >72 hours</p> <p><u>Outcomes important for decision-making:</u></p> <p><i>Maternal:</i> Adverse maternal events (short term) defined as: Postpartum haemorrhage requiring blood transfusion² Perineal tears grade 3 or 4 Postpartum depression</p> <p><i>Infant:</i> Admission to the neonatal unit/NICU</p> <p><u>Outcomes less important for decision-making:</u> Postpartum haemorrhage >1000 ml³</p>

<p>Intrapartum caesarean section⁴ Transfer to hospital from home birth (mother or child) (No GRADE since no control group)</p> <p>Comment to O: Apgar score <7 at 5 min is reported as an Important outcome as no studies reported Apgar score <4 at 5 min.</p> <p>¹ According to LÖF's classification. Studies allowing up to 5% post-term births ($\geq 42+0$) were accepted as labour starting at 41+6 gestational weeks will in some cases lead to birth after 42+0 gestational weeks.</p> <p>² In case this Apgar score is not available, studies presenting other Apgar scores will be accepted.</p> <p>³ In case this amount of haemorrhage is not available, studies presenting other amounts will be accepted.</p> <p>⁴ See discussion</p>	
Study design	
Systematic reviews –commented upon, 2015-	
Randomised controlled trials	
Non-randomised controlled studies (≥ 100 patients in each comparison group)	
Case series and case reports for maternal and neonatal mortality and transfer to hospital	
Publication year	Language
2005-	English, Danish, Norwegian, Swedish
Planned subgroup analyses	
<p>Primiparous and multiparous women</p> <p>Home birth compared with birth at obstetric unit, and birth at FMU compared with obstetric unit birth</p> <p><u>Sensitivity analyses:</u></p> <p>Concerning critical outcomes in different countries</p> <p>One or two midwives</p> <p>Birth outside hospital is integrated in ordinary health care</p>	

8 Method

Systematic literature search (Appendix 1)

During May 2024, with an update in March 2025, two of the authors; two medical librarians (IS, AL), performed systematic searches in Medline, Embase, the Cochrane Library, and Cinahl, Websites of Scandinavian national and regional HTA-organisations were screened. Reference lists of relevant reports were also scrutinised for additional references. Search strategies, eligibility criteria and a graphic presentation of the selection process are presented in Appendix 1. These authors independently of one another screened the obtained abstracts to decide eligibility for full-text retrieval. All

abstracts were screened using the Rayyan tool (Ouzzani et al., 2016). Any disagreements were resolved in consensus. At least two authors read all full-text reports, independently of one another, and it was finally decided in a consensus meeting which reports should be included in the assessment.

The HTA was registered in International prospective register of systematic reviews (PROSPERO) on 7th October 2024 (number CRD42024570558) prior to data extraction.

Critical appraisal and certainty of evidence

Characteristics of the included studies are presented in Appendix 2. The excluded studies and the reasons for exclusion are presented in Appendix 3. Included studies were critically appraised using an adjusted checklist from the Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU) for assessment of non-randomised controlled studies. Data were extracted by at least two authors and summarised for each outcome in Appendix 4. When possible, data were pooled in weighted meta-analyses (STATA, version 18) using the random effects model with odds ratio (OR) as point estimate with 95% CI. Data are also presented as the absolute effect, calculated as the total number of events divided by the total over all included studies. This means that the absolute effect may differ from the weighted meta-analysis results and might even point in the opposite direction.

When available, adjusted OR (AOR) was used in meta-analyses. If AOR was presented with 99% CI in the article, this was recalculated to 95% CI in meta-analyses. In case of a zero-event outcome in one study arm continuity correction using a 0.5 zero-cell correction was used (in line with methodology used in included studies). Pooled weighted risk differences (RD) as point estimates with 95% CI are presented as supplementary data (Appendix 5). The certainty of evidence for each outcome was assessed using the GRADE approach for cohort studies (Atkins et al., 2004, GRADE Working group). The primary effect measure was AOR if available, otherwise OR was calculated from presented counts in the original studies (Deeks et al., 2024a). OR was chosen over RR to be more comparable to AOR. If only one study reported an outcome with AOR the certainty of evidence was based on OR.

Heterogeneity between studies was explored by calculating the I^2 . In meta-analysis with fewer than 5 studies, the I^2 value was assessed qualitatively due to large uncertainty.

Summary of the results per outcome and the associated certainty of evidence are presented in a Summary-of-findings table (Chapter 3).

Prespecified subgroup analyses were performed for primiparous and multiparous women and for home births and FMU births, respectively.

Sensitivity analysis was performed for births outside hospital integrated in ordinary health care vs obstetric unit births. Data were missing for sensitivity analyses on: 'critical outcomes in different countries' and 'one or two midwives being present at birth'.

Ongoing research

A search in Clinicaltrials.gov (22 Nov 2024) using the search terms (*homebirth OR "home birth" OR "home births" OR "home childbirth" OR "home childbirths" OR "home delivery"*)

OR "home deliveries" OR "out-of-hospital birth" OR "out-of-hospital births" OR "out-of-hospital childbirth" OR "out-of-hospital childbirths" OR "out-of-hospital delivery" OR "out-of-hospital deliveries" OR "non-hospital birth" OR "non-hospital births" OR "non-hospital childbirth" OR "non-hospital childbirths" OR "non-hospital delivery" OR "non-hospital deliveries" OR "out-of-clinic birth" OR "out-of-clinic births" OR "out-of-clinic childbirth" OR "out-of-clinic childbirths" OR "out-of-clinic delivery" OR "out-of-clinic deliveries" OR "non-clinic birth" OR "non-clinic births" OR "non-clinic childbirth" OR "non-clinic childbirths" OR "non-clinic delivery" OR "non-clinic deliveries" OR "out-of-institution birth" OR "out-of-institution births" OR "out-of-institution childbirth" OR "out-of-institution childbirths" OR "out-of-institution delivery" OR "out-of-institution deliveries" OR "non-institution birth" OR "non-institution births" OR "non-institution childbirth" OR "non-institution childbirths" OR "non-institution delivery" OR "non-institution deliveries" OR "out-of-facility birth" OR "out-of-facility births" OR "out-of-facility childbirth" OR "out-of-facility childbirths" OR "out-of-facility delivery" OR "out-of-facility deliveries" OR "non-facility birth" OR "non-facility births" OR "non-facility childbirth" OR "non-facility childbirths" OR "non-facility delivery" OR "non-facility deliveries") AND (midwife OR midwives OR midwifery OR planned) identified 20 trials. A search in WHO International Clinical Trials Registry Platform (ICTRP) (22 Nov 2024) using the same search string as above, identified 8 trials. In total, 28 unique ongoing trials were identified.

9 Results

Search results and study selection (Appendix 1)

The literature search identified 3,170 records after removal of duplicates. DedupEndNote (Lobbestael, 2023) was used for deduplication. After reading the abstracts, 2,963 records were excluded. 217 reports were sought for retrieval. One report could not be retrieved, and 182 reports were excluded after full-text reading. Nine cohort studies, 18 case series, and two case reports (a total of 29 studies presented in 30 reports) were finally included in the assessment (Appendix 2). Five of the case series were cohort studies which were used as case series since they did not include a control group. In addition, three systematic reviews (SR) were commented upon.

Included studies

No RCTs or SRs meeting the PICO were identified. Nine cohort studies met the inclusion criteria (Brocklehurst et al., 2011, Davis et al., 2011, Davis et al., 2012, Farry et al., 2019, Hermus et al., 2017, Hiraizumi et al., 2013, Homer et al., 2019, Lindgren et al., 2008a, Scarf et al., 2019). The studies were conducted in high-income countries and reflect different models for planned home and FMU births. Most were performed in countries with public integration of out-of-hospital births, such as Australia, the Netherlands, New Zealand, and the United Kingdom. In contrast, Lindgren et al. (2008a) represents the non-integrated Swedish setting, where home births were privately arranged. Seven studies included only planned home births. One study included home and FMU births (Brocklehurst et al., 2011), although outcomes for FMU births were reported solely in the subgroup analysis based on place of birth. Additionally, one study (Farry et al., 2019) included only FMU births. All nine studies included births at obstetric units as a comparison group. The obstetric unit birth group included more primiparous women and more women with low socioeconomic status, language barriers, and obstetric

risk factors than the groups giving birth at home or in an FMU. The study by Scarf et al., 2019 is only included for the outcome transfer to hospital and in subgroups in comparative analyses since otherwise overlapping with the study by Homer et al., 2019.

In addition, for the outcome maternal and/or perinatal mortality, eight case series (Catling-Paull et al., 2013, Davies-Tuck et al., 2018, de Jonge et al., 2015, Galera-Barbero et al., 2021, Huitfeldt et al., 2016, Suzuki et al., 2016, Sweet et al., 2022, White et al., 2020) and two case reports (Fritschel et al., 2015, Smit et al., 2014a, Smit et al., 2014b) were included but assessed separately from the cohort studies. The included case series originated from Australia, the Netherlands, Norway, Spain, the United States, and Japan.

In addition, for the outcome transfer to hospital (only relevant in home and FMU births), 16 case series were included (Alcaraz-Vidal et al., 2024, Amelink-Verburg et al., 2008, Blix et al., 2016, Bolten et al., 2016, Catling-Paull et al., 2013, Galera-Barbero et al., 2021, Geerts et al., 2014, Hill et al., 2024, Huitfeldt et al., 2016, Maimburg et al., 2018, McMurtrie et al., 2009, Offerhaus et al., 2013, Rowe et al., 2013, Suzuki et al., 2016, Sweet et al., 2022, White et al., 2020). The studies covered diverse geographical contexts, including Australia, Germany, Japan, the Netherlands, the Nordic countries, and the United Kingdom. While definitions and thresholds for transfer varied slightly across studies, most distinguished between intrapartum and postpartum transfer of the mother and/or neonate. Some studies also reported urgency of transfer. Two cohort studies had serious problems with directness (Farry et al., 2019, Hiraizumi et al., 2013), four studies had some problems with directness (Davis et al., 2011, Davis et al., 2012, Hermus et al., 2017, Homer et al., 2019). Three studies had major problems with risk of bias (Davis et al., 2011, Davis et al., 2012, Hiraizumi et al., 2013). Six studies had some problems with risk of bias (Brocklehurst et al., 2011, Farry et al., 2019, Hermus et al., 2017, Homer et al., 2019, Lindgren et al., 2008a, Scarf et al., 2019). Depending on specific outcomes, one study had no problems with precision for any outcome (Davis et al., 2012), two studies had no or some problems with precision (Brocklehurst et al., 2011, Homer et al., 2019). Two studies had serious problems with precision for all outcomes (Hiraizumi et al., 2013, Lindgren et al., 2008a). Four studies had between no and major problems with precision (Davis et al., 2011, Farry et al., 2019, Hermus et al., 2017, Scarf et al., 2019) (Table 1). Details of the risk of bias per outcome are shown in Table 2. For some outcomes I^2 values were high (see forest plots). However, we did not downgrade for heterogeneity since there were too few studies to formally evaluate heterogeneity (Deeks et al., 2024b).

Table 1. Summary of critical appraisal for the included cohort studies. Main analysis.

Author, year	Directness	Risk of bias	Precision*	
Brocklehurst, 2011	+	?	+ ¹	? ²
Davis, 2011	?	-	+ ³	- ⁴
Davis, 2012	?	-	+	
Farry, 2019	-	?	+ ⁵	- ⁷
Hermus, 2017	?	?	? ⁸	- ⁹
Hiraizumi, 2013	-	-	-	
Homer, 2019	?	?	+ ¹⁰	? ¹¹
Lindgren, 2008	+	?	-	

Green=no problems, yellow=some problems, red=major problems

* within individual studies the precision varied for different outcomes, see number below

¹ for the outcomes: intrapartum caesarean section, admission to neonatal ward or NICU, adverse infant events (asphyxia, Apgar score <7 at 5 min), perineal tear grade 3 or 4, postpartum haemorrhage requiring transfusion, maternal admission to ICU

² for the outcomes: peri/neonatal mortality (within 7 or 28 days), neonatal mortality (within 7 or 28 days), admission to NICU

³ for the outcome: intrapartum caesarean section

⁴ for the outcome: peri/neonatal mortality (within 7 or 28 days), neonatal mortality (within 7 or 28 days)

⁵ for the outcomes: postpartum haemorrhage (>500 ml or >/≥1000 ml),

⁶ for the outcomes: intrapartum caesarean section, adverse infant events (asphyxia, Apgar score <7 at 5 min)

⁷ for the outcomes: peri/neonatal mortality (within 7 or 28 days), neonatal mortality (within 7 or 28 days), maternal admission to ICU, maternal mortality

⁸ for the outcomes: postpartum haemorrhage (>500 ml or >/≥1000 ml), perineal tear grade 3 or 4

⁹ for the outcomes: admission to neonatal ward or NICU, postpartum haemorrhage requiring transfusion, peri/neonatal mortality (within 7 or 28 days), neonatal mortality (within 7 or 28 days), maternal mortality

¹⁰ for the outcomes: intrapartum caesarean section, postpartum haemorrhage requiring transfusion, maternal admission to ICU

¹¹ for the outcomes: perineal tear grade 3 or 4, peri/neonatal mortality (within 7 or 28 days), neonatal mortality (within 7 or 28 days), admission to NICU

Table 2. Critical appraisal of the included cohort studies per outcome. Main analysis.

Outcome	Risk of bias		Consistency	Directness			Precision		
Maternal mortality	? (4,5,8)		+	+	?	-	-		
Maternal admission to ICU	? (1,4,7)		+	+	?	-	+	-	
Peri/neonatal mortality (within 7 or 28 days)	? (1,4,5,7,8)	- (2)	+	+	?	-	?	-	
Neonatal mortality (within 7 or 28 days)	? (1,4,5,7,8)	- (2)	+	+	?	-	?	-	
Apgar score <7 at 1 and/or 5 min, asphyxia	? (1,4)	- (6)	+	+	-	-	+	?	-
Postpartum haemorrhage requiring transfusion	? (1,5,7)		+	+	?	-	+	?	
Perineal tear grade 3 or 4	? (1,5,7)	- (6)	?	+	?	-	+	?	-
Admission to neonatal ward or NICU	? (1,4,5,7)		+	+	?	-	+	-	
Postpartum haemorrhage <500 ml or >/≥1000 ml	? (4,5)	- (3,6)	+	?	-	-	+	?	-
Intrapartum caesarean section	? (1,4,7)	- (2)	+	+	?	-	+	?	

Green=no problems, yellow=some problems, red=major problems.

References: ¹ Brocklehurst, 2011; ² Davis, 2011; ³ Davis, 2012; ⁴ Farry, 2019; ⁵ Hermus, 2017; ⁶ Hiraizumi, 2013; ⁷ Homer, 2019; ⁸ Lindgren, 2008a

Results per outcome

Outcomes critical for decision-making:

Maternal:

Maternal mortality (Appendix 4.1)

Maternal mortality in the planned home/FMU birth group compared with the obstetric unit birth group, was reported in three cohort studies (Farry et al., 2019, Hermus et al., 2017, Lindgren et al., 2008a) with 2,990 participants in the home/FMU birth group and 15,135 participants in the obstetric unit birth group and in three case series (Catling-Paull et al., 2013, Galera-Barbero et al., 2021, Sweet et al., 2022) with 3,929 participants, in total 22,054 participants. No maternal death was reported in any of the studies.

Conclusion: It is uncertain whether maternal mortality is different in planned home/FMU birth, compared with obstetric unit birth in women with an expected low-risk birth. Very low certainty of evidence (GRADE ⊕○○○).

Maternal admission to ICU (Appendix 4.2)

Maternal admission to ICU in the planned home/FMU birth group compared with the obstetric unit birth group, was reported in three cohort studies (Brocklehurst et al., 2011, Farry et al., 2019, Homer et al., 2019) with 22,949 participants in the home/FMU birth group and 677,759 participants in the obstetric unit birth group. The crude event rate across studies was 0.3% in the home/FMU birth group and 0.4% in the obstetric unit

group. Meta-analysis of the cohort studies showed a lower rate of maternal admission to ICU for the planned home/FMU birth group compared with the obstetric unit birth group, OR 0.36 (95% CI 0.19 to 0.70) (Figure 1a) and AOR 0.41 (95% CI 0.19 to 0.89) (Figure 1b).

Figure 1a. Odds ratio for maternal admission to intensive care unit (ICU)

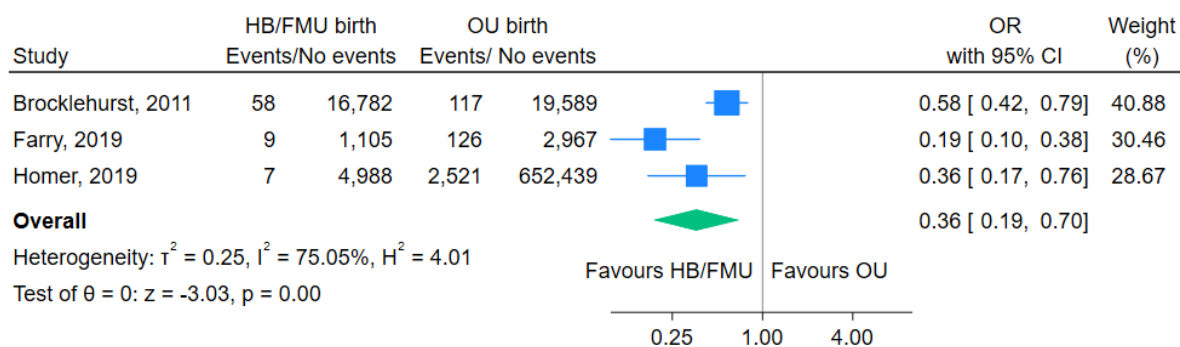
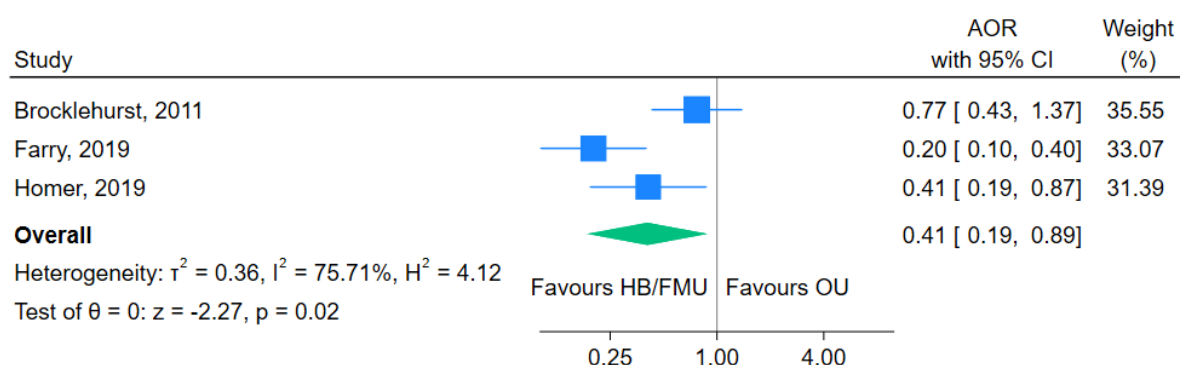


Figure 1b. Adjusted* odds ratio for maternal admission to intensive care unit (ICU)



*Adjusted for: Brocklehurst: maternal age, parity, ethnic group, understanding English, BMI, index of multiple deprivation score, gestational age. Farry: maternal age, parity, smoking, ethnicity, BMI, socioeconomic status. Homer: maternal age, parity, country of birth, gestational age.

Conclusion: Planned home/FMU birth compared with obstetric unit birth in women with an expected low-risk birth may be associated with reduced maternal admission to ICU. Low certainty of evidence (GRADE ⊕⊕OO).

Infant:

Outcomes not reported were Apgar score <4 at 5 min, time at neonatal ward or NICU >72h, therapeutic hypothermia, neonatal seizures, mechanical ventilation, meconium aspiration, hypoxic-ischemic encephalopathy (HIE) grade 2-3, and resuscitation.

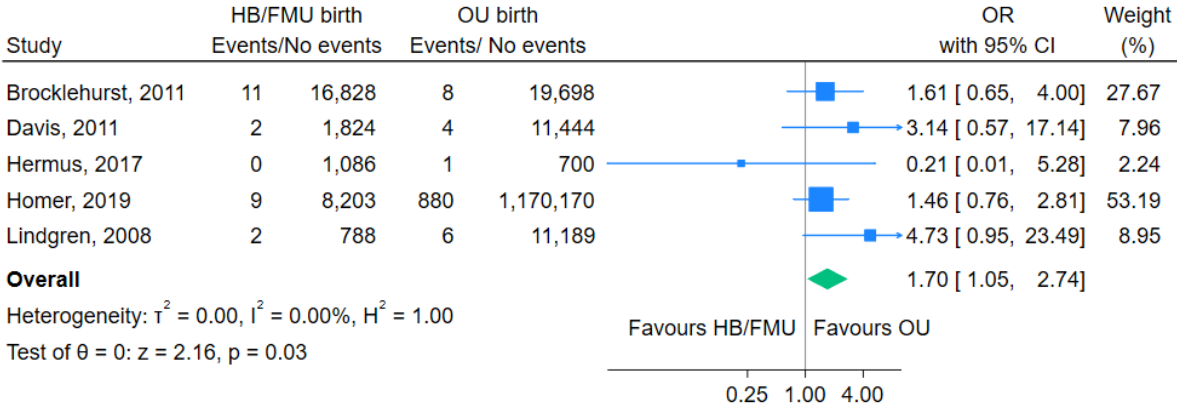
Peri/neonatal mortality (Appendix 4.3)

Peri/neonatal mortality (intrapartum and neonatal mortality within 7 or 28 days) in the planned home/FMU birth group compared with the planned obstetric unit birth group, was reported in five cohort studies (Brocklehurst et al., 2011, Davis et al., 2011, Hermus et al., 2017, Homer et al., 2019, Lindgren et al., 2008a) with 28,753 participants in the home/FMU birth group and 1,214,100 in the obstetric unit birth group and in eight case

series (Catling-Paull et al., 2013, Davis Tuck et al., 2018, de Jonge et al., 2015, Galera-Barbero et al., 2021, Huitfeldt et al., 2015, Suzuki et al., 2016, Sweet et al., 2022, White et al., 2020) with 473,233 participants in the planned home/FMU birth group, and in two case reports (Fritschel et al., 2015, Smit et al., 2014a and b). The crude event rate across studies was 0.8 per 1,000 births in the home/FMU birth group and 0.7 per 1,000 births in the obstetric unit group. Meta-analysis of the cohort studies showed an increased risk of peri/neonatal mortality in unadjusted analysis, OR 1.70 (95% CI 1.05 to 2.74) (Figure 2a) in the planned home/FMU birth group compared with the obstetric unit birth group. One of the studies (Homer et al., 2019) presented adjusted results for peri/neonatal mortality, the AOR was 1.55 (95% CI 0.80 to 3.00) (Figure 2b) in the planned home/FMU birth group compared with the obstetric unit birth group.

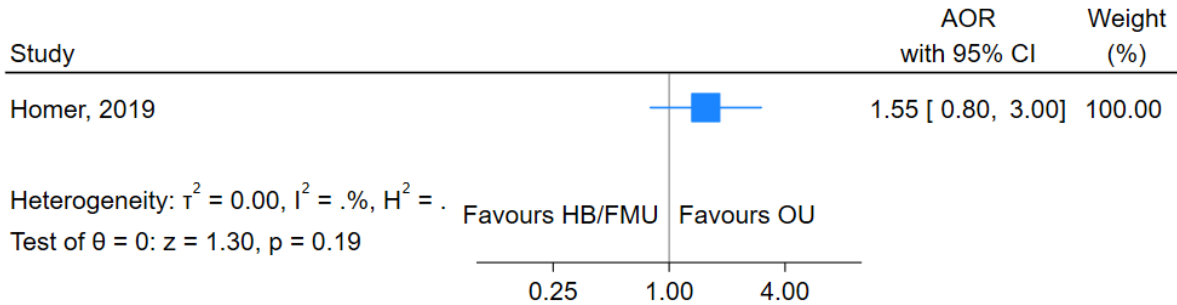
Peri/neonatal mortality in case series in the planned home/FMU birth group varied between 0 and 5.2 per 1,000 and was 0.8 per 1,000 in the largest study (de Jonge et al., 2015, 466,112 neonates).

Figure 2a. Odds ratio for peri/neonatal mortality*



*Note: The differences in denominators for perinatal/neonatal mortality and neonatal mortality in Brocklehurst and Homer align with those presented in their respective articles

Figure 2b. Adjusted* odds ratio for peri/neonatal mortality



*Adjusted for maternal age, parity, country of birth, and gestational age

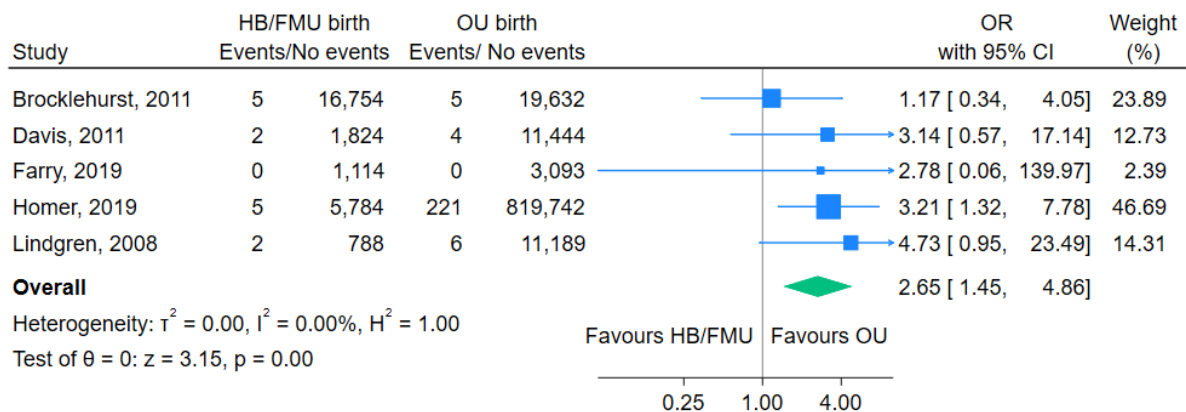
Conclusion: Planned home/FMU birth compared with obstetric unit birth in women with an expected low-risk birth may be associated with an increased risk of peri/neonatal mortality. Low certainty of evidence (GRADE ⊕⊕OO).

Neonatal mortality (Appendix 4.3)

Neonatal mortality (within 7 or 28 days) in the planned home/FMU birth group compared with the planned obstetric unit birth group, was reported in five cohort studies (Brocklehurst et al., 2011, Davis et al., 2011, Farry et al., 2019, Homer et al., 2019, Lindgren et al., 2008a) with 26,278 participants in the planned home/FMU birth group and 865,336 participants in the obstetric unit birth group and seven case series (Catling-Paull et al., 2013, Davis Tuck et al., 2018, de Jonge et al., 2015, Galera-Barbero et al., 2021, Suzuki et al., 2016, Sweet et al., 2022, White et al., 2020) with 472,738 participants and two case reports (Fritschel et al., 2015, Smit et al., 2014 a and b). The crude event rate across cohort studies was 0.5 per 1,000 births in the home/FMU birth group and 0.3 per 1,000 births in the obstetric unit group. Meta-analysis of the cohort studies showed an increased risk of neonatal mortality in unadjusted analysis OR 2.65 (95% CI 1.45 to 4.86) (Figure 2a) in the planned home/FMU birth group compared with the obstetric unit birth group. One of the studies (Homer et al., 2019) presented adjusted results for neonatal mortality, AOR 3.18 (95% CI 1.30 to 7.77) (Figure 3b) in the planned home/FMU birth group compared with the obstetric unit birth group.

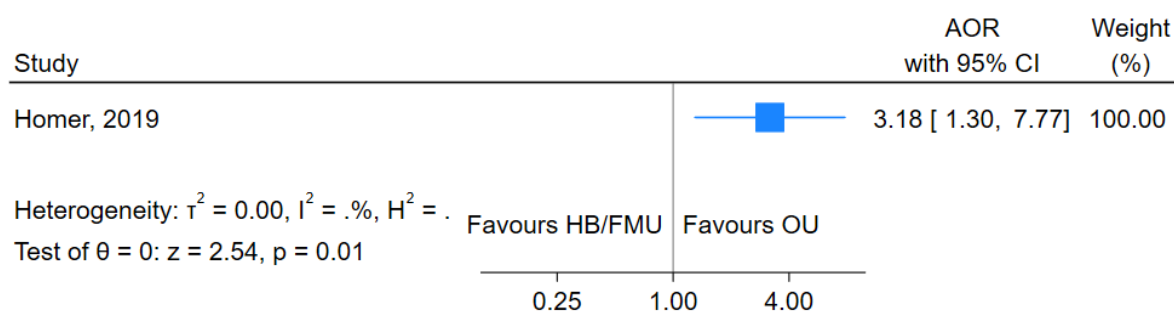
Neonatal mortality in case series in the planned home/FMU birth group varied between 0 and 5.2 per 1000 and was 0.4 per 1000 in the largest study (de Jonge et al., 2015, 466,112 neonates).

Figure 3a. Odds ratio for neonatal mortality*



*Note: The differences in denominators for perinatal/neonatal mortality and neonatal mortality in Brocklehurst and Homer align with those presented in their respective articles

Figure 3b. Adjusted* odds ratio for neonatal mortality



*Adjusted for maternal age, parity, country of birth, and gestational age

Conclusion: Planned home/FMU birth compared with obstetric unit birth in women with an expected low-risk birth may be associated with an increased risk of neonatal mortality. Low certainty of evidence (GRADE ⊕⊕OO).

Apgar score <7 at 1 and/or 5 min (Appendix 4.4)

Apgar <7 at 5 min in the planned home/FMU birth group compared with the planned obstetric unit birth group, was reported in three cohort studies (Brocklehurst et al., 2011, Farry et al., 2019, Hiraizumi et al., 2013) with 18,082 neonates in the home/FMU birth group and 22,919 neonates in the obstetric unit birth group. The crude event rate across studies was 0.8% in the home/FMU birth group and 1,0% in the obstetric unit group. Meta-analysis of the cohort studies showed no difference in asphyxia in the planned home/FMU birth group compared with the obstetric unit birth group, OR 0.68 (95% CI 0.30 to 1.53) and AOR 0.65 (95% CI 0.25 to 1.64, two studies) (Figure 4a and 4b).

Figure 4a. Odds ratio for Apgar <7 at 1 and/or 5 min

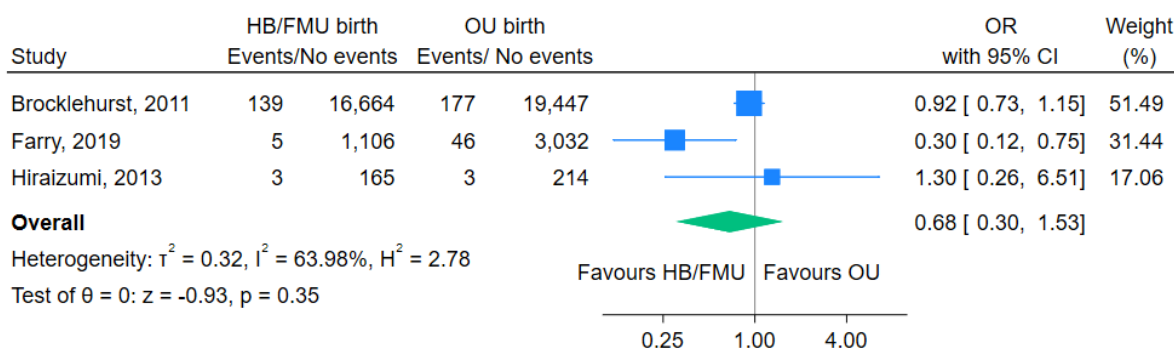
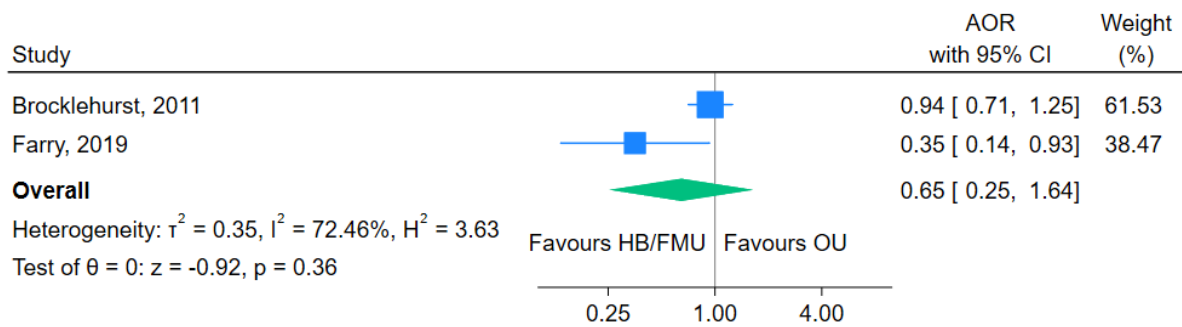


Figure 4b. Adjusted* odds ratio for Apgar <7 at 5 min



*Adjusted for: Brocklehurst: maternal age, parity, ethnic group, understanding English, BMI, index of multiple deprivation score, gestational age. Farry: maternal age, parity, smoking, ethnicity, BMI, socioeconomic status.

Conclusion: Planned home/FMU birth compared with obstetric unit birth in women with an expected low-risk birth may be associated with no difference in neonates with an Apgar score <7 at 1 and/or 5 minutes. Low certainty of evidence (GRADE ⊕⊕OO).

Outcomes important for decision making:

Maternal:

The outcome postpartum depression was not reported in any of the included studies.

Postpartum haemorrhage requiring transfusion (Appendix 4.5)

Postpartum haemorrhage requiring transfusion in the planned home/FMU birth group compared with the planned obstetric unit birth group, was reported in three cohort studies (Brocklehurst et al., 2011, Hermus et al., 2017, Homer et al., 2019) with 25,985 participants in the home/FMU birth group and 1,191,983 participants in the obstetric unit group. The crude event rate across studies was 0.6% in the home/FMU birth group and 0.5% in the obstetric unit group. Meta-analysis of the cohort studies showed no difference in postpartum haemorrhage requiring transfusion in the planned home/FMU birth group compared with the obstetric unit group, OR 0.72 (95% CI 0.44 to 1.19) (Figure 5a) and AOR 0.89 (95% CI 0.60 to 1.32, two studies) (Figure 5b).

Figure 5a. Odds ratio for postpartum haemorrhage requiring blood transfusion

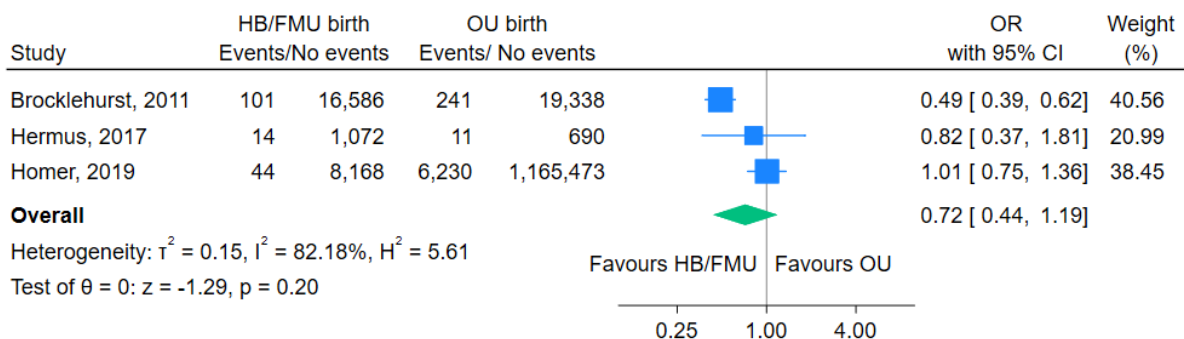
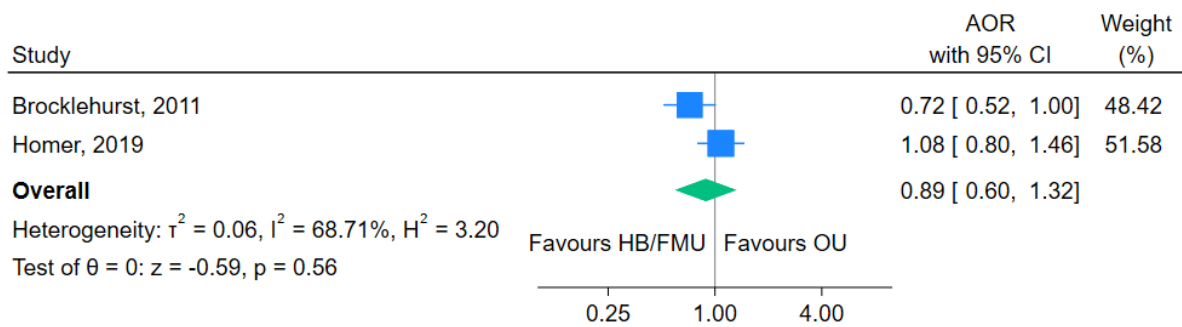


Figure 5b. Adjusted* odds ratio for postpartum haemorrhage requiring transfusion



*Adjusted for: Brocklehurst: maternal age, parity, ethnic group, understanding English, BMI, index of multiple deprivation score, gestational age. Farry: maternal age, parity, smoking, ethnicity, BMI, socioeconomic status.

Conclusion: Planned home/FMU birth compared with obstetric unit birth in women with an expected low-risk birth may be associated with no difference in postpartum haemorrhage requiring transfusion. Low certainty of evidence (GRADE ⊕⊕OO).

Perineal tear grade 3 or 4 (Appendix 4.6)

Perineal tear grade 3 or 4, in the planned home/FMU birth group compared with the planned obstetric unit birth group, was reported in four cohort studies (Brocklehurst et al., 2011, Hermus et al., 2017, Hiraizumi et al., 2013, Homer et al., 2019) with 26,072 participants in the home/FMU birth group and 1,101,021 participants in the obstetric unit birth group. The crude event rate across studies was 1.6% in the home/FMU birth group and 2.0% in the obstetric unit group. Meta-analysis of the cohort studies showed no difference in perineal tear grade 3 or 4 in home/FMU birth group compared with the obstetric unit birth group in the unadjusted analysis, OR 0.72 (95% CI 0.35 to 1.48) (Figure 6a) but a reduction in perineal tears in the adjusted analysis, AOR 0.64 (95% CI 0.45 to 0.93, two studies) (Figure 6b).

Figure 6a. Odds ratio for perineal tear grade 3-4

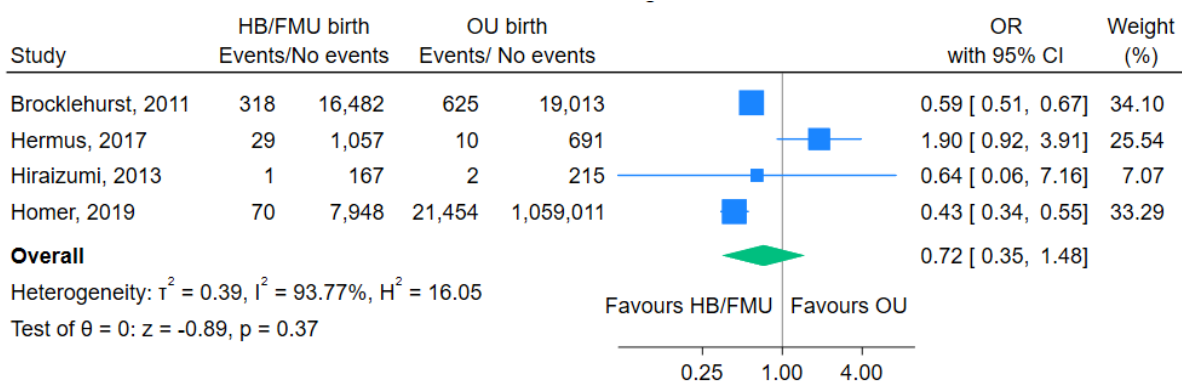
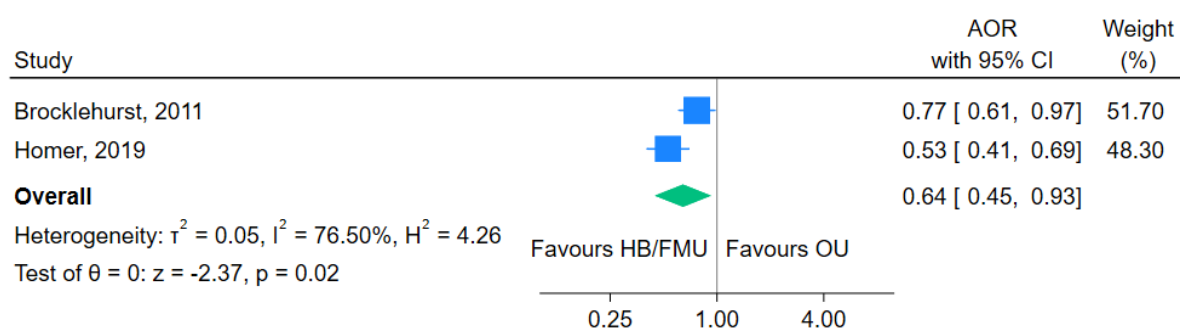


Figure 6b. Adjusted* odds ratio for perineal tear grade 3-4



*Adjusted for: Brocklehurst: maternal age, parity, ethnic group, understanding English, BMI, index of multiple deprivation score, gestational age. Farry: maternal age, parity, smoking, ethnicity, BMI, socioeconomic status.

Conclusion: Planned home/FMU birth compared with obstetric unit birth in women with an expected low-risk birth may be associated with a lower rate of perineal tears grade 3 or 4. Low certainty of evidence (GRADE ⊕⊕OO).

Admission to neonatal ward or NICU (Appendix 4.7)

Any admission to neonatal ward or NICU, in the planned home/FMU birth group compared with the planned obstetric unit birth group, was reported in four cohort studies (Brocklehurst et al., 2011, Farry et al., 2019, Hermus et al., 2017, Homer et al., 2019) with 24,685 neonates in the home/FMU birth group and 843,396 neonates in the obstetric unit birth group. The crude event rate across studies was 1.4% in the home/FMU birth group and 0.9% in the obstetric unit group. Meta-analysis of the cohort studies showed a reduction in the rate of neonates admitted to NICU after home/FMU births compared to obstetric unit births, OR 0.60 (95% CI 0.53 to 0.68) (Figure 7a) and AOR 0.67 (95% CI 0.56 to 0.81, three studies) (Figure 7b).

Figure 7a. Odds ratio for admission to NICU

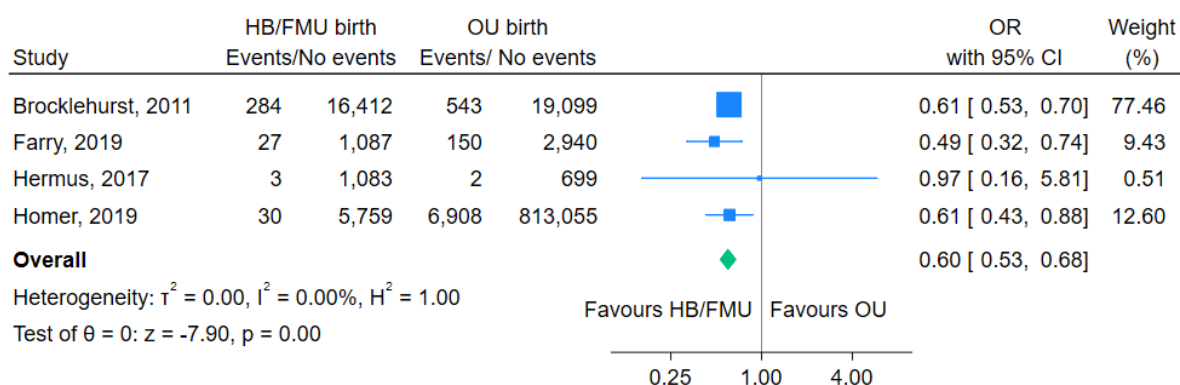
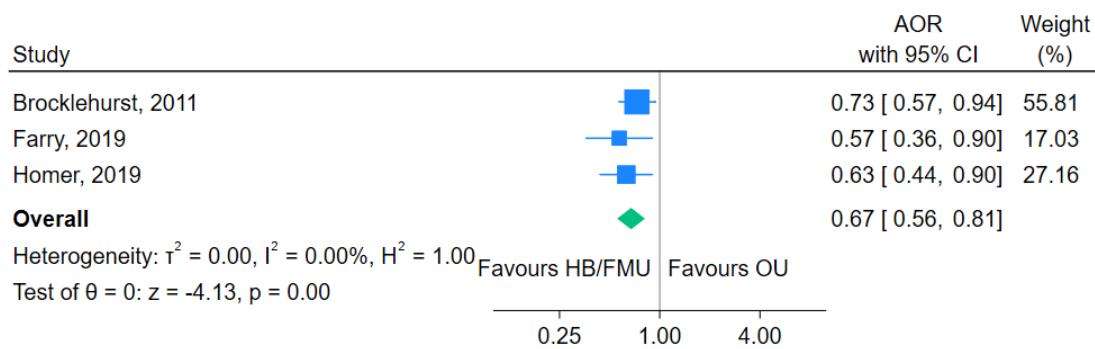


Figure 7b. Adjusted* odds ratio for admission to NICU



*Adjusted for: Brocklehurst: maternal age, parity, ethnic group, understanding English, BMI, index of multiple deprivation score, gestational age. Farry: maternal age, parity, smoking, ethnicity, BMI, socioeconomic status. Homer: maternal age, parity, country of birth, gestational age.

Conclusion: Planned home/FMU birth compared with obstetric unit birth in women with an expected low-risk birth may be associated with a lower rate of NICU admissions. Low certainty of evidence (GRADE ⊕⊕OO).

Outcomes less important for decision making:

Postpartum haemorrhage (Appendix 4.8)

Postpartum haemorrhage (>500 ml or \geq / $>$ 1000 ml) in the planned home/FMU birth group compared with the planned obstetric unit birth group, was reported in four cohort studies (Davis et al., 2011, Farry et al., 2019, Hermus et al., 2017, Hiraizumi et al., 2013) with 4,176 participants in the home/FMU birth group and 15,236 participants in the obstetric unit birth group. The crude event rate across studies was 4.1% in the home/FMU birth group and 4.0% in the obstetric unit group. Meta-analysis of the cohort studies showed a reduction in postpartum haemorrhage in the planned home/FMU birth group compared with the obstetric unit birth group, OR 0.72 (95% CI 0.53 to 0.98) (Figure 8a). One of the studies (Farry et al., 2019) presented adjusted results for postpartum haemorrhage, AOR 0.54 (95% CI 0.42 to 0.68) for home/FMU births compared with obstetric unit births (Figure 8b).

Figure 8a. Odds ratio for postpartum haemorrhage

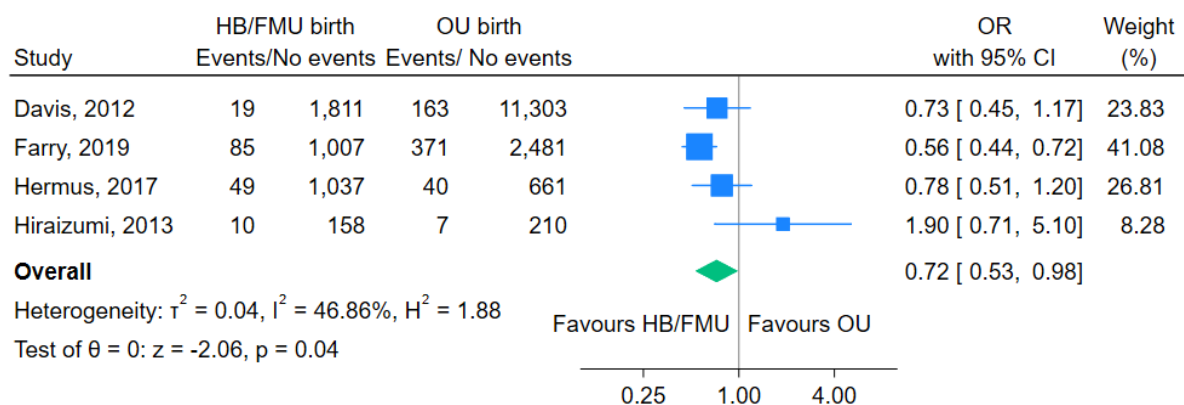
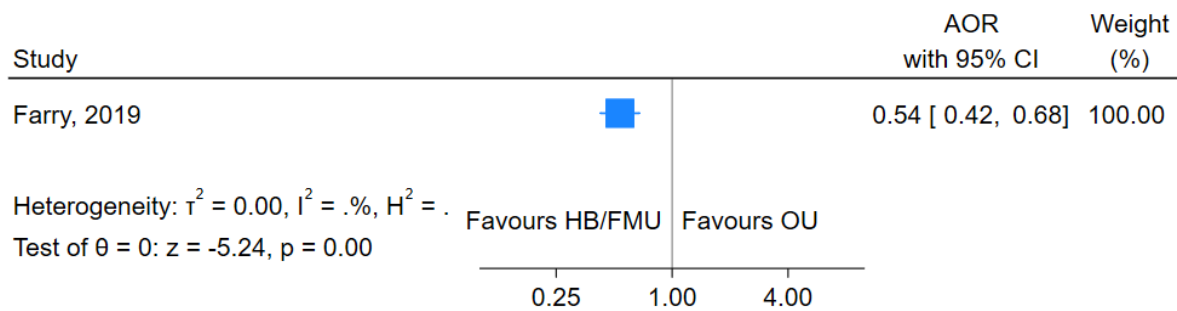


Figure 8b. Adjusted* odds ratio for postpartum haemorrhage



*Adjusted for maternal age, parity, smoking, ethnicity, BMI, and socioeconomic status

Conclusion: Planned home/FMU birth compared with hospital birth in women with an expected low-risk birth may be associated with a lower rate of postpartum haemorrhage. Low certainty of evidence (GRADE ⊕⊕OO)

Intrapartum caesarean section (Appendix 4.9)

Intrapartum caesarean section in the planned home/FMU birth group compared with the planned obstetric unit birth group, was reported in four cohort studies (Brocklehurst et al., 2011, Davis et al., 2011, Farry et al., 2019, Homer et al., 2019) with 27,975 participants in the home/FMU birth group and 1,205,928 participants in the obstetric unit birth group. The crude event rate across studies was 2.6% in the home/FMU birth group and 7.9% in the obstetric unit group. Meta-analysis of the cohort studies showed a decreased risk of intrapartum caesarean section in the home/FMU birth group compared with the obstetric unit birth group, OR 0.24 (95% CI 0.21 to 0.28) (Figure 9a) and AOR 0.29 (95% CI 0.26 to 0.33, three studies) (Figure 9b).

Figure 9a. Odds ratio for intrapartum caesarean section

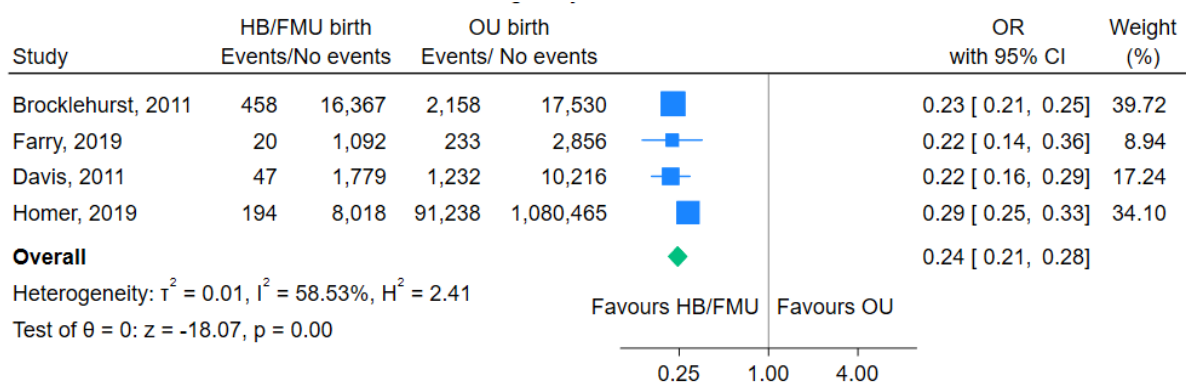
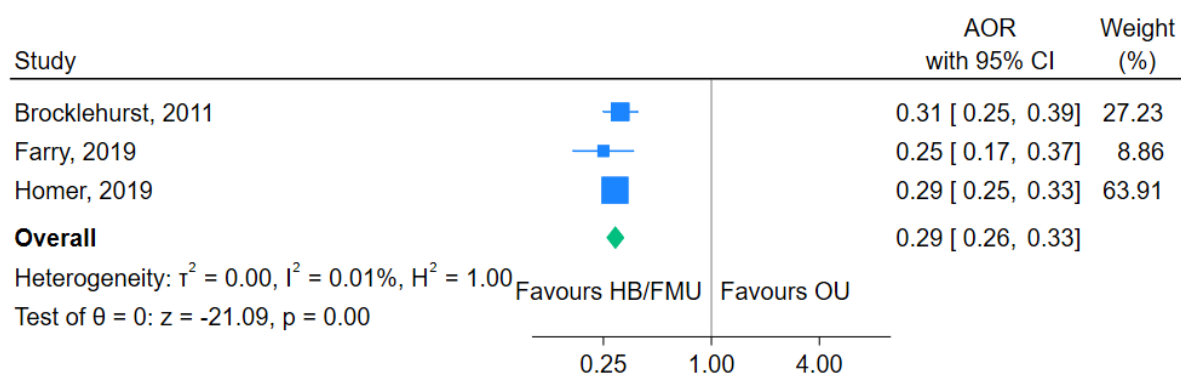


Figure 9b. Adjusted* odds ratio for intrapartum caesarean section



*Adjusted for: Brocklehurst: maternal age, parity, ethnic group, understanding English, BMI, index of multiple deprivation score, gestational age. Farry: maternal age, parity, smoking, ethnicity, BMI, socioeconomic status. Homer: maternal age, parity, country of birth, gestational age.

Conclusion: Planned home/FMU birth compared with obstetric unit birth in women with an expected low-risk birth may be associated with a lower rate of intrapartum caesarean section. Low certainty of evidence (GRADE ⊕⊕OO).

Transfer to hospital (Appendix 4.10)

Transfer to hospital during labour or after birth for mother or neonate in nulliparous and multiparous women in the planned home/FMU birth group, was reported in four cohort studies (Farry et al., 2019, Hermus et al., 2027, Hiraizumi et al., 2013, Scarf et al., 2019) with 4,192 participants and in 12 case series (Alcaraz-Vidal et al., 2024, Amelink-Verburg et al., 2008, Bolten et al., 2016, Catling-Paull et al., 2013, Galera-Barbero et al., 2021, Geerts et al., 2014, Maimburg et al., 2018, McMurtrie et al., 2009, Rowe et al., 2013, Suzuki et al., 2016, Sweet et al., 2022, White et al., 2020) with 24,538 participants. Transfer rates during labour or after birth varied between 9.3% and 33.3%. Transfer rate was 20.7% in the largest study (Rowe et al., 2013, 16,619 women). Urgent transfer was reported in two studies (Hermus et al., 2017, Amelink-Verburg et al., 2008) and occurred in 3.4% in both studies.

Outcomes in subgroup analyses according to parity

In the subgroup analyses according to parity, the included studies did not provide enough data to perform adjusted meta-analyses for any outcome.

Nulliparous women

Five cohort studies (Brocklehurst et al., 2011, Hermus et al., 2017, Homer et al., 2019, Scarf et al., 2019) with 210,090 participants contributed outcome data in planned home births vs obstetric unit births in nulliparous women (Supplementary file, Appendix 5, Figures 1a to 9b). Two case series with 198,811 participants contributed outcome data for peri/neonatal and neonatal mortality for home births (de Jonge et al., 2015, Galera-Barbero et al., 2021) (Appendix 4.3). One cohort study (Farry et al., 2019) and 11 case series (Blix et al., 2016, Bolten et al., 2016, Galera-Barbero et al., 2021, Geerts et al., 2014, Hill et al., 2024, Huitfelt et al., 2016, Maimburg et al., 2018, Offerhaus et al., 2013, Rowe et al., 2013, Suzuki et al., 2016, White et al., 2020) with 267,316

participants contributed data on transfer to hospital during labour or after birth for home/FMU births (Appendix 4.10).

Outcomes of meta-analyses of cohort studies are presented in the Supplementary file (Appendix 5), Figures 1a to 9b.

Meta-analyses of cohort studies showed a significantly higher risk for peri/neonatal death for home births compared with obstetric unit births; OR 2.12 (95% CI 1.02 to 4.44) (3 studies; Brocklehurst et al., 2011, Hermus et al., 2017, Homer et al., 2019) (Supplementary file, Appendix 5, Figure 2a). Peri/neonatal mortality was 1.0/1,000 and neonatal mortality was 0.5/1,000 in home births in de Jonge et al. (2015). Galera-Barbero et al. (2021) reported no peri/neonatal mortality in home births in 296 participants.

Transfer rates varied between 14.4% and 60.6% for home/FMU births and was 49.3% in the largest study (Offerhaus et al., 2013, 195,967 participants). Urgent or potentially urgent transfer occurred in 4.5%-25.8%.

Multiparous women

Four cohort studies (Brocklehurst et al., 2011, Hermus et al. 2017, Homer et al. 2019, Scarf et al., 2019) with 961,399 participants contributed outcome data in planned home births vs obstetric unit births in multiparous women (Supplementary file, Appendix 5, Figures 10a to 18b). Two case series with 268,050 participants contributed outcome data for peri/neonatal mortality and neonatal mortality for planned home births (de Jonge et al., 2015, Galera-Barbero et al., 2021) (Appendix 4.3). One cohort study (Farry et al., 2019) and eight case series (Bolten et al., 2016, Galera-Barbero et al., 2021, Geerts et al., 2014, Maimburg et al., 2018, Offerhaus et al., 2013, Rowe et al., 2013, Suzuki et al., 2016, White et al., 2020) with 272,772 participants contributed data on transfer to hospital during labour or after birth for planned home/FMU births (Appendix 4.10).

Outcomes of meta-analyses of cohort studies are presented in the Supplementary file (Appendix 5), Figures 10a to 18b.

Meta-analyses of cohort studies on peri/neonatal mortality showed no difference in peri/neonatal mortality in planned home births vs obstetric unit births, OR 1.18 (95% CI 0.57 to 2.47) (Supplementary file, Appendix 5, Figure 11a). Peri/neonatal mortality was 0.6 per 1,000 and neonatal mortality was 0.3 per 1,000 in home births in de Jonge et al. (2015). Galera-Barbero et al. (2021) including 524 participants reported no mortality in home births.

Transfer rates during labour or after birth in home/FMU births varied between 2.8% and 23% and was 14.7% in the largest study (Offerhaus et al., 2013; 257,030 participants). Urgent or potentially urgent transfer occurred in 2.4-2.8%.

Outcomes in subgroup analyses according to planned place of birth

Planned home births (excluding freestanding midwifery units, FMU) vs obstetric unit births

Seven cohort studies (Brocklehurst et al., 2011, Davis et al., 2011, Davis et al., 2012, Hermus et al., 2017, Hiraizumi et al., 2013, Homer et al., 2019, Lindgren et al., 2008a) with 1,243,293 participants contributed outcome data in planned home births vs obstetric unit births (Supplementary file, Appendix 5, Figures 19a to 27b). Seven case series (Catling-Paull et al., 2013, Davies Tuck et al., 2018, de Jonge et al., 2015, Galera-Barbero et al., 2021, Suzuki et al., 2016, Sweet et al., 2022, White et al., 2020) with 472,738 participants reported on peri/neonatal and neonatal mortality in home births (Appendix 4.3). Three cohort studies (Hermus et al., 2017, Hiraizumi et al., 2013, Scarf et al., 2019) and 10 case series (Alcaraz-Vidal et al., 2024, Bolten et al., 2016, Galera-Barbero et al., 2021, Geerts et al., 2014, Maimburg et al., 2018, McMurtrie et al., 2009, Rowe et al., 2013, Suzuki et al., 2016, Sweet et al., 2022, White et al., 2020) with 25,809 participants contributed data on transfer to hospital during labour or after birth for planned home births (Appendix 4.10).

Outcomes of meta-analyses of cohort studies are presented in Supplementary file (Appendix 5), Figures 19a-27b.

Meta-analyses showed a significantly higher risk of peri/neonatal mortality (five studies, Brocklehurst et al., 2011, Davis et al., 2011, Hermus et al., 2017, Homer et al., 2019, Lindgren et al., 2008a); OR 1.70 (95% CI 1.05 to 2.74) (Figure 20a), and neonatal mortality (four studies, Brocklehurst et al., 2011, Davis et al., 2011, Homer et al., 2019, Lindgren et al., 2008a); OR 2.71 (95% CI 1.46 to 5.01) (Figure 21a) for home births vs obstetric unit births.

Peri/neonatal mortality in planned home births in case series varied between 0 and 5.2 per 1,000 and was 0.8 per 1,000 in the largest study (de Jonge et al., 2015, 466,112 neonates). Neonatal mortality varied between 0 and 5.2 per 1,000 and was 0.4 per 1,000 in de Jonge et al. (2015).

Transfer rates varied between 10.7% and 33.3% for home births and was 20.7% in the largest study (Rowe et al., 2013, 16,619 women). Urgent or potentially urgent transfer occurred in 3.4-4.9% (three studies).

Planned births in freestanding midwifery units (FMU) vs obstetric unit births

Two cohort studies (Brocklehurst et al., 2011, Farry et al., 2019) with 35,195 participants contributed outcome data in FMU births vs obstetric unit births (Supplementary file, Appendix 5, Figures 28a to 36b). No case series reported data on mortality. One cohort study (Farry et al., 2019) and one case series (Rowe et al., 2013) with 12,311 participants contributed data on transfer to hospital during labour or after birth for FMU births (Appendix 4.10).

Outcomes of meta-analyses of the cohort studies are presented in Supplementary file (Appendix 5), Figures 28a to 36b. No significant differences were seen in peri/neonatal mortality or neonatal mortality for FMU births vs obstetric unit births (Supplementary file, Appendix 5, Figures 29 and 30).

Transfer rates were 21.7% and 21.9%, respectively for FMU births. Potentially urgent transfer was reported in 6.5% (one study).

Sensitivity analyses

Two cohort studies (Brocklehurst et al., 2011, Hermus et al., 2017) with 38,332 participants contributed outcome data for births outside hospital integrated in ordinary health care vs obstetric unit births. In the sensitivity analyses all outcomes were based on ORs as AORs were not feasible due to few events across the included studies. Outcomes of meta-analyses are presented in Supplementary file (Appendix 5), Figures 37-45. No significant difference was seen in peri/neonatal mortality for births outside hospital integrated in ordinary health care vs obstetric unit births.

Planned sensitivity analyses concerning outcomes in different countries, settings with one or two midwives assisting at home/FMU births were not possible to perform due to lack of definition of health care systems.

10 Ethical aspects

The benefit-risk balance of planned home/FMU birth compared with obstetric unit births remains uncertain due to limited high-quality evidence. While meta-analyses of cohort studies suggest potential maternal benefits for low-risk births, such as less frequent maternal ICU admissions and severe perineal tears there was a significantly higher risk of peri/neonatal mortality in planned home/FMU births.

If planned home birth and births in FMU were to be integrated into routine maternity care, further ethical aspects must be considered.

The principle of Human Dignity

Respect for human dignity involves recognising the inherent worth of every individual and upholding their rights and integrity. In maternity care, this includes respecting women's autonomy and their right to make informed choices about childbirth. The European Court of Human Rights has clarified, in *Ternovszky v. Hungary* (2010), that the right to private life encompasses a woman's right to decide on the circumstances and place of birth. This interpretation does not imply an obligation for public health services to fund births outside hospitals, but it does require that such choices are respected and not unduly restricted.

The Principle of Needs and Solidarity

Healthcare priorities should be guided by the Ethical Platform developed by the Swedish Parliament, which states that those with the greatest needs should be prioritised over those with lesser needs. The needs are normally associated with the severity of the condition. Healthy women with low-risk births represent a population with low clinical severity. Introducing planned home/FMU births would require substantial staffing commitments, including the availability of two experienced midwives on an on-call basis. In a maternity system where it is already challenging to ensure continuous, one-to-one care within hospital settings, this additional demand could strain existing resources and lead to displacement effects. Allocating significant healthcare resources to a low-risk

group must therefore be carefully evaluated against the imperative to prioritise patients with greater medical needs.

The Principle of Cost-Effectiveness

Healthcare interventions must deliver clear and demonstrable benefits relative to their cost and resource requirements. Although planned home/FMU births may offer benefits for women — such as fewer medical interventions — the scientific evidence regarding both maternal outcomes and outcomes for children is not robust. Under the Swedish Patient Safety Act (2010:659) (Patientlag, 2010), all publicly funded care must be based on science and proven experience, and new models of care must clearly demonstrate safety and effectiveness. Planned home/FMU births may be associated with increased risk for peri/neonatal death. Moreover, the implementation of planned home/FMU births within publicly funded healthcare must be carefully assessed for its potential to divert resources from areas with greater clinical need. If the implementation of such models compromises the overall capacity of the maternity care system, this would conflict with the principle of cost-effectiveness.

The Principle of Autonomy

Respect for patient autonomy is fundamental in Swedish healthcare. Under the Swedish Patient Act (2014:821) (Patientlag, 2014), patients have the right to participate in care decisions and to receive individualised and balanced information. Women considering planned home/FMU births must therefore be provided with comprehensive information on both the potential benefits and risks. Legally, the fetus does not possess individual rights under the Swedish law before birth; the woman is the sole rights-bearing individual. However, healthcare providers retain an ethical duty to consider the wellbeing of the unborn child.

Limited access to regulated, midwife-assisted out-of-hospital births may lead some women to choose unassisted home births, sometimes driven by prior negative hospital experiences (Johansson et al., 2023).

11 Organisational aspects

Time frame for the putative introduction of the new health technology

Planned home births and births in FMUs already exist in Sweden, though in a limited scale and primarily outside the public healthcare system. Broader adoption depends on political decisions informed by ongoing discussions on medical safety, resource allocation, and healthcare priorities.

Present use of the technology in other hospitals in Region Västra Götaland

In VGR, no public hospitals offer home birth and there is no public FMU. However, in Gothenburg, *BB Gårda* – Sweden's first privately owned FMU – has provided both home and FMU birth for low-risk births since 2023 (Barnmorsketeamet, 2025). While women pay out-of-pocket for services at *BB Gårda*, any complications requiring hospital treatment are covered by public healthcare.

Consequences of the new health technology for personnel

The introduction or expansion of planned home and FMU births within the Swedish healthcare system would significantly impact healthcare personnel, particularly midwives, obstetricians, neonatologists, and emergency medical teams.

If home and FMU births are formally integrated into the healthcare organisation, this would allow for the use of a shared medical record system, which could improve communication, coordination, and patient safety across care settings. Any changes to roles or scheduling would need to be aligned with broader service planning.

Consequences for other clinics or supporting functions at the hospital or in Region Västra Götaland

Publicly funded home and/or FMU births in VGR would affect antenatal care, maternity units, ambulance services and potentially neonatal care, requiring adjustments in staffing, coordination, and emergency preparedness.

Antenatal clinics should continue using established risk assessment to ensure that only women with expected low-risk births are offered home and FMU births. Prenatal counselling should provide balanced, evidence-based information.

Dedicated home birth/FMU teams would need to be established, with targeted training in close collaboration with obstetricians, anaesthesiologists, and neonatologists. Staffing models must ensure sufficient capacity across both hospital and community-based care, particularly during nights, weekends, and holidays. Redistribution of midwives may challenge staffing at the hospital unless addressed through recruitment and retention.

Obstetricians would provide clinical backup and contribute to multidisciplinary planning, including standardised transfer procedures and emergency management. These responsibilities are not expected to require substantial additional staffing but may necessitate workflow adjustments.

Ambulance services play a crucial role in facilitating timely and safe transfers during complications. While planned home births do not appear to increase overall ambulance use (Blix et al., 2014), the system must remain prepared for rare emergencies requiring rapid hospital access. Time to hospital from the intended birthplace needs to be considered when counselling pregnant women.

Neonatal teams should be prepared to stabilise and manage newborns transferred from home or FMU settings, with strong inter-service coordination essential for safe care.

Potential displacement effects should also be considered. Establishing publicly funded home/FMU births without proportional increase in staffing may draw experienced midwives from the hospital, potentially affecting the availability and quality of care for higher-risk patients and possibility for educating the next generation. Similar effects could occur if ambulance or neonatal resources are diverted for rare but urgent transfers. Proactive workforce planning and resource allocation will be essential to minimise these risks.

12 Economic aspects

Present costs of currently used technologies

Current costs per birth at Sahlgrenska University hospital range largely between 35.7 and 156 thousand SEK, depending on the need of care, ranging from vaginal uncomplicated birth to very complicated caesarean section, see table 3.

Table 3. Current costs per birth at Sahlgrenska University Hospital

Type of birth	Costs
Vaginal birth, uncomplicated	35,706 SEK
Vaginal birth, complicated	64,369 SEK
Vaginal birth, very complicated	96,575 SEK
Caesarean section, uncomplicated	89,327 SEK
Caesarean section, complicated	120,082 SEK
Caesarean section, very complicated	155,539 SEK

Source: Region Västra Götaland 2024.

According to the FMU BB Gårda a "care package birth" costs SEK 65,000 for a primiparous woman and SEK 55,000 for a multiparous woman. Midwives offering home birth in VGR charge SEK 35,000 per birth.

Expected costs of the new health technology

In Region Västra Götaland, up to 3,522 of the yearly 15,000 births can be classified as low-risk births. Among these births, 1,679 involve primiparous and 1,843 involve multiparous women. Based on data from Denmark and Norway, the actual number of eligible women who would choose a home or FMU birth is expected to be much lower (Blix et al., 2016). Although some studies have attempted to calculate the costs associated with home or FMU births, these calculations remain uncertain due to the difficulty of accurately assessing the risk of rare but severe maternal or neonatal outcomes. Further, several studies did not take the costs for emergency standby pre-hospital-, obstetric-, and neonatal care at the hospital into consideration (Schröder et al., 2012, Scarf et al., 2020, Scarf et al., 2021). These costly standby activities, including e.g. operation theatres, on-call physicians and -nurses and intensive care beds need to be available for both home birth, birth at a FMU as well as obstetric unit births, and their costs should therefore be assigned equally to all birth settings. In some of the reviewed studies, midwifery costs were calculated based on the number of hours a midwife assists the mother, without accounting for broader organisational resources required to operate such services (Scarf et al., 2020). In other words, the costs represent the reimbursement rates paid the funding authority (Schröder et al., 2012, Scarf et al., 2021).

It should be noted that home and FMU births are not independent of hospital services, as they are dependent on hospital-based activities such as emergency patient transfers and on-call support. In integrated settings, some resources could be planned and used by both home/FMU and obstetric unit settings (e.g. training, administration) which may lead to lower overall costs per home/FMU birth.

Costing approach in VGR

Introducing home or FMU birth in VGR would incur costs related to materials, transportation for midwives in the case of home birth, and suitable facilities in the case of FMU births. Staffing and emergency transfer costs are difficult to estimate as transfer rates largely depend on the proportion of primiparous versus multiparous women and on patient selection criteria, as shown in this report. Staffing represents the primary cost factor in the implementation of planned home or FMU births. Within the current staffing structure in VGR hospitals, it is not feasible to offer home or FMU births without significant adjustments. Hospital midwives are rarely responsible for only one low-risk patient in active labour; instead, they typically care for multiple patients and perform several concurrent tasks, such as monitoring women who recently gave birth, supporting women undergoing induction of labour, and managing clinical documentation. Under these conditions, it is not possible to reassign two hospital-based midwife to attend a home birth on demand without compromising other parts of the service. Moreover, women planning home births typically belong to a low-risk group and are therefore given lower clinical priority compared to women with greater medical needs, particularly in situations of staff shortages. So far, no cost-effectiveness calculations from alternative models, such as the continuity-of-care system used in the Swedish initiative '*Min Barnmorska*' or the nationally organised home birth model in Denmark, have yet been published (Karolinska Universitetssjukhuset and SLO BMM, 2023, Lindgren et al., 2014).

Midwives working in an FMU would likely have additional responsibilities beyond attending births, such as providing antenatal and postnatal care. *BB Gårda*, currently the only FMU operating in Sweden, lists the cost of a "care package birth" on its website as SEK 65,000 for primiparous women and SEK 55,000 for multiparous women (Barnmorsketeamet, 2025). These packages include further consultations, that are, however, similarly offered free of charge to women who participate in ordinary antenatal care and give birth in hospital settings. The birth itself includes on-call access to a midwife with 24-hour availability from gestational week 38+0 to 41+6, and the presence of two midwives during birth. These packages include further consultations, that are, however, similarly offered free of charge to women who participate in ordinary antenatal care and give birth in hospital settings.

Total change in costs

It is not possible to calculate a total change in costs for including home births in public health care. Cost estimations are complicated by the unknown number of women who would opt for home or FMU births.

Review of literature on cost analysis

Five studies meeting the inclusion criteria in terms of study design, quality of cost estimation, directness, and risk of bias, were included in the economic analysis (Appendix 6, Table 4). The included studies were conducted in Australia, England, the Netherlands, Norway and Italy. Although all studies were of good quality, their findings were not fully comparable due to differences in healthcare settings. Among them, Scarf et al. (2020) reported slightly higher costs for home births (2.5% higher), while the other studies reported lower costs for home births, ranging from 10% to 61.4% in comparison with the costs of birth in an obstetric unit (Table 4).

It should be noted that cost analysis studies differ in several aspects, including their analytical perspective (e.g., healthcare or societal), the costing methods used—such as the top-down approach, which allocates total health service expenditures to individual services using aggregate data, or the bottom-up (micro-costing) approach, which identifies, measures, and values each individual resource utilised (Drummond et al., 2015). They also vary in their data sources (primary data collection versus secondary databases) and in the types of cost components included. For instance, training costs are included in Schröder et. al. (2012), but not in Scarf et al. (2020), which means that the unit cost cannot be compared across studies. In summary, it can be noted that most of the studies collected cost data on implementation costs of planned home birth or birth at FMU while lacking costs of preparation including training, guidelines development, etc. Despite limitations, we have considered the following studies for inclusion which provided a certain level of detail of the costs of birth at home and in an obstetric unit.

Table 4. Summary of costs of birth at home and in an obstetric unit, a relevant literature review

Reference & reporting country	Costing perspective	Unit of reported costs	Cost of treatment (local currency)			Difference with obstetric unit costs		Quality of cost estimation
			Home	FMU*	Obstetric unit	Home	FMU*	
Scarf et. al., 2021, Australia	Public sector perspective	Mean	AUS\$ 4,748	N.A.**	AUS\$ 5,463	AUS\$ 715 or 13.1% lower	N.A.**	Good
Scarf et. al., 2020, Australia	Health care perspective	Median (Range)	AUS\$ 2,150. (1,486-5,015)	AUS\$ 2,100 (1,555-3,808)	AUS\$ 2,097 (1,545-3,949)	AUS\$ 5,277 or 2.5% higher	*AUS\$ 3.2 or 0.15% lower (no difference)	Good
Schröder et. al., 2012, England	Healthcare perspective	Mean (Standard Error)	£1,066 (8.9)	£14,35 (13.5)	£1,631 (10.1)	£565 or 34.4% lower	*£196 or 12% lower	Good
Joranger et. al., 2024, Norway	Societal	Mean (Credible Interval)	Without on-call €1,872 (1,694 to 2,071) With on-call	N.A.**	€4,077 (3,575 to 4,615)	Without on-call €2,205 or 54% lower With on-call	N.A.**	Good

			€5,531 (5,171- 5,906)			€1,454 or 35.7% higher		
Cicero et al., 2022, Italy	Third-payer (National Health Services)	Mean	€707	€1,042	€1,832	€1,124 or 61.4% lower	€789 or 43.1% lower	Good

* Freestanding Midwifery Unit, **Not applicable

A few studies accounted for on-call costs of midwives for home birth. Cicero et al. (2022) considered on-call costs only in the private regime of out-of-hospital births, though the cost specific to on-call was not reported separately. According to Joranger et al. (2024), a planned home birth costs 54% less than a low-risk obstetric unit birth (€1,872 for planned home birth and €4,077 for birth at hospital) when on-call costs are not included. However, including on-call costs, it increased by 35.7% (€5,531 at home vs €4,077 at obstetric unit). When comparing the costs (without on-call costs) between FMUs and obstetric units, the reported studies found lower costs in FMUs, by 0.10% and 43.1%, respectively. However, while including on-call costs, it increased by 35.7% (€5,531 at home vs €4,077 at hospital).

All countries, included in the review of cost analysis above, have publicly funded healthcare systems, however the care process itself may work differently than in Sweden. Results from the reviewed studies may thus not be transferable to the Swedish context.

In Sweden, Caseload midwifery is a model where a primary midwife (within a small team) provides continuous care to a group of pregnant women through the entire maternity pathway - pregnancy, childbirth, and postnatal care (Wassén et al., 2022). Each midwife is responsible for a specific "caseload" – typically about 40 women per year per midwife. The midwife follows these women throughout their care journey, often being on flexible schedules and on-call during births. On the contrary, standard care in Sweden today means that the pregnant woman meets the same midwife during most visits to maternity care before and after the birth, while labour and postnatal care take place at the hospital with other midwives. A woman who receives caseload midwifery care incurs an additional cost of 10,000 SEK, assuming a decrease in caesarean sections, or 12,000 SEK if no such reduction occurs. In VGR, if 10–30% of pregnant women (out of approximately 19,000 births per year) were to utilise the caseload model, the additional annual cost would amount to 19–67 million SEK. This suggests that the caseload model would result in a net increase in costs, although some reallocation of existing resources cannot be excluded. However, due to the lack of quality-adjusted outcome data, a full cost-effectiveness analysis could not be performed.

The Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU) conducted a review of economic studies in the area of home birth (SBU, 2023d). The PICO of that review was not exactly the same as in the current review and therefore, some studies which were reviewed by the former one have not been included here. However, our findings are mostly in the same line of the review by SBU, informing that birth at home is often cost-saving. However, inclusion of on-call costs as well as training, guidelines, and resources needed at the hospital etc. may increase the costs for

home birth. Like SBU stated, it should be noted that the knowledge from other countries can only be used with necessary adjustments as the healthcare systems are different from that of Sweden.

13 Discussion

Summary of main results

This HTA analysis compared maternal and child mortality and severe morbidity in planned expected low-risk home/FMU births compared to obstetric unit births. Regarding outcomes critical for decision making, no maternal deaths were reported. Maternal admission to intensive care may be reduced in home/FMU births.

Planned expected low-risk home/FMU births may be associated with an increased risk of peri/neonatal and neonatal mortality compared to planned obstetric unit births with no difference in neonates with a low Apgar score. Several critical outcomes for the children were not reported in any of the included articles.

Regarding outcomes important for decision making, home/FMU births may be associated with no difference in postpartum haemorrhage requiring transfusion, a lower rate of third- and fourth- degree perineal tears, and a lower rate of NICU admissions compared to obstetric unit births.

For outcomes less important for decision making, home/FMU birth may be associated with a lower rate of postpartum haemorrhage, and a lower rate of intrapartum caesarean section.

The certainty of evidence for conclusions was low for all outcomes (GRADE ⊕⊕OO) except for maternal mortality where it was very low (GRADE ⊕OOO).

Transfer rates to the hospital were between 9.3 to 33.3%, and higher for nulliparous women (14.4-60.6%).

The outcome postpartum depression was not identified in any of the included studies.

In summary, although planned home and FMU births may offer maternal benefits in terms of reduced intervention rates, an increase in peri/neonatal mortality may occur.

Overall completeness and applicability of evidence

Scientific evidence on planned home/FMU births remains limited due to the complete absence of RCTs. The current evidence is based exclusively on observational studies, which are subjected to various forms of bias.

Selection bias is a key concern in non-randomised studies (Deeks et al., 2003). As reported in the available studies, women choosing home/FMU birth settings are more likely to be multiparous, native speakers, have higher education levels and socioeconomic status, and fewer medical or psychosocial risk factors, thus residual confounding is likely (Brocklehurst, 2011). Further, outcome reporting might be affected by detection and reporting bias (Núñez and Matthews, 2025). Diagnoses based on

subjective clinical assessment such as postpartum haemorrhage, vaginal tears, or low Apgar scores may be underdiagnosed or underreported due to differences in clinical surveillance, documentation standards, and implications for care, such as the need for transfer. This is reflected in findings that show a reduced risk of postpartum haemorrhage in home/FMU births, without a corresponding decrease in blood transfusion rates (a more objective measure). Similarly, while no difference is observed in the risk of low Apgar scores, an increased risk of perinatal or neonatal mortality (so called hard endpoints) has been reported in home/FMU births. Findings of reduced risk of intrapartum caesarean section rates and NICU admissions must be considered in the light of increased peri/neonatal mortality in the home/FMU birth group. This is the reason for the outcome intrapartum caesarean section being categorised as "*less important for decision-making*". The optimal rate of intrapartum caesarean sections in low-risk populations remains unknown. While unnecessary interventions should be avoided, caesarean sections must be performed when medically indicated. Therefore, the rate of intrapartum caesarean sections should be interpreted in conjunction with other indicators, such as rates of infant asphyxia or mortality.

Most studies lack the power to evaluate rare but serious outcomes, such as perinatal or neonatal mortality, leading to substantial statistical imprecision.

Some of the eligible studies have been conducted in countries where home births/FMU births are integrated into the publicly funded healthcare system, with established protocols for collaboration and emergency transfer. Factors such as availability of midwives, geographical distances, and emergency infrastructure may influence outcomes.

Agreements and disagreements with other studies and systematic reviews

Three systematic reviews have so far evaluated the safety and outcomes of planned home/FMU births: Hutton et al. (2019) on perinatal and neonatal mortality, Scarf et al. (2018) on perinatal outcomes including stillbirth and early neonatal death, and Reitsma et al. (2020) on maternal outcomes and obstetric interventions.

This HTA analysis found a significantly increased rate of peri/neonatal and neonatal mortality in planned home/FMU births compared with obstetric unit births among women with a low-risk birth. These findings contrast with previous systematic reviews by Hutton et al. (2019) and Scarf et al. (2018). However, these reviews did not define a strict low-risk population as defined in the current PICO, thus increasing the risk for selection bias. Further, the comparison group was not obstetric unit birth but obstetric unit birth including AMU births.

In this HTA, preplanned subgroup analyses of primiparous and multiparous women, showed a significantly higher peri/neonatal mortality for planned home births compared with obstetric unit births in primiparous women, OR 2.12 (95% CI 1.02 to 4.44), while no significant difference was noted for multiparous women, OR 1.18 (95% CI 0.57 to 2.47). However, no data were available for meta-analysis of adjusted data, and 95% CI was wide, indicating imprecision of the results. Further, the ORs were not compared statistically, to investigate if they differed significantly.

The systematic review by Hutton et al. (2019), reported no statistically significant difference in peri/neonatal mortality between planned home and obstetric unit births in well-integrated healthcare systems for neither nulliparous nor multiparous women. However, in less integrated systems, Hutton reported higher point estimates – particularly among nulliparous women – though the wide confidence intervals limited the certainty of these findings. Thus, the elevated mortality risk observed in our HTA may reflect inclusion of studies from less integrated systems, such as Sweden and Australia.

Similarly, the systematic review by Scarf et al. (2018) found no significant difference in stillbirth and early neonatal death across birth settings, with odds ratios near 1.0. They neither found significant differences in Apgar scores nor NICU admissions, suggesting comparable short-term neonatal outcomes. In contrast, our HTA found a consistent, though imprecise, increased neonatal mortality in planned home/FMU births in the defined low-risk population. Scarf et al. (2018) included studies with broader risk profiles and did not stratify results by the level of healthcare system integration, potentially obscuring setting-specific risks. Their analysis focused only on early neonatal mortality, whereas our HTA also considered deaths up to 28 days. Additionally, studies not captured in Scarf’s review, including a more recent Australian cohort (Homer et al., 2019) and an earlier Swedish study conducted in a non-integrated setting (Lindgren et al., 2008a) - may have contributed to the observed trend.

Our findings should also be compared with the recent assessment by the Swedish Agency for Health Technology Assessment and Assessment of Social Services (*SBU*, 2023b, 2023c) based on two systematic reviews: Hutton et al. (2019), covering peri/neonatal mortality, and Reitsma et al. (2020), covering maternal outcomes and obstetric interventions. The SBU concluded that for low-risk primiparous and multiparous women with uncomplicated singleton pregnancies at term, planned midwife-attended home birth may not differ significantly from planned obstetric unit birth in terms of perinatal or neonatal mortality, low Apgar score, or neonatal care admission. However, due to the low certainty of evidence, an increased risk cannot be ruled out. Furthermore, the available data was insufficient to assess several important maternal outcomes, including severe perineal tears and postpartum haemorrhage (*SBU*, 2023b, 2023c).

Unlike the two reviews, which included mixed-risk populations without clear risk stratification, our HTA applied stricter criteria to define low-risk births. By including a broader range of cohort studies from both integrated and less integrated healthcare systems, our analysis revealed a more consistent increase in peri/neonatal mortality, underscoring the importance of risk-specific evidence and system integration when assessing the safety of planned home or FMU births.

For maternal outcomes, our findings were more closely aligned with previous reviews. Both Scarf et al. (2018) and Reitsma et al. (2020) reported significantly lower rates of obstetric interventions in planned home/FMU births. In line with our HTA, this included a lower rate of intrapartum caesarean sections. Reitsma also found no increased risk of postpartum haemorrhage or ICU admissions and identified a lower risk of third- and fourth- degree perineal tears, especially among multiparous women. Our HTA similarly found fewer interventions and lower risk of severe perineal trauma in planned home/FMU births, while showing no significant difference in maternal ICU admission or postpartum haemorrhage requiring transfusion.

In summary, these comparisons suggest that while lower maternal risks of planned home/FMU birth are consistently supported across reviews, conclusions regarding neonatal safety are more context sensitive and depend on the study population's risk profile. These differences highlight the impact of selection bias in observational studies and emphasise the need to interpret evidence on birth settings within the context of the specific healthcare system.

Implications for research

To determine the differences concerning mortality and severe morbidity for mother and child in home and FMU births compared to obstetric unit births, well-designed large observational studies are needed. Because many women have strong preferences regarding their place of birth and serious outcomes are rare, randomised studies are difficult in this context. High-quality observational evidence – particularly from prospective cohort studies – offers the most realistic approach to assessing safety. Future research should prioritise carefully designed studies with clear definitions of low-risk populations, rigorous risk stratification, robust adjustment for confounding factors, and comprehensive reporting of both neonatal and maternal outcomes preferably with hard endpoint measures. Large registry-based studies can also contribute valuable data, particularly in countries where home birth is less integrated into the healthcare system. In the Swedish context, the introduction of the new procedure codes will facilitate register-based follow-up of out-of-obstetric unit birth.

14 Future perspectives

Scientific knowledge gaps

As discussed above, important scientific knowledge gaps remain. Most notably, it is unclear whether planned home/FMU births offer similar safety in terms of neonatal outcomes compared with obstetric unit births, in contrast this report found a higher peri/neonatal mortality among planned home/FMU births. The current evidence base is largely observational and subjected to limitations such as selection, detection and reporting bias and inconsistent outcome definitions. Many studies lack adequate stratification by parity and risk level, and results are often imprecise due to low event rates.

Furthermore, few studies provide data specific to healthcare contexts comparable to Sweden, which limits the applicability of international findings to the national setting.

Ongoing research

A search in Clinicaltrials.gov and WHO ICTRP (<https://www.who.int/clinical-trials-registry-platform/identified>) (22 November 2024) identified 20 and 8 trial records, respectively. None of these ongoing studies fulfilled the current PICO.

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Declaration of interests

The authors have no conflicts of interest related to the content of this HTA.

Project time

The HTA was accomplished during the period of 2024-09-18 to 2025-11-19.
Literature searches were conducted 2024-05-30, and updated 2025-03-14.

Components of this Health Technology Assessment

- ✓ Description of methods
- ✓ PICO
- ✓ Full literature search
- ✓ Flowchart
- ✓ Selection based on relevance
- ✓ Quality assessment
- ✓ Data tabulation
- ✓ Evidence synthesis
- ✓ Meta-analysis
- ✓ Certainty of evidence by GRADE
- ✓ Summary
- ✓ Economical aspects
- ✓ Organisational aspects
- ✓ Ethical aspects
- ✓ Ongoing studies
- ✓ Excluded articles
- ✓ Participation of experts
- ✓ External review
- ✓ Knowledge gaps identified
- ✓ Conflict of interest reported

Appendix 1: PICO, study selection, search strategies, and references

Question(s) at issue:

What are the differences concerning mortality and severe morbidity for mother and child in high-income countries when comparing planned birth outside hospital (home birth or birth at FMU) with planned birth at hospital (obstetric unit) in low-risk birth?

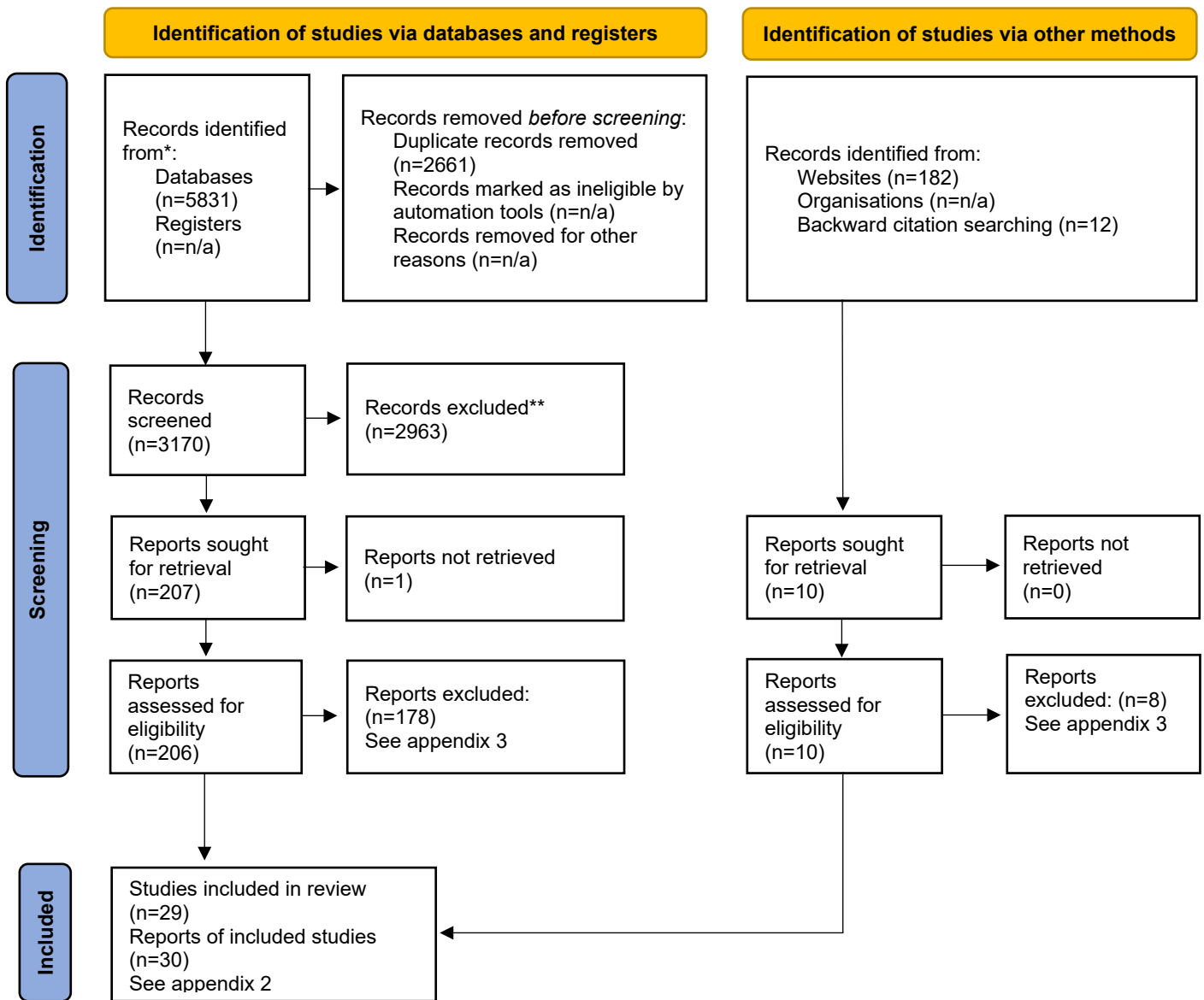
PICO: (*P=Patient I=Intervention C=Comparison O=Outcome*)

PICO	
P	<p>Healthy women with normal pregnancy and expected low-risk birth (as defined by the authors) in high income countries (according to OECD definition) with ICM-certified midwife education or similar (before 2011).</p> <p><i>Low-risk birth=singletons, cephalic position, spontaneous onset of labour, normal blood pressure, no previous caesarean section, full term (w 37+0 – 41+6)¹</i></p>
I	Planned birth outside hospital, led by midwife at home (home birth) or in a free-standing midwifery unit (FMU birth)
C	Planned birth at hospital, where both obstetricians and midwives work in a team, and with ability to perform emergency interventions, including surgery (obstetric unit birth)
O	<p><u>Outcomes critical for decision-making:</u></p> <p><i>Maternal:</i> Maternal mortality (within 42 days) Admission to intensive care unit</p> <p><i>Infant:</i> Peri/neonatal mortality (the fetus alive at first assessment at the unit in association with birth). Includes intrapartum mortality, neonatal mortality within 7 days after birth or neonatal mortality up to 28 days after birth</p> <p>Neonatal mortality. Includes neonatal mortality within 7 days after birth or neonatal mortality up to 28 days after birth</p> <p>Adverse infant events (short term), defined as: Therapeutic hypothermia Apgar score <4 at 5 min² Neonatal seizures Mechanical ventilation Meconium aspiration syndrome Hypoxic Ischemic Encephalopathy (HIE) 2-3 Resuscitation</p> <p>Length of stay at neonatal ward/NICU >72 hours</p> <p><u>Outcomes important for decision-making:</u></p> <p><i>Maternal:</i> Adverse maternal events (short term) defined as: Postpartum haemorrhage requiring blood transfusion² Perineal tears grade 3 or 4 Postpartum depression</p> <p><i>Infant:</i> Admission to the neonatal unit/NICU</p>

<p><u>Outcomes less important for decision-making:</u> Postpartum haemorrhage >1000 ml³ Intrapartum caesarean section⁴ Transfer to hospital from home birth (mother or child) (No GRADE since no control group)</p> <p>Comment to O: Apgar score <7 at 5 min is reported as an Important outcome as no studies reported Apgar score <4 at 5 min.</p> <p>¹ According to LÖF's classification. Studies allowing up to 5% post-term births (≥42+0) were accepted as labour starting at 41+6 gestational weeks will in some cases lead to birth after 42+0 gestational weeks.</p> <p>² In case this Apgar score is not available, studies presenting other Apgar scores will be accepted.</p> <p>³ In case this amount of haemorrhage is not available, studies presenting other amounts will be accepted.</p> <p>⁴ See discussion</p>	
Study design	
Systematic reviews –commented upon, 2015-	
Randomised controlled trials	
Non-randomised controlled studies (≥100 patients in each comparison group)	
Case series and case reports for maternal and neonatal mortality and transfer to hospital	
Publication year	Language
2005-	English, Danish, Norwegian, Swedish
Planned subgroup analyses	
Primiparous and multiparous women	
Home birth compared with birth at hospital, and birth at FMU compared with obstetric unit birth	
<u>Sensitivity analyses:</u>	
Concerning critical outcomes in different countries	
One or two midwives	
Birth outside hospital is integrated in ordinary health care	

Selection process – flow diagram

PRISMA 2020 flow diagram for new systematic reviews which included searches of databases, registers and other sources



From: Page et al., 2021

Search strategies

Database: Ovid MEDLINE(R) ALL (OvidSP)

Date: 30 May 2024

No. of results: 1,540

Search updated: 14 Mar 2025, 92 results

#	Searches	Results
1	exp *Home Childbirth/	2252
2	(homebirth* or ((birth* or childbirth* or delivery or deliveries) adj3 (home or out-of-hospital* or non-hospital* or out-of-clinic* or non-clinic* or out-of-institution* or non-institution* or out-of-facilit* or non-facilit*))).ab,kf,ti.	5349
3	1 or 2	6244
4	exp Nurse Midwives/	7606
5	midwi*.ab,kf,ti.	31326
6	planned.ab,kf,ti.	107482
7	4 or 5 or 6	141082
8	3 and 7	1664
9	exp *Birthing Centers/	668
10	(birthcenter* or birthcentr* or birth-center* or birth-centr* or birthing center* or birthing centr* or community birth*).ab,kf,ti.	1210
11	9 or 10	1524
12	4 or 5	34351
13	11 and 12	583
14	((((midwi* adj3 unit) or (midwi* adj3 units) or (midwi* adj3 cent*) or (midwi* adj3 clinic) or (midwi* adj3 clinics)) and (birth* or childbirth* or delivery or deliveries)).ab,kf,ti.	701
15	8 or 13 or 14	2566
16	(comment or editorial or letter).pt.	2250076
17	15 not 16	2431
18	limit 17 to (danish or english or norwegian or swedish)	2334
19	limit 18 to yr="2005 -Current"	1540

exp/ = term from the Medline controlled vocabulary, including terms found below this term in the MeSH hierarchy

adj3 = next to each other, in any order, up to 2 word(s) in between

.ab,kf,ti. = abstract, author keyword and title

.pt. = publication type

***** = truncation of word for alternate endings

Database: Embase 1974 to 2024 May 29 (OvidSP)

Date: 2024-05-30

No of results: 1868 ref.

Search updated: 14 Mar 2025, 89 results

#	Searches	Results
1	exp *home delivery/	2169
2	(homebirth* or ((birth* or childbirth* or delivery or deliveries) adj3 (home or out-of-hospital* or non-hospital* or out-of-clinic* or non-clinic* or out-of-institution* or non-institution* or out-of-facilit* or non-facilit*))).ab,kf,ti.	6555

3	1 or 2	7305
4	exp midwife/	36998
5	"midwi*".ab,kf,ti.	35224
6	planned.ab,kf,ti.	194789
7	4 or 5 or 6	241907
8	3 and 7	2310
9	exp *maternity ward/	1057
10	(birthcenter* or birthcentr* or birth-center* or birth-centr* or birthing center* or birthing centr* or community birth*).ab,kf,ti.	1464
11	9 or 10	2308
12	4 or 5	48230
13	11 and 12	809
14	((midwi* adj3 unit) or (midwi* adj3 units) or (midwi* adj3 cent*) or (midwi* adj3 clinic) or (midwi* adj3 clinics)) and (birth* or childbirth* or delivery or deliveries).ab,kf,ti.	845
15	8 or 13 or 14	3532
16	limit 15 to (article or article in press or conference paper or note or "review")	2907
17	limit 16 to (danish or english or norwegian or swedish)	2749
18	limit 17 to yr="2005 -Current"	1868

exp/ = term from the Embase controlled vocabulary, including terms found below this term in the Emtree hierarchy

adj3 = next to each other, in any order, up to 2 word(s) in between

.ab,kf,ti. = abstract, author keyword and title

* = truncation of word for alternate endings

Database: The Cochrane Library (Wiley)

Date: 30 May 2024

No of results: 221 ref

Search updated: 14 Mar 2025, 11 results

Cochrane reviews: 10

Cochrane protocols: 0

Trials: 211

Editorials: 0

Special collections: 0

Clinical answers: 0

ID	Search	Hits
#1	MeSH descriptor: [Home Childbirth] explode all trees	61
#2	(homebirth* OR ((birth* OR childbirth* OR delivery OR deliveries) NEAR/2 (home OR "out of hospital" OR "out of hospitals" OR "non hospital" OR "non hospitals" OR "out of clinic" OR "out of clinics" OR "non clinic" OR "non clinics" OR "out of institution" OR "out of institutions" OR "non institution" OR "non institutions" OR "out of facility" OR "out of facilities" OR "non facility" OR "non facilities"))):ti,ab,kw (Word variations have been searched)	609
#3	#1 OR #2	609
#4	MeSH descriptor: [Nurse Midwives] explode all trees	137
#5	(midwi*):ti,ab,kw (Word variations have been searched)	3306
#6	(planned):ti,ab,kw (Word variations have been searched)	84663
#7	#4 OR #5 OR #6	87520

#8	#3 AND #7	148
#9	MeSH descriptor: [Birthing Centers] explode all trees	20
#10	(birthcenter* OR birthcentr* OR "birth center" OR "birth centers" OR "birth centre" OR "birth centres" OR "birthing center" OR "birthing centers" OR "birthing centre" OR "birthing centres" OR "community birth" OR "community births" OR "community birthing"):ti,ab,kw (Word variations have been searched)	100
#11	#9 OR #10	100
#12	#4 OR #5	3306
#13	#11 AND #12	28
#14	((midwi* NEAR/2 unit) OR (midwi* NEAR/2 units) OR (midwi* NEAR/2 cent*) OR (midwi* NEAR/2 clinic) OR (midwi* NEAR/2 clinics)) AND (birth* OR childbirth* OR delivery OR deliveries)):ti,ab,kw (Word variations have been searched)	212
#15	#8 OR #13 OR #14	377
#16	(clinicaltrials OR trialsearch):so	507199
#17	(conference proceeding):pt	242579
#18	#16 OR #17	749778
#19	#15 NOT #18	254
Limit search to publication Year 2005-		221

MeSH descriptor: [] explode all trees = term from the MeSH controlled vocabulary, including terms found below this term in the hierarchy
NEAR/2 = Next to each other, in any order, up to 0 / 3 word(s) in between
:ti,ab,kw = title, abstract and author keywords
:pt = publication type
:so = source
***** = truncation of word for alternate endings

Database: CINAHL (EBSCOhost)

Date: 30 May 2024

No. of results: 1939 ref.

Search updated: 14 Mar 2025, 71 results

#	Query	Limiters/Expanders	Results
S17	S8 OR S13 OR S14	Limiters - Publication Date: 20050101-20241231; Language: Danish, English, Norwegian, Swedish Expanders - Apply related words; Apply equivalent subjects Search modes - Find all my search terms	1,939
S16	S8 OR S13 OR S14	Limiters - Language: Danish, English, Norwegian, Swedish Expanders - Apply related words; Apply equivalent subjects Search modes - Find all my search terms	2,389
S15	S8 OR S13 OR S14	Expanders - Apply related words; Apply equivalent subjects Search modes - Find all my search terms	2,463
S14	TI (((midwi* N2 unit) OR (midwi* N2 units) OR (midwi* N2 cent*) OR (midwi* N2 clinic) OR (midwi* N2 clinics)) and (birth* OR childbirth* OR delivery OR deliveries)) OR AB (((midwi* N2 unit) OR (midwi* N2 units) OR (midwi* N2 cent*) OR (midwi* N2 clinic) OR (midwi* N2 clinics)) and (birth* OR childbirth* OR delivery OR deliveries))	Expanders - Apply related words; Apply equivalent subjects Search modes - Find all my search terms	595

S13	S11 AND S12	Expanders - Apply related words; Apply equivalent subjects Search modes - Find all my search terms	644
S12	S4 OR S5	Expanders - Apply related words; Apply equivalent subjects Search modes - Find all my search terms	41,823
S11	S9 OR S10	Expanders - Apply related words; Apply equivalent subjects Search modes - Find all my search terms	1,451
S10	TI (birthcenter* OR birthcentr* OR birth-center* OR birth-centr* OR "birthing center*" OR "birthing centr*" OR "community birth*") OR AB (birthcenter* OR birthcentr* OR birth-center* OR birth-centr* OR "birthing center*" OR "birthing centr*" OR "community birth*")	Expanders - Apply related words; Apply equivalent subjects Search modes - Find all my search terms	1,076
S9	(MM "Alternative Birth Centers")	Expanders - Apply related words; Apply equivalent subjects Search modes - Find all my search terms	832
S8	S3 AND S7	Expanders - Apply related words; Apply equivalent subjects Search modes - Find all my search terms	1,587
S7	S4 OR S5 OR S6	Expanders - Apply related words; Apply equivalent subjects Search modes - Find all my search terms	74,369
S6	TI planned OR AB planned	Expanders - Apply related words; Apply equivalent subjects Search modes - Find all my search terms	33,157
S5	TI midwi* OR AB midwi*	Expanders - Apply related words; Apply equivalent subjects Search modes - Find all my search terms	34,059
S4	(MH "Midwives+")	Expanders - Apply related words; Apply equivalent subjects Search modes - Find all my search terms	17,020
S3	S1 OR S2	Expanders - Apply related words; Apply equivalent subjects Search modes - Find all my search terms	4,913
S2	TI (homebirth* OR ((birth* OR childbirth* OR delivery OR deliveries) N2 (home OR out-of-hospital OR non-hospital* OR out-of-clinic OR non-clinic* OR out-of-institution OR non-institution* OR out-of-facility OR non-facilit*))) OR AB (homebirth* OR ((birth* OR childbirth* OR delivery OR deliveries) N2 (home OR out-of-hospital OR non-hospital* OR out-of-clinic OR non-clinic* OR out-of-institution OR non-institution* OR out-of-facility OR non-facilit*)))	Expanders - Apply related words; Apply equivalent subjects Search modes - Find all my search terms	4,005
S1	(MM "Home Childbirth")	Expanders - Apply related words; Apply equivalent subjects Search modes - Find all my search terms	2,275

MH "+" = term from the Cinahl controlled vocabulary, including terms found below this term in the Cinahl hierarchy

N2 = Next to each other, in any order, up to 2 word(s) in between

TI = title

AB = abstract

MM = word in major subject heading and core concept

***** = truncation of word for alternate endings

The websites listed below were visited 30 May 2024 and 14 Mar 2025.

Source	Search terms / Browsing	No. of results	No. of relevant results	No. of relevant new results 14 Mar 2025
SBU www.sbu.se Limit to <i>Rapporter</i> or <i>Rapporter från andra HTA-organisationer</i> Mark <i>Visa även träffar äldre än 5 år</i>	Hemförlossning	2	1	2
	Hemförlossningar	2	1 (duplicate)	2 (duplicates)
	Hemfödelse	0	0	0
	Hemfödslar	0	0	0
	Förlossning	59	1 (duplicate)	2 (duplicates)
	Förlossningar	59	1 (duplicate)	2 (duplicates)
	Förlossningsinrättning	0	0	0
	Förlossningsinrättningar	0	0	0
	Förlossningscenter	0	0	0
	Förlossningsklinik	9	0	0
	Förlossningskliniker	9	0	0
	Barnmorskeledd	0	0	0
	Barnmorskeledda	0	0	0
	Barnmorskeassisterad	1	1 (duplicate)	2 (duplicates)
	Barnmorskeassisterade	1	1 (duplicate)	2 (duplicates)
Folkehelseinstituttet (Norge) https://www.fhi.no/publ/ Limit to publication type <i>Systematisk oversikt</i> or <i>Metodevurdering</i> .	Hjemmefødsel	0	0	0
	Hjemmefødsler	0	0	0
	Fødsel	6	0	0
	Fødsler	5	0	0
	Fødestue	2	0	0
	Fødestuer	2	0	0
	Fødeavdeling	1	0	0
	Fødeavdelinger	1	0	0
	Fødesentra	0	0	0
	Fødesenter	0	0	0
	Fødesentre	0	0	0
	Fødselssentra	0	0	0
	Fødselssenter	0	0	0
	Fødselssentre	0	0	0
	Mor-barn klinikk	0	0	0
	Mor-barn klinikker	0	0	0
	Jordmorstyrt	1	0	0
	Jordmorstyrte	1	0	0
	Jordmorassistert	0	0	0
	Jordmorassisterte	0	0	0
Behandlingsrådet (Danmark) https://behandlingsraadet.dk/fin-d-evalueringer-analyser	Browsat	0	0	0

<p>Nationale Kliniske Anbefalinger og Retningslinjer (Danmark)</p> <p>https://www.sst.dk/da/Fagperson/Retningslinjer-og-procedurer/NKA-og-NKR/NKR-og-NKA-efter-omraade</p>	Browsat	0	0	0
<p>CAMTÖ</p> <p>https://www.regionorebrolan.se/sv/forskning/kontakt-och-organisation/hta-enheten-camto/</p>	Browsat	0	0	0
<p>HTA Region Stockholm</p> <p>https://www.chis.regionstockholm.se/hta/rapporter/</p>	Browsat	0	0	0
<p>Regional samverkansgrupp HTA (tidigare Metodrådet) i Sydöstra sjukvårdsregionen</p> <p>https://sydostrasjukvardsregionen.se/samverkansgrupper/hta/genomforda-bedomningar/</p>	Browsat	0	0	0
<p>HTA Syd</p> <p>https://vardgivare.skane.se/kompetens-utveckling/sakkunnigrupper/hta-skane/#110365</p>	Browsat	0	0	0
<p>Medicinska rådet, Region Dalarna (30 May 2024)</p> <p>https://www.regiondalarna.se/plus/vard/utveckling-och-utbildning/kunskapsstyrning/medicinska-radet/</p> <p>Vetenskapliga rådet, Region Dalarna (14 Mar 2025)</p> <p>https://www.regiondalarna.se/plus/vard/utveckling-och-utbildning/kunskapsstyrning/vetenskapliga-radet/</p>	Browsat	0	0	0
<p>International HTA database</p> <p>https://database.inahta.org/</p> <p>Limit to Year 2015-2024</p>	((birth* OR childbirth* OR delivery OR deliveries) AND (home OR (out-of-hospital*) OR (non-hospital*) OR (out-of-clinic*) OR (non-clinic*) OR (out-of-institution*) OR (non-institution*) OR (out-of-facilit*) OR (non-facilit*)) AND (midwif* OR planned)) OR (homebirth* AND (midwif* OR planned)) OR ((birthcenter* OR birthcent* OR (birth-center*) OR (birth-centr*) OR (birthing center*) OR (birthing centr*) OR (community birth*)) AND midwif*) OR (midwi* AND (unit OR units OR cent* OR clinic OR clinics) AND (birth* OR	19	2	0

	childbirth* OR delivery OR deliveries))			
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Reference lists

A comprehensive review of reference lists brought 12 new records.

Reference lists

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Project: HTA - Midwife assisted births outside hospital compared with hospital births

Appendix 2 – Characteristics of included studies

Author Year Country, region	Study design (cohort, case series, systematic review)	Study period (YYMMDD- YYMMDD)	Definition study groups: 1 Home delivery (HB) 2 Freestanding midwife-led birth unit (FMU) 3 Obstetric unit birth (OU)	Patients per group (n)	Definition “low-risk”	Percentage nulliparous/ multiparous women	PICO outcome variables	Comment
Brocklehurst (Birthplace in England Collaborative Group) 2011 England	Prospective cohort study	080401- 100430	1. HB 2. FMU 3. OU	All 47,828 1.HB = 16,840 2.FMU = 11,282 3.OU =19,706	Inclusion: Healthy women according to NICE intrapartum care guidelines Exclusions: stillbirth before start of labour, elective CS or CS before labour, preterm <37 w, multiple pregnancy, no antenatal care	Nulliparous 27.2% 46.0% 54.0%	Composite of PNM and (stillbirth after start of care in labour + early NNM), HIE, MAS, brachial plexus injury, fractured humerus, fractured clavicle Secondary: Neonatal and maternal morbidities, maternal interventions, mode of birth, perineal trauma 3-4, blood transfusion, admission to a higher level of care, NICU, Apgar <7 ⁵ Transfer	Postterm ≥42+0 w: HB: 1.8% FMU: 1.0% OU: 2.7% No of women with complicating conditions identified at start of labour are also presented Partly overlapping with Rowe 2013 regarding transfer
Davis 2012 New Zealand	Retrospective cohort study	060101 - 071231	1. HB 3. OU (secondary or tertiary hospital) Only low risk women included	All 13,333 1. HB=1,830 3. OU=11,503	Exclusions: previous CS, stillbirth, previous PPH (>1,000 mL), severe HDP, GDM, Rh sensitization, ABO incompatibility, existing essential hypertension, diabetes, thyroid	Mean parity (SD): 1. HB 1,4 (1,4) 3. OU secondary hospital 0,9 (1,2) OU tertiary hospital 0,7 (1,0)	PPH >1000 ml	Same cohort as Davis 2011

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					disease, drug and/or alcohol abuse, heart disease, pulmonary disease/asthma, haematological disorder, neurological disorder, renal/urinary tract disorder, muscular skeletal disorder, any consultation with or transfer of care to another practitioner during the Antenatal period, multiple birth, foetal death before onset of labour, labour before 36 + 6 w or after 41 + 6 w, induced labour, breech or shoulder presentation, transverse lie, and elective CS.			

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Davis 2011 New Zealand	Retrospective cohort study	060101- 071231	1. HB 3. OU (secondary or tertiary hospital) Only low risk women included	All 13,333 1. HB=1,830 3. OU=11,503 (7,380+4,123)	Same as Davis 2012	mean parity (SD): 1. HB 1,4 (1,4) 3. OU secondary hospital 0,9 (1,2) OU tertiary hospital 0,7 (1,0)	Mode of birth: Intrapartum CS, vacuum, forceps Secondary: perineal trauma, PPH>1000 ml, 5 minute Apgar score <7, NICU, NNM	Same cohort as Davis 2012 Only outcome given with absolute numbers is mode of birth, otherwise only: RR with primary unit (FMU+AMU) as reference.
Farry 2019 New Zealand South Auckland	Retrospective cohort study	12 months (no dates, before 2019)	2. FMU (3 different freestanding primary level midwife-led maternity units, PMU) 3. OU (one tertiary care unit)	All 4,207 2. HB=1,114 3. OU=3,093	Low risk term singletons, cephalic presentation (exclusions listed, only antenatal risk factors, not risk factors at admission)	1. 32.4%/67.6% 2. 39.1%/60.9%	CS, PPH >500 ml, NICU <12 h, Apgar score <7 at 5, transfer rates, NNM, maternal mortality, maternal admission to ICU<12h after birth	No home deliveries. No primary outcome.
Hermus 2017 The Netherlands	Prospective cohort study	130701- 131231	1. HB 3. OU (Conventional hospital labour	All 1,787 1. 399+687= 1,086 2. 348+353= 701	Low risk term singletons, exclusions according to a "List of	1. 36.7%/63.3% 2. 49.6%/50.4%	PPH >1000ml, blood transfusion, perineal laceration grade 3-4, maternal mortality	8.5% missing data.

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Appendix 2 – Characteristics of included studies

Author Year Country, region	Study design (cohort, case series, systematic review)	Study period (YYMMDD- YYMMDD)	Definition study groups: 1 Home delivery (HB) 2 Freestanding midwife-led birth unit (FMU) 3 Obstetric unit birth (OU)	Patients per group (n)	Definition “low-risk”	Percentage nulliparous/ multiparous women	PICO outcome variables	Comment
			setting, midwife led)		Obstetric Indications”		intrapartal death+neonatal death <24 h, Transfer to OU, NICU	
Hiraizumi 2013 Japan, Red Cross Katsushi Hospital, Tokyo	Retrospective cohort study	2007 - 2011 (no exact date)	1. HB 2. OU (hospital, standard obstetric care)	All 1. HB=168 3. OU=217	Low risk 37-41 w, singletons, according to exclusion list	1. 24%/76% 3. 26%/74%	HB/OU: Mode of birth, perineal tear grade 3-4, PPH ≥1000 ml, transfer rates, neonatal asphyxia, (Apgar score < 7 at 1 and/or 5 min) (no PO) Results analysed combined for HB + AMU	NB CS, VE table 1 and 2 does not agree, these outcomes cannot be presented, also transfer rates figures in table 2 and 3 do not agree. Partly overlapping with Suzuki 2016
Homer 2019 Australia, all eight states and territories	Retrospective population based cohort study	000101- 121231	1. HB 3. OU FMU not available, only “Birth centres” (AMU and FMU)	All 1,179,915 1. HB=8,212 3. OU=1,171,703	Low risk term (37-41 w) singletons, exclusions according to: Women were also excluded if they had: Received no antenatal care.	Nulliparous: 1. HB: 27.9% 3. OU: 42.2%	Caesarean section, perineal lacerations grade 3-4, PPH with blood transfusion, maternal admission ICU at least 48 hours,	Partly overlap with Scarf 2018. Partly overlapping with Catling – Paull 2013 and Davies Tuck

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Appendix 2 – Characteristics of included studies

Author Year Country, region	Study design (cohort, case series, systematic review)	Study period (YYMMDD- YYMMDD)	Definition study groups: 1 Home delivery (HB) 2 Freestanding midwife-led birth unit (FMU) 3 Obstetric unit birth (OU)	Patients per group (n)	Definition “low-risk”	Percentage nulliparous/ multiparous women	PICO outcome variables	Comment
					<p>A previous caesarean section. A breech or non-vertex presentation. Labour induced for any reason. An elective caesarean section (pre-labour). Pre-existing (essential) and/or pregnancy-related hypertension. Pre-existing or gestational diabetes. Antepartum haemorrhage or any other relevant pregnancy complications. ICD-10-AM Diagnosis O10 Pre-existing hypertension complicating pregnancy, childbirth and the puerperium. O11 Pre-eclampsia</p>		<p>intrapartum stillbirth, early neonatal death (0-7d), late neonatal death 8-28 d), NICU >48 h</p>	<p>2018 regarding stillbirth and NND. Transfer rates not available.</p>

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					superimposed on chronic hypertension. O13 Gestational (pregnancy-induced) hypertension. O14 Pre-eclampsia. O15 Eclampsia. O24 Diabetes mellitus in pregnancy. O30 Multiple gestation. O31.2 Continuing pregnancy after intrauterine death of one fetus or more. O36.4 Maternal care for intrauterine death. O42 Premature rupture of membranes. O46 Antepartum haemorrhage. O75.5 Delayed delivery after artificial rupture of membranes.			

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					O75.7 Vaginal delivery following previous caesarean section. P95 Fetal death of unspecified cause.			
Lindgren 2008a Sweden	Retrospective cohort study	920101- 041231	1. HB 3. OU	All 12,238 1. HB 897 3. OU 11,341 Low risk HB 790 OU 11,195	Inclusion control group: spontaneous, full- term, singleton birth (gestational week 37 to 42) Low risk: singletons, cephalic presentation, term, no diabetes)	Nulliparous 1. HB 26% (229/897) 3. OU 62% (7,039/11,341) Multiparous 1. 74% (668/897) 3. OU 38% (4,302/11,341)	Maternal mortality, peri/neonatal mortality	A randomly selected control group was identified from the Medical Birth Register.
Scarf 2019 Australia, New South Wales	Retrospective population based cohort study	2000- 2012	1. HB 3. OU FMU not available, only “Birth centres” (AMU and FMU)	All 466,454 1. HB:1,824 3. OU: 464,630	Low risk singleton, vertex presentation, 37-41 weeks, spontaneous onset, no previous CS, no pregnancy complication	1. 546/1,278 3: 209,664/254,966	Transfer rate, mode of delivery, NICU admissions, stillbirth, early neonatal death	Partly overlap with Homer 2019 *BC are both FMU and AMU, no separate analysis by type of BC Partly overlap with Catling- Paul 2013

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								regarding transfer
Alcaraz-Vidal 2024, Spain, 29 hospitals in Catalonia	Case series	2016- 2017	1. HB	HB: 750	Women aged 18-40 years, low-risk pregnancies, single fetus in cephalic position, spontaneous onset of labour week 37+0-42+0, no previous CS, no previous pregnancy complications	Nulliparous HB 43.6% (327/750)	Transfer rate	
Amelink- Verburg 2008, The Netherlands	Retrospective case series	010101- 031231	1. HB	Low risk HB+AMU 280,097 60.2% intended HB = 168,618	Term, no previous CS*	NR	Transfer rate reported for HB (urgent, not urgent, first stage, second stage, early postpartum)	*No definition of low risk Partly overlapping with Offerhaus 2013
Blix 2016 Norway, Sweden, Denmark, Iceland	Retrospective case series	No 080101- 121231 Swe 090101- 131231	HB	All 3,068 No 482 Swe 445 Dk 1,843 Iceland 298	Low risk, included 4.7% previous CS	18.6% (572/3,068)/ 79.7% (2,446/3,068)	Transfer rate reported for HB: During labour, after birth, vehicle, urgency,	Data will be reported only for nulliparous women since 4.7% CS in multiparous

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		Dk March 100301- 130515 Iceland 100101- 131231					indication for transfer	women
Bolten 2016 The Netherlands	Retrospective case series	Sept 2009- March 2011	1. HB	1. HB 2,050	Low risk, according to Dutch definition, singleton, term	42.3% (868/2,050)/ 57.7% (1182/2050)	Transfer rate for HB, during first, second stage, postpartum	Partly overlapping with Geerts 2014
Catling-Paull 2013 Australia, 5 territories	Retrospective case series	January 2005 - December 2010	HB	1. HB 1,807	Low risk*	1. 31.8% / 68.2%	Maternal mortality Stillbirth NND <7 days transfer rate	*No definition of low risk, no data on previous CS Partly overlap with Davies Tuck 2018, McMurtrie 2009, Scarf 2019
Davies Tuck 2018 Australia, Victoria	Retrospective case series	000101- 151231	1.HB No OU: The planned OU group also includes BC/AMU births. For the period of this	Low risk HB n=3,202	“Specifically, a high risk pregnancy was defined as: a multiple pregnancy, a post-term (> 41+6 weeks of gestation) pregnancy, a non- cephalic	1,103 (34.5%)/ 2,099 (65.5%)	Stillbirth NND	High risk HB as reported in the article not included in this analysis. NND not defined as early or late.

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			study however all BC births were integrated within a larger hospital health service.		presentation in labour, obesity (BMI class 2 or greater: data only available from 2009 onwards), a prior caesarean, previous uterine surgery, grand multiparity (≥5 previous births), any significant maternal medical condition such as pre-existing diabetes, hypertension, renal, cardiac, liver, respiratory, endocrine, immunological, renal, or gastrointestinal disease as determined by individual ICD-10 codes. All other women were classified as having			Not specified whether stillbirth combines antepartum and intrapartum stillbirth. Partly overlapping with Catling- Paull 2013, Homer 2019.

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					a low risk pregnancy.”			
de Jonge 2015 The Netherlands	Case series	000101- 091231	1.HB no OU	n=466,112 (62.7%) had planned to have a home birth at the onset of labour	Low risk term singletons, cephalic presentation, no previous CS exclusions according to a "List of Obstetric Indications”.	198,515 (42.6%) primiparous 267,527 (57.4%) multiparous	Intrapartum and NND (uncertain and certain time of death), 0–28 days, Intrapartum and NND (certain time of death), 0– 28 days, Intrapartum death, NND 0–7 days, NND 0–28 days	8.5% unknown. Probabilistic data linkage No OU=therefore included as case series Partly overlapping with Smit 2014a and b
Fritschel 2015 USA, Texas	Case report	Jan 2014	1. HB	1 case			NND	Fatal legionellosis after water birth
Galera- Barbero 2021 Spain, Balearic islands	Case series	1989- 2019	1. HB	820	Low risk according to “Guide to Clinical Practice for Childbirth Assistance” i.e. singletons, no previous CS, BMI ≤30,	296 (36.1%)/ 524 (63.9%)	Maternal mortality, intrapartum stillbirth, NND, transfer rate	42+ w: n=3 (<0.5%) More outcomes in article

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					37-41 weeks			
Geerts 2014 The Netherlands	Prospective case series	Sept 2009-Dec 2010	HB (OU - Hospital deliveries, midwifery led)	HB 1279 (Hospital deliveries 781)	Low risk, term, singletons, prolonged rupture of membranes excluded	41.3% (528/1,279) 58.7% (751/1,279)	Transfer rate	Same population included in Bolten 2016
Hill 2024 Germany	Case series	2010- 2015	1.HB 2.FMU	All 23,160 Data not presented separately for HB and FMU	Exclusions: Multiples, preterm birth (42+0 w), malpresentation pregnancy BMI>40, PROM at term >24h, SGA, IUFD before or after onset of labour, induction, anemia, antepartum bleeding after 28+0 w, fetal abnormality, hypertension, diabetes and previous CS	Nulliparous 23,160	Transfer rate, urgency of transfer	Data for vehicle used for transport
Huitfeldt 2016	Retrospective case series	070521- 110627	FMU	FMU=495	Low risk, term singleton, vertex,	23% (115/495) 77% (380/495)	Transfer rate, PNM for nulliparous	Data will be reported only

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Norway, Oslo					BMI <30, previous CS included			for nulliparous women since 1.3% CS in multiparous women
Maimburg 2018 Denmark, Århus	Case series	150201- 170131	HB	HB=268	Low risk, term, vertex, previous CS not mentioned	44% (117/268) 56% (151/268)	Transfer rate	
McMurtrie 2009 Australia New South Wales	Case series	Nov 2005 -March 2009	HB	HB=70	Low risk term previous CS not mentioned	Data not provided	Transfer rate	Partly overlapping with Catling- Paul 2013
Offerhaus 2013 The Netherlands	Case series	2000- 2008	HB	HB=452,997	Low risk, term, singletons, vertex, no previous CS, no malformations	Nullips 195,967 (54.8%) Multips 257,030 (59.5%)	Transfer rate	Partly overlapping with Amelink- Verburg 2008
Rowe 2013 England	Case series	080401- 100430	HB FMU	HB: 16,632 FMU: 11,210	Inclusion: Healthy, term, women according to NICE intrapartum care guidelines Exclusions: stillbirth before start of labour, elective CS or CS before labour, preterm <37 w, postterm >42+0 w,	HB: Nulliparous: 4,489/16,619 (27.0%) Multiparous 12,130/16,619 (73.0%) FMU: Nulliparous 5,152/11,197 (46.0%) Multiparous	Secondary analysis of Brocklehurst 2011. Transfer rate, reasons for transfer, urgency, timing, and duration of the transfer process.	*Secondary analysis of Brocklehurst 2011 (Birthplace in England Collaborative Group) but >42+0 excluded in Rowe 2013

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					multiple pregnancy, no antenatal care	6,045/11,197 (54.0%) *Figures from Table 1, but not correct (10 missing)		
Smit 2014a The Netherlands	Case series Aims, methods, results in 2014a	April 2008- April 2009	HB	8 cases of umbilical cord prolapse		Nullips 2/ Multips 6	Perinatal mortality, presented in table in 2014b	Part 1 of article of Smit et al 2014 Probably included into de Jonge 2015
Smit 2014b The Netherlands	Case series Cont. results in 2014b	April 2008- April 2009	HB	8 cases of umbilical cord prolapse		Nullips 2/ Multips 6	Perinatal mortality presented in table in 2014b	Part 2 of article of Smit et al 2014 Probably included into de Jonge 2015
Suzuki 2016 Japan, one perinatal center in Tokyo	Retrospective case series	2009- 2012	HB	HB: 123	Based on medical, gynaecologic, obstetric history (as no previous CS, PPH, grade 3-4 lacerations) multiple pregnancy, complications during labour	HB 32 /123 (26%)	Transfer rate and perinatal outcome	Partly overlapping with Hiraizumi 2013

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Sweet 2022 Australia, Victoria	Retrospective case series	2009- 2019	HB	561 commenced labour at home, 483 had HB 473 with midwife, 10 before midwife arrived	According to list: Singleton, vertex, 37-42 w, no previous CS, age < 40y, BMI <35, parity ≤4, etc	131 (27.1%)/ 352 (72.9%)* *refers to all women who actually had a homebirth not women commencing labour at home	Maternal mortality, stillbirth and NNM, transfer rate before and after birth	Partly overlap with Catling- Paull 2013, Davies Tuck 2018, Homer 2019, White 2019
White 2020 Australia, Victorian state	Case series	2010- 2017	HB	191 HB	No risk factors, after 36 weeks	17.3% (33/191) 82.7% (158/191)	Transfer rate, NNM	

Abbreviations: AMU alongside midwifery unit, BC birth centre, BMI body mass index, BPE Birthplace England, CS cesarean section, FMU freestanding midwifery unit, HB home birth, GDM gestational diabetes, HDP hypertensive disorders of pregnancy, ICU intensive care unit, NND neonatal death, NZ COMCORD New Zealand College of Midwives Clinical Outcomes Research, OU obstetric unit, PMU primary level midwife-led unit, PNM perinatal mortality, PPH postpartum haemorrhage, SCN special care nursery, w weeks

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Appendix 3. Excluded articles

Author, year	Reason for exclusion
Alliman, 2016	Wrong study design (review, not systematic)
Anderson, 2021	Wrong focus (cost analysis)
Bachilova, 2018	Wrong population (not only women with normal pregnancies and expected normal births)
Baczek, 2020	Wrong study design (review, not systematic)
Baker, 2022	Wrong population, intervention and outcome (case series, not mortality, not transfer, only vaginal birth included)
Bayoglu Tekin, 2015	Wrong intervention (in hospital)
Bellini, 2025	Wrong outcome (case series, not mortality or transfer)
Benyshek, 2018	Wrong focus (placentophagy)
Bland, 2009	Wrong population, intervention and outcome (case series, not mortality, not transfer)
Blix, 2012	Wrong population (not only women with normal pregnancies and expected normal births)
Bovbjerg, 2016	Wrong population (not only women with normal pregnancies and expected normal births)
Bovbjerg, 2024	Wrong population (not only women with normal pregnancies and expected normal births)
Buchanan, 2022	Wrong outcome (case control study, not mortality or transfer)
Burns, 2012	Wrong topic (water birth)
Burns, 2022	Wrong population (not only women with normal pregnancies and expected normal births)
Caine, 2008	Wrong publication type (editorial)
Capiotti, 2020	Wrong population (not only women with normal pregnancies and expected normal births)
Carlson, 2019	Wrong intervention (in hospital)
Chang, 2011	Wrong population (not only women with normal pregnancies and expected normal births)
Cheng, 2013	Wrong population (not only women with normal pregnancies and expected normal births)
Cheyney, 2014	Wrong population (not only women with normal pregnancies and expected normal births)
Christensen, 2017	Wrong intervention (alongside midwifery units with access to intensive care)
Cicero, 2022	Wrong focus (cost analysis)
Cicero, 2024	Wrong population (not only women with normal pregnancies and expected normal births)
Cox, 2013	Wrong population (not only women with normal pregnancies and expected normal births)
Cox, 2015	Wrong population (not only women with normal pregnancies and expected normal births)
Cross-Sudworth, 2018	Wrong population (not only women with normal pregnancies and expected normal births)
Darling, 2019a	Wrong focus (comparison insured-uninsured women)
Darling, 2019b	Wrong population (includes w 42+) (case series)
de Jonge, 2009	Duplicate data with de Jonge, 2015

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Appendix 3. Excluded articles

Author, year	Reason for exclusion
de Jonge, 2013	Wrong comparison (alongside midwife led unit)
de Jonge, 2017	Wrong comparison (comparison between different countries)
Dencker, 2017	Wrong intervention (in hospital)
Dixon, 2009	Wrong intervention (management of third stage of labour)
Dixon, 2013	Wrong focus (physiologic vs active management)
Dixon, 2014	Wrong population (not only women with normal pregnancies and expected normal births)
Edqvist, 2016	Wrong population (not specified if only low-risk women according to the PICO were included)
Edwards, 2009	Wrong study design (case report, not mortality, not transfer)
Elder, 2016	Wrong study design (review, not systematic)
Elkington, 2023	Wrong focus (risk factors for transfer for postpartum haemorrhage)?
Erickson, 2020	Wrong population (not only women with normal pregnancies and expected normal births)
Evers, 2010	Wrong population (not only women with normal pregnancies and expected normal births)
Fahy, 2010,	Wrong focus (third stage of labour)
Ford, 2008	Wrong intervention (mixed attended/unattended)
Galkova, 2022	Wrong outcome (case series, not mortality or transfer)
Gao, 2024	Wrong population (not only women with normal pregnancies and expected normal births)
Gaudineau, 2013	Wrong intervention (in hospital)
Gravesteijn, 2024	Wrong focus (Covid-19 lockdown)
Grigg, 2017	Wrong population (not only women with normal pregnancies and expected normal births)
Grunebaum, 2022	Wrong intervention (not ICM certified midwives)
Grunebaum, 2020	Wrong population (not only women with normal pregnancies and expected normal births)
Grunebaum, 2017a	Wrong population (not only women with normal pregnancies and expected normal births)
Grunebaum, 2017b	Wrong population (not only women with normal pregnancies and expected normal births)
Grunebaum, 2016	Wrong population (not only women with normal pregnancies and expected normal births)
Grunebaum, 2015a	Wrong population (not only women with normal pregnancies and expected normal births)
Grunebaum, 2015b	Wrong focus (frequency of risk factors)
Grunebaum, 2015c	Wrong publication type (editorial)
Grunebaum, 2014a	Wrong publication type (editorial)
Grunebaum, 2014b	Wrong population (not only women with normal pregnancies and normal expected births)
Grunebaum, 2013	Wrong population (not only women with normal pregnancies and normal expected births)
Grunebaum, 2019	Wrong population (not only women with normal pregnancies and normal expected births)

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Appendix 3. Excluded articles

Author, year	Reason for exclusion
Gutteridge, 2015	Wrong population (study population not clearly defined)
Halfdansson, 2024	Wrong population (not only women with normal pregnancies and expected normal births)
Halfdansson, 2018	Wrong population (not only women with normal pregnancies and expected normal births)
Halfdansson, 2015	Wrong population (not only women with normal pregnancies and expected normal births)
Hansel, 2022	Wrong focus (associations between small for gestational age and different factors)
Hays, 2022	Wrong focus (description of a program)
Hendrix, 2009	Wrong focus (cost analysis), incorrect control group (midwifery unit)
Heron, 2009	Wrong population (not only women with normal pregnancies and expected normal births)
Hickson, 2020	Wrong study design (review, not systematic)
Hildingsson, 2015	Wrong population, wrong outcome (case series, not mortality, transferred women with instrumental birth excluded)
Hitzert, 2017	Wrong focus (cost analysis)
Hollowell, 2017	Wrong comparison (different midwife units)
Hollowell, 2015	Wrong study design (review, not systematic)
Homer, 2014	Wrong population (not only women with normal pregnancies and expected normal births)
Hoque, 2024	Wrong population (not high-income setting)
Hu, 2024	Wrong focus (hypothetical cost model, no data)
Hutton, 2019	Wrong population (not only women with normal pregnancies and expected normal births)
Hutton, 2016a	Wrong population (not only women with normal pregnancies and expected normal births)
Hutton, 2016b	Wrong publication type (editorial)
Hutton, 2009	Wrong population (not only women with normal pregnancies and expected normal births)
Ingnatov, 2017	Wrong intervention (midwife led units)
Janssen, 2015	Wrong focus (cost analysis)
Janssen, 2009	Wrong population (not only women with normal pregnancies and expected normal births)
Jensen, 2017	Wrong intervention (mixed planned/unplanned home birth)
Johansen, 2011	Wrong focus (risk factors)
Johnson, 2005	Wrong population (not only women with normal pregnancies and expected normal births)
Jolles, 2023	Wrong focus (birth centre staffing models)
Joranger, 2024	Wrong focus (cost analysis)
Kallianidis, 2016	Wrong population (not only women with normal pregnancies and expected normal births)
Kataoka, 2018	Wrong population (not only women with normal pregnancies and expected normal births)

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Appendix 3. Excluded articles

Author, year	Reason for exclusion
Kataoka, 2013	Wrong population (not only women with normal pregnancies and expected normal births)
Kennare, 2010	Wrong population (not only women with normal pregnancies and expected normal births)
Kenny, 2015	Wrong intervention (in hospital)
Kildea, 2016	Wrong population (not only women with normal pregnancies and expected normal births)
Kobayashi, 2017	Wrong intervention (assessment and support interventions)
Krepelka, 2023	Wrong intervention (mixed midwife attended/unattended)
Krepelka, 2020	Wrong intervention (mixed midwife attended/unattended)
Laws, 2010	Wrong population (not only women with normal pregnancies and expected normal births)
Li, 2014	Duplicate data with Brocklehurst, 2011
Li, 2017	Wrong population (not only women with normal pregnancies and expected normal births)
Lindgren, 2008b	Wrong population (not only women with normal pregnancies and expected normal births)
Lukasse, 2014	Wrong comparison (different midwife units)
Lukasse, 2006	Wrong intervention (in hospital)
Lundeen, 2016	Wrong population (not only women with normal pregnancies and expected normal births)
Macfarlane, 2019	Wrong focus (time, day and year)
Malloy, 2010	Wrong population (not only women with normal pregnancies and expected normal births)
Miller, 2012	Wrong study design (survey study)
Molina Perez, 2020	Wrong intervention (mixed in/out of hospital)
Monk, 2017	Wrong outcome (case series, not mortality)
Monk, 2014	Wrong population (not only women with normal pregnancies and expected normal births)
Nethery, 2021	Wrong comparison (different midwife units)
Nethery, 2018	Wrong population and intervention (case series, not mortality; not all midwives certified)
Nguyen, 2009	Wrong population (not only women with normal pregnancies and expected normal births)
Nguyen, 2010	Wrong focus (epidural analgesia)
Norum, 2013	Wrong comparison (different midwife units)
Nove, 2012	Wrong population (not only women with normal pregnancies and expected normal births)
O'Leary, 2020	Wrong intervention (in hospital)
Offerhaus, 2014	Wrong outcome (variation in intervention rates among midwifery practices)
Offerhaus, 2020	Wrong focus (caseload midwifery)
Oian, 2018	Wrong population (not only women with normal pregnancies and expected normal births)
Okui, 2024	Wrong intervention (mixed midwife led/physician led)

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Appendix 3. Excluded articles

Author, year	Reason for exclusion
Olsen, 2023	Wrong publication type (systematic review)
Oude, 2020	Wrong population (not only women with normal pregnancies and expected normal births)
Ovaskainen, 2021	Wrong population (not only women with normal pregnancies and expected normal births)
Ovaskainen, 2019	Wrong population (not only women with normal pregnancies and expected normal births)
Overgaard, 2011	Wrong intervention (FMUs located in community hospitals with an ICU but without obstetric service)
Overgaard, 2012	Wrong study design (overlap, secondary analysis of Overgaard 2011).
Park, 2018	Wrong language (Korean)
Permezel, 2015	Wrong intervention (in hospital)
Phillippi, 2018	Wrong publication type (systematic review)
Pillai, 2020	Wrong population (not only women with normal pregnancies and expected normal births)
Potera, 2013	Wrong publication type (research summary)
Ravelli, 2009	Wrong population (not only women with normal pregnancies and expected normal births)
Reitsma, 2020	Wrong population (not only women with normal pregnancies and expected normal births)
Rollet, 2024	Wrong intervention (alongside midwifery unit)
Rossi, 2018	Wrong population (not only women with normal pregnancies and expected normal births)
Rowe, 2020	Wrong population (not only women with normal pregnancies and expected normal births)
Rowe, 2012	Duplication with Rowe 2013
Royds-Jones, 2006	Wrong population, wrong outcome (case series, not mortality)
Scarf, 2021	Wrong focus (cost analysis), included in health economy analysis
Scarf, 2020	Wrong focus (cost analysis), included in health economy analysis
Scarf, 2018	Wrong population (not only women with normal pregnancies and expected normal births)
Schildberger, 2023	Wrong intervention (comparison of planned hospital with transferred home birth)
Schroeder, 2012	Wrong focus (cost analysis), included in health economy analysis
Schroeder, 2017	Wrong focus (cost analysis)
Seijmonsbergen-Schermers, 2024a	Wrong intervention (mixed intervention)
Seijmonsbergen-Schermers, 2024b	Wrong population, outcome (case series, not mortality or transfer)
Seijmonsbergen-Schermers, 2020	Wrong intervention (not led by obstetricians)
Shorten, 2009	Wrong publication type (editorial)
Sidery, 2025	Wrong comparison

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Author, year	Reason for exclusion
Smith, 2013	Wrong population (not only women with normal pregnancies and expected normal births)
Snapp, 2020	Wrong intervention (water birth)
Snowden, 2015	Wrong population (not only women with normal pregnancies and expected normal births)
Sprague, 2018	Wrong population (not only women with normal pregnancies and expected normal births)
Stapleton, 2013	Wrong intervention (not possible to separate AMU/FMU)
Statens beredning för medicinsk utvärdering (SBU), 2023a	Wrong publication type (method description)
Statens beredning för medicinsk utvärdering (SBU), 2023b	Wrong publication type (evidence summary, not a primary study))
Statens beredning för medicinsk utvärdering (SBU), 2023c	Wrong publication type (evidence summary, not a primary study)
Stoll, 2014	Wrong population (not only women with normal pregnancies and expected normal births)
Stolp, 2015	Wrong population (only women who needed ambulance transfer)
Stramrood, 2011	Wrong study design (survey study)
Strozik, 2023	Wrong population (pregnancy related emergency calls)
Suto, 2015	Wrong intervention (unclear intervention, mixed AMU/FMU)
Symon, 2010	Wrong study design
Symon, 2007	Wrong outcome
Symon, 2009	Wrong population (not only women with normal pregnancies and expected normal births)
Thornton, 2017	Wrong intervention (not ICM certified midwives)
Tucker, 2010	Wrong population (not only women with normal pregnancies and expected normal births)
van der Kooy, 2011	Wrong intervention (not led by obstetricians)
van der Kooy, 2012	Wrong focus (No application)
van der Kooy, 2016	Wrong population (not only women with normal pregnancies and expected normal births)
van der Kooy, 2017	Wrong population (not only women with normal pregnancies and expected normal births)
van Haaren-ten Haken, 2015	Wrong study design (survey study)
Van Wagner, 2012	Wrong population (not only women with normal pregnancies and expected normal births)
Wallace, 2024	Wrong population (not only women with normal pregnancies and expected normal births)
Wallis, 2009	Wrong publication type (research summary)
Walton, 2012	Wrong publication type (research summary)
Wasden, 2017	Wrong population (not only women with normal pregnancies and expected normal births)
Watterberg, 2021	Wrong publication type (review)

Project: HTA - Midwife assisted births outside hospital compared with hospital births

Appendix 3. Excluded articles

Author, year	Reason for exclusion
Wax, 2010	Wrong intervention (mixed attended/unattended)
Way, 2022	Wrong population (not only women with normal pregnancies and expected normal births)
Whittington, 2020	Wrong publication type (review)
Wiegerinck, 2015	Wrong population (not only women with normal pregnancies and expected normal births)
Wiegerinck, 2014	Wrong population (neonates admitted to NICU)
Wiegerinck, 2018	Wrong intervention (mixed midwife-led/general practitioner-led)

Abbreviations: AMU alongside midwifery unit, FMU freestanding midwifery unit, ICM International Confederation of Midwives, NICU neonatal intensive care unit

Project: HTA - Midwife assisted births outside hospital compared with hospital births

Appendix 4.1

Outcome variable: Maternal mortality

* + No or minor problems
 ? Some problems
 - Major problems

Author year country	Study design	Number of patients	Withdrawals - dropouts	Results		Comments	Directness *	Study limitations *	Precision *
				Intervention	Control				
Farry 2019 New Zealand South Auckland	Retrospective cohort study	All: 4,207 FMU: 1,114 OU: 3,093	0	FMU 0/1,114	OU 0/3,093	Maternal death within 42 days after birth	-	?	-
Hermus 2017 The Netherlands	Retrospective cohort study	HD: 1,086 OU: 701	0	HD Nulliparous: 0/399 Multiparous: 0/687 Total: 0/1,086	OU Nulliparous: 0/348 Multiparous: 0/353 Total: 0/701	Maternal death within 24 h after birth	?	?	-
Lindgren 2008a Sweden	Retrospective cohort study	HD: 790 OU: 11,195	0	HD 0/790	OU 0/11,195	Follow-up time not stated	+	?	-
Catling-Paull 2013 Australia 5 territories	Case series	HD: 1,807	0	HD 0	NA	Follow-up time not stated			
Galera-Barbero 2021 Spain Balearic Islands	Case series	HD: 820	0	HD Nulliparous 0/296 Multiparous 0/524 Total 0/820	NA	Follow-up time not stated			
Sweet 2022 Australia Victoria	Case series	HD: 561	0	HD: 0/561	NA	Follow-up time not stated.			

Abbreviations: HD home delivery, FMU freestanding midwifery units, NA not applicable, OU obstetric unit

Project: HTA - Midwife assisted births outside hospital compared with hospital births

Appendix 4.2

Outcome variable: Maternal admission to ICU

* + No or minor problems
 ? Some problems
 - Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness *	Study limitations *	Precision *
				Intervention	Control				
Brocklehurst, Birthplace in England Collaborative Group 2011 England	Prospective cohort study	HD: 16,840 FMU: 11,282 OU: 19,706		HD All women 58/16,840 (0.4%) OR 0.61 (99% CI 0.29-1.27) AOR 0.77 (99% CI 0.36-1.65) Nulliparous 26/4,568 (0.6%) OR 0.67 (99% CI 0.27-1.69) AOR 0.66 (99% CI 0.26-1.66) Multiparous 32/12,256 (0.3%) OR 0.75 (99% CI 0.32-1.73) AOR 0.78 (99% CI 0.32-1.92)	OU All women 117/19,706 (0.6%) Nulliparous 83/10,626 (0.8%) Multiparous 34/9,049 (0.4%)	Admission to a higher level of care. Adjusted for maternal age, ethnicity, understanding of English, marital/partner status, BMI, SES, parity and gestation (completed weeks). AOR restricted to women who were not missing any potential confounder data (n=62,635).	+	+/?	+
				FMU All women 24/11,282 (0.2%) OR 0.27 (99% CI 0.11-0.69) AOR 0.32 (99% CI 0.13-0.84) Nulliparous 15/5,187 (0.2%) OR 0.31 (99% CI 0.11-0.86) AOR					

Project: HTA - Midwife assisted births outside hospital compared with hospital births

Appendix 4.2

Outcome variable: Maternal admission to ICU

* + No or minor problems
 ? Some problems
 - Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness *	Study limitations *	Precision *
				Intervention	Control				
				0.35 (99% CI 0.13-0.96) Multiparous 9/6,078 (0.1%) OR 0.26 (99% CI 0.06-1.05) AOR 0.28 (99% CI 0.07-1.22)					
Farry 2019 New Zealand South Auckland	Retrospective cohort study	FMU: 1,114 OU: 3,093		FMU 9/1,114 (0.8%) OR 0.192 (95% CI 0.097-0.378) AOR 0.201 (95% CI 0.102-0.398)	OU 126/3,093 (4.1%)	Admission within 12 h to ICU (theatre, high dependency unit, or intensive care unit). Adjusted for parity, smoking, ethnicity, BMI, SES, age. Table 5 shows same absolute numbers for PPH and maternal ICU admission but different ORs and AORs. Numbers corrected for maternal ICU admissions after author contact.	-	?	-
Homer 2019 Australia All eight states and territories	Retrospective population based cohort study	HD: 8,212 OU: 1,171,703	0	HD 7/4,995* (0.14%) OR 0.36 (99% CI 0.14-0.96) AOR 0.41 (99% CI 0.15-1.08)	OU 2,521/654,960* (0.38%)	*Five states excluded in analysis. Admission at least 48 h to ICU or high dependency unit as defined by each state and territory. Adjusted for maternal age, country of birth, gestational age, and parity	?	?	+

Abbreviations: AOR adjusted odds ratio, BMI body mass index, CI confidence interval, FMU freestanding midwifery units, HD home delivery, ICU intensive care unit, OR odds ratio, OU obstetric unit, PPH postpartum haemorrhage, SES socioeconomic status

Project: HTA - Midwife assisted births outside hospital compared with hospital births

Appendix 4.3

Outcome variable: Peri/neonatal and neonatal mortality

* + No or minor problems
? Some problems
- Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness *	Study limitations *	Precision *
				Intervention	Control				

Brocklehurst, Birthplace in England Collaborative Group 2011 England	Prospective cohort study	HB: 16,840 FMU: 11,282 AMU: 16,710 OU: 19,706	HB: 1 FMU: 0 OU: 0	HB Perinatal mortality (stillbirth and NNM <7d) 11/16,839 Nulliparous 6/4,562 Multiparous 5/12,250 Stillbirth 6/16,839 Nulliparous 4/4,568 Multiparous 2/12,255 NNM <7 d 5/16,759 Nulliparous 2/4,544 Multiparous 3/12,199 FMU Perinatal mortality (stillbirth and NNM <7d) 9/11,273 Nulliparous 4/5,187 Multiparous 5/6,078 Stillbirth	OU Perinatal mortality (stillbirth and NNM <7d) 8/19,706 Nulliparous 5/10,621 Multiparous 3/9,046 Stillbirth 3/19,706 Nulliparous 1/10,626 Multiparous 2/9,049 NNM <7 d 5/19,637 Nulliparous 4/10,593 Multiparous 1/9,013	No statistics in article	+	+/?	?
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Project: HTA - Midwife assisted births outside hospital compared with hospital births

Appendix 4.3

Outcome variable: Peri/neonatal and neonatal mortality

* + No or minor problems
 ? Some problems
 - Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness *	Study limitations *	Precision *
				Intervention	Control				
				4/11,282 Nulliparous 1/5,187 Multiparous 3/6,078 NNM <7 d 5/11,263 Nulliparous 3/5,180 Multiparous 2/6,066					
Davis 2011 New Zealand	Retrospecti ve cohort study	HB: 1,830 OU: 11,503 (secondary hospital: 7,380 + tertiary hospital 4,123)	HB: 4 OU: 55	HB Peri/neonatal mortality (intrapartum death and NNM <28 d) 2/1,826 (0.11%) Intrapartum death 0/1,826 NNM <28 d 2/1,826 (0.11%)	OU Peri/neonatal mortality (intrapartum death and NNM <28 d) 4/11,448 (0.03%) Intrapartum death 0/11,448 NNM <28 d 4/11,488 (0.03%) (0/7,353 in secondary hospital, 4/4,095 (0.10%) in tertiary hospital)	NB NNM tertiary hospital 0.15% in article. No statistics in article	?	-	-
Farry 2019 New Zealand South Auckland	Retrospecti ve cohort study	FMU: 1,114 OU: 3,093	0	FMU NNM 0/1,114	OU NNM 0/3,093	NNM not defined No statistics in article	-	?	-
Hermus 2017 The Netherlands	Retrospecti ve cohort study	HB: 1,086 OU: 701		HB Perinatal mortality <24 h postpartum Nulliparous: 0/399 Multiparous: 0/687	OU Perinatal mortality <24 h postpartum Nulliparous: 1/348 Multiparous: 0/353		?	?	-

Project: HTA - Midwife assisted births outside hospital compared with hospital births

Appendix 4.3

Outcome variable: Peri/neonatal and neonatal mortality

* + No or minor problems
? Some problems
- Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness *	Study limitations *	Precision *
				Intervention	Control				
				Total: 0/1,086 (0.0%)	Total: 1/701 (0.1%), n.s.*	* Calculated from data (Fisher's exact test)			
Homer 2019 Australia All eight states and territories	Retrospective population based cohort study	HB: 8,212 OU: 1,171,703	0	HB Peri/neonatal mortality (intrapartum death, early and late NNM) 9/8,212 (0.11%) OR 1.46 (99% CI 0.62-3.47) AOR 1.55 (99% CI 0.65-3.69) Primiparous 4/2,295 (0.17%) OR NA AOR 2.12 (0.58-7.82) Multiparous 5/5,889 (0.08%) OR NA AOR 1.29 (0.40-4.14) Intrapartum death 4/8,212 OR NA AOR 1.56 (99% CI 0.42-5.71) Early NNM (<7d) 5/5,789 OR NA AOR 3.18	OU Peri/neonatal mortality (intrapartum death, early and late NNM) 880/1,171,050 (0.075%) Primiparous 406/4994,019 (0.08%) Multiparous 474/677,031 (0.07%) Intrapartum death 378/1,171,703 (0.032%) Early NNM (<7d) 221/819,963 (0.027%)	Adjusted for maternal age, country of birth, gestational age, and parity. 99% CI! NB sum of intrapartum death early and late NNM in OU=693, but in Table 6 in article the sum=880 Partly overlapping with Davies Tuck 2018. Cells with less than 5 observations specified as NA for HB in article, but numbers for NNM calculated (total-(OU+BC))	?	?	?

Project: HTA - Midwife assisted births outside hospital compared with hospital births

Appendix 4.3

Outcome variable: Peri/neonatal and neonatal mortality

* + No or minor problems
 ? Some problems
 - Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness *	Study limitations *	Precision *
				Intervention	Control				
				(99% CI 0.98-10.30)					
				Late NNM (7< 29 d) 0/5,789 OR or AOR NA	Late NNM (7< 29 d) 94/819,963 (0.011%)				
Lindgren 2008a Sweden	Retrospecti ve cohort study	HB: 790 OU: 11,195	0	HB 2/790 Intrapartum death 0 NNM <28d 2/790	OU 6/11,195 Intrapartum death 1/11,195 NNM <28d 5/11,195	No statistics in article	+	?	-
Scarf 2019 Australia New South Wales	Retrospecti ve population based cohort study	HB: 1,824 OU: 464,400		HB Intrapartum death Nulliparous 0/546 Multiparous 0/1,278 Early NNM Nulliparous 0/546 Multiparous 0/1,278	OU Intrapartum death Nulliparous 94/209,544 (0.04%) Multiparous 83/254,856 (0.03%) Early NNM Nulliparous 123/209,664(0.06%) Multiparous 127/254966(0.05%)	Is part of Homer 2019, therefore these data are only included for NNM in subgroup analyses of parity. No statistics in article	+	-	-
Catling-Paull 2013 Australia 5 territories	Retrospecti ve case series	HB: 1,807 Nullips: 575 Multips: 1,232	55	Stillbirth 2/1,807 Early NNM 4/1,807 PNM 6/1,807 (3.3/1,000)	NA	3/6 cases of deaths were expected because of malformations			
Davies Tuck 2018 Australia	Case series (population	HB: 3,202	0	Stillbirth 2/3,202 NNM	NA	Not specified whether stillbirth combines			

Project: HTA - Midwife assisted births outside hospital compared with hospital births

Appendix 4.3

Outcome variable: Peri/neonatal and neonatal mortality

* + No or minor problems
 ? Some problems
 - Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness *	Study limitations *	Precision *
				Intervention	Control				
Victoria	based cohort study, but OU included also BC births)			3/3,202		anteartum and intrapartum stillbirth. NNM not defined as early or late. Partly overlapping with Homer 2019			
de Jonge 2015 The Netherlands	Case series (nation-wide cohort study, but no OU e.g. secondary obstetrician led care at the onset of labour)	HB: 466,112	Unknown 71,909	Nulliparous Intrapartum 113/198,515 NNM <7 d 95/198,412 NNM <28 d 100/198,412 Intrapartum and NNM <28 days 203/198,515 Multiparous Intrapartum 87/267,526 NNM <7 d 72/267,444 NNM <28 d 76/267,444 Intrapartum and NNM <28 days 158/267,526	NA	From the article: "The moment of death is not always recorded identically in the three databases of the national perinatal register. We conducted separate analyses based on intrapartum and neonatal mortality rates with and without cases for which the moment of death was not consistent between the three databases. The true mortality incidences are likely to be between these two rates." We have reported the uncertain and certain time of death in the table.			

Project: HTA - Midwife assisted births outside hospital compared with hospital births

Appendix 4.3

Outcome variable: Peri/neonatal and neonatal mortality

* + No or minor problems
 ? Some problems
 - Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness *	Study limitations *	Precision *
				Intervention	Control				
Galera-Barbero 2021 Spain Balearic Islands	Case series	HB: 820	0	Intrapartum death 0/820 Nulliparous 0/296 Multiparous 0/524 Early NNM 0/820 Nulliparous 0/296 Multiparous 0/524	NA				
Huitfeldt 2016 Norway	Case series	FMU: 495	0	No cases of fetal/neonatal death	NA				
Suzuki 2016 Japan One perinatal center in Tokyo	Cohort study (here case series)	HB: 123	0	No cases of fetal/neonatal death	NA				
Sweet 2022 Australia Victoria	Case series	HB: 483	78 transferred during birth or changed model of care were excluded	Stillbirth 0 Early NNM 1/483 (0.2%)	NA	The neonatal death occurred after a birth that occurred in water, without the midwife being present.			
White 2020 Australia Victorian state	Case series	HB: 191 Nullips: 33 Multips: 158	0	Early NNM 1/191	NA	The neonatal death occurred after maternal emergency transfer following intrapartum haemorrhage			
Fritschel 2015 USA Texas	Case report	HB: one case	NA	1 late NNM (19 d)	NA	Legionellosis after home water birth.			

Project: HTA - Midwife assisted births outside hospital compared with hospital births

Appendix 4.3

Outcome variable: Peri/neonatal and neonatal mortality

* + No or minor problems
? Some problems
- Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness *	Study limitations *	Precision *
				Intervention	Control				
Smit 2014a and 2014b The Netherlands	Case report	HB: 8 cases	NA	1 NNM	NA	NNM in 1/8 cases with umbilical cord prolapse, I para, 40 w Probably included in de Jonge 2015			

Abbreviations: AOR adjusted odds ratio, BC birth center, BMI body mass index, FMU freestanding midwifery units, HB home birth, NA not applicable, NNM neonatal mortality, OR odds ratio, OU obstetric unit

Project: HTA - Midwife assisted births outside hospital compared with hospital births

Appendix 4.4

Outcome variable: Infant adverse events

* + No or minor problems
 ? Some problems
 - Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness *	Study limitations *	Precision *
				Intervention	Control				
Brocklehurst, Birthplace in England Collaborative Group 2011 England	Prospective cohort study	HB: 16,840 FMU: 11,282 OU: 19,706		Apgar score <7 at 5 min HB Nulliparous 65/4,552 (1.43%) OR 1.45 (99% CI 0.92-2.29) AOR 1.43 (99% CI 0.90-2.28) Multiparous 74/12,235(0.63%) OR 0.69 (99% CI 0.44-1.09) AOR 0.70 (99% CI 0.43-1.12) FMU Nulliparous 56/5,180 (0.93%) OR 0.98 (99% CI 0.63-1.52) AOR 1.04 (99% CI 0.67-1.62) Multiparous 35/6,067(0.56%) OR 0.61 (99% CI 0.31-1.18) AOR 0.63 (99% CI 0.32-1.25)	Apgar score <7 at 5 min OU Nulliparous 101 /10,578 (1.01%) Multiparous 76/9,017 (9.4%)	Apgar score <4 at 5 min not reported (as in PICO). Statistics stratified for nulliparous and multiparous women, no statistics for all women. Adjusted for maternal age, ethnicity, understanding of English, marital/partner status, BMI, SES, parity and gestation (completed weeks). AOR restricted to women who were not missing any potential confounder data (n=61,900).	+	+/?	+
Farry 2019 New Zealand South Auckland	Retrospective cohort study	All: 4,207 FMU: 1,114 OU: 3,093	0	Apgar score <7 at 5 min 5/1,111 (0.5%) OR 0.298 (95% CI 0.118-0.752)	Apgar score <7 at 5 min 46/3,078 (1.5%)	Apgar score <4 not reported (as in PICO). Adjusted for parity, smoking, ethnicity, BMI, SES, age.	-	?	?

Project: HTA - Midwife assisted births outside hospital compared with hospital births

Appendix 4.4

Outcome variable: Infant adverse events

* + No or minor problems
 ? Some problems
 - Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness *	Study limitations *	Precision *
				Intervention	Control				

				AOR 0.354 (95% CI 0.135-0.926)					
Hiraizumi 2013 Japan Red Cross Katsushi Hospital	Retrospective cohort study	HB+ AMU: 291 (HB: 168 AMU: 123) OU: 217	0	Neonatal asphyxia HB 3/168 (1.8%)	Neonatal asphyxia OU 3/217 (1.4%)	Apgar score <4 not reported (as in PICO). Neonatal asphyxia defined as Apgar score <7 at 1 and/or 5 min No statistics presented for HB vs OU (only for HB+AMU vs OU and HB vs AMU)	-	-	-

Abbreviations: AMU alongside midwifery unit, AOR adjusted odds ratio, BMI body mass index, CI confidence interval, FMU freestanding midwifery units, HB home birth, OR odds ratio, OU obstetric unit, SES socioeconomic status

Project: HTA - Midwife assisted births outside hospital compared with hospital births

Appendix 4.5

Outcome variable: Postpartum haemorrhage requiring blood transfusion

* + No or minor problems
 ? Some problems
 - Major problems

Author year country	Study design	Number of patients n=	With- drawals - dropouts	Results		Comments	Directness *	Study limitations *	Precision *
				Intervention	Control				
Brocklehurst, Birthplace in England Collaborative Group 2011 England	Prospective cohort study	HB: 16,840 FMU: 11,282 OU: 19,706		HB 101/16,687 (0.6%) OR 0.54 (99% CI 0.36-0.80) AOR 0.72 (99% CI 0.47-1.12) FMU 67/11,230 (0.5%) OR 0.42 (99% CI 0.28-0.64) AOR 0.48 (99% CI 0.32-0.73)	OU 241/19,579 (1.2%)	Adjusted for maternal age, ethnicity, understanding of English, marital/partner status, BMI, SES, parity, and gestation (completed weeks). AOR restricted to women who were not missing any potential confounder data (n=62,219). In article (supplementary table 8.6) data also shown according to parity	+	+/?	+
Hermus 2017 The Netherlands	Retrospective cohort study	HB: 1,086 OU: 701	0	HB Nulliparous: 9/399 Multiparous: 5/687 Total: 14/1,086 (1.3%) Adjusted p-value, n.s.	OU Nulliparous: 5/348 Multiparous: 6/353 Total: 11/701 (1.6%)		?	?	-
Homer 2019 Australia All eight states and territories	Retrospective population based cohort study	All: 1,251,420 HB: 8,212 OU: 1,171,703	0	HB 44/8,212 (0.54%) OR 1.01 (99% CI 0.68-1.49) AOR 1.08 (99% CI 0.73-1.60)	OU 6,230/1,171,703 (0.53%)	Adjusted for maternal age, country of birth, gestational age and parity	?	?	+

Abbreviations: AOR adjusted odds ratio, CI confidence interval, HB home birth, OR odds ratio, OU obstetric unit

Project: HTA - Midwife assisted births outside hospital compared with hospital births

Appendix 4.6

Outcome variable: Perineal tear grade 3 or 4

* + No or minor problems
 ? Some problems
 - Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness *	Study limitations *	Precision *
				Intervention	Control				
Brocklehurst, Birthplace in England Collaborative Group 2011 England	Prospective cohort study	HB: 16,840 FMU: 11,282 OU: 19,706		HB 318/16,800 (1.9%) OR 0.58 (99% CI 0.45-0.76) AOR 0.77 (99% CI 0.57-1.05) FMU 259/11,262 (2.3%) OR 0.72 (99% CI 0.56-0.94) AOR 0.78 (99% CI 0.58-1.05)	OU 625 /19,638 (3.2%)	Adjusted for maternal age, ethnicity, understanding of English, marital/partner status, BMI, SES, parity and gestation (completed weeks). AOR restricted to women who were not missing any potential confounder data (n=62,482). In article (supplementary table 8.6) data also shown according to parity.	+	+/?	+
Hermus 2017 The Netherlands	Retrospective cohort study	HB: 1,086 OU: 701	0	HB Nulliparous: 18/399 (4.5%), p<0.01 Multiparous: 11/687 (1.6 %), n.s. Total: 29/1,086 (2.6%)	OU Nulliparous: 3/348 (0.9%) Multiparous: 7/353 (2.0 %) Total: 10/701 (1.4%)		?	?	?
Hiraizumi 2013 Japan Red Cross Katsushi Hospital	Retrospective cohort study	HB+AMU: 291 (HB: 168, AMU: 123) OU: 217	0	HB 1/168 (0.6%)	OU 2/217 (0.9%)	No statistics for HB vs OU, only HB+AMU vs OU and HB vs AMU. No adjustment.	-	-	-
Homer 2019 Australia	Retrospective population based cohort study	HB: 8,212 OU: 1,171,703	0	HB 70/8,018 (0.09%) CS excluded in denominator OR 0.43	OU 21,454/1,080,465 (2.0%) CS excluded in denominator	Adjusted for maternal age, country of birth, gestational age, and parity 99% CI!	?	?	?

Project: HTA - Midwife assisted births outside hospital compared with hospital births

Appendix 4.6

Outcome variable: Perineal tear grade 3 or 4

* + No or minor problems ? Some problems - Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness *	Study limitations *	Precision *
				Intervention	Control				
All eight states and territories				(99% CI 0.32-0.59) AOR 0.53 (99% CI 0.36-0.73)					

Abbreviations: AMU alongside midwifery unit, AOR adjusted odds ratio, BMI body mass index, CI confidence interval, CS caesarean section, HB home birth, OR odds ratio, OU obstetric unit, SES socioeconomic status

Project: HTA - Midwife assisted births outside hospital compared with hospital births

Appendix 4.7

Outcome variable: Admission to neonatal ward or NICU

* + No or minor problems
 ? Some problems
 - Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness *	Study limitations *	Precision *
				Intervention	Control				
Brocklehurst, Birthplace in England Collaborative Group 2011 England	Prospective cohort study	HB: 16,840 FMU: 11,282 OU: 19,706		Any NICU admission HB Nulliparous 127/4,535 (2.85%) OR 0.81 (99% CI 0.54-1.20) AOR 0.79 (99% CI 0.54-1.17) Multiparous 157/12,145(1.31%) OR 0.68 (99% CI 0.47-0.99) AOR 0.67 (99% CI 0.46-0.98) FMU Nulliparous 120/5,181 (2.16%) OR 0.59 (99% CI 0.37-0.95) AOR 0.59 (99% CI 0.37-0.94) Multiparous 73/6,060 (1.22%) OR 0.64 (99% CI 0.38-1.06) AOR 0.64 (99% CI 0.38-1.06)	Any NICU admission OU Nulliparous 372/10,597 (3.61%) Multiparous 171/9,015 (1.92%)	Any admission to NICU and not according to PICO=admission for at least 72 hours Statistics stratified for nulliparous and multiparous women, no statistics for all women. Adjusted for maternal age, ethnicity, understanding of English, marital/partner status, BMI, SES, parity and gestation (completed weeks). AOR restricted to women who were not missing any potential confounder data (n=61,848).	+	+/?	+
Farry 2019 New Zealand South Auckland	Retrospective cohort study	FMU: 1,114 OU (TMH): 3,093	0	FMU 27/1,114 (2.4%) OR 0.477 (95% CI 0.315-0.723)	OU 150/3,090 (4.9%)	Any admission to NICU and not according to PICO=admission for at least 72 hours	-	?	+

Project: HTA - Midwife assisted births outside hospital compared with hospital births

Appendix 4.7

Outcome variable: Admission to neonatal ward or NICU

* + No or minor problems
 ? Some problems
 - Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness *	Study limitations *	Precision *
				Intervention	Control				
				AOR 0.571 (95% CI 0.362-0.902) Excluding CS babies: OR 0.168 (95% CI 0.082-0.345)		Adjusted for parity, smoking, ethnicity, BMI, SES, age The non-caesarean section babies born in the OU remained more likely to be admitted to NICU			
Hermus 2017 The Netherlands	Retrospective cohort study	HB: 1,086 OU: 701	0	HB Nulliparous: 3/399 Multiparous: 0/687 Total: 3/1,086 (0.3 %) n.s.*	OU Nulliparous: 2/348 Multiparous: 0/353 Total: 2/701 (0.3 %)	Admission to NICU within 24 h postpartum and not according to PICO=admission for at least 72 hours * Calculated from data (Fishers exact test)	?	?	-
Homer 2019 Australia All eight states and territories	Retrospective population based cohort study	HB: 8,212 OU: 1,171,703	0	HB 30/5,789* (0.52%) OR 0.61 (99% CI 0.38-0.98) AOR 0.63 (99% CI 0.39-1.01)	OU 6,908/819,963* (0.084%)	*Some state(s) seems to be missing. Admission to SCN and/or NICU for more than 48 h and not according to PICO=admission for at least 72 hours. Adjusted for maternal age, country of birth, gestational age and parity 99% CI!	?	?	+
Scarf 2019 Australia, New South Wales	Retrospective population based cohort study	HB: Nullips: 546 Multips: 1,278 OU: Nullips: 209,664 Multips: 254,966	0	NICU <48 h Nulliparous 26/546 (4.8%) Multiparous 19/1,278 (1.5%) NICU >48 h Nulliparous 2/546 (0.4%)	NICU <48 h Nulliparous 20,401/209,544 (9.7%) Multiparous 15,457/254,856 (6.1%) NICU >48 h Nulliparous 778/209,544 (0.37%)	NICU <48 h and NICU >48 h Figures for HB calculated from Figure 1 and 2 No statistics. Differences in demographics (table 3) Is part of Homer 2019, which present data for NICU >48 h therefore only data separated for nulliparous and multiparous	+	-	+

Project: HTA - Midwife assisted births outside hospital compared with hospital births

Appendix 4.7

Outcome variable: Admission to neonatal ward or NICU

* + No or minor problems
? Some problems
- Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness *	Study limitations *	Precision *
				Intervention	Control				
				Multiparous 1/1,278 (0.08%) NICU admissions in total, <48 h and >48 h nulli- and multiparous 48/1,824 (2.63%)	Multiparous 663/254,856 (0.26%) NICU admissions in total, <48 h and >48 h nulli- and multiparous 37,299/464,400 (8.03%)	women are presented for NICU >48 h.			

Abbreviations: AOR adjusted odds ratio, BMI body mass index, CI confidence interval, FMU freestanding midwifery units, HB home birth, NICU neonatal intensive care unit, OR odds ratio, OU obstetric unit, SCN special care nursery, SES socioeconomic status, TMH tertiary-level obstetric-led maternity hospital

Project: HTA - Midwife assisted births outside hospital compared with hospital births

Appendix 4.8

Outcome variable: Postpartum haemorrhage >500 ml or ≥/≥1000 ml

* + No or minor problems
 ? Some problems
 - Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness *	Study limitations *	Precision *
				Intervention	Control				
Davis 2012 New Zealand	Retrospective cohort study	HB: 1,830 OU: 11,503 (7,380 secondary hospital + 4,123 tertiary hospital)	HB: 0 OU: 37	HB 19/1,830 (1.0%)	OU 163 (96+67)/11,466 (7,359+4,107) (1.4%)	OU secondary hospital or tertiary hospital (only low risk)	?	-	+
Farry 2019 New Zealand South Auckland	Retrospective cohort study	FMU: 1,114 OU: 3,093	FMU: 22 OU: 241	FMU 85/1,092 (7.8%) OR 0.489 (95% CI 0.389-0.615) AOR 0.536 (95% CI 0.424-0.676) Excluding CS: OR 0.692 (95% CI 0.534-0.898)	OU 371/2,852 (13.0%)	PPH defined as >500 ml Adjusted for parity, smoking, ethnicity, BMI, SES, age Table 5 shows same absolute numbers for PPH and maternal ICU admission but different ORs and AORs. Corrected for maternal ICU after author contact.	-	?	+
Hermus 2017 The Netherlands	Retrospective cohort study	HB: 1,086 OU: 701		HB Nulliparous: 28/399 Multiparous: 21/687 Total: 49/1,086 (4.5%) n.s*	OU Nulliparous: 26/348 Multiparous 14/353 Total: 40/701 (5.7%)	* Calculated from data (Fishers exact test)	?	?	?
Hiraizumi 2013 Japan Red Cross Katsushi Hospital	Retrospective cohort study	HB+AMU: 291 (HB: 168 AMU: 123) OU: 217	0	HB 10/168 (6.0%)	OU 7/217 (3.2%)	No statistics presented for HB vs OU (only HB+AMU vs OU and HB vs AMU)	-	-	-

Abbreviations: AMU alongside midwifery unit, AOR adjusted odds ratio, BMI body mass index, CI confidence interval, CS caesarean section, FMU freestanding midwifery units, HB home birth, ICU intensive care unit, OR odds ratio, OU obstetric unit, PPH postpartum haemorrhage, SES socioeconomic status

Project: HTA - Midwife assisted births outside hospital compared with hospital births

Appendix 4.9

Outcome variable: Intrapartum caesarean section

* + No or minor problems
 ? Some problems
 - Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness *	Study limitations *	Precision *
				Intervention	Control				
Brocklehurst, Birthplace in England Collaborative Group 2011 England	Prospective cohort study	HB: 16,840 FMU: 11,282 OU: 19,706		HB 458/16,825 (2.8%) OR 0.23 (99% CI 0.17-0.30) AOR 0.31 (99% CI 0.23-0.41) FMU 405/11,280 (3.5%) OR 0.28 (99% CI 0.21-0.37) AOR 0.32 (99% CI 0.24-0.42)	OU 2,158 /19,688 (11.1%)	Adjusted for maternal age, ethnicity, understanding of English, marital/partner status, BMI, SES, parity and gestational age (completed weeks). AOR restricted to women who were not missing any potential confounder data (n=62,592). In article (supplementary table 8.6) data also shown according to parity	+	+/?	+
Davis 2011 New Zealand	Retrospective cohort study	HB: 1,830 (Primary unit 2,877) OU: 11,503 (7,380 secondary hospital +4,123 tertiary hospital)	HB: 4 OU: 55 Excluded due to planned place of birth at labour not recorded n=243	HB 47/1,826 (2.6%) HB vs primary unit (ref) RR 0.81 (95% CI 0.56-1.15), p=0.24 ARR 0.86 (95% CI 0.60- 1.24) p=0.424	OU 1,232 (622+610) / 11,448 (7,353+4,095) (10.8%) (Primary unit 91/2,873, 3.2%)	Adjusted for maternal age, parity, ethnicity, smoking. Crude RR and ARR also available for secondary and tertiary vs primary unit	?	-	+
Farry 2019 New Zealand South Auckland	Retrospective cohort study	FMU: 1,114 OU: 3,093	0	FMU 20/1,112* (1.8%) OR 0.224 (95% CI 0.141-0.356) AOR 0.250 (95% CI 0.157-0.339)	OU 233/3,089* (7.5%)	*Denominator according to Table 5. Adjusted for parity, smoking, ethnicity, BMI, SES, age	-	?	?

Project: HTA - Midwife assisted births outside hospital compared with hospital births

Appendix 4.9

Outcome variable: Intrapartum caesarean section

* + No or minor problems
 ? Some problems
 - Major problems

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments	Directness *	Study limitations *	Precision *
				Intervention	Control				
Hiraizumi 2013 Japan Red Cross Katsushi Hospital	Retrospective cohort study	HB+ AMU: 291 (HB: 168 AMU: 123) OU: 217	0	?	?	Not possible to calculate due to incorrect figures in table	-	-	-
Homer 2019 Australia All eight states and territories	Retrospective population based cohort study	HB 8,212 OU 1,171,703	0	HB 194/8,212 (2.4%) OR 0.29 (99% CI 0.24-0.35) AOR 0.29 (99% CI 0.24-0.35)	OU 91,238/1,171,703 (7.8%)	Adjusted for maternal age, country of birth, gestational age and parity 99% CI! OR and AOR are exactly the same (article checked)	?	?	+
Scarf 2019 Australia New South Wales	Retrospective population based cohort stud	HB: Nullips 546 Multips 1,278 OU: Nullips 209,664 Multips 254,966	0	Nulliparous 29/546 (5.3%) Multiparous 1/1,278 (0.08%)	Nulliparous 30,629/209,544 (14.6%) Multiparous 6,300/254,856 (2.5%)	Is part of Homer 2019, therefore only data separated for nulliparous and multiparous women are presented. Figures for HB calculated from Figure 1 and 2. Missing data for mode of birth for 120 nulliparous and 110 multiparous women. No statistics	+	?/-	?

Abbreviations: AMU alongside midwifery unit, AOR adjusted odds ratio, ARR adjusted relative risk, BMI body mass index, CI confidence interval, FMU freestanding midwifery units, HB home birth, OR odds ratio, OU obstetric unit, RR relative risk, SES socioeconomic status

Project: HTA - Midwife assisted births outside hospital compared with hospital births

Appendix 4.10

Outcome variable: Transfer to hospital

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments
				Intervention	Control	

Brocklehurst, Birthplace in England Collaborative Group 2011 England	Prospective cohort study (here case series)	HB: 16,840 FMU: 11,282 OU: 19,706	Timing of transfer missing: HB 97 (0.6%) FMU 60 (0.5%)	<p>Transfer before delivery</p> <p>All women HB 2,387 (14.2%) FMU 1,863 (16.5%)</p> <p>Nulliparous HB 1,605/4,568 (35.1%) FMU 1,535/5,187 (29.6%)</p> <p>Multiparous HB 782/12,256 (6.4%) FMU 321/ 6,078 (5.3%)</p> <p>Transfer after delivery</p> <p>All women HB 1,046 (6.2%) FMU 545 (4.8%)</p> <p>Nulliparous HB 407/4,568 (8.9%) FMU 306/5,187 (5.9%)</p> <p>Multiparous HB 639/12,256 (5.2%) FMU 238/ 6,078 (3.9%)</p> <p>All transferred HB 3,530/16,840 (21.0%) FMU 2,468/11,282 (21.9%)</p> <p>Nulliparous HB 2,057/4,568 (45.0%) FMU 1,884/5,187 (36.3%)</p> <p>Multiparous HB 1,472/12,256 (12.0%)</p>		Instead of data from Brocklehurst 2011, the more detailed data presented by Rowe 2013 based on the same study population are included, see Rowe 2013 below.
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Project: HTA - Midwife assisted births outside hospital compared with hospital births

Appendix 4.10

Outcome variable: Transfer to hospital

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments
				Intervention	Control	
				FMU 573/ 6,078 (9.4%)		
Farry 2019 New Zealand South Auckland	Retrospective cohort study (here case series)	FMU: 1,114 OU: 3,093	0	<p>FMU Total 104/1,114 (9.3%): Intrapartum 75/1,114 (6.7%)</p> <p>Intrapartum: Primiparous 52/361 (14.4%)* vs Multiparous 23/753 (3.1%) p<0.001</p> <p>Postpartum <12h: 29/1,114 (2.6%) NS for primiparous vs multiparous</p>	OU NA	*18% in article
Hermus 2017 The Netherlands	Retrospective cohort study (here case series)	HB: 1,086 OU: 701	0	<p>HB *Referral during labour or within 2 h postpartum Nulliparous: 232/399 (58.1%) Multiparous: 129/687 (18.8%) Total: 361/1086 (33.2%)</p> <p>*Urgent referral Nulliparous: 18/399 (4.5%) Multiparous: 19/687 (2.8%) Total: 37/1086 (3.4%)</p>	OU NA	*Calculated from Table 2 which presents “no referral during labour or within 2 h postpartum” and “no urgent referral”. Table 2 also presents “birth occurred in the place originally planned at the onset of labour”
Hiraizumi 2013 Japan Red Cross	Retrospective cohort study (here case series)	HB+ AMU: 291 (HB 168	0	<p>HB 42/168 (25.0%) in Table 3 but in Table 2 35/168 (21%) (26 during labour and 9 postpartum)</p>	OU NA	

Project: HTA - Midwife assisted births outside hospital compared with hospital births

Appendix 4.10

Outcome variable: Transfer to hospital

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments
				Intervention	Control	
Katsushi Hospital		AMU 123) OU: 217		Main indication (Table 3): failure to progress (n=13) and PPH (n=10)		
Scarf 2019 Australia New South Wales	Retrospective cohort study (here case series)	HB: Nullips 546 Multips 1,278 OU: Nullips 209,664 Multips 254,966	0	HB Nulliparous 126/546 (23.1%) Multiparous 96/1,278 (7.5%)	OU NA	
Alcaraz-Vidal 2024 Spain Catalonia	Cohort study, (here case series)	HB: 750 OU: 2,713	0	HB 108/750 (14.4%)		Hospital births attended by midwife
Amelink-Verburg 2008 The Netherlands	Retrospective case series	HB+ AMU: 280,097	NR	HB No transfer 70.7% Transfer 29.3% Urgent transfer 3.4% Transfer first stage 18.5% Second stage 5.6% Early postpartum 1.9%		Total number of births not separated for HB and AMU but transfer reported for HB in percentages Data not separated for HB/AMU for nulliparous/multiparous women. Partly overlapping with Offerhaus 2013
Blix 2016 Denmark Sweden	Retrospective case series	HB: 3,068 Nullips: 572	10-20% missing	HB Nulliparous Transfer 186/572 (32.5%) During labour 137/572 (24.0%)		Data presented here only for nulliparous women, since CS (4.7%) was included in multiparous women

Project: HTA - Midwife assisted births outside hospital compared with hospital births

Appendix 4.10

Outcome variable: Transfer to hospital

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments
				Intervention	Control	
Norway Iceland		Multips: 2,446		Postpartum 49/572 (8.6%) Non-urgent 127/186 (68.3%) Potentially urgent 48/186 (25.8%) Missing 11/186 (5.9%)		
Bolten 2016 The Netherlands	Retrospective cohort study, here case series	HB: 2,050 Nullips: 868 Multips: 1,182	0	HB Nulliparous 509/868 (58.6%) Multiparous 173/1,182 (14.6%) Nulliparous First stage 310/868 (35.7%) Second stage 141/868 (16.2%) Postpartum 58/868 (6.7%) Multiparous First stage 110/1,182 (9.3%) Second stage 17/1,182 (1.4%) Postpartum 46/1,182 (3.9%)		Partly overlapping with Geerts 2014
Catling-Paull 2013 Australia 5 territories	Retrospective case series	HB: 1,807 Nullips: 575 Multips: 1,232	55	HB Transfer 315/1,807 (17.4%) Before birth 286/1,807 (15.8%) After birth 29/1,807 (1.6%)		Data not separated for nulliparous/multiparous women. Partly overlap with Davies Tuck 2018, McMurtrie 2009, Scarf 2019.

Project: HTA - Midwife assisted births outside hospital compared with hospital births

Appendix 4.10

Outcome variable: Transfer to hospital

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments
				Intervention	Control	
Galera-Barbero 2021 Spain Balearic Islands	Case series	HB: 820	0	HB Transfer During first stage 88/820 (10.7%) Nulliparous 70/296 (23.6%) During delivery 69/70 (98.6%) Postpartum 1/70 (1.4%) Multiparous 18/524 (3.4%) During delivery 16/18 (88.9%) Postpartum 2/18 (10.1%)		
Geerts 2014 The Netherlands	Prospective case series	HB: 1,279 Nullips: 528 Multips: 751	52	HB 395/1,279 (30.9%) Nulliparous 60.6%* Multiparous 18.0%*		*Only percentages, no exact figures for parity Same population included in Bolten 2016.
Hill 2024 Germany	Case series	HB+FMU 23,160 Nullips*	0	HB+FMU Nulliparous 7,080/23,160 (30.6%) non-urgent 6,687/23,160 (94%) urgent 395/23,160 (5.7%)		*No data reported for multiparous women
Huitfeldt 2016 Norway	Case series	FMU: 495	0	FMU Nulliparous 48.7% (56/115)		Data not reported for multiparous women since they included previous CS (1.3%, 5/380)

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Appendix 4.10

Outcome variable: Transfer to hospital

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments
				Intervention	Control	
Oslo		Nullips: 115 Multips: 380		44.3% (51/115) during labour 4.3% (5/115) after birth 3.5% (4/115 urgent)		
Maimburg 2018 Denmark Århus	Case series	HB: 268 Nullips: 117 Multips: 151	0	HB 28% (76/268) Nulliparous 52% (61/117) Multiparous 10% (15/151) During labour 75% (57/76) After birth 25% (19/76)		
McMurtrie 2009 Australia New South Wales	Case series	HB: 70 Data on parity not presented		HB 14.3% (10/70) During labour 10% (7/70) After birth 4.3% (3/70)		Partly overlapping with Catling-Paull 2013
Offerhaus 2013 The Netherlands	Case series	HB: 452,997 Nullips: 195,967 Multips: 257,030	Unknown Nullips 30,212 Multips 35,262	HB Nulliparous No referral 50.7% Urgent referral 5.4% Non urgent referral 43.9% Of these were neonatal referrals 1.4% Multiparous No referral 85.3% Urgent referral 2.5% Non-urgent referral 12.3% Of these were neonatal referrals 0.3%		Absolute figures not given, only percentages Partly overlapping with Amelink- Verburg 2008
Rowe* 2013 England	Case series	HB: Nullips: 4,489/		HB Nulliparous 44.1% (2,008/4,489)		*Secondary analysis of Brocklehurst 2011 (Birthplace in England Collaborative Group) but >42+0 weeks

Project: HTA - Midwife assisted births outside hospital compared with hospital births

Appendix 4.10

Outcome variable: Transfer to hospital

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments
				Intervention	Control	
		16,619 (27.0%) Multips: 12,130/ 16,619 (73.0%) FMU: Nullips: 5,152/ 11,197 (46.0%) Multips: 6,045/ 11,197 (54.0%)		During labour 34.2% After birth 8.6% Not known 1.3% Potentially urgent 11.5% Multiparous 11.6% (1,448/12,130) During labour 6.0% After birth 5.0% Not known 0.6% Potentially urgent 2.4% FMU Nulliparous 34.5% (1,868/5,162) During labour 26.9% After birth 6.0% Not known 1.5% Potentially urgent 11.2% Multiparous 567/6,045 (9.2%) During labour 4.9% After birth 3.9% Not known 0.5% Potentially urgent 2.6%		excluded in Rowe 2013 (included in Brocklehurst 2011) Data on reason for transfer, timing of transfer, and urgency of reason for transfer also in article.
Suzuki 2016 Japan One perinatal center in Tokyo	Cohort study (here case series)	HB: 123	0	HB 38/123 (31%) Before labour 12/123 (9.8%) First/sec stage 14/123 (11%) Third stage 9/123 (7.3%) Neonate only 3/123 (2.4%)		Partly overlapping with Hiraizumi 2013

Project: HTA - Midwife assisted births outside hospital compared with hospital births

Appendix 4.10

Outcome variable: Transfer to hospital

Author year country	Study design	Number of patients n=	Withdrawals - dropouts	Results		Comments
				Intervention	Control	
				Nulliparous: 17/32 (53%) Multiparous: 21/91 (23%)		
Sweet 2022 Australia Victorian state	Cohort study (here cases series)	HB: 561	0	HB All 20.3% (114/561) Transfer before birth 13.2% (74/561) Maternal transfer postpartum 4.8% (27/561) Neonatal transfer 2.3% (13/561)		
White 2020 Australia Victorian state	Case series	HB: 191 Nullips: 33 Multips: 158	0	HB All Antenatal 11% (21/191) Intrapartum 11.5% (22/191) Post-natal 2.6% (5/191) Nulliparous Antenatal 18.2% (6/33) Intrapartum 21.2% (7/33) Post-natal 9.1% (3/33) Multiparous Antenatal 9.5% (15/158) Intrapartum 9.5% (15/158) Post-natal 1.3% (2/158)		Antenatal transfer includes hemorrhage, hypertension, prolonged rupture of the membranes, suspected fetal growth restriction etc

AOR adjusted odds ratio, CS caesarean section, CI confidence interval, FMU freestanding midwifery units, HB home birth, NA not applicable, OR odds ratio, OU obstetric unit, PPH postpartum haemorrhage

Supplementary file

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Subgroup analyses according to parity

Nulliparous women

Critical for decision-making

Maternal

Maternal admission to intensive care unit (ICU) in nulliparous women

Figure 1a. Odds ratio for maternal admission to ICU for home/FMU births vs obstetric unit births in nulliparous women

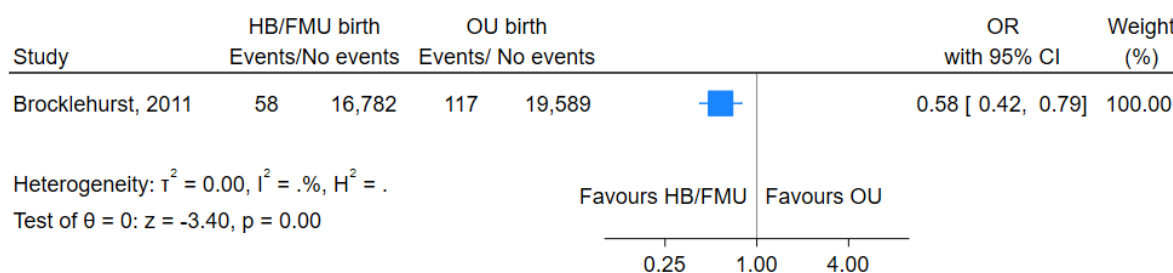
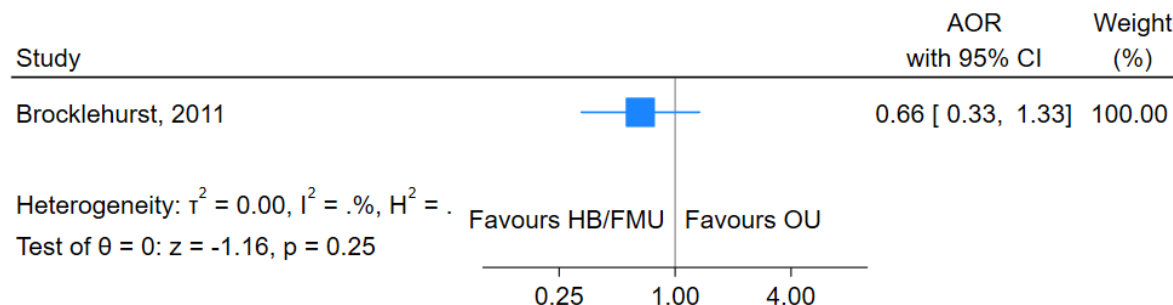


Figure 1b. Adjusted* odds ratio for maternal admission to ICU for home/FMU births vs obstetric unit births in nulliparous women



*Adjusted for maternal age, parity, ethnic group, marital or partner status, understanding English, BMI, index of multiple deprivation score, and gestational age.

Infant

Peri/neonatal mortality in nulliparous women

Figure 2a. Odds ratio for peri/neonatal mortality for home/FMU births vs obstetric unit births in nulliparous women

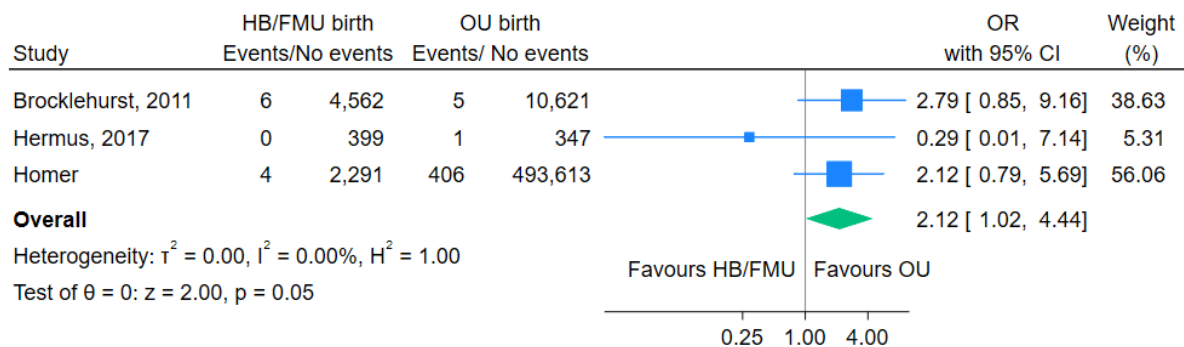
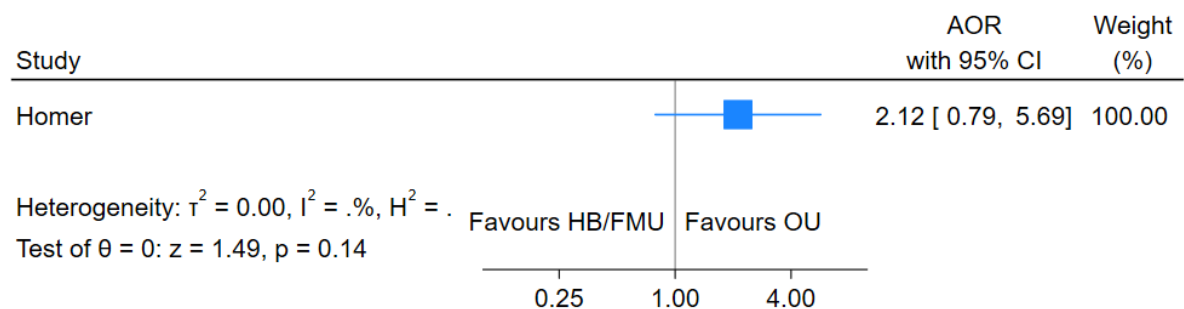


Figure 2b. Adjusted* odds ratio for peri/neonatal mortality home/FMU births vs obstetric unit births in nulliparous women

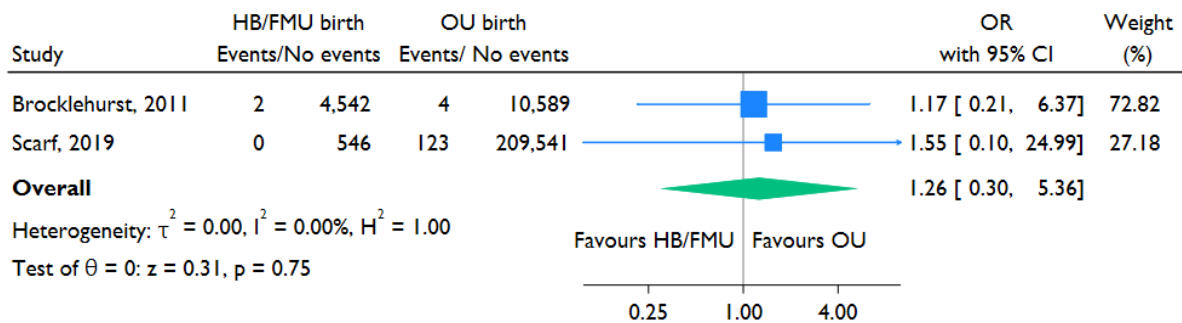


*Adjusted for maternal age, parity, country of birth, and gestational age.

Neonatal mortality in nulliparous women

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Appendix 5: - Supplementary file

Figure 3. Odds ratio for neonatal mortality home/FMU births vs obstetric unit births in nulliparous women



Apgar score <7 at 5 min

Figure 4a. Odds ratio for Apgar score <7 at 5 min for home/FMU births vs obstetric unit births in nulliparous women

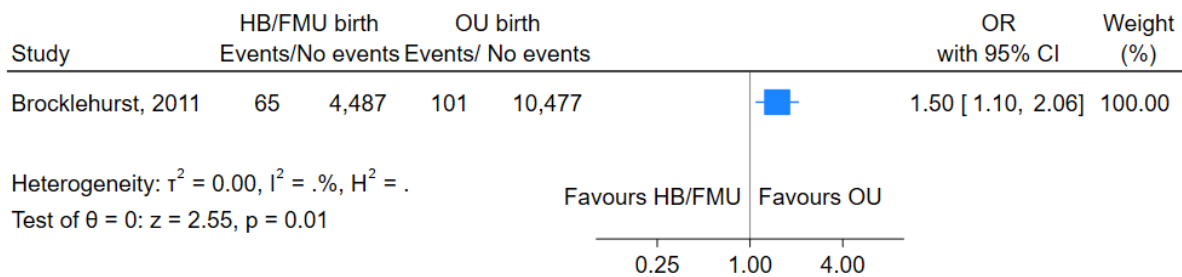
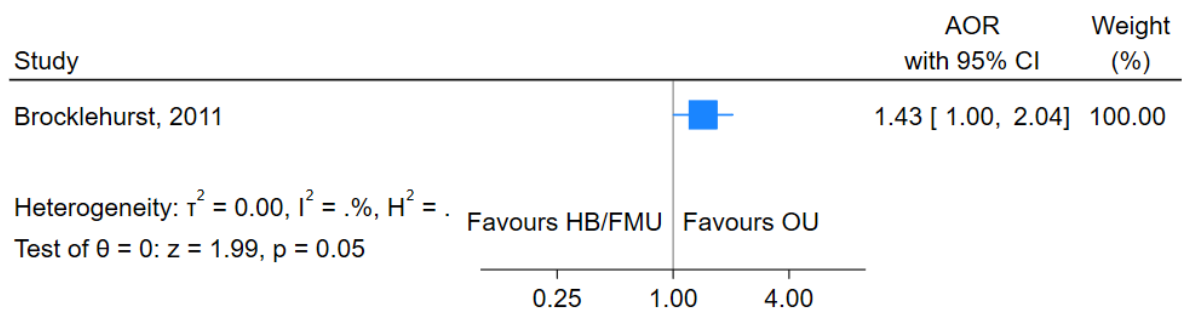


Figure 4b. Adjusted* odds ratio for Apgar score <7 at 5 min for home/FMU births vs obstetric unit births in nulliparous women



*Adjusted for maternal age, parity, ethnic group, marital or partner status, understanding English, BMI, index of multiple deprivation score, and gestational age.

Important for decision-making

Maternal

Postpartum haemorrhage requiring transfusion

Project: HTA - Midwife assisted births outside hospital compared with hospital births
Appendix 5: - Supplementary file

Figure 5a. Odds ratio for postpartum haemorrhage requiring transfusion for home/FMU births vs obstetric unit births in nulliparous women

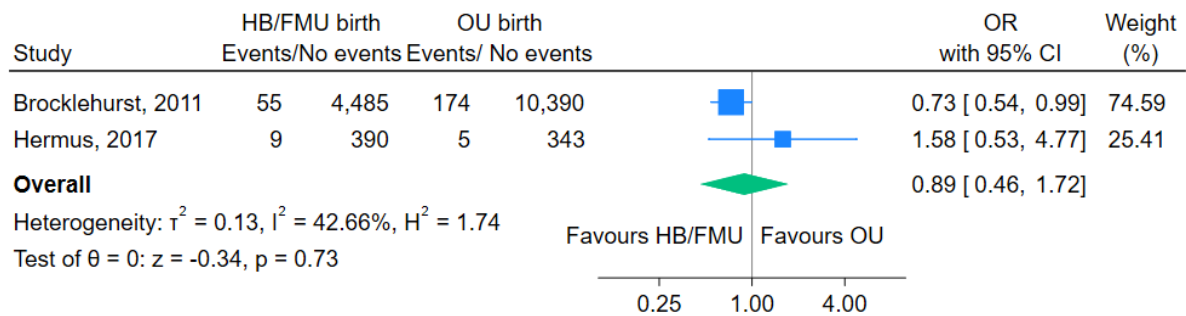
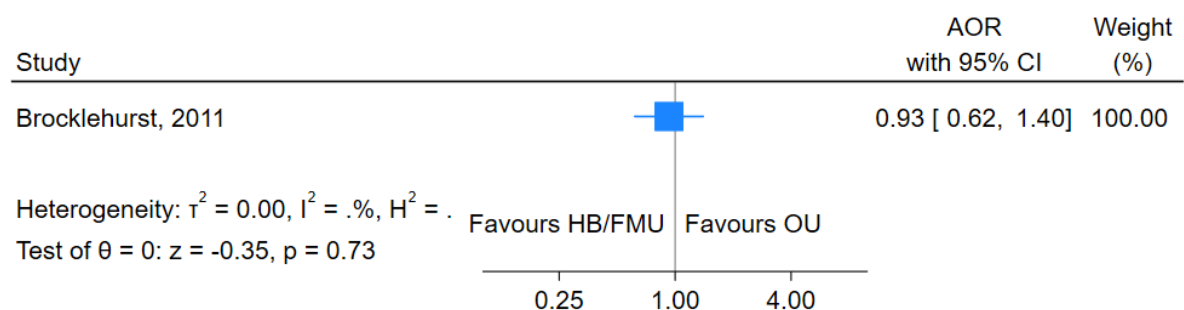


Figure 5b. Adjusted odds ratio for postpartum haemorrhage requiring transfusion for home/FMU births vs obstetric unit births in nulliparous women



*Adjusted for maternal age, parity, ethnic group, marital or partner status, understanding English, BMI, index of multiple deprivation score, and gestational age

Figure 6a. Odds ratio for perineal tear grade 3-4 for home/FMU births vs obstetric unit births in nulliparous women

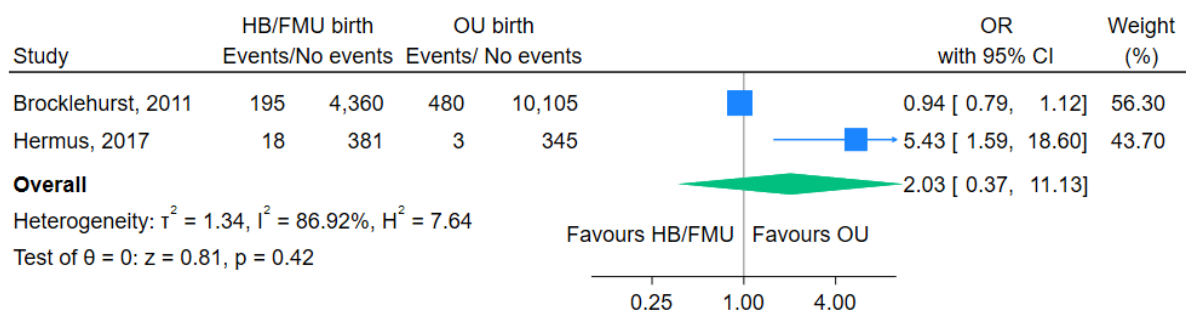
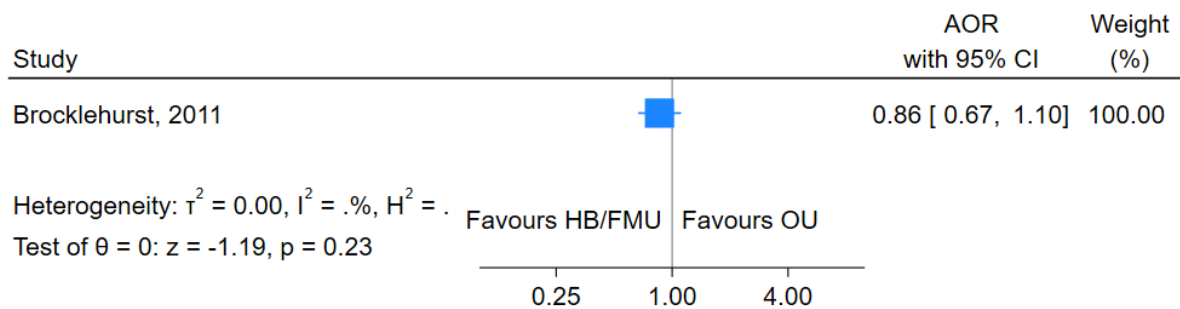


Figure 6b. Adjusted* odds ratio for perineal tear grade 3-4 for home/FMU births vs obstetric unit births in nulliparous women

Project: HTA - Midwife assisted births outside hospital compared with hospital births
Appendix 5: - Supplementary file



*Adjusted for maternal age, parity, ethnic group, marital or partner status, understanding English, BMI, index of multiple deprivation score, and gestational age

Infant

Admission to neonatal intensive care units (NICU)

Figure 7a. Odds ratio for admission to NICU for infants of nulliparous women in home/FMU births vs obstetric unit births

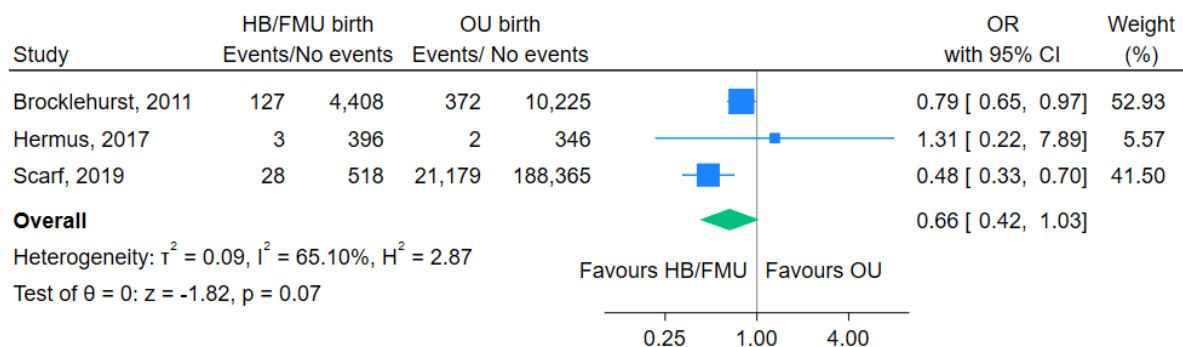
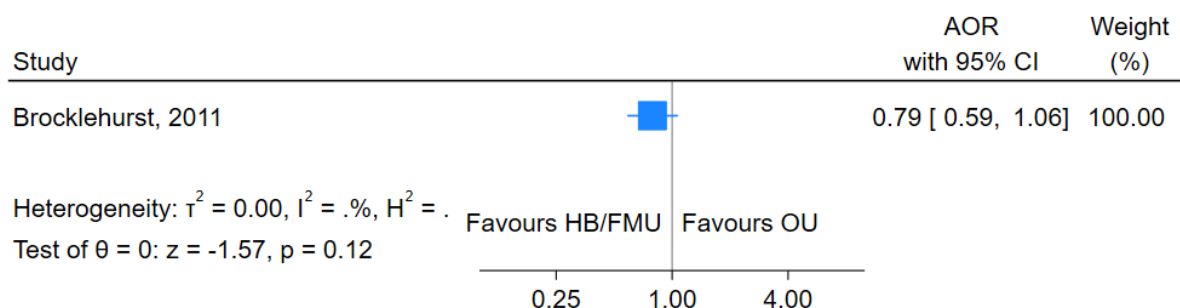


Figure 7b. Adjusted* odds ratio for admission to neonatal intensive care units (NICU) for infants of nulliparous women in home/FMU births vs obstetric unit births



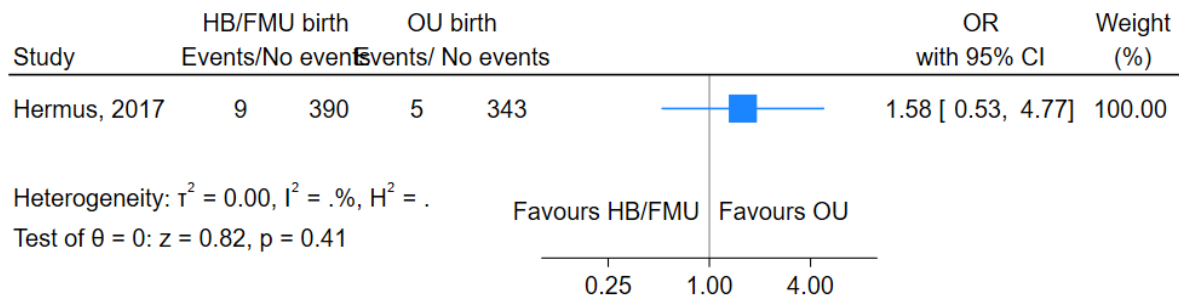
*Adjusted for maternal age, parity, ethnic group, marital or partner status, understanding English, BMI, index of multiple deprivation score, and gestational age

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Less important for decision-making

Postpartum haemorrhage (≥1000 ml)

Figure 8. Odds ratio for postpartum haemorrhage for home/FMU births vs obstetric unit births in nulliparous women



Intrapartum caesarean section

Figure 9a. Odds ratio for intrapartum caesarean section for home/FMU births vs obstetric unit births in nulliparous women

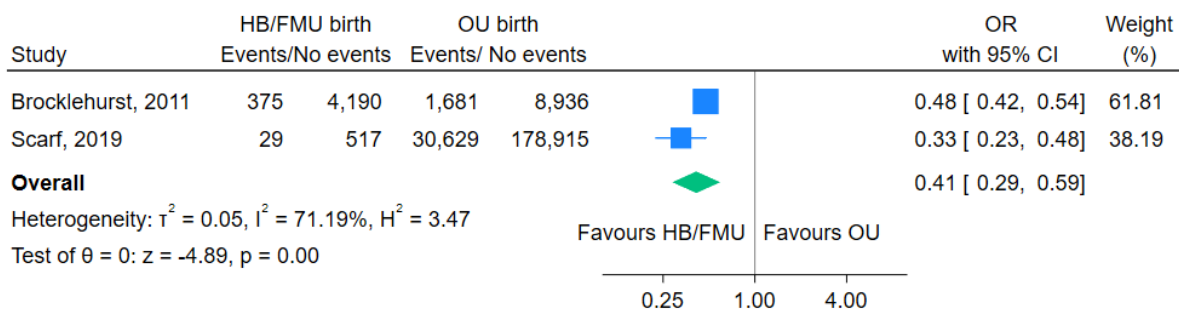
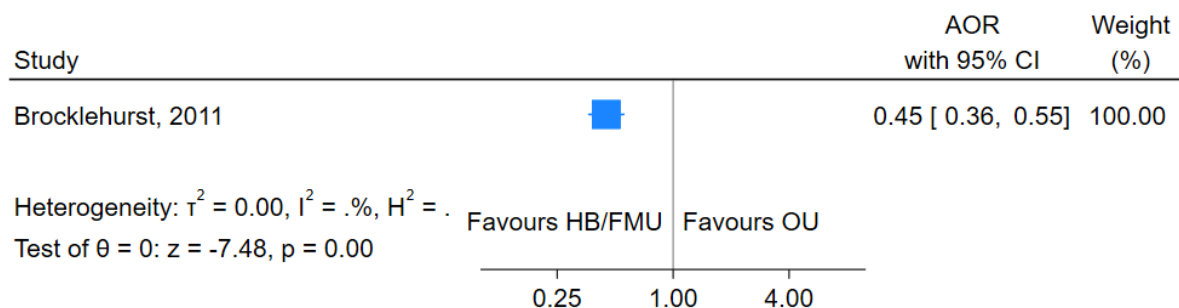


Figure 9b. Adjusted* odds ratio for intrapartum caesarean section for home/FMU births vs obstetric unit births in nulliparous women



*Adjusted for maternal age, parity, ethnic group, marital or partner status, understanding English, BMI, index of multiple deprivation score, and gestational age

Multiparous women

Critical for decision-making

Maternal

Maternal admission to intensive care unit (ICU)

Figure 10a. Odds ratio for maternal admission to ICU for home/FMU births vs obstetric unit births in multiparous women

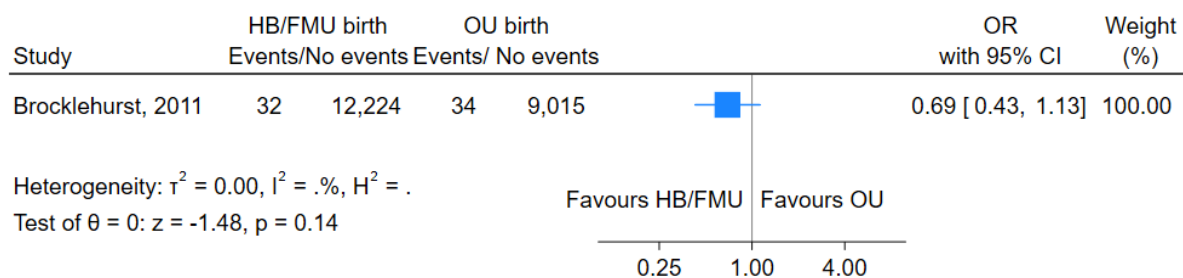
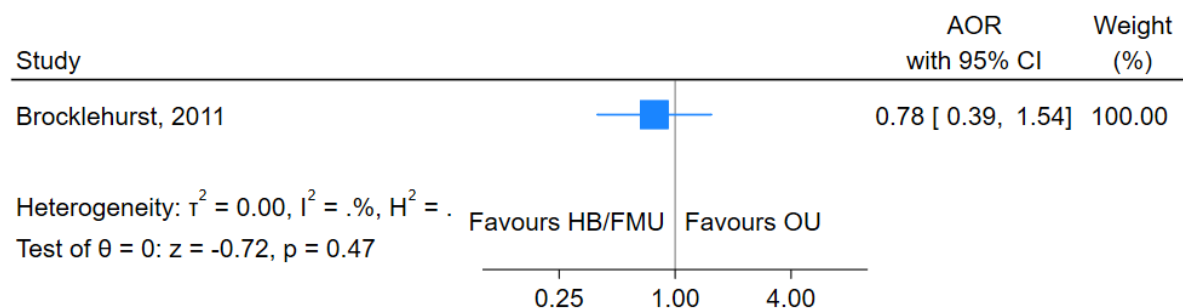


Figure 10b. Adjusted* odds ratio for maternal admission to ICU for home/FMU births vs obstetric unit births in multiparous women



*Adjusted for maternal age, parity, ethnic group, marital or partner status, understanding English, BMI, index of multiple deprivation score, and gestational age

Infant

Peri/neonatal mortality

Figure 11a. Odds ratio for peri/neonatal mortality for home/FMU births vs obstetric unit births in multiparous women

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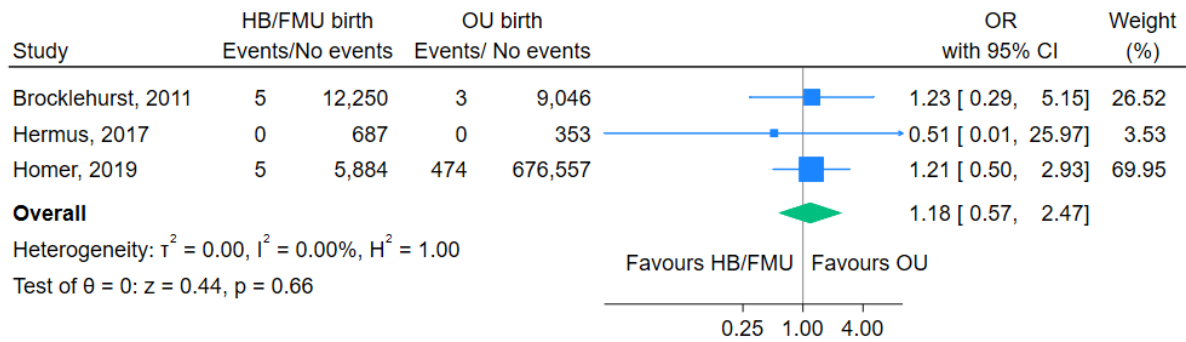
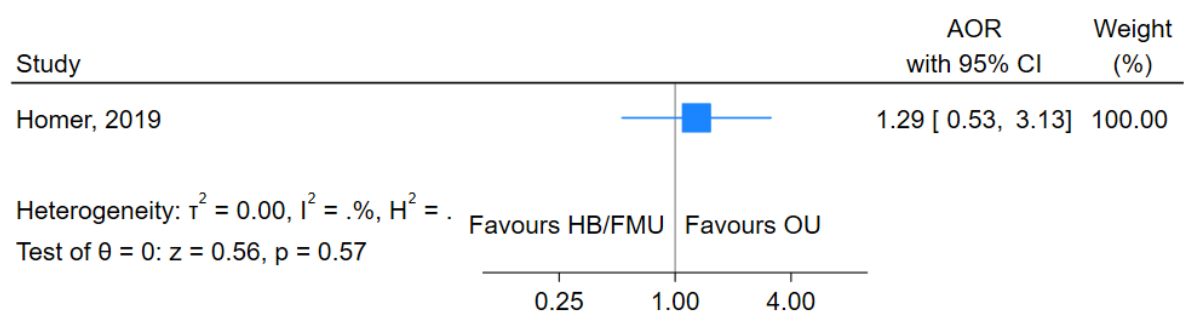


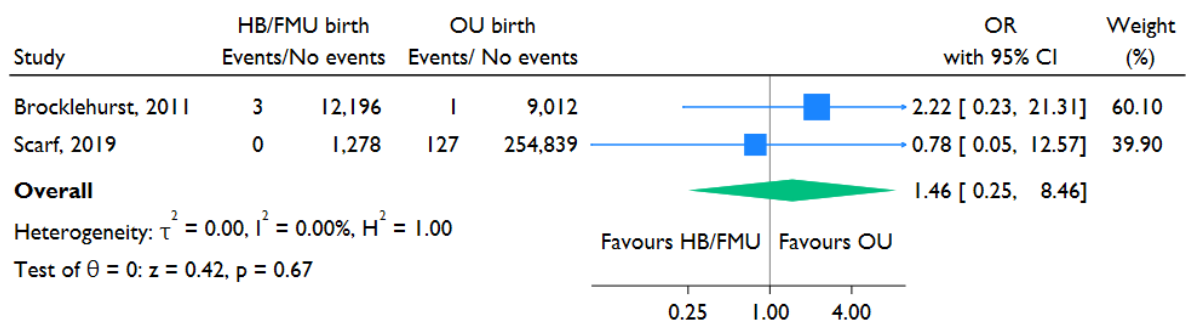
Figure 11b. Adjusted* odds ratio for peri/neonatal mortality for home/FMU births vs obstetric unit births in multiparous women



*Adjusted for maternal age, parity, country of birth, and gestational age.

Neonatal mortality

Figure 12. Odds ratio for neonatal mortality for home/FMU births vs obstetric unit births in multiparous women



Apgar <7 at 5 min

Figure 13a. Odds ratio for Apgar score <7 at 5 min for home/FMU births vs obstetric unit births in multiparous women

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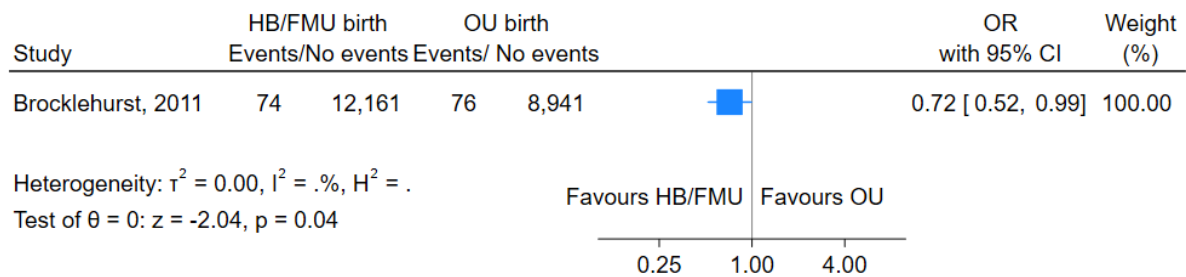
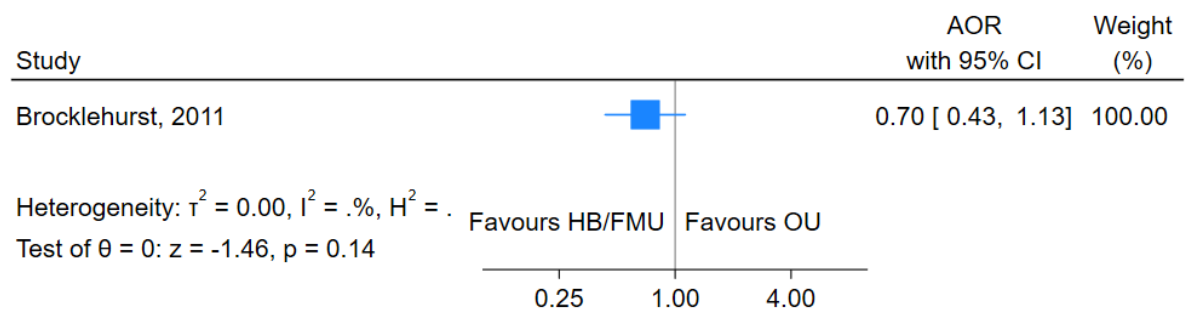


Figure 13b. Adjusted* odds ratio for Apgar score <7 at 5 min for home/FMU births vs obstetric unit births in multiparous women



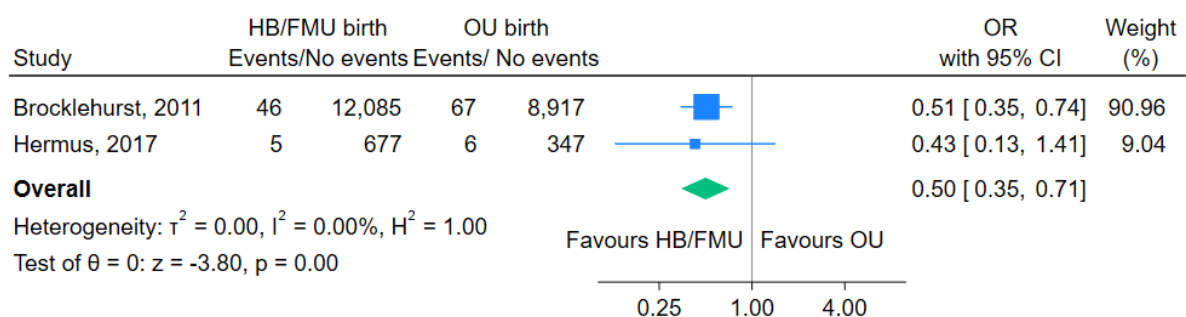
*Adjusted for maternal age, parity, ethnic group, marital or partner status, understanding English, BMI, index of multiple deprivation score, and gestational age.

Important for decision-making

Maternal

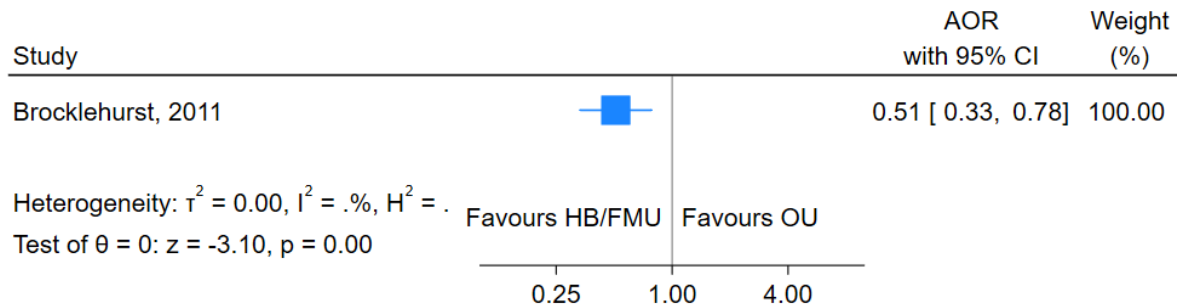
Postpartum haemorrhage requiring transfusion

Figure 14a. Odds ratio for postpartum haemorrhage requiring transfusion for home/FMU births vs obstetric unit births in multiparous women



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Figure 14b. Adjusted* odds ratio for postpartum haemorrhage requiring transfusion for home/FMU births vs obstetric unit births in multiparous women



*Adjusted for maternal age, parity, ethnic group, marital or partner status, understanding English, BMI, index of multiple deprivation score, and gestational age.

Perineal tears grade 3-4

Figure 15a. Odds ratio for perineal tears grade 3-4 for home/FMU births vs obstetric unit births in multiparous women

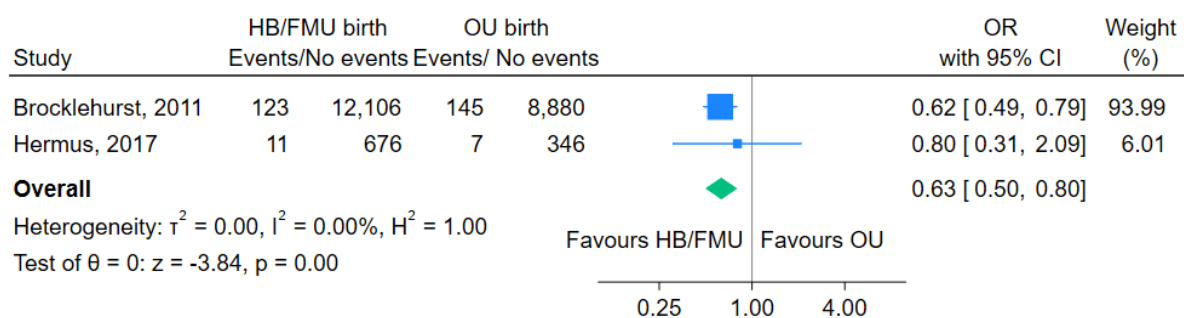
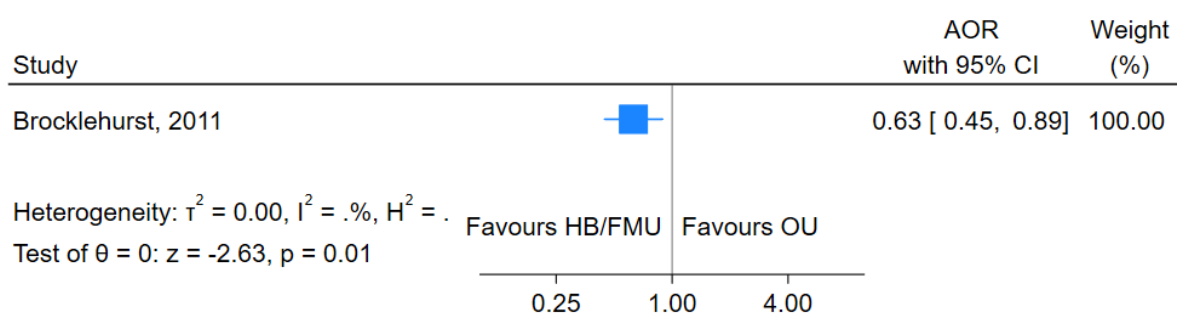


Figure 15b. Adjusted* odds ratio for perineal tears grade 3-4 for home/FMU births vs obstetric unit births in multiparous women



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*Adjusted for maternal age, parity, ethnic group, marital or partner status, understanding English, BMI, index of multiple deprivation score, and gestational age.

Infant

Admittance to neonatal intensive care units (NICU)

Figure 16a. Odds ratio for admission to NICU for infants of multiparous women in home/FMU births vs obstetric unit births

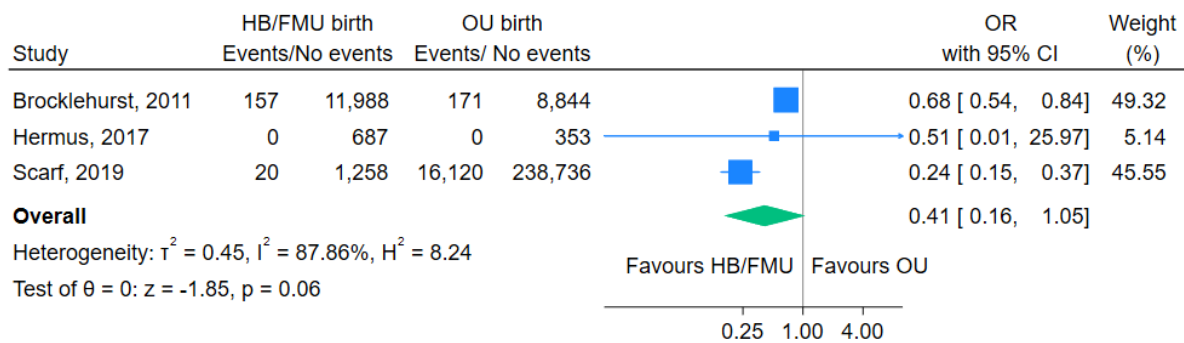
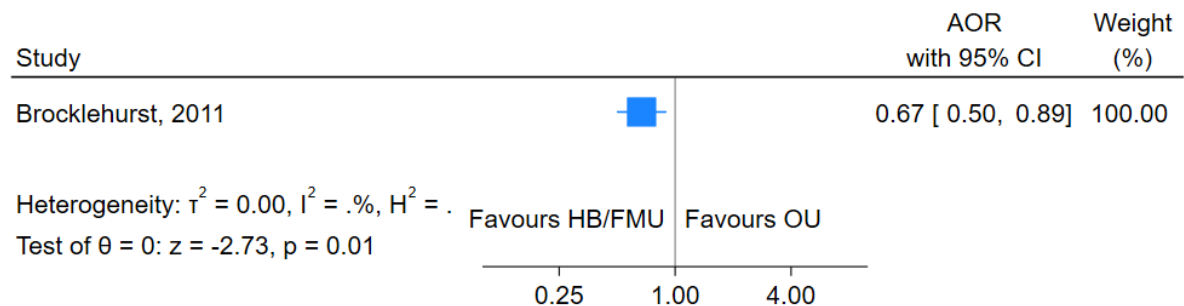


Figure 16b. Adjusted* odds ratio for admission to NICU for home/FMU births vs obstetric unit births in infants of multiparous women

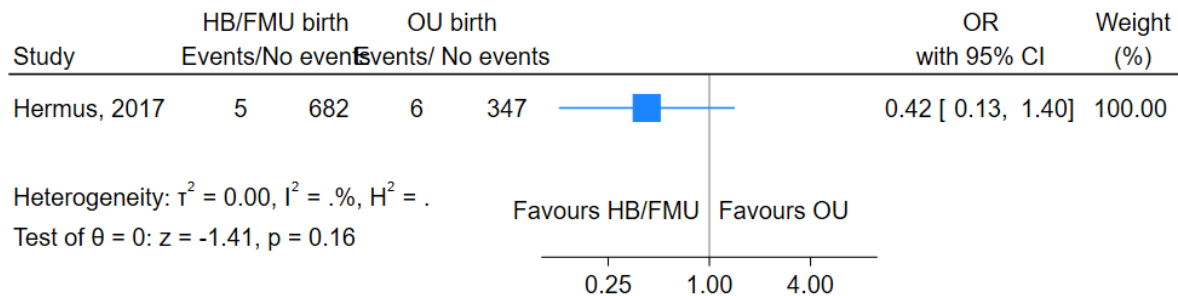


*Adjusted for maternal age, parity, ethnic group, marital or partner status, understanding English, BMI, index of multiple deprivation score, and gestational age.

Less important for decision-making

Postpartum haemorrhage (≥ 1000 ml)

Figure 17. Odds ratio for postpartum haemorrhage for home/FMU births vs obstetric unit births in multiparous women



Intrapartum caesarean section

Figure 18a. Odds ratio for intrapartum caesarean section for home/FMU births vs obstetric unit births in multiparous women

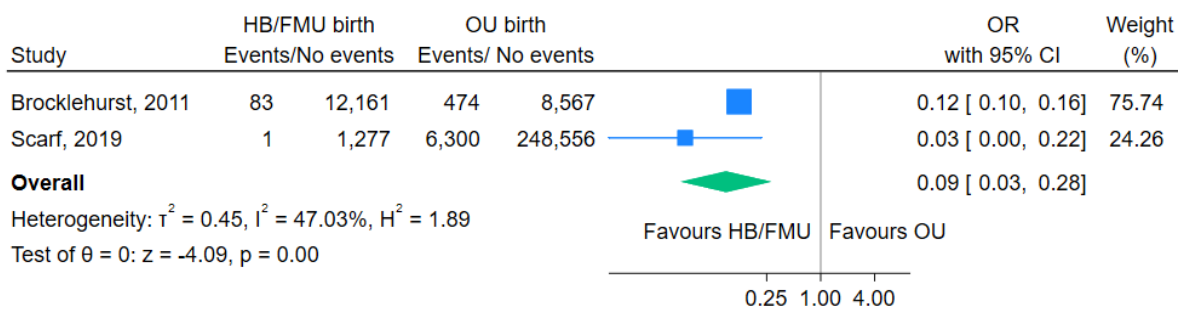
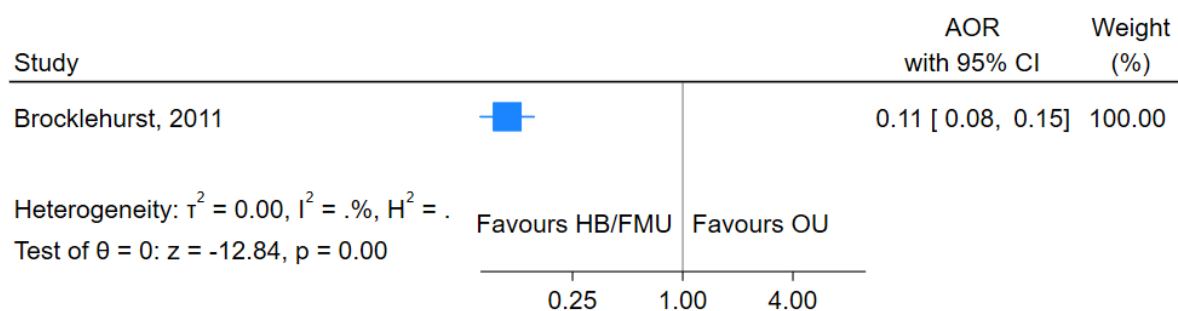


Figure 18b. Adjusted* odds ratio for intrapartum caesarean section for home/FMU births vs obstetric unit births in multiparous women



*Adjusted for maternal age, parity, ethnic group, marital or partner status, understanding English, BMI, index of multiple deprivation score, and gestational age.

Subgroup analyses according to place of birth:

Planned home births (HB) vs obstetric unit (OU) births

Critical for decision-making

Maternal

Maternal admission to intensive care unit (ICU)

Figure 19a. Odds ratio for maternal admission to ICU in planned home births vs obstetric unit births

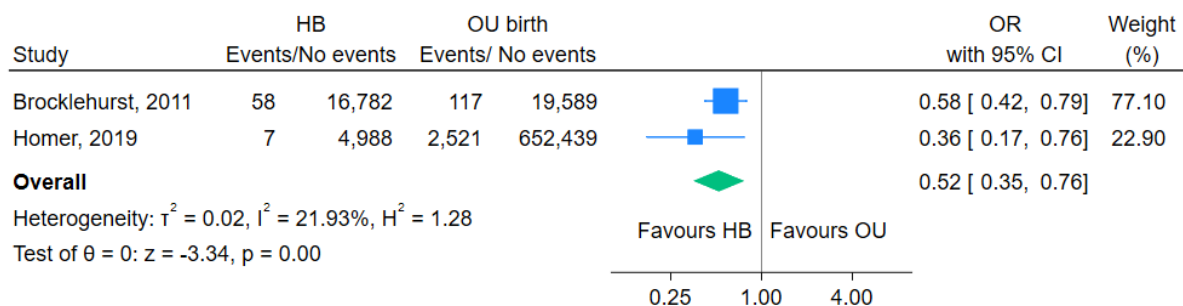
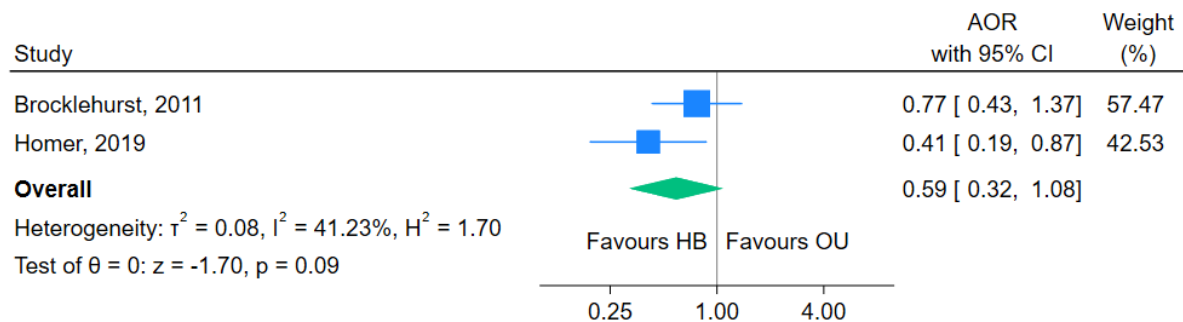


Figure 19b. Adjusted* odds ratio for maternal admission to ICU in planned home births vs obstetric unit births



Adjusted for: Brocklehurst: maternal age, parity, ethnic group, marital or partner status, understanding English, BMI, index of multiple deprivation score, gestational age; Homer: maternal age, parity, country of birth, gestational age

Infant

Peri/neonatal mortality

Figure 20a. Odds ratio for peri/neonatal mortality in planned home births vs obstetric unit births

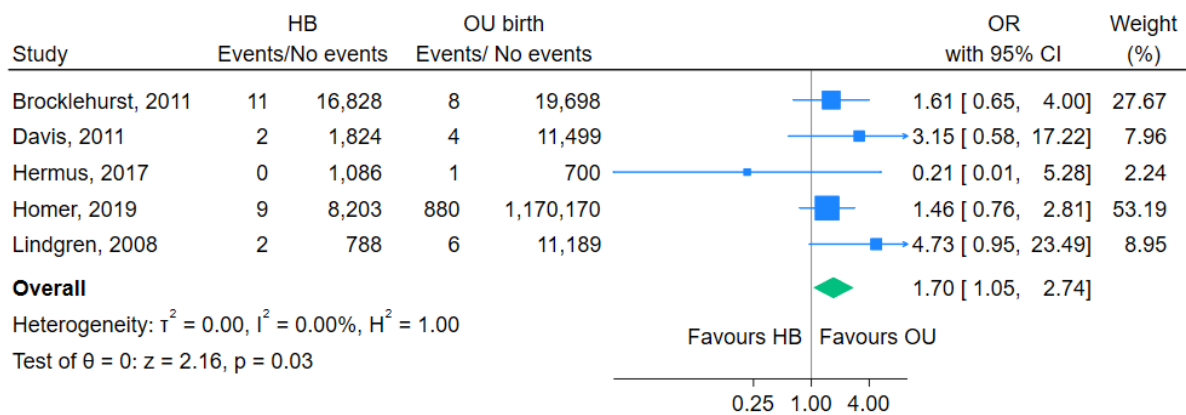


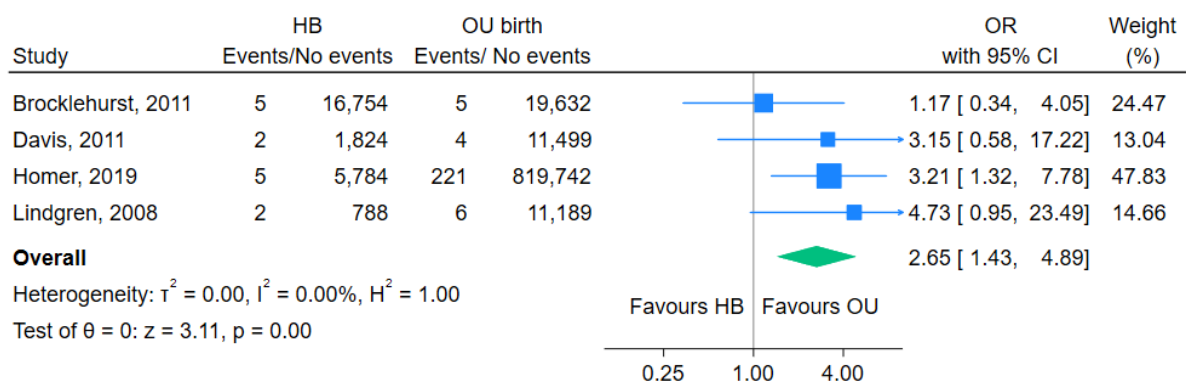
Figure 20b. Adjusted* odds ratio for peri/neonatal mortality in planned home births vs obstetric unit births



*Adjusted for maternal age, parity, country of birth, and gestational age

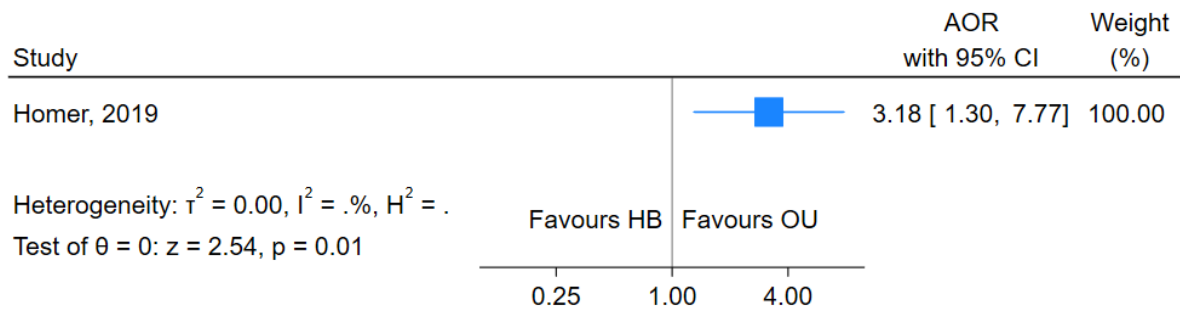
Neonatal mortality

Figure 21a. Odds ratio for neonatal mortality in planned home births vs obstetric unit births



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Figure 21b. Adjusted* odds ratio for neonatal mortality in planned home births vs obstetric unit births



*Adjusted for maternal age, parity, country of birth, and gestational age

Apgar score <7 at 1 and/or 5 min

Figure 22a. Odds ratio for Apgar score <7 at 1 and/or 5 min in planned home births vs obstetric unit births

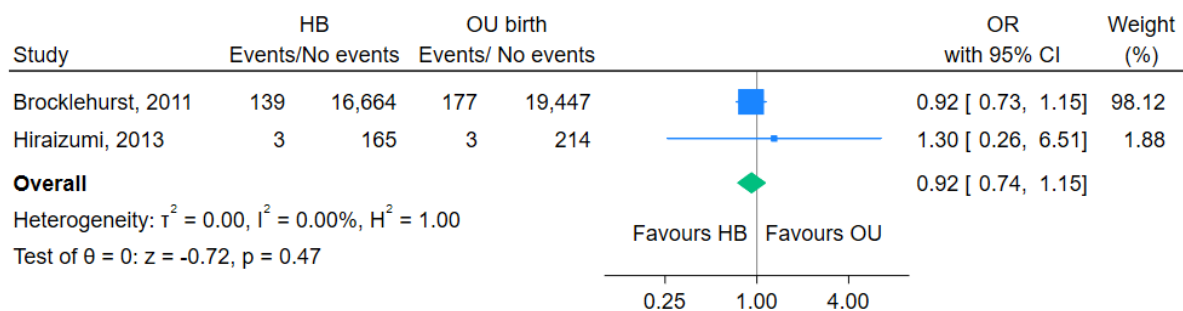
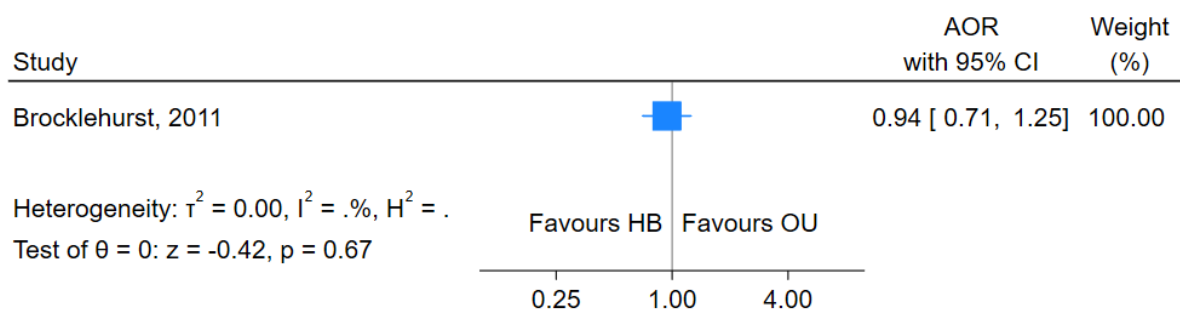


Figure 22b. Adjusted* odds ratio for Apgar score <7 at 5 min in planned home births vs obstetric unit births



*Adjusted for maternal age, parity, ethnic group, marital or partner status, understanding English, BMI, index of multiple deprivation score, and gestational age

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Important for decision-making

Maternal

Postpartum haemorrhage requiring transfusion

Figure 23a. Odds ratio for postpartum haemorrhage requiring transfusion in planned home births vs obstetric unit births

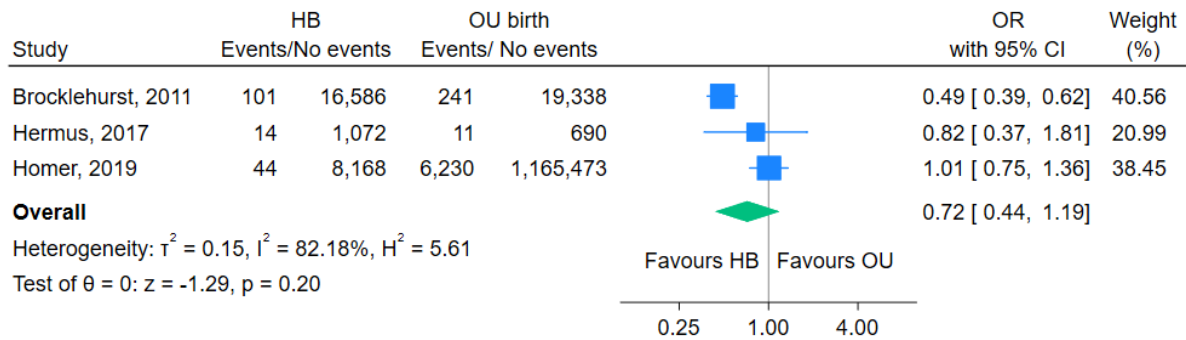
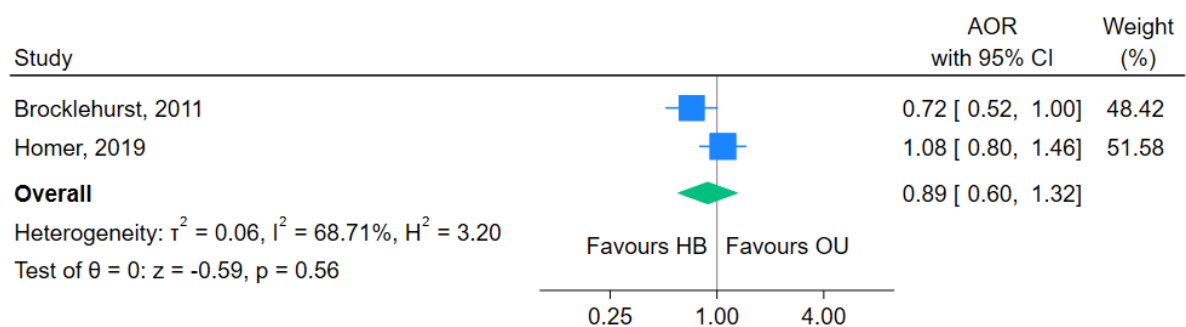


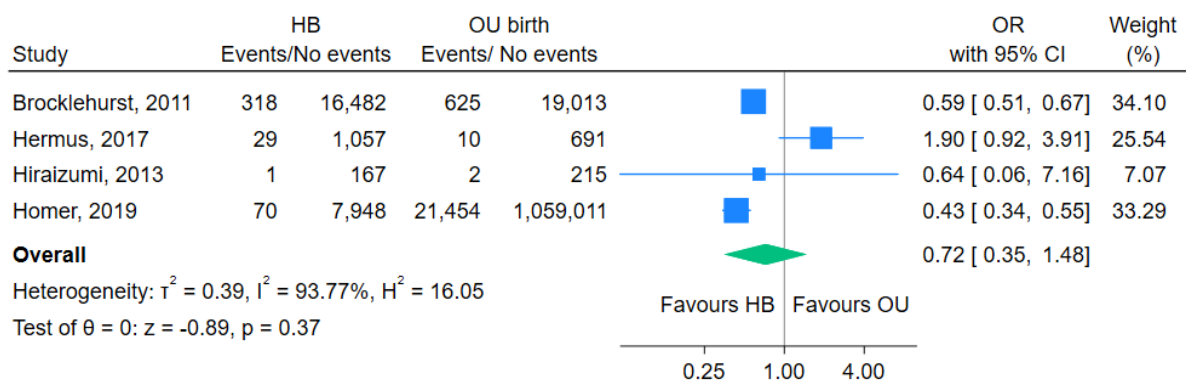
Figure 23b. Adjusted* odds ratio for postpartum haemorrhage requiring transfusion in planned home births vs obstetric unit births



*Adjusted for: Brocklehurst: maternal age, parity, ethnic group, marital or partner status, understanding English, BMI, index of multiple deprivation score, gestational age; Homer: maternal age, parity, country of birth, gestational age

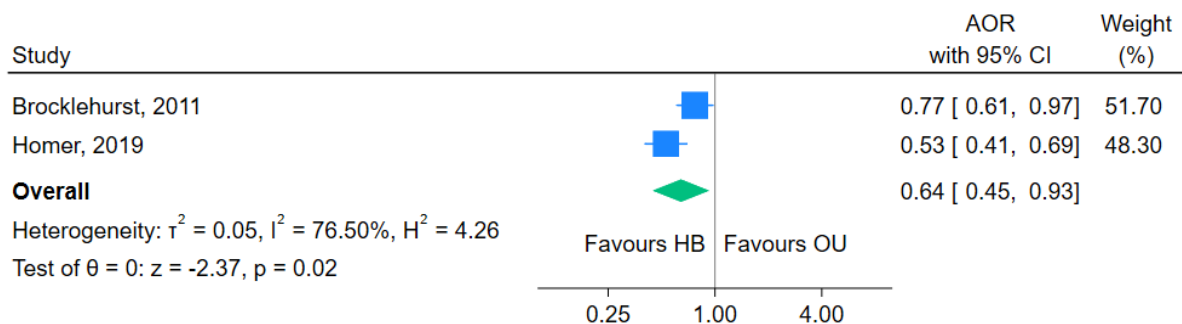
Perineal tears grade 3-4

Figure 24a. Odds ratio for perineal tears grade 3-4 in planned home births vs obstetric unit births



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Figure 24b. Adjusted* odds ratio for perineal tears grade 3-4 in planned home births vs obstetric unit births

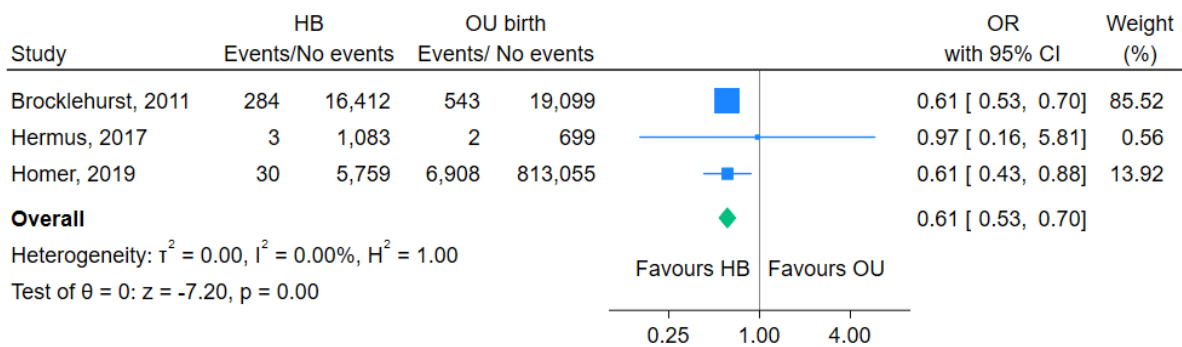


*Adjusted for: Brocklehurst: maternal age, parity, ethnic group, marital or partner status, understanding English, BMI, index of multiple deprivation score, gestational age; Homer: maternal age, parity, country of birth, gestational age

Infant

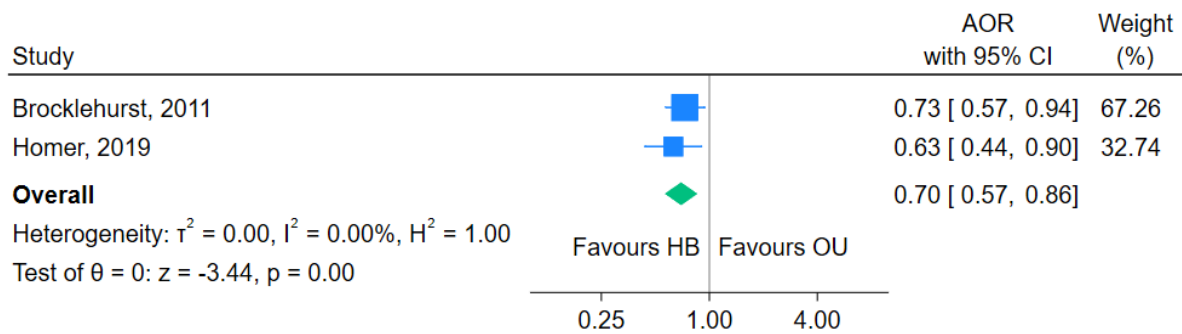
Admission to neonatal intensive care units (NICU)

Figure 25a. Odds ratio for admission to NICU for infants in planned home births vs obstetric unit births



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Figure 25b. Adjusted* odds ratio for admission to NICU for infants in planned home births vs obstetric unit births

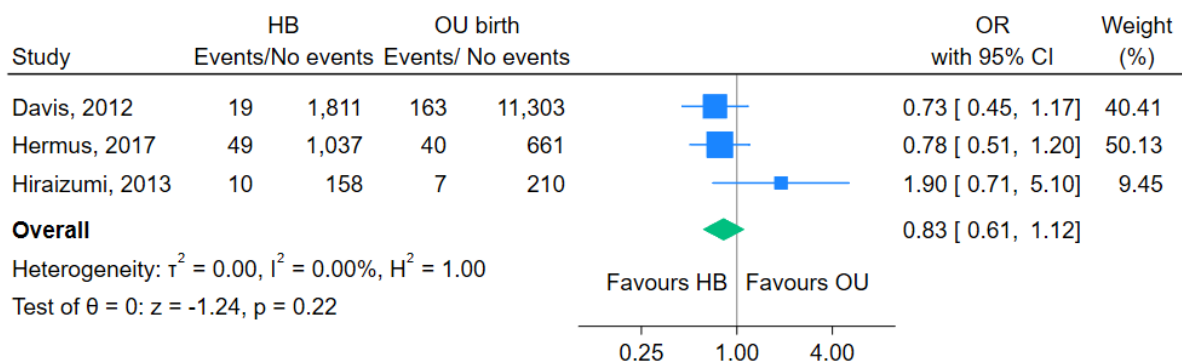


*Adjusted for: Brocklehurst: maternal age, parity, ethnic group, marital or partner status, understanding English, BMI, index of multiple deprivation score, gestational age; Homer: maternal age, parity, country of birth, gestational age

Less important for decision-making

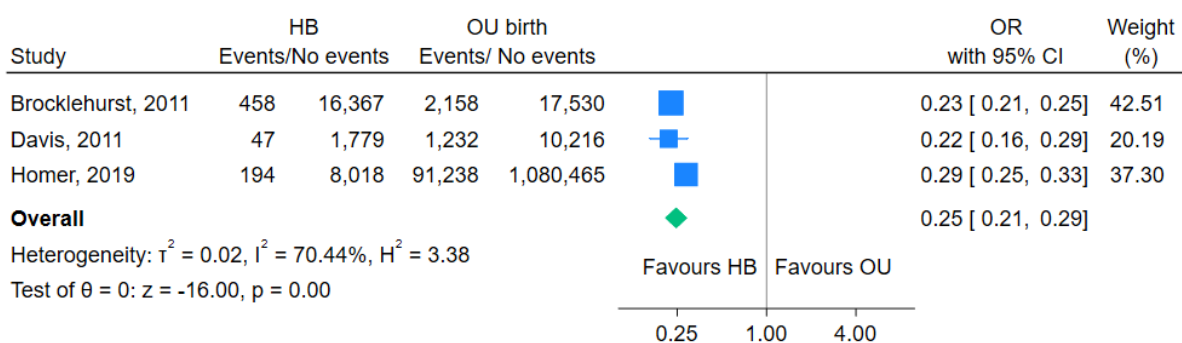
Postpartum haemorrhage (>500, >/≥1000 ml)

Figure 26. Odds ratio for postpartum haemorrhage in planned home births vs obstetric unit births



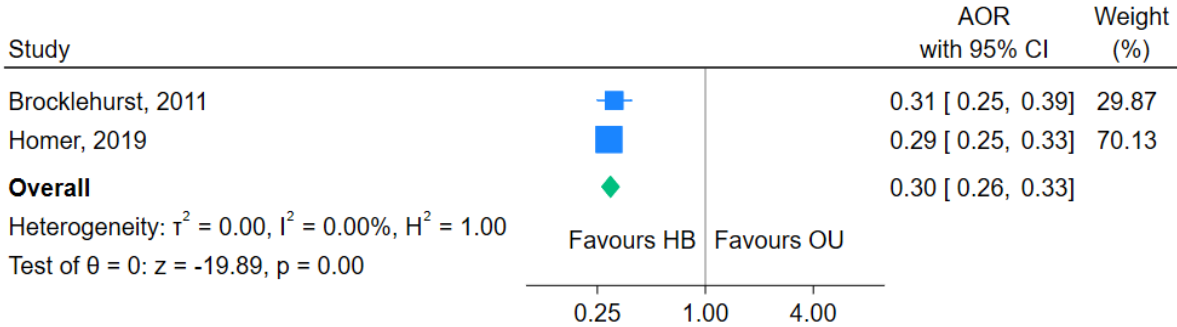
Intrapartum caesarean section

Figure 27a. Odds ratio for intrapartum caesarean section in planned home births vs obstetric unit births



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Figure 27b. Adjusted* odds ratio for intrapartum caesarean section in planned home births vs obstetric unit births



*Adjusted for: Brocklehurst: maternal age, parity, ethnic group, marital or partner status, understanding English, BMI, index of multiple deprivation score, gestational age; Homer: maternal age, parity, country of birth, gestational age

Births in FMU vs obstetric unit (OU) births

Critical for decision-making

Maternal

Maternal admission to intensive care unit (ICU)

Figure 28a. Odds ratio for maternal admission to ICU in planned FMU births vs obstetric unit births

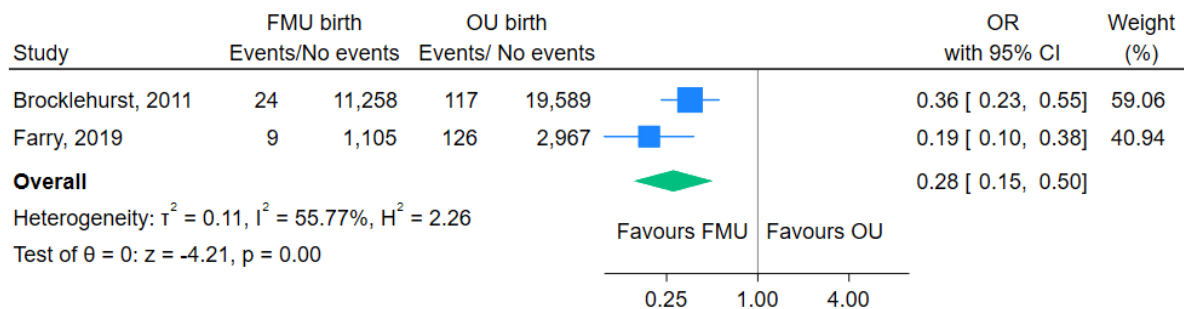
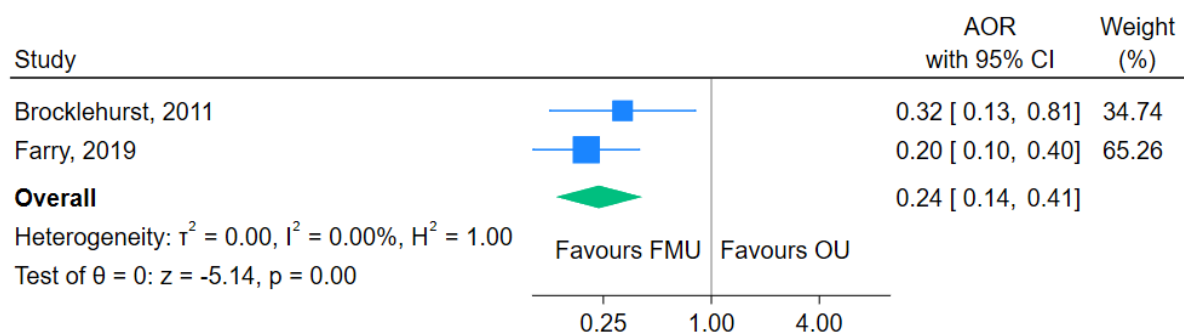


Figure 28b. Adjusted* odds ratio for maternal admission to ICU in planned FMU births vs obstetric unit births

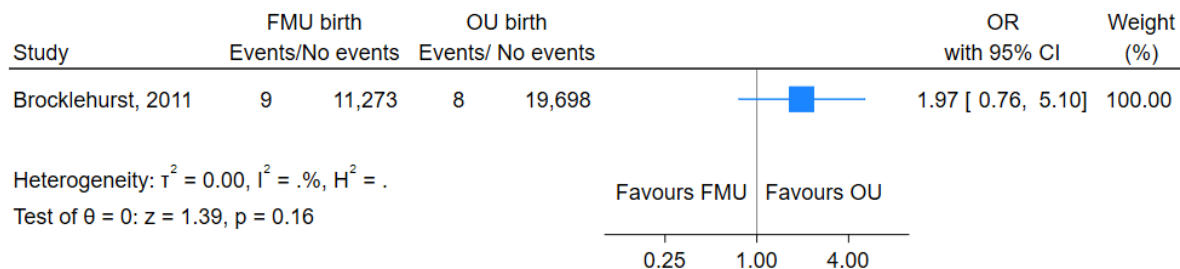


*Adjusted for: Brocklehurst: maternal age, parity, ethnic group, marital or partner status, understanding English, BMI, index of multiple deprivation score, gestational age; Farry: maternal age, parity, smoking, ethnic group, BMI, socioeconomic status

Infant

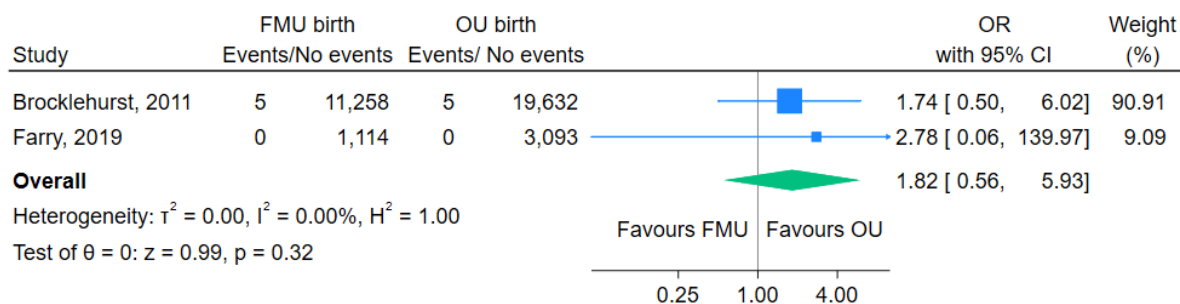
Peri/neonatal mortality

Figure 29. Odds ratio for peri/neonatal mortality in planned FMU births vs obstetric unit births



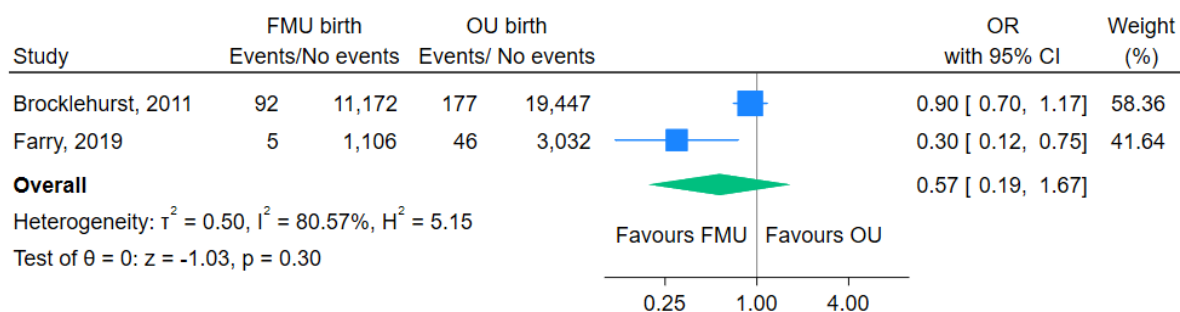
Neonatal mortality

Figure 30. Odds ratio for neonatal mortality in planned FMU births vs obstetric unit births



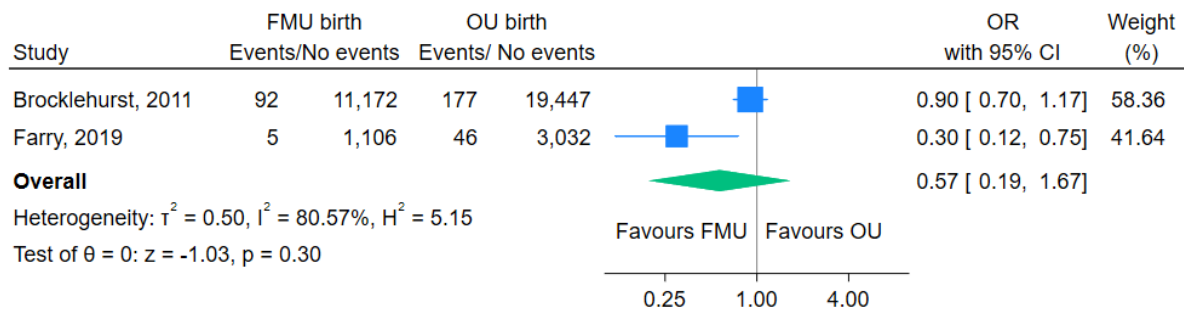
Apgar score <7 at 5 min

Figure 31a. Odds ratio for Apgar score <7 at 5 min in planned FMU births vs obstetric unit births



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Figure 31b. Adjusted* odds ratio for Apgar score <7 at 5 min in planned FMU births vs obstetric unit births



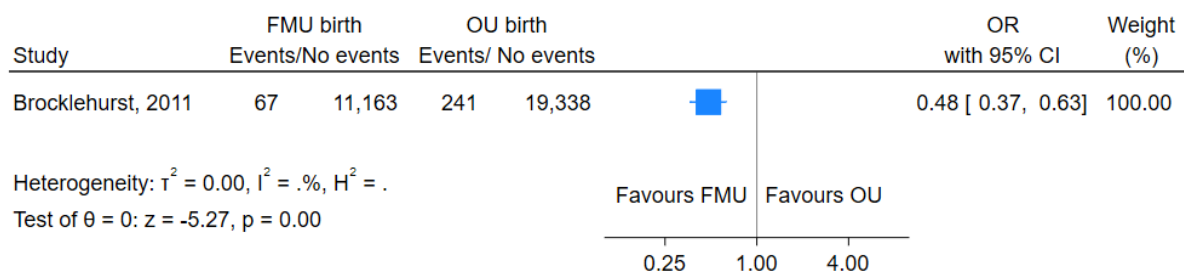
*Adjusted for: Brocklehurst: maternal age, parity, ethnic group, marital or partner status, understanding English, BMI, index of multiple deprivation score, gestational age; Farry: maternal age, parity, smoking, ethnic group, BMI, socioeconomic status

Important for decision-making

Maternal

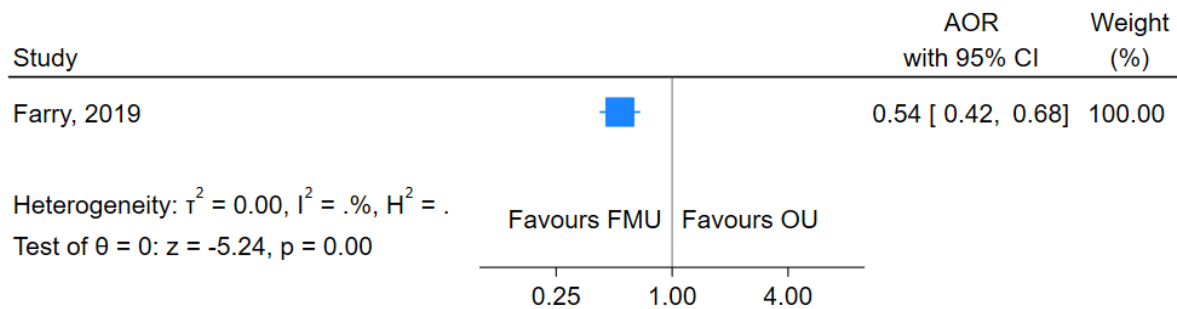
Postpartum haemorrhage requiring transfusion

Figure 32a. Odds ratio for postpartum haemorrhage requiring transfusion in planned FMU births vs obstetric unit births



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Figure 32b. Adjusted* odds ratio for postpartum haemorrhage requiring transfusion in planned FMU births vs obstetric unit births



*Adjusted for maternal age, parity, ethnic group, marital or partner status, understanding English, BMI, index of multiple deprivation score, and gestational age

Perineal tears grade 3-4

Figure 33a. Odds ratio for perineal tears grade 3-4 in planned FMU births vs obstetric unit births

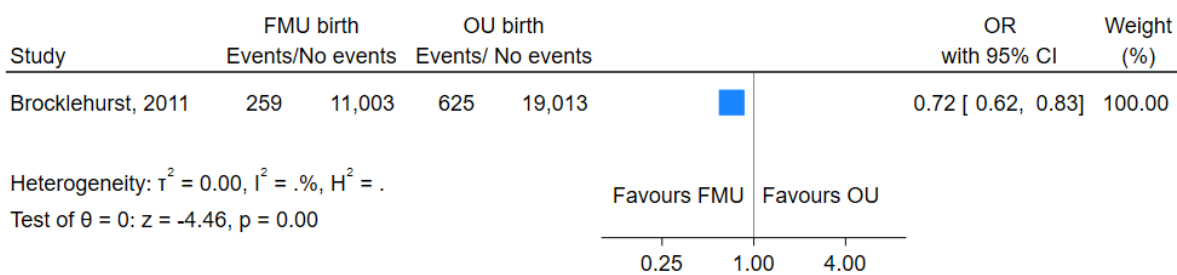
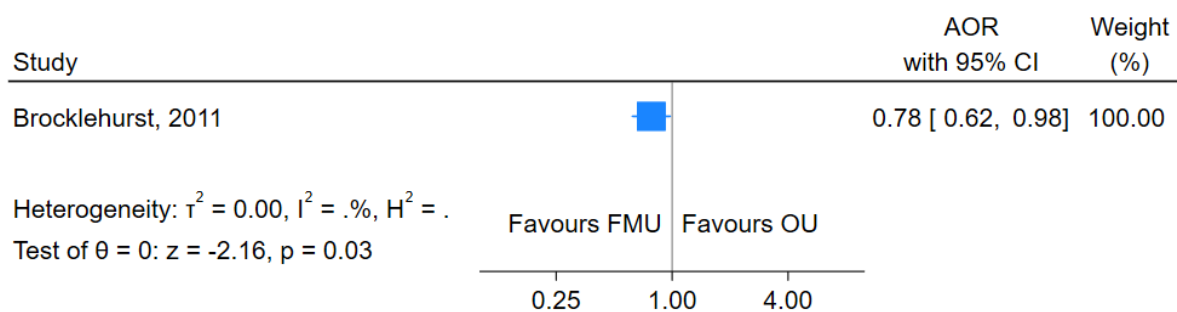


Figure 33b. Adjusted* odds ratio for perineal tears grade 3-4 in planned FMU births vs obstetric unit births



*Adjusted for maternal age, parity, ethnic group, marital or partner status, understanding English, BMI, index of multiple deprivation score, and gestational age

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Infant

Admission to neonatal intensive care units (NICU)

Figure 34a. Odds ratio for admission to NICU for infants in planned FMU births vs obstetric unit births

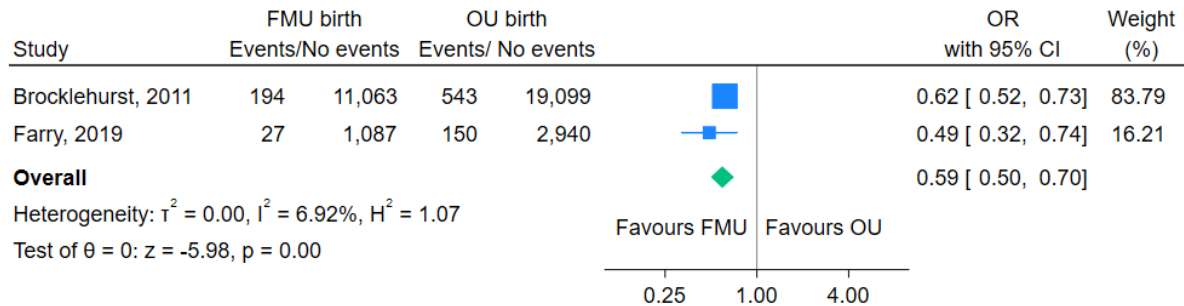
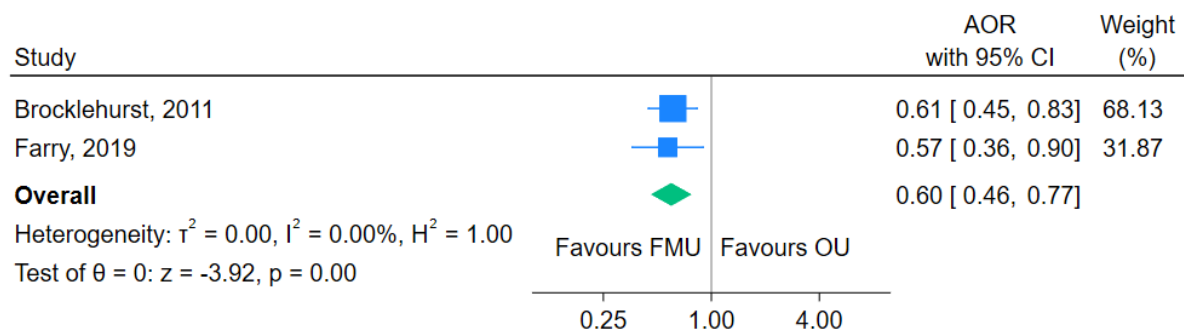


Figure 34b. Adjusted* odds ratio for admission to admission to NICU in planned FMU births vs obstetric unit births



*Adjusted for: Brocklehurst: maternal age, parity, ethnic group, marital or partner status, understanding English, BMI, index of multiple deprivation score, gestational age; Farry: maternal age, parity, smoking, ethnic group, BMI, socioeconomic status

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Less important for decision-making

Postpartum haemorrhage

Figure 35a. Odds ratio for postpartum haemorrhage in planned FMU births vs obstetric unit births

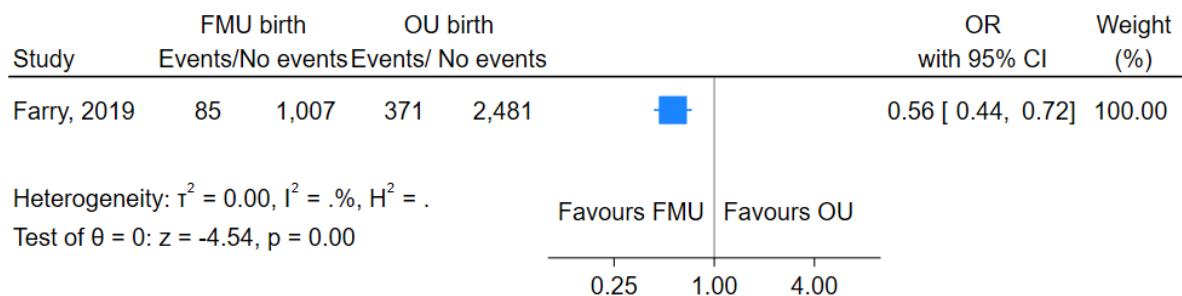
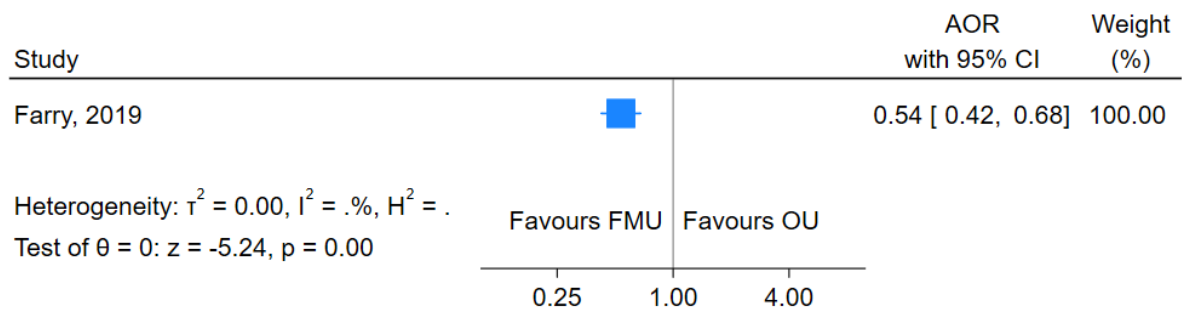


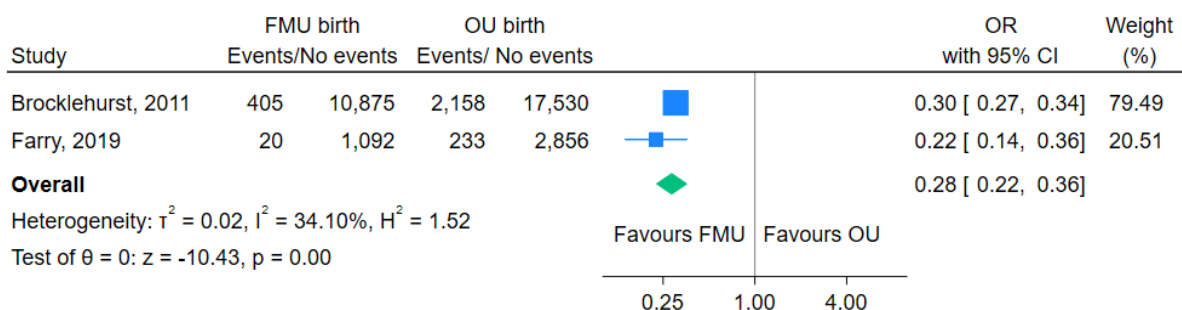
Figure 35b. Adjusted* odds ratio for postpartum haemorrhage in planned FMU births vs obstetric unit births



*Adjusted for maternal age, parity, smoking, ethnic group, BMI, and socioeconomic status

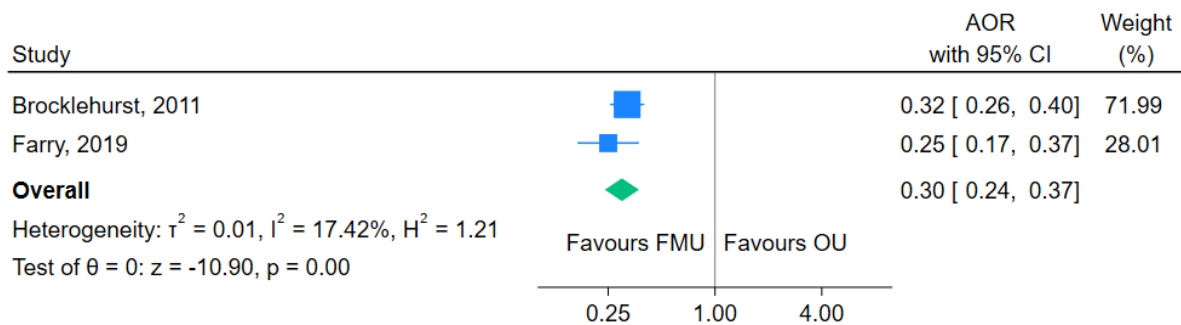
Intrapartum caesarean section

Figure 36a. Odds ratio for intrapartum caesarean section in planned FMU births vs obstetric unit births



Project: HTA - Midwife assisted births outside hospital compared with hospital births
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Figure 36b. Adjusted* odds ratio for intrapartum caesarean section in planned FMU births vs obstetric unit births



*Adjusted for: Brocklehurst: maternal age, parity, ethnic group, marital or partner status, understanding English, BMI, index of multiple deprivation score, gestational age; Farry: maternal age, parity, smoking, ethnic group, BMI, socioeconomic status

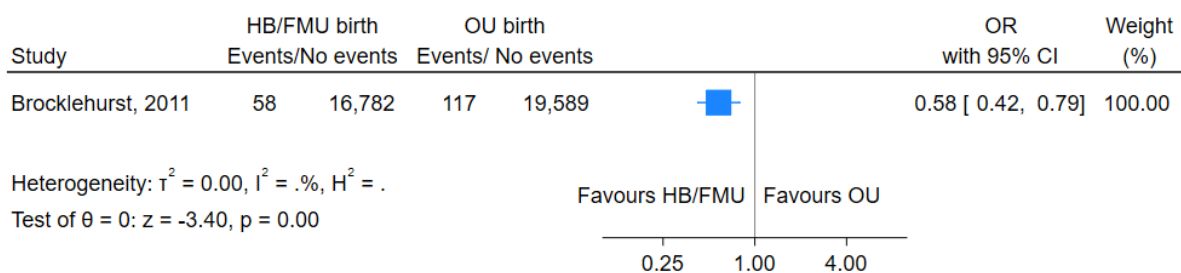
Sensitivity analysis of births outside hospital integrated in ordinary health care vs obstetric unit births

Critical for decision-making

Maternal

Maternal admission to intensive care unit (ICU)

Figure 37. Odds ratio for maternal admission to ICU of births outside hospital integrated in ordinary health care vs obstetric unit births

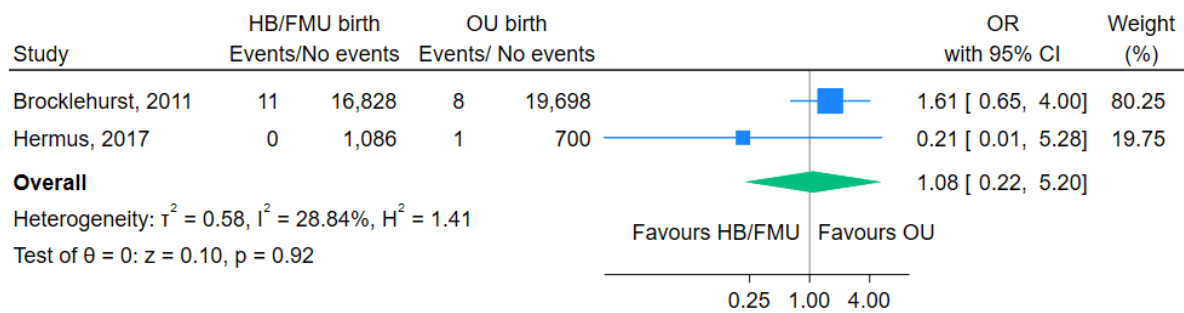


Project: HTA - Midwife assisted births outside hospital compared with hospital births
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Infant

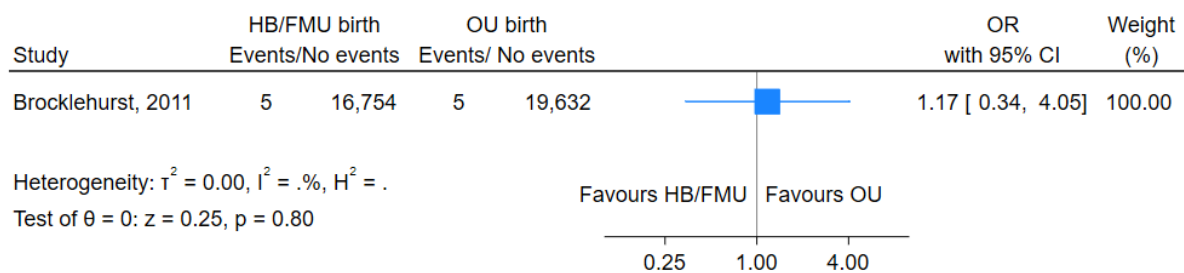
Peri/neonatal mortality

Figure 38. Odds ratio for peri/neonatal mortality of births outside hospital integrated in ordinary health care vs obstetric unit births



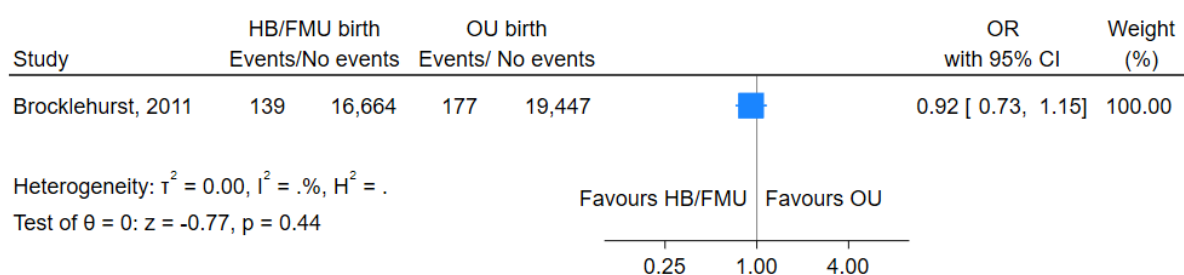
Neonatal mortality

Figure 39. Odds ratio for neonatal mortality of births outside hospital integrated in ordinary health care vs obstetric unit births



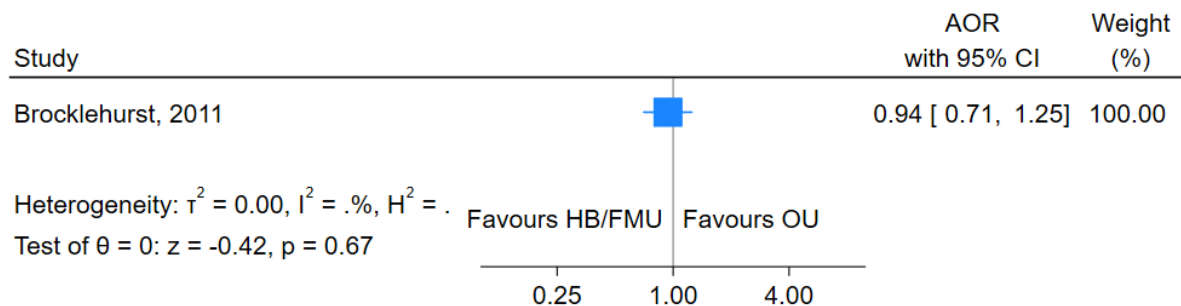
Apgar score <7 at 5 min

Figure 40a. Odds ratio for Apgar score <7 at 5 min of births outside hospital integrated in ordinary health care vs obstetric unit births



Project: HTA - Midwife assisted births outside hospital compared with hospital births
Appendix 5: - Supplementary file

Figure 40b. Adjusted* odds ratio for Apgar score <7 at 5 min of births outside hospital integrated in ordinary health care vs obstetric unit births



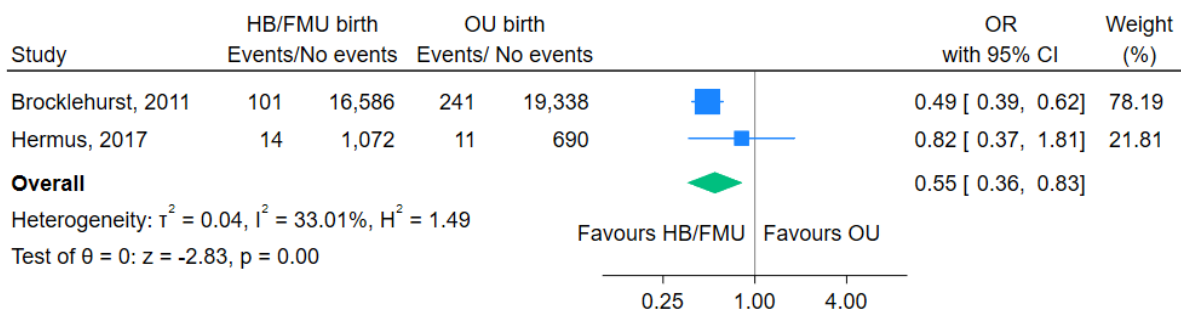
*Adjusted for maternal age, parity, ethnic group, marital or partner status, understanding English, BMI, index of multiple deprivation score, and gestational age

Important for decision-making

Maternal

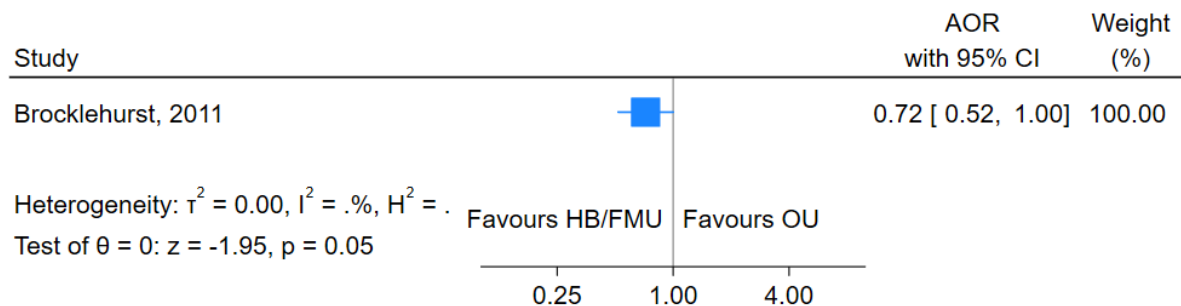
Postpartum haemorrhage requiring transfusion

Figure 41a. Odds ratio for postpartum haemorrhage requiring transfusion of births outside hospital integrated in ordinary health care vs obstetric unit births



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Appendix 5: - Supplementary file

Figure 41b. Adjusted* odds ratio for postpartum haemorrhage requiring transfusion of births outside hospital integrated in ordinary health care vs obstetric unit births



*Adjusted for maternal age, parity, ethnic group, marital or partner status, understanding English, BMI, index of multiple deprivation score, and gestational age

Perineal tears grade 3-4

Figure 42a. Odds ratio for perineal tear grade 3-4 of births outside hospital integrated in ordinary health care vs obstetric unit births

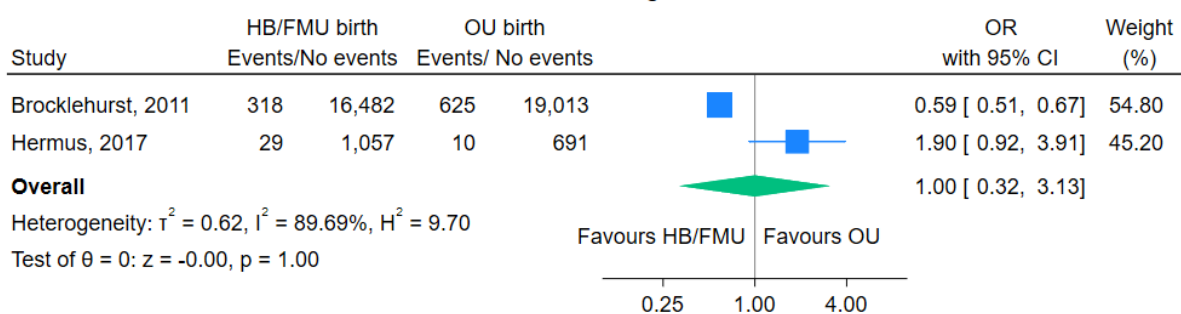
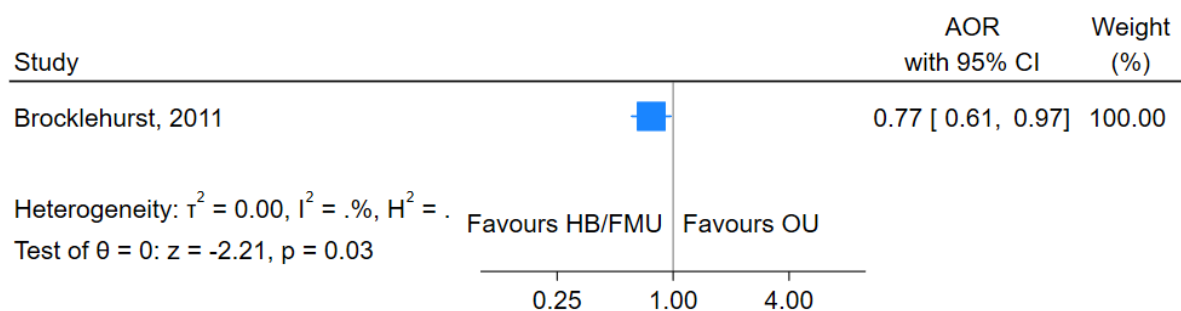


Figure 42b. Adjusted* odds ratio for perineal tear grade 3-4 of births outside hospital integrated in ordinary health care vs obstetric unit births



*Adjusted for maternal age, parity, ethnic group, marital or partner status, understanding English, BMI, index of multiple deprivation score, and gestational age

Infant

Admission to neonatal intensive care unit (NICU)

Figure 43a. Odds ratio for admission to NICU of births outside hospital integrated in ordinary health care vs obstetric unit births

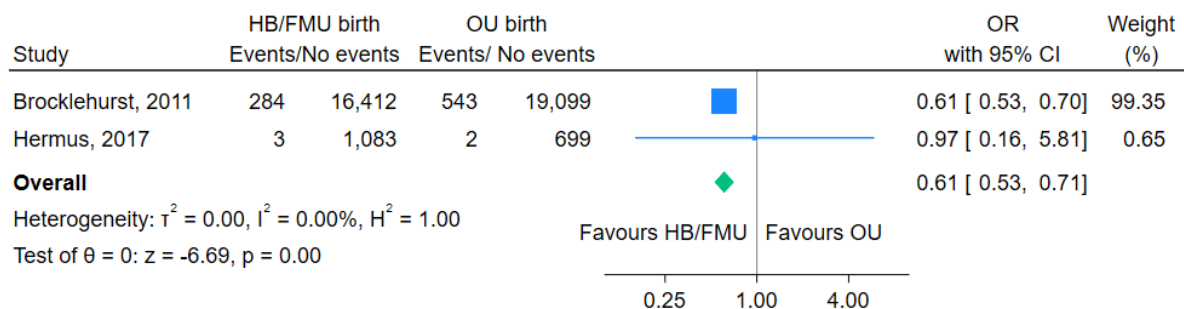
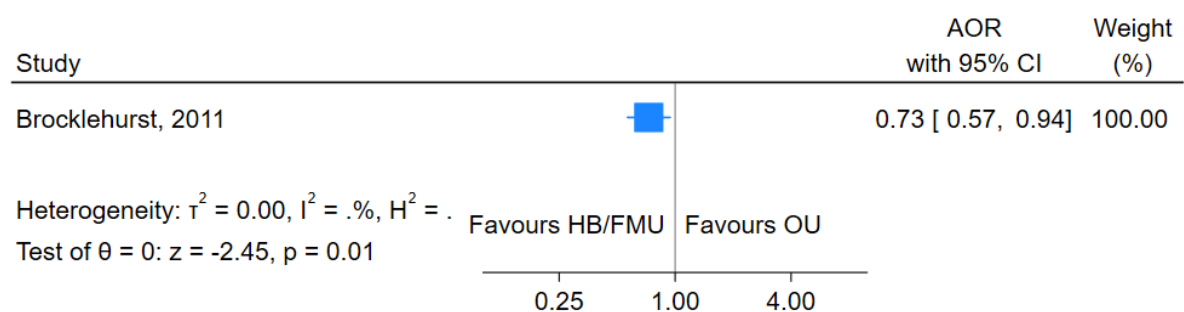


Figure 43b. Adjusted* odds ratio for admission to NICU of births outside hospital integrated in ordinary health care vs obstetric unit births

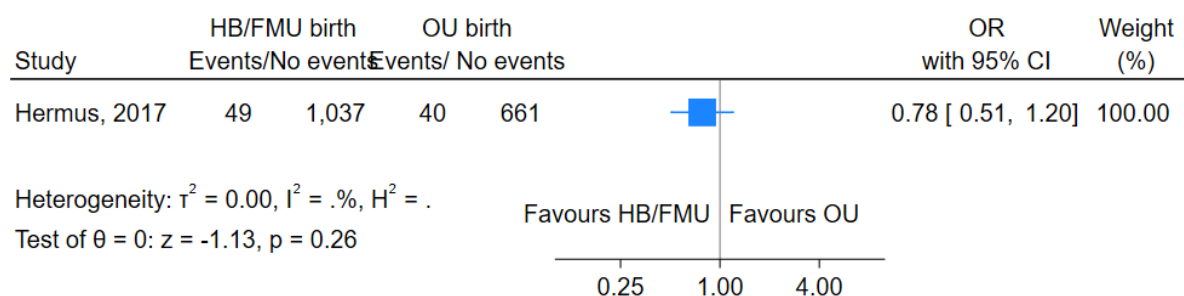


*Adjusted for maternal age, parity, ethnic group, marital or partner status, understanding English, BMI, index of multiple deprivation score, and gestational age

Less important for decision making

Postpartum haemorrhage (≥ 1000 ml)

Figure 44. Odds ratio for postpartum haemorrhage of births outside hospital integrated in ordinary health care vs obstetric unit births



Intrapartum caesarean section

Figure 45a. Odds ratio for intrapartum caesarean section of births outside hospital integrated in ordinary health care vs obstetric unit births

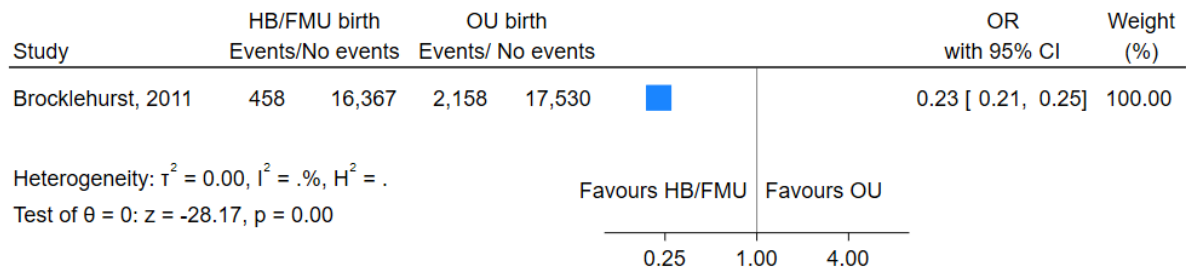
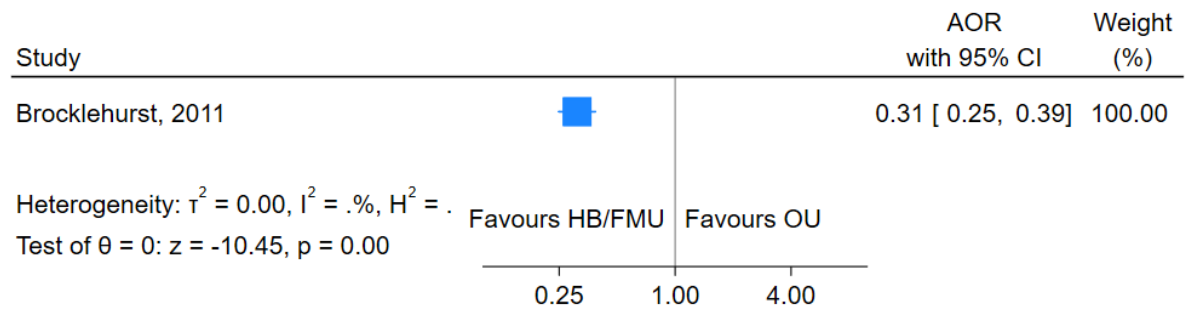


Figure 45b. Adjusted* odds ratio for intrapartum caesarean section of births outside hospital integrated in ordinary health care vs obstetric unit births



*Adjusted for maternal age, parity, ethnic group, marital or partner status, understanding English, BMI, index of multiple deprivation score, and gestational age

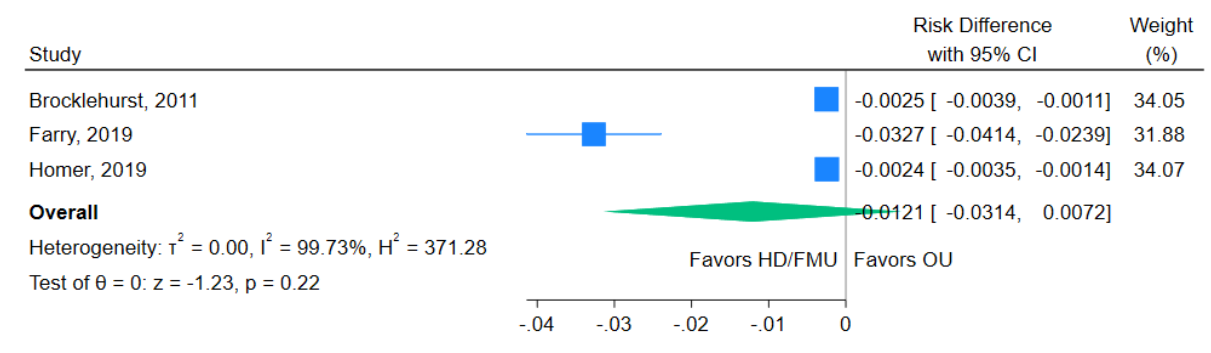
Weighted risk difference (RD) with 95% confidence interval (CI) for planned home/FMU births vs obstetric unit births in women with a low-risk pregnancy

Critical for decision-making

Maternal

Maternal admission to intensive care unit (ICU)

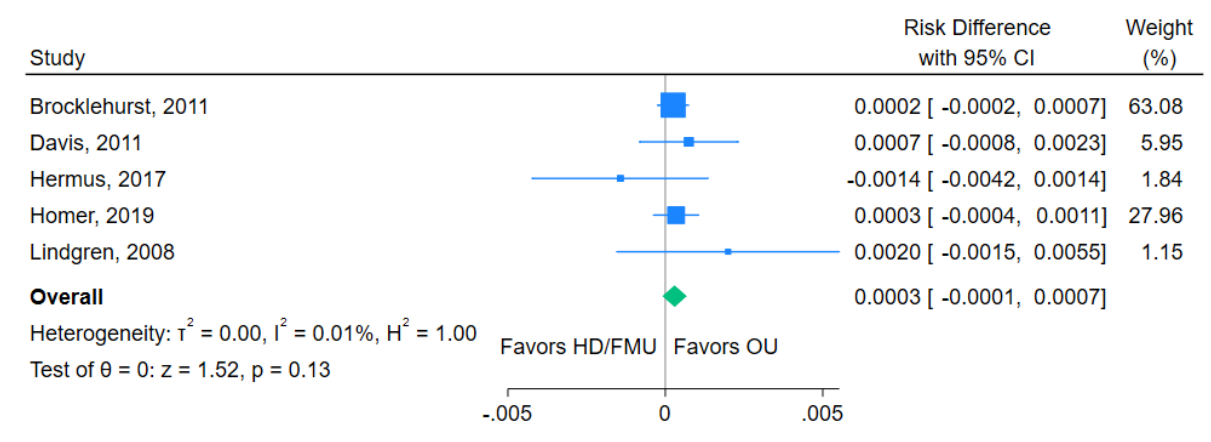
Figure 46. Weighted RD (95% CI) for maternal admission to ICU in women with home/FMU births vs obstetric unit births



Infant

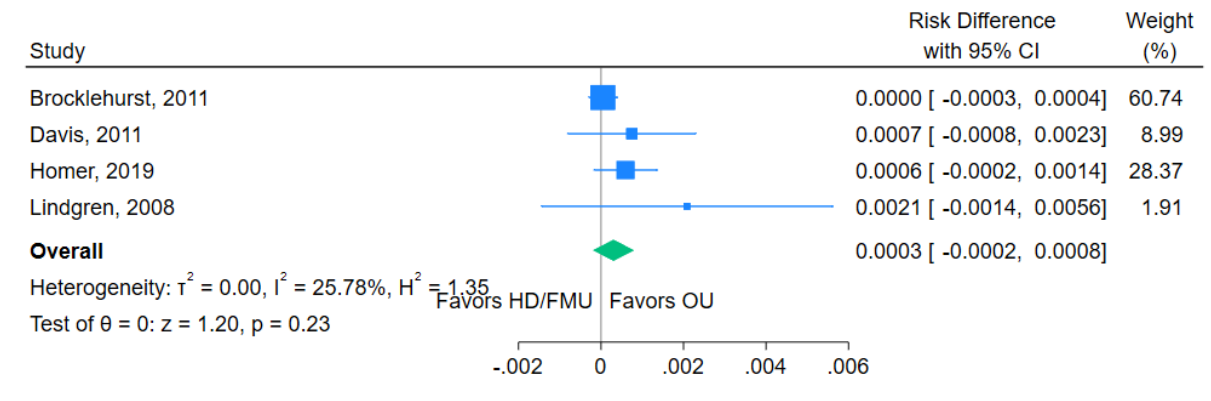
Peri/neonatal mortality

Figure 47. Weighted RD (95% CI) for peri/neonatal mortality for home/FMU births vs obstetric unit births



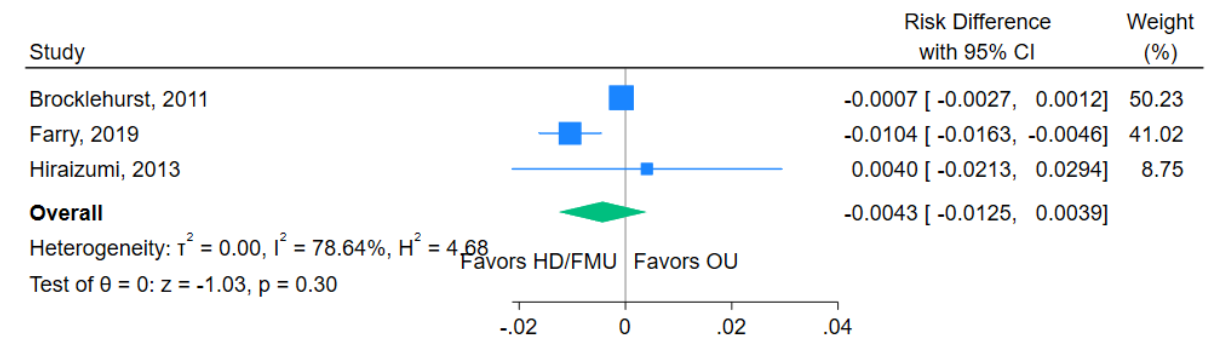
Neonatal mortality

Figure 48. Weighted RD (95% CI) for neonatal mortality home/FMU births vs obstetric unit births



Apgar score <7 at 1 and/or 5 min

Figure 49. Weighted RD (95% CI) for Apgar score < 1 and/or 5 min for infants in home/FMU births vs obstetric unit births

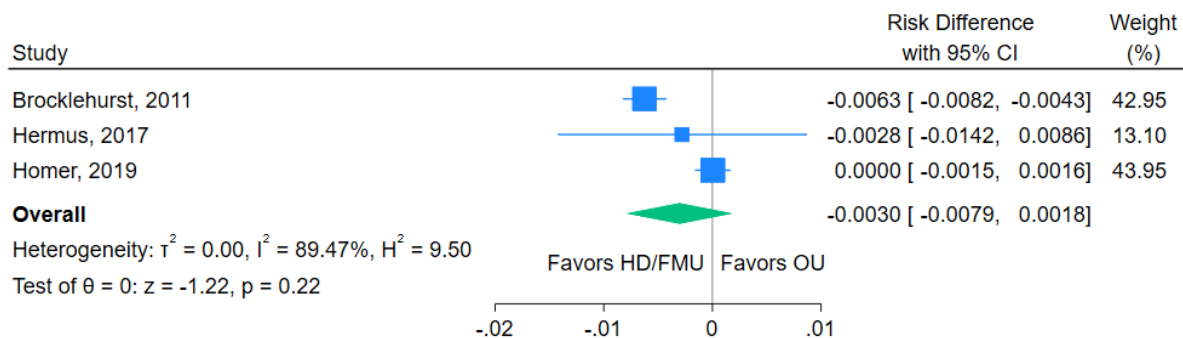


Important for decision-making

Maternal

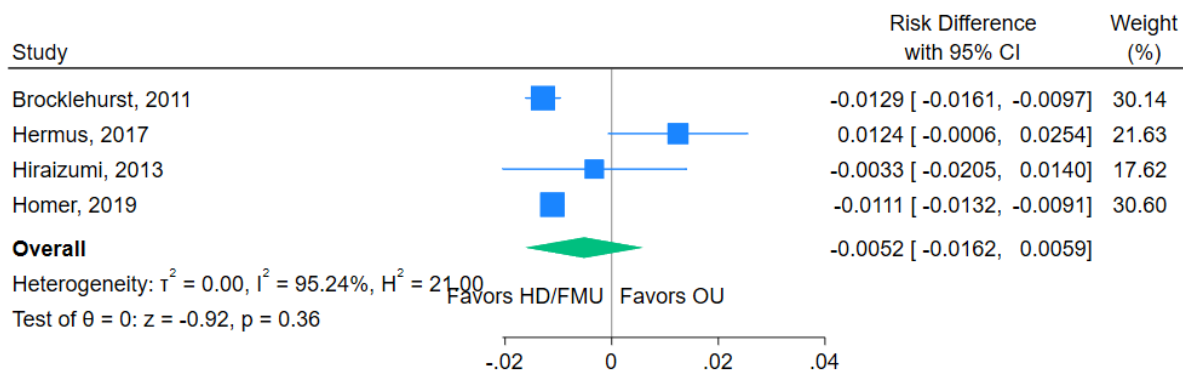
Postpartum haemorrhage requiring transfusion

Figure 50. Weighted RD (95% CI) for postpartum haemorrhage requiring blood transfusion for home/FMU births vs obstetric unit births



Perineal tears grade 3-4

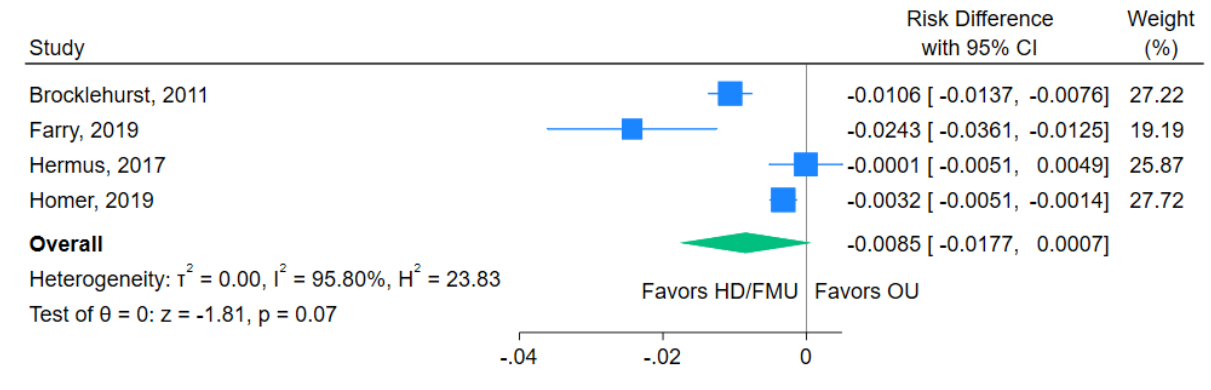
Figure 51. Weighted RD (95% CI) for perineal tears grade 3-4 for home/FMU births vs obstetric unit births



Infant

Admission to neonatal intensive care unit (NICU)

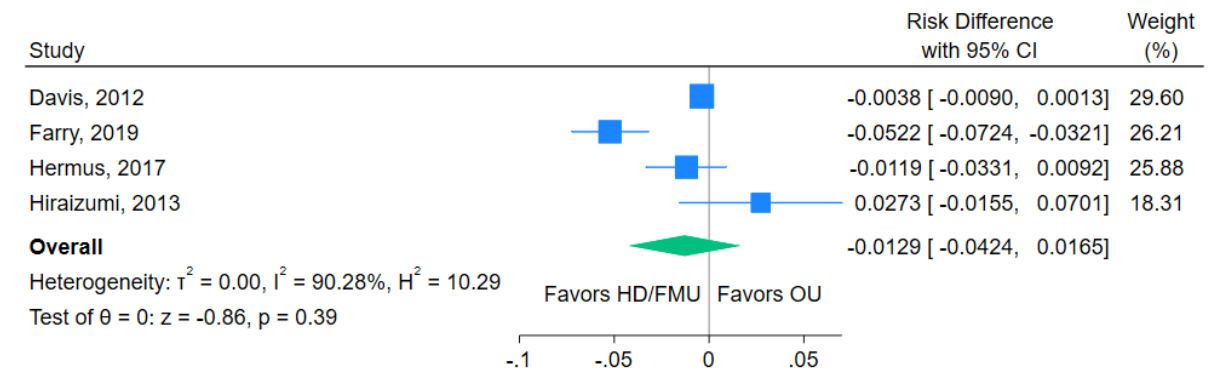
Figure 52. Weighted RD (95% CI) for admission to NICU for infants in home/FMU births vs obstetric unit births



Less important for decision-making

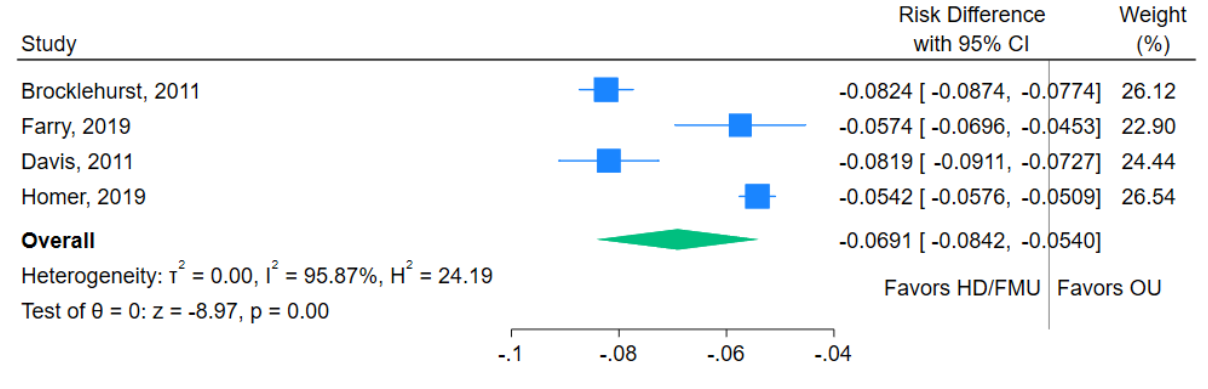
Postpartum haemorrhage (>500 ml, \geq />1000 ml)

Figure 53. Weighted RD (95% CI) for postpartum haemorrhage for home/FMU births vs obstetric unit births



Intrapartum caesarean section

Figure 54. Weighted RD (95% CI) for intrapartum caesarean section in planned FMU births vs obstetric unit births



Project: HTA - Midwife assisted births outside hospital compared with hospital births
Appendix 6 – Health economics studies

First author, year	Commented or excluded
Anderson, 2021	Excluded - Wrong population (P) (not specifically mentioned if the participants are at low-risk concerning mortality and morbidity for mother and child)
Cicero, 2022	Commented
Hendrix, 2009	Excluded- Incorrect control group (group midwifery unit);
Hitzert, 2017	Excluded- Insufficient methodology
Hu, 2024	Excluded -Hypothetical model
Janssen, 2015	Excluded - Incorrect population (P), includes caesarean section
Joranger, 2024	Commented
Nove, 2012	Excluded - No cost data presented
Scarf, 2018	Excluded - Wrong population (not only women with normal pregnancies and expected normal births)
Scarf, 2020	Commented
Scarf, 2021	Commented
Schroeder, 2012	Commented
Schroeder, 2017	Excluded - Small study; compares birth center vs hospital, not home births; overlaps with 2012