The Royal College of Midwives

Socioeconomic Value of the Midwife

A systematic review, meta-analysis, meta-synthesis and economic analysis of midwife-led models of care

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Executive Summary

Introduction

Work to date by the Royal College of Midwives (RCM) indicates that investing in midwives and midwife-led care is central to delivering high quality maternity care. The purpose of this study is to provide a robust assessment of evidence for the clinical and socioeconomic effectiveness of midwife-led models of care. This will provide evidence of the quality and safety of midwife-led models of care and inform maternity care policy.

This report presents methods and findings of an overall literature based review of midwife-led care. The report is divided into three discrete sections each addressing a specific component of the evaluation, namely:

SECTION 1 presents a systematic review and meta-analysis of randomised trials of midwife-led models of care compared with other models of care for childbearing women. This review builds from and extends the current Cochrane review on midwife-led models of care.

SECTION 2 presents a meta-synthesis of qualitative research on midwife-led care.

SECTION 3 presents an assessment of the cost effectiveness of midwife-led care in the United Kingdom.
Antenatal and intranatal with or without postnatal care and intranatal with or without postnatal care), (ii) maternal risk status (low and mixed risk)

Summaries for each section are presented here.

SECTION 1:
A systematic review and meta-analysis of randomised trials of midwife-led models of care compared with other models of care for childbearing women.

This section describes a systematic review evaluating the effectiveness of midwife-led models of care for childbearing women. This review extends the current Cochrane review on 'Midwife-led versus other models of care for childbearing women' (Hatem et al., 2008) in three important ways: (i) searches were extended beyond studies with a randomised trial design to include studies with a randomised controlled trials (RCT), controlled clinical trials (CCT) and controlled before and after (CBA) design (ii) the model of midwife-led care was extended beyond those that had both antepartum and intrapartum components to include models of midwife-led care where midwife-led care is provided in the intrapartum period with or without ante and/or postpartum care (e.g. intrapartum care, or ante and intrapartum care, or intrapartum and postpartum but not ante or postpartum care only) (iii) this review and meta-analysis includes a recent trial (Begley et al., 2009) that appears to meet the inclusion criteria for the Cochrane review and which was published after the most recent update of the Cochrane review.

Comprehensive literature searches were undertaken across multiple databases. All citations were screened independently by two reviewers and duplicate independent data extraction was performed on all included studies. The risk of bias of included studies was assessed independently by two reviewers. Data were synthesised using a fixed-effect model of meta-analysis.

Our search identified 5733 unique citations corresponding to 29 studies for potential inclusion.
Of the 29 potentially eligible studies, 17 RCTs were included. Included studies varied in the (i) scope of model of care (antenatal and intranatal with or without postnatal care and intranatal with or without postnatal care), (ii) maternal risk status (low and mixed risk status) and (iii) midwife-led work organisational models (caseload and team models of midwife-led care). Planned subgroup analyses were performed to assess the effects of these subgroups compared to the overall results with all trials combined.

Findings indicate that women randomised to midwife-led care were significantly less likely than women randomised to other models of care to have:

Amniotomy	**Opiate analgesia**
Augmentation/artificial oxytocin during labour	**Instrumental vaginal birth (forceps/vacuum)**
Regional analgesia (epidural/spinal)	**Episiotomy**

Women randomised to midwife-led care were significantly more likely than women randomised to other models of care to have:

Attendance at birth by known midwife	**High perceptions of control during labour and childbirth**
Spontaneous vaginal birth	
No intrapartum analgesia/anaesthesia	**Longer labours**

There was no statistically significant difference between women randomised to midwife-led models of care and women randomised to other models of care in:

Mean number of antenatal visits	**Perineal laceration requiring suturing**
Antenatal hospitalisation	**Postpartum haemorrhage (as defined by trial authors)**
Antepartum haemorrhage	**Maternal death**
Fetal loss/neonatal death before 24 weeks	**Duration of postnatal hospital stay (days)**
Fetal loss/neonatal death equal to/after 24 weeks	**Postpartum depression**
Overall fetal loss and neonatal death Induction of labour	**Breastfeeding initiation**
Caesarean birth	**Prolonged backache**
Intact perineum	

Infants of women randomised to midwife-led care had significantly shorter lengths of neonatal hospital stay. There was no statistically significant difference between infants of women randomised to midwife-led models of care and infants of women randomised to other models of care in:

- Low birth weight
- Preterm birth
- 5-minute Apgar score below or equal to 7
- Admission to special care nursery/neonatal intensive care unit
- Neonatal convulsions

When subgroup interactions for scope of model of care are considered, all outcomes were consistent with the above effects for all trials combined, with the exception that women in midwife-led models of care without an antenatal component appeared to have similar use of 'opiate analgesia' whether allocated to midwife-led models of care or other models of care.

Similarly, when subgroup interactions for maternal risk status are considered, all outcomes in this subgroup comparison were consistent with the effects for all trials combined, with the exception of use of 'opiate analgesia' during labour for which women in the 'mixed risk' trials appeared to have similar use of 'opiate analgesia' whether allocated to midwife-led models of care or other models of care.

Subgroup interactions for midwife-led work organisational models did not find evidence that the difference in the effects of midwife-led versus other models of care varies between trials in which a caseload or a team model of midwife-led care was tested.

Based on the evidence contained in this review, the majority of women will benefit from midwife-led models of care, including models that have and do not have an antenatal component, without any adverse consequences for them or their infants. The clear benefit and absence of evidence of harm provides grounds for midwife-led models of care becoming the dominant model of care for childbearing women.

SECTION 2: A meta-synthesis of qualitative research on midwife-led care

The objective of this section was to identify and synthesise all available completed qualitative research relating to midwife-led care undertaken since 1980. On completion of the search, eleven papers were identified as meeting the inclusion and quality criteria. The analysis used the classic stages of Noblit and Hare's original seminal work on qualitative meta-synthesis: compare and contrast metaphors, phrases, ideas, concepts, relationships and themes in the original texts; undertake reciprocal and refutational translations to establish how far the themes arising from the included studies are similar, or different; then synthesise the themes arising from the preceding steps.

The three central themes to emerge from the meta-synthesis were:

- Relationally-mediated benefits for women experiencing midwifery led models: increased agency, more empathic care
- Problematic interface between midwifery led units and host units: clash of models and culture
- Greater agency for midwives in midwifery led models, though bounded by the relationship with the host maternity unit

It is already known that relationship effects are powerful in influencing clinical outcomes or labour and birth. What this meta-synthesis adds is

the suggestion that these effects work primarily by increasing agency and a sense of empowerment in women. In addition, midwives facilitate this more effectively in midwifery led models because of their own enhanced sense of autonomy and agency. They also benefit from the relationships they share with women in these settings.

Certain characteristics of midwifery led care settings contribute to all of the above. Smallness of scale is dominant among these, though others include an orientation towards normality. Smallness of scale crucially allows time for relationship and time for availability. Scale effects are a common thread shared across all studies and a distinctive organisational characteristic of midwifery led models. This is a key difference with host maternity hospitals where there is a propensity towards increasing the size of provision as smaller maternity units are rationalised. However, a cause for concern is the sometimes conflictual relationship between midwifery led units and their host labour wards and further investigation and research should be undertaken with a view to improving this interface.

The findings suggest that current trends in centralisation of birthing facilities could be detrimental to the experience and outcomes of care unless birth centres or their characteristics are introduced alongside this centralised provision. However this must be weighed against evidence of economies of scale for the provision of neonatal care.

SECTION 3:
Cost effectiveness of midwife-led care for eligible women in the United Kingdom.

In this era of budgetary constraints it is important to optimise value for money in the health service through efficient work practices. Midwife-led maternity care for eligible maternities may offer a cost-effective alternative to the prevailing model of consultant-led maternity care. This section of the report examines the potential for a cost-effective expansion of midwife-led maternity services in the United Kingdom.

The evidence base for the cost-effectiveness of midwife-led maternity services is limited. A review of the literature uncovered only four trials that met the inclusion criteria for this study, three of which were conducted in the United Kingdom and one in the Republic of Ireland. The results of these studies were used to estimate the potential cost differential associated with expanding midwife-led care.

The estimated mean cost saving for each eligible maternity is UK£12.38. This translates to an aggregate saving of £1.16 million per year, if half of all eligible maternities avail of midwife-led care. This equates to an aggregate gain of 37.5 quality adjusted life years (QALYs) when expressed in terms of health gain using a NICE cost-effectiveness threshold of £30,000 per QALY.

It is crucial that a midwife's caseload is sufficiently large to attain operational efficiency. If a service is under-utilised, as occurred in one of the included studies, cost per maternity increases and will compare unfavourably to other models of care. This applies equally to consultant-led services. It is important to note also that cost savings during the antenatal period constitute a large proportion of the projected cost savings. However, in practice there may be little scope for such cost savings as much antenatal care is currently provided by midwives.

Results are highly sensitive to changes in the rate of fetal loss and neonatal death. In any model of maternity care, it is imperative that safety standards are not compromised as this would not be justified by any cost differential that might emerge. The uptake of midwife-led maternity services affects results on two levels, first by its role in determining caseload per midwife and thus mean cost per maternity, second at the aggregate level by determining the total number of women who switch to maternity-led services nationally.

Midwife-led services for eligible women may offer a cost-effective alternative to the prevailing maternity care model, but this is based on limited evidence. The midwife-led model of care, including models that have and do not have an antenatal component, merits further attention from policy makers.

Introduction

This report presents methods and findings of an overall literature based evaluation of midwife-led care. The report is divided into three discrete sections each addressing a specific component of the evaluation, namely:

SECTION 1 presents a systematic review and meta-analysis of randomised trials of midwife-led models of care compared with other models of care for childbearing women. This review builds from and extends the current Cochrane review on midwife-led models of care.

SECTION 2 presents a meta-synthesis of qualitative research on midwife-led care.

SECTION 3 presents an assessment of the cost effectiveness of midwife-led care for eligible women in the United Kingdom.

SECTION 1

Systematic review and meta-analysis of randomised trials of midwife-led models of care compared with other models of care for childbearing women

1.1 INTRODUCTION & BACKGROUND

This section describes a systematic review of randomised controlled trials (RCT), controlled clinical trials (CCT) and controlled before and after studies (CBA) evaluating the effectiveness of midwife-led models of care for childbearing women. This review extends the current Cochrane review on 'Midwife-led versus other models of care for childbearing women' (Hatem et al., 2008) in four important ways:

(i) searches were extended beyond studies with a randomised trial design to include studies with a RCT, CCT and CBA design;

(ii) the model of midwife-led care was extended beyond those that had both antepartum and intrapartum components to include models of midwife-led care where midwife-led care is provided in the intrapartum period with or without ante and/or postpartum care (e.g. intrapartum care, or ante and intrapartum care, or intrapartum and postpartum but not ante or postpartum care only);

(iii) this review and meta-analysis includes a recent trial (Begley et al., 2009) that appears to meet the inclusion criteria for the Cochrane review but which was published prior to the most recent update of the Cochrane review and is therefore not included in the current Cochrane review;

(iv) risk of bias tables were completed and are included here to facilitate comprehensive study assessment, although they were not required at the time of the most recent update of the Cochrane review.

1.2 METHODS

1.2.1 CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

1.2.1.1 Types of studies

Randomised controlled trials (RCT), controlled clinical trials (CCT) and controlled before and after studies (CBA) were considered for inclusion in this review. Design characteristics of RCTs, CCTs and CBAs were based on criteria used in the Cochrane Effective Practice and Organisation of Care (EPOC) group guidelines.

1.2.1.2 Types of participants

All pregnant women, irrespective of their perceived 'risk' status, who access a midwife-led model at booking, during pregnancy or at the onset of labour.

1.2.1.3 Types of interventions

1.2.1.3.1 Intervention

Midwife-led models of care where the midwife is the lead professional and lead carer in the planning, organisation and delivery of care given to a woman from initial booking to the postnatal period. In this review, studies where midwife-led care is provided in the intrapartum period with or without ante and/or postpartum care (e.g. intrapartum care,

or ante and intrapartum care, or intrapartum and postpartum but not ante or postpartum care only) were included. Studies that focus on specific interventions (e.g. midwife-led debriefing to reduce maternal depression after operative childbirth) rather than a midwife-led model of care were excluded.

1.2.1.3.2 Comparator

Comparator interventions are the same as those in the current Cochrane review (Hatem et al., 2008) include medical-led and shared models of care.

Medical-led models of care include:
(i) obstetrician-provided care and
(ii) family doctor provided care.

Shared models of care include models of care where decisions on the planning and organisation and delivery of the care are shared between different health care professionals.

1.2.2 TYPES OF OUTCOME MEASURES

1.2.1.1 Antenatal

Mean number of antenatal visits
Antenatal hospitalisation
Antepartum haemorrhage
Fetal loss/neonatal death before 24 weeks
Fetal loss/neonatal death equal to/after 24 weeks
Overall fetal loss and neonatal death

1.2.1.2 Labour

Amniotomy
Augmentation/artificial oxytocin during labour
No intrapartum analgesia/anaesthesia
Regional analgesia (epidural/spinal)
Opiate analgesia
Mean labour length
Induction of labour
Attendance at birth by known midwife
High perceptions of control during labour and childbirth

1.2.1.3 Birth and immediate postnatal

Caesarean birth
Instrumental vaginal birth (forceps/vacuum assisted births)
Spontaneous vaginal birth (as defined by trial authors)
Episiotomy
Perineal laceration requiring suturing
Intact perineum
Postpartum haemorrhage (as defined by trial authors)
Maternal death

1.2.1.4 Postnatal

Duration of postnatal hospital stay (days)
Postpartum depression
Breastfeeding initiation
Prolonged backache (as defined by trial authors)

1.2.1.5 Neonatal

Low birth weight (< 2500 g)
Preterm birth (< 37 weeks)
5-minute Apgar score below or equal to 7
Admission to special care nursery/neonatal intensive care unit
Mean length of neonatal hospital stay (days)
Neonatal convulsions (as defined by trial authors)

1.2.3 SEARCH METHODS FOR IDENTIFICATION OF STUDIES

The search was carried out across the following 12 electronic databases.

- Midwives Information and Resource Service (MIDIRS)
- Applied Social Sciences Index and Abstracts (ASSIA)
- The Health Management Information Consortium (HMIC)
- Cochrane Database of Systematic Reviews (CDSR)
- Cochrane Central Register of Controlled Trials (CENTRAL)
- Medical Literature Analysis and Retrieval System Online (MEDLINE)
- The Cumulative Index to Nursing and Allied Health Literature (CINAHL)
- Exerpta Medica Database (EMBASE)
- Database of Abstracts of Reviews of Effects (DARES)
- Health Technology Assessment Database
- NHS Economic Evaluation Database (NHSEED)
- Cochrane Methodology Register

A detailed search strategy was developed and tested for each database that avoided any study design delimiter thus the likelihood of finding relevant studies (Appendix A). The reference list of all potentially eligible studies for other potentially eligible studies was searched. The search was restricted to English language publications.

1.2.4 DATA COLLECTION AND ANALYSIS

Data collection and analysis methodology was informed by the Cochrane Handbook of Systematic Reviews of Interventions (Higgins and Green, 2008). All citations identified from our search were downloaded into a reference management database (Endnote), duplicates identified and removed and the remaining references uploaded to an online application designed specifically for the screening and data extraction phases of a systematic review (DistillerSR, Evidence Partners, Ottawa, Canada).

1.2.3.1 Selection of studies

All citations were screened independently by two reviewers (DD & MB) across three screening levels using purposefully designed level specific forms within DistillerSR. All forms were based on the inclusion criteria as appropriate. In level I, the title of each citation was screened. Citations not excluded at this level progressed to level II where

title and abstracts, where available, were screened. Citations not excluded at level II progressed to full-text screening. If there was disagreement between authors for any citation at level I and level II, the citation progressed to level III (full-text screening). Any disagreement or uncertainty at level III was resolved by discussion between both authors. A third author was available to resolve disagreements but this was not required.

1.2.3.2 Data extraction and management

The authors of the current Cochrane systematic review on midwife-led versus other models of care for childbearing women (Hatem et al., 2008) have gone to extensive effort, including contacting authors of included trials, to inform and validate the data within that review. Recognising this fact, and given that these data are published and available publically, the review presented here uses outcome data and some characteristics of included studies information from the review by Hatem et al for any study that is included in both this review and in the Cochrane review. For studies not included in the current Cochrane review, two authors (DD & MB) extracted data from the reports of the studies using data extraction forms adapted from the 'Data extraction Template' of the Cochrane Pregnancy and Childbirth Group (available from http://pregnancy.cochrane.org/author-resources-new-reviews). Disagreements were resolved through discussion. A third colleague was available to resolve disagreements but this was not required.

1.2.3.3 Assessment of risk of bias in included studies

The risk of bias of included studies was assessed using the Cochrane Collaboration's risk of bias assessment tool (Hatem et al., 2008). This tool assesses the internal validity of a trial through the extent to which bias is evident across six domains (sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting and other biases) and is completed by review authors describing how each of the domains was reported for each included study and a judgment on the risk of bias for that domain (i.e. 'Yes' for low risk of bias, 'No' for low risk of bias and 'Unclear' when insufficient information is reported to enable an informed judgment) (Hatem et al., 2008). Risk of bias tables were completed for all included studies, including studies already included in the Cochrane review, by one author (DD) and cross-checked by a second author (MB).

1.2.3.3.1 Sequence generation (Selection bias)

Successful randomisation requires two interrelated procedures i.e. sequence generation and allocation concealment. Sequence generation refers to the method used for determining the assignment of each participant to a study group and is the first element of randomisation in randomised trial (Schulz and Grimes, 2002a). Trials with inadequate sequence generation have been associated with larger estimates of effects than trials with adequate sequence generation (Schulz et al., 1995). Generation of an unpredictable randomised assignment sequence (and concealment of that allocation, which is discussed later) minimises the likelihood of selection bias by ensuring that study participants with known and unknown differences in prognosis are distributed equally across control and intervention groups. Trials that use a method of sequence generation and subsequent participant allocation that is not truly random are often referred to as quasi-randomised trials. Schultz and Grimes (2002b) argue against such an approach noting humorously that 'Quasi-random…resembles quasi-pregnant, in that they both elude definition'.

1.2.3.3.2 Allocation concealment (Selection bias)

The means by which the randomised assignment sequence is withheld from those responsible for enrolment of participants and their allocation to a treatment is known as allocation concealment (Pildal et al., 2005). Trials with inadequate reporting of allocation concealment have been shown to be associated with a 41% exaggeration of effect estimates while those with unclear reporting are associated with a 30% exaggeration (Schulz et al., 1995). Despite the importance of allocation concealment, many studies do not report allocation concealment adequately. In examining trial protocols from 1994 and 1995, Pidal et al. (2005) found that 94% had unclear reporting of allocation concealment in subsequent publications. More recently, Hewitt et al (2005) reviewed 234 randomised controlled trials published in 2002 in four major medical journals (the BMJ, JAMA, the Lancet, and the New England Journal of Medicine). Despite the publication of the CONSORT statement in 1996, which made recommendations for the improved reporting of randomised trials including allocation concealment (Begg et al., 1996), reporting of allocation concealment was inadequate in 41 (18%) and unclear in 61 (26%) of the included trials.

1.2.3.3.3 Blinding (Performance, Attrition, Detection bias)

In contrast to allocation concealment, which seeks to minimise selection bias by concealing the randomisation sequence before and until allocation, blinding seeks to prevent systematic differences between groups in:

(i) the care that is provided (performance bias);
(ii) withdrawals from a study (attrition bias); and
(iii) how outcomes are determined (detection bias)

(Higgins and Green, 2008) by concealing the allocation after randomisation (Forder et al., 2005).

While there are inconsistencies in the terminology surrounding the concept of blinding (Devereaux et

al., 2001, Lang, 2000), there is general consensus that blinding describes the concealment of group allocation from participants and/or investigators and/or outcome assessors. Empirical evidence of the impact of lack of blinding in randomised studies suggest that effect estimates are exaggerated by 7% in non-blinded trials, compared with blinded trials (Wood et al., 2008). However, lack of blinding of outcome assessment alone has been associated with a 35% exaggeration in treatment effects (Juni et al., 1999). Given the characteristics inherent in different models of maternity care (e.g. different care providers, possibly different environment), it is unreasonable to expect blinding of participants and professionals providing care. However, blinded outcome assessment is both possible and desirable.

1.2.3.3.4 Incomplete outcome reporting (Attrition bias)

Common reasons for excluding participants from a trial post their randomisation into control or intervention groups include:

(i) loss to follow-up (e.g. participant data no longer available because records cannot be located);
(ii) protocol violation (e.g. a participant does not receive the treatment to which they have been allocated); and
(iii) ineligibility (e.g. a participant is identified after randomisation as not having met one or more inclusion criteria).

While it may seem intuitive, excluding such participants can bias trial findings by introducing an imbalance in characteristics of participants between the control and intervention groups (Dumville et al., 2006). Work by Tierney and Stewart (2005) demonstrated that meta-analysis of trials with participant exclusions show greater beneficial effects for the experimental treatment than trials in which all, or most, participants have been included as randomised. Within this review, all participants reported as excluded were, where data were available within the trial publication(s), restored to the group to which they were randomised. This enabled an intention to treat analysis for all participants for which data were available. Judgments on the risk of bias for 'Incomplete outcome reporting' were made based on data available for restored groups.

1.2.3.3.5 Selective reporting (Reporting bias)

Reports of each included study were considered free of selective outcome reporting if all outcomes listed in the protocol or the methods section of the publication were reported adequately or could be extracted from its results section. Availability of study protocols was determined by searches in PubMed and in the World Health Organisation (WHO) International Clinical Trials Registry Platform (ICTRP). The WHO ICTRP provides a single point of search access for trials registered by contributing registers (http://www.who.int/ictrp/about/en/) (Ewart et al., 2009).

1.2.3.4 Measures of treatment effect

1.2.3.4.1 Dichotomous data

Where data are available, the relative effect of outcomes in midwife-led care relative to outcomes in other models of care is expressed using summary relative risks (RR) (also known as risk ratios) with 95% confidence intervals (95%CI).

1.2.3.4.2 Continuous data

Differences in outcomes measured on a continuous level are reported using the difference in means (mean difference), which measures the absolute difference between the mean value on a given outcome for the control and intervention groups (Higgins and Green, 2008), with 95% confidence intervals (95%CI).

1.2.3.5 Unit of analysis issues

This review includes data from one RCT with randomisation at the level of the 'geographic area' (North Staffordshire Changing Childbirth Research Team, 2000:296). This study and it's data are included in the current Cochrane review (Hatem et al., 2008) with appropriate adjustment of sample sizes.

1.2.3.6 Dealing with missing data

As noted above, all participants reported as excluded were, where data were available within the trial publication(s), restored to the group to which they were randomised for the review presented here. This enabled an intention to treat analysis for all participants for whom data were available. For all studies, denominators for maternal outcomes were the numbers of women randomised for whom outcomes were known. This included women who had a miscarriage or termination of pregnancy. As in the Cochrane review, this denominator was also used for perineal outcomes. Denominators for neonatal outcomes were the number of infants for whom outcomes were known with infant outcomes being attributed to the group to which the child's mother had been randomised.

1.2.3.7 Assessment of heterogeneity

Variation in intervention effects across studies beyond that expected by chance is termed statistical heterogeneity (Higgins and Green, 2008). The extent to which this heterogeneity influences the meta-analysis was measured in this review using the I2 statistic. I2 describes the amount of variability in the summary effect estimates that is due to heterogeneity across studies, rather than sampling error or chance (Higgins and Green, 2008, Higgins and Thompson, 2002).

1.2.3.8 Data synthesis

While there is consensus that the choice between a fixed and random effects model of meta-analysis should not be based on the results of a statistical test of heterogeneity (Borenstein et al., 2009, Higgins and Green, 2008, Whitehead, 2002), controversy exists as to which model to choose and in what circumstances (Baigent et al., 2010, Early Breast Cancer Trialists' Collaborative Group (EBCTCG), 1990, Greenland, 1994, Poole and Greenland, 1999). Arguments in favour of a random effects model are that a fixed-effect model is only appropriate if there is reason to believe that all studies contributing to the meta-analysis are functionally identical and if the purpose of the meta-analysis is to generate a common treatment effect size (Borenstein et al., 2009) (for example, mean difference or risk ratio). Random effect models enable differences in treatment effects across studies to influence the overall estimate of treatment effect and its precision (Whitehead, 2002). Further, findings of fixed-effect meta analyses are, it is suggested, only generalisable to a population with the same characteristics as those who contributed data to the meta-analysis (Whitehead, 2002).

Critics of the random effects model argue strongly that it is misleading to suggest that the fixed-effect model assumes that there is no heterogeneity in treatment effects across studies (Early Breast Cancer Trialists' Collaborative Group (EBCTCG), 1990). Such erroneous assumptions may have originated from the term 'fixed effects', which Peto (2010) argues '…is wholly misleading and should have been abandoned long ago…'. Instead, Peto advocates for the use of the term 'weighted average method', which he suggests is more appropriate to the function of the method and can be used to calculate a weighted average of trial results without any assumption that the treatment effect in each is the same. Importantly, random-effects meta-analyses have been demonstrated to have given seriously wrong conclusions in meta-analysis of trials of aspirin for prevention of non-fatal myocardial infarction (Peto, 2010) and of trials of magnesium in acute myocardial infarction (Baigent et al., 2010). A further criticism of random effects models is how the model attributes weight to events within studies and therefore the overall weight given to a study in the meta-analysis. The 'weighted average method' weights each trial for each outcome relative to the number of events in the trial, irrespective of the size of the trial. In contrast, a random-effects model gives greater weight to events in smaller studies. This has the effect of giving relatively greater weight to events in smaller trials than events in larger trials. This is, argues Peto (2010), inappropriate and may increase vulnerability to publication bias (Greenland, 1994). Finally, random-effect models assume that results from studies in the meta-analysis are representative of the total population. This requires knowing the total population in advance from which a random sample is selected. Such assumptions are unreasonable and unlikely to be met.

For these reasons, this review synthesises data using a fixed-effect model of meta-analysis.

1.2.3.9 Subgroup analysis and investigation of heterogeneity

Planned subgroup analyses were similar to those in the current Cochrane review (Hatem et al., 2008) with the exception of scope of model of care, which is additional:

(i) Scope of model of care (midwife-led model of care with antenatal and intranatal with or without postnatal care compared with midwife-led model of care with intranatal with or without postnatal care)
(ii) Maternal risk status (women of low risk status compared with women of mixed risk status)
(iii) Midwife-led work organisational models (caseload midwife-led models of care compared with team midwife-led models of care)

All outcomes are considered in subgroup analysis (i), while subgroup analyses (ii) and (iii) are, as in the current Cochrane review (Hatem et al., 2008), restricted to the following outcomes:

1.2.3.9.1 Antenatal

Fetal loss/neonatal death before 24 weeks
Fetal loss/neonatal death equal to/after 24 weeks
Overall fetal loss and neonatal death

1.2.3.9.2 Labour

No intrapartum analgesia/anaesthesia
Regional analgesia (epidural/spinal)
Opiate analgesia

1.2.3.9.3 Birth and immediate postnatal

Caesarean birth
Instrumental vaginal birth (forceps/vacuum)
Spontaneous vaginal birth (as defined by trial authors)

1.2.3.9.4 Postnatal

Postpartum depression

1.2.3.9.5 Neonatal

5-minute Apgar score below or equal to 7

1.2.3.10 Sensitivity analysis

Sensitivity analysis was conducted for trial quality comparing high quality trials with overall effect estimates. For the purpose of this review, trials were regarded as high quality if sequence generation, allocation concealment and incomplete outcome data scored 'yes' for each judgement in risk of bias assessments.

1.3 RESULTS

1.3.1 DESCRIPTION OF STUDIES

Individual studies were often reported across multiple papers. For clarity of presentation, one paper was deemed as the principal publication arising from a particular study and it is that which is referenced here. However, all papers contributing to individual study reports are given in Appendix B.

1.3.1.1 Results of the search

The search identified 5733 unique citations corresponding to 29 studies for potential inclusion.

1.3.1.2 Included studies

Of the 29 potentially eligible studies, 17 were included (Begley et al., 2009, Biro et al., 2000, Byrne et al., 2000, Chambliss et al., 1992, Flint and Poulengeris, 1987, Harvey et al., 1996, Hicks et al., 2003, Homer et al., 2001, Hundley et al., 1994, Kenny et al., 1994, Law and Lam, 1999, MacVicar et al., 1993, North Staffordshire Changing Childbirth Research Team, 2000, Rowley et al., 1995, Turnbull et al., 1996, Waldenstrom et al., 2001, Waldenstrom et al., 1997) (see Appendix C for 'Characteristics of included studies'). Eleven of the studies included in this review (Biro et al., 2000, Flint and Poulengeris, 1987, Harvey et al., 1996, Hicks et al., 2003, Homer et al., 2001, Kenny et al., 1994, MacVicar et al., 1993, North Staffordshire Changing Childbirth Research Team, 2000, Rowley et al., 1995, Turnbull et al., 1996, Waldenstrom et al., 2001) are included in the current Cochrane review (Hatem et al., 2008) and 6 are additional (Begley et al., 2009, Byrne et al., 2000, Chambliss et al., 1992, Hundley et al., 1994, Law and Lam, 1999, Waldenstrom et al., 1997).

The number of women participating in included studies ranged from 200 (Hicks et al., 2003) to 3510 (MacVicar et al., 1993)with 20,371 women participating across all studies. All studies were conducted in high-income countries. Six studies were conducted in Australia (Biro et al., 2000, Byrne et al., 2000, Homer et al., 2001, Kenny et al., 1994, Rowley et al., 1995, Waldenstrom et al., 2001), 4 in England (Flint and Poulengeris, 1987, Hicks et al., 2003, MacVicar et al., 1993, North Staffordshire Changing Childbirth Research Team, 2000), 2 in Scotland (Hundley et al., 1994, Turnbull et al., 1996) and 1 in each of Canada (Harvey et al., 1996), Ireland (Begley et al., 2009), Sweden (Waldenstrom et al., 1997), the United States (Chambliss et al., 1992) and Hong Kong (Law and Lam, 1999). The earliest study was published in 1987 (Flint and Poulengeris, 1987), the most recent in 2009 (Begley et al., 2009) and nine were published between 1992 and 1999 (Chambliss et al., 1992, Harvey et al., 1996, Hundley et al., 1994, Kenny et al., 1994, Law and Lam, 1999, MacVicar et al., 1993, Rowley et al., 1995, Turnbull et al., 1996, Waldenstrom et al., 1997).

Studies differed in the scope of the model of midwife-led care. Eleven provided antenatal and intranatal and at least some postpartum care (Begley et al., 2009, Biro et al., 2000, Flint and Poulengeris, 1987, Harvey et al., 1996, Hicks et al., 2003, Homer et al., 2001, Kenny et al., 1994, Rowley et al., 1995, Turnbull et al., 1996, Waldenstrom et al., 2001, Waldenstrom et al., 1997), one provided antenatal and intranatal care (MacVicar et al., 1993), one provided intranatal and postnatal care (Byrne et al., 2000) and three provided intranatal care only (Chambliss et al., 1992, Hundley et al., 1994, Law and Lam, 1999). One study provided antenatal and intranatal care but did not provide information on postnatal component of care (North Staffordshire Changing Childbirth Research Team, 2000).

Studies included women with and without risk factors. Nine studies included women categorised as 'low risk' (Begley et al., 2009, Byrne et al., 2000, Flint and Poulengeris, 1987, Harvey et al., 1996, Hicks et al., 2003, Hundley et al., 1994, MacVicar et al., 1993, Turnbull et al., 1996, Waldenstrom et al., 2001) and eight included women with at least some risk factors (Biro et al., 2000, Chambliss et al., 1992, Homer et al., 2001, Kenny et al., 1994, Law and Lam, 1999, North Staffordshire Changing Childbirth Research Team, 2000, Rowley et al., 1995, Waldenstrom et al., 1997).

In studies where the midwife-led model of care spanned the antenatal and intranatal periods, care was organised around different work models. Eleven organised work using a team-based approach (Begley et al., 2009, Biro et al., 2000, Flint and Poulengeris, 1987, Harvey et al., 1996, Hicks et al., 2003, Homer et al., 2001, Kenny et al., 1994, MacVicar et al., 1993, Rowley et al., 1995, Waldenstrom et al., 2001, Waldenstrom et al., 1997) while two organised work using a caseload approach (North Staffordshire Changing Childbirth Research Team, 2000, Turnbull et al., 1996). Teams varied in size across studies while caseload sizes were between 34 and 40.

All included studies were RCTs, with randomisation at the level of the individual with the exception of one, which used cluster randomisation (Turnbull et al., 1996). Three trials used the Zelen method of consent (Flint and Poulengeris, 1987, Homer et al., 2001, MacVicar et al., 1993) and one stated explicitly that consent was deemed unnecessary by the responsible research committee (Chambliss et al., 1992).

1.3.1.3 Excluded studies

Twelve studies were excluded (Berglund et al., 2007, Berglund and Lindmark, 1998, Chapman et al., 1986, Eide et al., 2009, Giles et al., 1992, Heins et al., 1990, Klein et al., 1983, Lenaway et al., 1998, Marks et al., 2003, Runnerstrom, 1969, Slome et al., 1976,

Tucker et al., 1996). Two of these (Eide et al., 2009, Lenaway et al., 1998) used a CBA design but neither fulfilled the EPOC criteria of having at least two control and two intervention sites. Characteristics of excluded studies are presented in Appendix D.

1.3.2 RISK OF BIAS IN INCLUDED STUDIES

Risks of bias tables for each individual study are given in Appendix E. Judgements about each risk of bias item as a percentage across all included studies are presented in Figure 1.1 and judgements about each risk of bias item assessed for each included study are presented in Figure 1.2. The extent to which failure to meet a criterion reflects a failure in reporting or a failure to meet the criterion in the conduct of the study is unknown.

1.3.2.1 Allocation

1.3.2.1.1 Sequence generation

Eleven studies (Begley et al., 2009, Biro et al., 2000, Byrne et al., 2000, Harvey et al., 1996, Hicks et al., 2003, Homer et al., 2001, Hundley et al., 1994, Law and Lam, 1999, MacVicar et al., 1993, Rowley et al., 1995, Turnbull et al., 1996) reported adequate sequence generation procedures and 6 (Chambliss et al., 1992, Flint and Poulengeris, 1987, Kenny et al., 1994, North Staffordshire Changing Childbirth Research Team, 2000, Waldenstrom et al., 2001, Waldenstrom et al., 1997) give insufficient information to determine whether or not adequate sequence generation procedures had been used.

1.3.2.1.2 Allocation concealment

Fourteen studies (Begley et al., 2009, Biro et al., 2000, Byrne et al., 2000, Chambliss et al., 1992, Flint and Poulengeris, 1987, Harvey et al., 1996, Hicks et al., 2003, Homer et al., 2001, Hundley et al., 1994, Kenny et al., 1994, MacVicar et al., 1993, Turnbull et al., 1996, Waldenstrom et al., 2001, Waldenstrom et al., 1997) reported adequate procedures for allocation concealment. Three (Law and Lam, 1999, North Staffordshire Changing Childbirth Research Team, 2000, Rowley et al., 1995) give insufficient information to determine whether or not adequate sequence generation procedures had been used.

1.3.2.2 Blinding

Only one study (Chambliss et al., 1992) clearly blinded study participants. This was achieved under the questionable practice of not seeking consent from women to participate in the study. Personnel were blinded to both control and experimental group allocation in one study (Chambliss et al., 1992) and in two studies clinical staff were blinded to whether a particular woman was in the control group or was not in the study (MacVicar et al., 1993, Turnbull et al., 1996). None of the studies reported having used blinded outcome assessment.

1.3.2.3 Incomplete outcome data

Thirteen studies (Begley et al., 2009, Biro et al., 2000, Byrne et al., 2000, Chambliss et al., 1992, Flint and Poulengeris, 1987, Harvey et al., 1996, Hicks et al., 2003, Homer et al., 2001, Hundley et al., 1994, Kenny et al., 1994, Law and Lam, 1999, Turnbull et al., 1996, Waldenstrom et al., 2001) reported adequate outcome data for all randomised participants. Four studies (MacVicar et al., 1993, North Staffordshire Changing Childbirth Research Team, 2000, Rowley et al., 1995, Waldenstrom et al., 1997) give insufficient information to inform a judgement on this criterion.

1.3.2.4 Selective reporting

Trial protocols were identified for only one (Begley et al., 2009) of the 17 included trials. This is reflective of all the trials other than Begley et al (2009) being conducted prior to 2005 when the member journals of the International Committee of Medical Journal Editors (ICMJE) adopted the policy that all trials seeking publication in their respective journals should be registered in a public trials registry at or before randomisation of the first participant (De Angelis et al., 2005). It is likely that a detailed description of any future trials will be available in such registers. All outcomes from Begley (2009) are reported adequately and all outcomes listed in the methods section of reports for all other studies were reported adequately in or could be extracted from the results section.

1.3.3 EFFECTS OF INTERVENTIONS

Outcomes reported in and extracted from each included study and considered in this review are detailed within the characteristics of included studies (Appendix C).

1.3.4 COMPARISON 1: MIDWIFE-LED VERSUS OTHER MODELS OF CARE (all women)

All 17 randomised trials have been included in this comparison with over 20,000 women participating.

1.3.4.1 Antenatal outcomes

Women randomised to midwife-led care had significantly more antenatal visits than women randomised to other models of care (Mean difference (MD) 1.50; 95% CI 0.96 to 2.04, 1 study, 405 participants, Figure 1.3, Appendix G).

There was no statistically significant difference between women randomised to midwife-led models of care and women randomised to other models of care for:

- Antenatal hospitalisation (Relative Risk (RR) 0.96; 95% CI 0.89 to 1.03, 6 trials, 5990 participants, Figure 1.4)
- Antepartum haemorrhage (RR 0.87; 95% CI 0.66 to 1.14, 5 trials, 5308 participants, Figure 1.5)

Figures 1.1 – 1.4 see page 81. Figure 1.5 see page 82

- Fetal loss/neonatal death before 24 weeks (RR 0.88; 95% CI 0.73 to 1.05, 11 trials, 16213 participants, Figure 1.6)
- Fetal loss/neonatal death equal to/after 24 weeks (RR 1.16; 95% CI 0.81 to 1.66, 12 trials, 17927 participants, Figure 1.7)
- Overall fetal loss and neonatal death (RR 0.93; 95% CI 0.79 to 1.09, 13 trials, 18129 participants, Figure 1.8)

1.3.4.2 Labour

Women randomised to midwife-led care were less likely than women randomised to other models of care to have:

- Amniotomy (RR 0.80; 95% CI 0.75 to 0.85, 6 trials, 6068 participants, Figure 1.9)
- Augmentation/artificial oxytocin during labour (RR 0.85; 95% CI 0.81 to 0.89), 14 trials, 19035 participants, Figure 1.10)
- Regional analgesia (epidural/spinal) (RR 0.82; 95% CI 0.78 to 0.87, 16 trials, 19418 participants, Figure 1.11)
- Opiate analgesia (RR 0.92; 95% CI 0.88 to 0.95, 14 trials, 17723 participants, Figure 1.12)

Women randomised to midwife-led care were *more* likely than women randomised to other models of care to have:

- No intrapartum analgesia/anaesthesia (RR 1.17; 95% CI 1.07 to 1.28, 8 trials, 11693 participants, Figure 1.13)
- Longer labours (MD 0.49; 95% CI 0.26 to 0.72, 4 trials, 5089 participants, Figure 1.14)

There was *no* statistically significant difference between women randomised to midwife-led models of care and women randomised to other models of care in induction of labour (RR 0.94; 95% CI 0.89 to 1.01, 13 trials, 17987 participants, Figure 1.15)

1.3.4.3 Birth and immediate postnatal

Women randomised to midwife-led care were less likely than women randomised to other models of care to have:

- Instrumental vaginal birth (forceps/vacuum assisted birth) (RR 0.86; 95% CI 0.80 to 0.93, 16 trials, 19737 participants, Figure 1.16)
- Episiotomy (RR 0.86; 95% CI 0.8 2 to 0.90, 17 trials, 19866 participants, Figure 1.17)

Women randomised to midwife-led care were more likely than women randomised to other models of care to have:

- Attendance at birth by known midwife (RR 7.99; 95% CI 7.03 to 9.08, 6 trials, 5225 participants, Figure 1.18)
- Spontaneous vaginal birth (as defined by trial authors) (RR 1.04; 95% CI 1.02 to 1.06, 14 trials, 17117 participants, Figure 1.19)
- High perceptions of control during labour and childbirth (RR 1.74; 95% CI 1.32 to 2.30, 1 trial, 471 participants, Figure 1.20)

There was no statistically significant difference between women randomised to midwife-led models of care and women randomised to other models of care in:

- Caesarean birth (RR 0.94; 95% CI 0.87 to 1.02, 17 trials, 20010 participants, Figure 1.21)
- Intact perineum (RR 1.06; 95% CI 1.00 to 1.11, 11 trials, 14360 participants, Figure 1.22)
- Perineal laceration requiring suturing (RR 0.97; 95% CI 0.94 to 1.01, 9 trials, 12052 participants, Figure 1.23)
- Postpartum haemorrhage (as defined by trial authors) (RR 0.99; 95% CI 0.87 to 1.12, 10 trials, 12979 participants, Figure 1.24)
- Maternal death (RR 1.50; 95% CI 0.06 to 36.88, 1 trial, 2801 participants, Figure 1.25)

1.3.4.4 Postnatal

There was no statistically significant difference between women randomised to midwife-led models of care and women randomised to other models of care in:

- Duration of postnatal hospital stay (days) (MD -0.10; 95% CI -0.21 to 0.01, 3 trials, 3597 participants, Figure 1.26)
- Postpartum depression (RR 1.94; 95% CI 0.18 to 21.32, 1 trial, 1213 participants, Figure 1.27)
- Breastfeeding initiation (RR 1.01; 95% CI 0.97 to 1.05, 3 trials, 3205 participants, Figure 1.28)
- Prolonged backache (as defined by trial authors) (RR 1.40; 95% CI 0.62 to 3.13), 1 trial, 1822 participants, Figure 1.29)

Figures 1.6 – 1.8 see page 82. Figures 1.9 – 1.12 see page 83. Figures 1.13 – 1.16 see page 84.
Figures 1.17 – 1.20 see page 85. Figures 1.21 – 1.24 see page 86. Figures 1.25 – 1.29 see page 87

1.3.4.5 Neonatal

Infants of women randomised to midwife-led care had significantly shorter lengths of neonatal hospital stay (MD -1.83 (days); 95% CI -1.97 to -1.69, 3 trials, 1912 participants, Figure 1.30).

There was no statistically significant difference between infants of women randomised to midwife-led models of care and infants of women randomised to other models of care in:

- Low birth weight (< 2500 g) (RR 0.97; 95% CI 0.83 to 1.15, 7 trials, 11528 participants, Figure 1.31)
- Preterm birth (< 37 weeks) (RR 0.95; 95% CI 0.81 to 1.11, 7 trials, 11528 participants, Figure 1.32)
- 5-minute Apgar score below or equal to 7 (RR 1.01; 95% CI 0.79 to 1.31, 13 trials, 12039 participants, Figure 1.33)
- Admission to special care nursery/neonatal intensive care unit (RR 0.99; 95% CI 0.90 to 1.09, 14 trials, 19155 participants, Figure 1.34)
- Neonatal convulsions (as defined by trial authors) (RR 1.43; 95% CI 0.38 to 5.34, 3 trials, 4738 participants, Figure 1.35)

1.3.5 COMPARISON 2: MIDWIFE-LED VERSUS OTHER MODELS OF CARE (antenatal and intranatal with or without postnatal care compared to intranatal with or without postnatal care)

All 17 trials contribute data to this subgroup analysis. In Waldenstrom (1997), antenatal care was provided by a team of midwives in both control and intervention arms. This midwifery dominant and similarity of care for the antenatal component of both arms places this trial somewhere in between the two distinct sub-group comparisons of (i) antenatal and intranatal with or without postnatal care and (ii) intranatal with or without postnatal care. This has been included in the main analysis in subgroup (ii) This left twelve trials in the antenatal and intranatal with or without postnatal care subgroup (Begley et al., 2009, Biro et al., 2000, Flint and Poulengeris, 1987, Harvey et al., 1996, Hicks et al., 2003, Homer et al., 2001, Kenny et al., 1994, MacVicar et al., 1993, North Staffordshire Changing Childbirth Research Team, 2000, Rowley et al., 1995, Turnbull et al., 1996, Waldenstrom et al., 2001) and five trials in the intranatal with or without postnatal care (Byrne et al., 2000, Chambliss et al., 1992, Hundley et al., 1994, Law and Lam, 1999, Waldenstrom et al., 1997).

Summary effect estimates within each subgroup were consistent with the overall results if one considers the statistical significance of the findings, with three exceptions. In interpreting these analyses, it is important to remember that the key analysis is whether the most likely explanation for differences in the results for the two subgroups is chance, rather than a truly different effect for women in the different risk groups.

Unlike overall results of the main meta-analysis, there was no significant difference between midwife-led and other models of care in the number of women having 'No intrapartum analgesia/anaesthesia' in the 'intranatal with or without postnatal care' subgroup (RR 1.20; 95% CI 0.83 to 1.72, 2 trials, 3001 participants, 104 events) whereas women receiving midwife-led care in the 'antenatal and intranatal with or without postnatal care' subgroup were significantly more likely to have 'No intrapartum analgesia/anaesthesia' (RR 1.17; 95% CI 1.06 to 1.28, 6 trials, 8692 participants, 1395 events). However, there was no evidence of a difference in treatment effect between the two subgroups ($Chi^2 = 0.00$, $p = 0.95$).

There was evidence of a difference in treatment effect between the subgroups for 'Opiate analgesia' ($Chi^2 = 4.65$, $p = 0.03$). Trials that had an antenatal component demonstrated less use of opiate analgesia in midwife-led care (RR 0.90; 95% CI 0.86 to 0.95, 10 trials, 11850 participants, 4015 events), which was not evident in trials without an antenatal component (RR 0.94; 95% CI 0.88 to 1.00, 4 trials, 5873 participants, 2195 events). Trials with an antenatal component also had higher rates of spontaneous vaginal birth in midwife-led care (RR 1.04; 95% CI 1.02 to 1.06, trials, 12579 participants, 9125 events), which was not seen in trials confined to 'intranatal with or without postnatal care' (RR 1.03; 95% CI 1.00 to 1.07, 4 trials, 4538 participants, 3559 events). However, there was no evidence of a difference in treatment effect between the two subgroups ($Chi^2 = 0.04$, $p = 0.85$)

In summary, when subgroup interactions are considered, all outcomes in this subgroup comparison were consistent with the effects for all trials combined, with the exception of the use of 'opiate analgesia' during labour for which women in midwife-led models of care without an antenatal component appeared to have similar use of 'opiate analgesia' whether allocated to midwife-led or other models of care.

Figures 1.30 – 1.33 see page 88. Figures 1.34 – 1.35 see page 89

1.3.6 COMPARISON 3: MIDWIFE-LED VERSUS OTHER MODELS OF CARE (low compared to mixed risk pregnant women)

All 17 trials contribute data to this subgroup analysis; nine to the 'low risk' subgroup (Begley et al., 2009, Byrne et al., 2000, Flint and Poulengeris, 1987, Harvey et al., 1996, Hicks et al., 2003, Hundley et al., 1994, MacVicar et al., 1993, Turnbull et al., 1996, Waldenstrom et al., 2001) and eight to the 'mixed risk' group' (Biro et al., 2000, Chambliss et al., 1992, Homer et al., 2001, Kenny et al., 1994, Law and Lam, 1999, North Staffordshire Changing Childbirth Research Team, 2000, Rowley et al., 1995, Waldenstrom et al., 1997).

Summary effect estimates within each subgroup were consistent with the overall results if one considers the statistical significance of the findings, with three exceptions. As noted in Comparison 2, the interpretation of these analyses needs to explore whether the most likely explanation for differences in the results between the subgroups is chance, rather than a truly different effect for women in the different subgroups.

In the 'mixed-risk' subgroup, fewer women in midwife-led care experienced 'Fetal loss/neonatal death before 24 weeks' compared with women in other models of care and the result was statistically significant (RR 0.77; 95% CI 0.60 to 0.98, 4 trials, 4878 participants, 234 events). However, no difference was apparent in the 'low risk' group (RR 1.01; 95% CI 0.78 to 1.31, 7 trials, 11335 participants, 231 events).[1] The test for a difference between the two subgroups is not conclusive ($Chi^2 = 2.03$, $p = 0.15$).

Unlike overall summary effects, there was no significant difference in the number of 'mixed risk' women having 'No intrapartum analgesia/ anaesthesia' in the midwife-led and the other models of care groups (RR 1.00; 95% CI 0.79 to 1.25, 2 trials, 1367 participants, 234 events). However, there was no evidence of a difference in treatment effect between the two subgroups ($Chi^2 = 2.93$, $p = 0.09$). On the other hand, the difference between 'low risk' and 'mixed risk' women does reach statistical significance for 'opiate analgesia' ($Chi^2 = 10.48$, $p = 0.001$). Women in the midwife-led care group in trials that recruited 'mixed risk' women were less likely to use opiate analgesia (RR 0.79; 95% CI 0.72 to 0.86, 6 trials, 6215 participants, 1528 events) but the effect appears much smaller or non-existent for trials with only 'low risk' women (RR 0.96; 95% CI 0.92 to 1.01, 8 trials, 11508 participants, 4682 events).

In summary, when subgroup interactions are considered, all outcomes in this subgroup comparison were consistent with the effects for all trials combined, with the exception of use of 'opiate analgesia' during labour for which women in the 'mixed risk' trials appeared to have similar use of 'opiate analgesia' whether allocated to midwife-led models of care or other models of care.

1.3.7 COMPARISON 4: MIDWIFE-LED VERSUS OTHER MODELS OF CARE (caseload compared to team model of midwife-led care)

Subgroup analyses based on the work organisational model were done for trials that included an antenatal component. As discussed in comparison 2, antenatal care in Waldenstrom's trial (1997) was provided by a team of midwives in both the control and intervention groups and its inclusion in this subgroup comparison would skew results, because of this. This left twelve trials for this subgroup analysis (Begley et al., 2009, Biro et al., 2000, Flint and Poulengeris, 1987, Harvey et al., 1996, Hicks et al., 2003, Homer et al., 2001, Kenny et al., 1994, MacVicar et al., 1993, North Staffordshire Changing Childbirth Research Team, 2000, Rowley et al., 1995, Turnbull et al., 1996, Waldenstrom et al., 2001).

Summary effect estimates within each subgroup were consistent with the overall results if one considers the statistical significance of the findings, with four exceptions. As noted in Comparisons 2 and 3, the interpretation of these analyses needs to explore whether the most likely explanation for differences in the results between the subgroups is chance, rather than a truly different effect for women in the different subgroups.

There was no significant difference between midwife-led and other models of care in the number of women having 'No intrapartum analgesia/ anaesthesia' in the single trial in the 'caseload' subgroup that reported this outcome (RR 1.07; 95% CI 0.79 to 1.46, 1 trial, 1210 participants, 145 events), whereas women allocated midwife-led care in the 'team' subgroup were significantly more likely to have 'No intrapartum analgesia/ anaesthesia' (RR 1.18; 95% CI 1.07 to 1.30, 5 trials, 7482 participants, 1250 events). However, there was no evidence of a difference in treatment effect between the two subgroups ($Chi^2 = 0.47$, $p = 0.49$).

There was no statistically significant difference between midwife-led and other models of care in the number of women having 'opiate analgesia' in both 'caseload' (RR 0.94; 95% CI 0.83 to 1.07, 1 trial, 1210 participants, 515 events) and 'team' subgroups (RR 0.89; 95% CI 0.78 to 1.01, 9 trials, 10,640 participants, 3500 events). Women in nine trials that used a 'team' model of midwife care were less likely to have an 'Instrumental vaginal birth' if allocated to midwife-led care (RR 0.86; 95% CI 0.77

[1] For information, in the 'low-risk' subgroup, there was no statistically significant difference between groups for 'Fetal loss and neonatal deaths equal to or after 24 weeks gestation' (RR = 1.10 [95% CI: 0.69, 1.76]).

to 0.96, 9 trials, 10663 participants, 1215 events). This difference was not statistically evident in the two trials using a 'caseload' approach to midwife-led care (RR 0.89; 95% CI 0.73 to 1.09, 2 trials, 2714 participants, 327 events), but there was no evidence that there is truly a difference in treatment effect between the two subgroups ($Chi^2 = 0.09$, $p = 0.76$).

The last outcome in this subgroup analysis that appeared to be different from overall effects was 'spontaneous vaginal birth'. Consistent with the overall results of the main meta-analysis, women in trials that used 'team' midwife-led care were significantly more likely to achieve spontaneous vaginal birth (RR 1.05; 95% CI 1.02 to 1.07, 8 trials, 9865 participants, 7184 events), but this difference was not detected in trials that used 'caseload' midwife-led care (RR 1.01; 95% CI 0.96 to 1.06, 2 trials, 2174 participants, 1941 events). Once again, there was no evidence of a difference in treatment effect between the two subgroups ($Chi^2 = 1.93$, $p = 0.17$).

In summary, when subgroup interactions are considered, there is no good evidence that the difference in the effects of midwife-led versus other models of care varies between trials in which a caseload or a team model of midwife-led care was tested.

1.3.8 SENSITIVITY ANALYSIS

A sensitivity analysis was conducted including only trials of high quality, which for the purpose of this review, were trials that received a 'yes' judgement in sequence generation, allocation concealment and incomplete outcome data in risk of bias tables. Eight trials met the criteria for high quality (Begley et al., 2009, Biro et al., 2000, Byrne et al., 2000, Harvey et al., 1996, Hicks et al., 2003, Homer et al., 2001, Hundley et al., 1994, Turnbull et al., 1996). Effect estimates were consistent with overall effect estimates with the exception of three outcomes. Two outcomes, 'opiate analgesia' and 'instrumental vaginal birth', that had been significant, were not significant when contributing data were restricted to high quality trials. The point estimate for 'instrumental vaginal birth' here was similar to overall effects point estimate [RR 0.91 (95% CI 0.81 to 1.02) compared with RR 0.86 (95% CI 0.80 to 0.93)] and confidence intervals overlap suggesting that this sensitivity effect should be interpreted cautiously.

The point estimate for 'opiate analgesia' here is subjectively greater than point estimate for overall effects [RR 1.02 (95% CI 0.97 to 1.08) compared with RR 0.92 (95% CI 0.88 to 0.95)] and confidence intervals do not overlap providing some evidence that trial quality influences findings on use of opiate analgesia.

The third outcome to differ in the sensitivity analysis is the women's 'Duration of postnatal hospital stay'. The point estimate for here was similar to overall effects point estimate [MD -0.14 (95% CI -025 to -0.02) compared with MD -0.10 (95% CI -0.21 to 0.01)] and confidence intervals overlap heavily suggesting that this sensitivity effect should be interpreted cautiously

1.2 DISCUSSION

This review summarised 17 trials involving over 20,000 women. Women randomised to midwife-led care were less likely than women randomised to other models of care to have an amniotomy, augmentation/artificial oxytocin during labour, regional analgesia (epidural/spinal), opiate analgesia, instrumental vaginal birth and an episiotomy. Women randomised to midwife-led care were more likely to have more antenatal visits, not to have any analgesia/anaesthesia during labour, to be attended at birth by a known midwife, to have a spontaneous vaginal birth, to have high perceptions of control during labour and childbirth and to have a longer length of labour. Infants of mothers randomised to midwife-led care had shorter lengths of hospital stay.

Outcomes reported across trials are clinically relevant to evaluating models of maternity care. This may, in part, be due to use of a core set of outcome measures for evaluating models of maternity care (Devane et al., 2007) in the a priori consideration of outcomes to be extracted from included studies for the Cochrane review by Hatem et al.(2008) and consequently in this review. Populations of women in included trials represent a wide spectrum of women from those expecting a physiological pregnancy and birth to those with more complex clinical needs. Findings across these different populations of women, across models that did and did not have an antenatal component, and across those that use a caseload and those that use a team approach to care are broadly consistent with overall findings. Given the absence of evidence to the contrary, it is reasonable to suggest that such heterogeneity favours the external validity of the findings of this review.

This review provides robust evidence that midwife-led models of care, including models that have and do not have an antenatal component, are at least as safe as other models of care for childbearing women and result in less intervention. In the studies reviewed, midwife-led models of care were not associated with any adverse outcomes. Length of labour was however, significantly longer in midwife-led models of care. However, whether this is a benefit, a harm or inconsequential for women and maternity care professionals is a value judgement and one that is made in the absence of high quality evidence establishing norms for length of labour.

A significant strength of this review is the inclusion of models of midwife-led care that both include and exclude antenatal care components. This may extend the potential generalisability of review findings to those making decisions about the scope of midwife-led models of care. Studies in this review demonstrate that women benefit from midwife-led models of care that have an antenatal component and

those that begin during or shortly before the intrapartum period. We are confident that searches, study selection, data extraction and analysis strategies and procedures minimise the potential of bias being introduced into the review. A limitation of this review is that it does not include a review of the evidence of women's satisfaction with midwife-led and other models of care. However, there is ample evidence to suggest that women receiving midwife-led models of care will have higher levels of satisfaction than women accessing other models of care (Hatem et al., 2008). Given the variation in the instruments used to measure women's satisfaction and an absence of an agreed best approach to such measurement, this review would add little to that already available in Hatem et al. (2008).

Findings from this review are broadly consistent with findings from the current Cochrane review (Hatem et al., 2008) with some exceptions. Findings in the Cochrane review of a reduction in regional analgesia/anaesthesia, instrumental vaginal births and episiotomies are consistent with this review. Findings of reduced antenatal hospitalisation, fetal loss or neonatal death less than 24 weeks in the Cochrane review are not supported by this review, which found no difference between groups for these outcomes. The Cochrane review found that women randomised to midwife-led models of care were more likely to not use any intrapartum analgesia/anaesthesia, be attended at birth by a known midwife, have a spontaneous vaginal birth, initiate breastfeeding and have high perceptions of control during labour (Hatem et al. 2008) are consistent with this review with the exception that this review did not find a difference between groups in initiation of breastfeeding. All other outcomes are consistent between both reviews.

All trials included in this review were conducted in high-income countries. Nevertheless, given that midwives are the primary providers of antenatal and postnatal care in most low and middle income countries (Wiysonge and Okwundu, 2009) the findings of this will review may help inform decisions about the organisation of maternity care in these countries.

Based on the evidence contained in this review, the majority of women will benefit from midwife-led models of care, including models that have and do not have an antenatal component, without any adverse consequences for them or their infants. The clear benefit and absence of evidence of harm maintains that midwife-led models of care should become the dominant model of care for childbearing women.

SECTION 2

Meta-synthesis of midwife-led care

2.1 INTRODUCTION & BACKGROUND

Against a backdrop of increasing medicalisation of labour and rising caesarean rates across Western world maternity care systems (Johanson et al., 2002), maternity services internationally have been examining models and systems of care that demonstrate a reduction in routine intrapartum interventions. Among these have been initiatives to reduce caesarean section (Royal College of Obstetricians and Gynaecologists, 2001) and to humanise the birth environment (Fannin, 2003). In the last five years, there has been a focus on the growing body of research that suggests that midwives may play a key role in addressing the challenge of medicalisation (Wagner, 2008, Ashcroft et al., 2003).

Much of this focus has arisen out of research into alternative places of birth such as birth centres and midwifery led units (MLUs) where midwives are the primary carers. Though randomised controlled trials have only been done on birth centres and MLUs attached to maternity hospitals, termed integrated birth centres (IBCs) (Hodnett et al., 2010), there is a plethora of quasi-experimental research into free standing birth centres (FSBCs)/MLUs that are geographically separate to their host maternity hospital (Walsh and Downe, 2004). In addition, there is a substantial body of epidemiological studies on home birth (Fullerton et al., 2007). All of these studies demonstrate remarkable consistency in finding a reduction in labour and birth interventions. Because care in home births and birth centres is led by midwives, midwifery care has, by inference, become associated with these improved outcomes.

The other source for interest in midwife-led care arises from a parallel body of research examining the relational impact of models of maternity care. This diverse literature has evaluated one-to-one support in labour (Hodnett et al., 2007), continuity of care and carer models throughout antenatal and intrapartum care (Sandall et al., 2008), caseload midwifery (Benjamin et al., 2001) and team midwifery (Turnbull et al., 1996). Again, there is remarkable consistency in findings that these models reduce labour interventions. Though this literature includes the effects of labour companions like doulas, in the main, the principal carers in all these studies are midwives.

The term 'midwifery-led' has had an assumed rather than universal meaning but has over years evolved to mean autonomous care by a midwife, of women designated when entering the maternity services, to be at low obstetric risk. These women continue in the midwife's care unless complications develop where referral is made to the appropriate specialist, usually an obstetrician.

In recent years, the findings from research into alternative places of birth and from relational models have been combined in a specific systematic review of midwife-led care (Hatem et al., 2008). This review concluded that midwifery-led care led to a successful reduction in labour and birth interventions and a reduction in fetal loss/ neonatal death prior to 24 weeks gestation. This review examined randomised trials in this area but did not include an examination of research that adopted qualitative methods.

The results of the review therefore leave unanswered questions on why midwifery-led models achieve these outcomes. In order to address this question, a systematic review of all qualitative research was undertaken. Because qualitative research examines context, perceptions and experience in-depth, it is more likely to shed light on the mechanisms contributing towards better outcomes in midwifery led models of care.

2.2 METHOD

After undertaking a systematic search of qualitative research literature in the area of midwifery led care, the meta-synthesis method was applied to integrating and synthesising all papers. Meta-synthesis is a relatively new technique for systematically combining the findings of qualitative studies in a related area (Downe, 2008, Finlayson and Dixon, 2008). The approach is based on Noblit & Hare's (1988) seminal work in combining ethnographies of education institutions and rests on a rationale that synthesising research studies will produce an end product that is more than simply the sum of the individual parts (Campbell et al., 2003). Epistemologically, it sits within the continuum between interpretivism and critical realism (Heyman, 2009). Proponents point to it representing a third level of interpretation built upon the first level of research respondents and the second level of the researchers themselves within individual studies (Reid et al., 2009). However, the process of inducing or distilling new insights, concepts or theories from two prior iterations of data rests on the presupposition that the end product is somehow weightier and more conclusive than individual studies on their own. As Heyman (2009) states, this presupposition has more in common with the realist position of an underlying reality that can be accessed and argued for that is not apparent on the examination of individual papers.

Over the past 10 years, the stages of meta-synthesis have been debated and discussed at length (Bondas and Hall, 2007, Finlayson and Dixon, 2008, Walsh and Downe, 2005, Zimmer, 2006) and the approach taken here has evolved from Downe's previous extensive experience with the method (Downe et al., 2009, Downe et al., 2007, O'Connell and Downe, 2009). It is based on a structured and focused literature search (Walsh and Downe, 2005), on the combining of findings from studies using different methodological approaches (Downe et al., 2009) and on a quality assessment of included studies (Downe et al., 2007, Walsh and Downe, 2006).

2.2.1 SEARCH STRATEGY

The review objective was to identify and synthesise available completed qualitative research relating to midwife-led care.

2.2.1.1 Inclusion Criteria

- Qualitative research describing and analysing midwife-led care during two phases of care, one of which must be intrapartum care
- Papers published or completed between January 1980 and April 2010
- Papers in the English language

2.2.1.2 Exclusion Criteria

- Quantitative research, opinion papers, literature reviews
- Non-English language papers only
- Papers prior to 1980

2.2.1.3 Search Terms

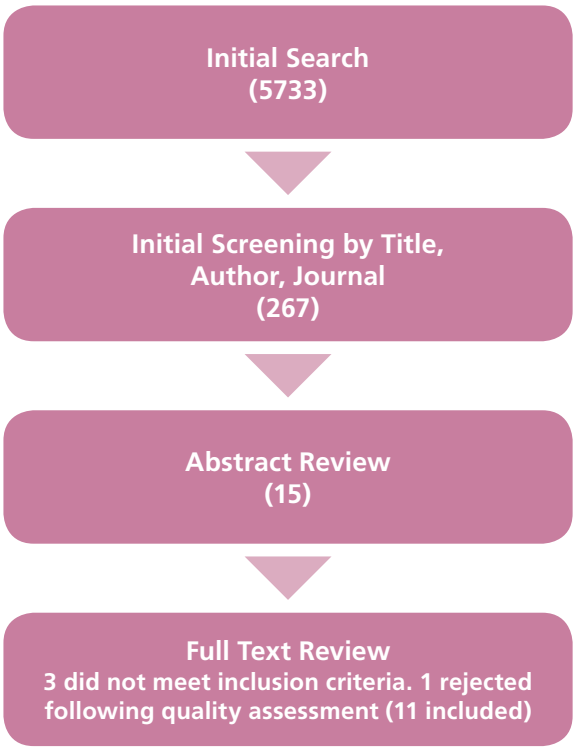
Given the poor indexing of non-randomised trial study designs within citation databases, specific detailed search strategies without study design delimiters were developed and tested for each of twelve databases searched to increase the likelihood of finding relevant studies irrespective of study design. Experts in the field were contacted, and a request for any unpublished studies was made through two relevant internet groups. The formal search period covered 1980 to May 2010.

2.2.2 ANALYTIC STRATEGY

Qualitative researchers recognise that the interpretation of data is, legitimately, influenced by the prior beliefs of researchers. One technique used to make any such influence transparent is to set out any prior perspectives that may have had a bearing on interpretations, a process termed 'reflexivity' (Kingdon, 2005). The authors of this review came to this exercise with certain preconceived ideas. Broadly, these were that labour and birth were usually straightforward processes, and birth centres or home were probably the best locations for preserving physiological labour and birth. In addition, midwives were the appropriate professional childbirth attendant to undertake care in these birth settings. To maximise the credibility of the interpretations in the light of these preconceptions, the following established techniques were used to support the robustness of the research stages: looking for data saturation (making sure there were no new themes in the data that had been overlooked) and actively searching for disconfirming data (data that did not 'fit' the initial interpretation).

The analysis used the following stages: compare and contrast metaphors, phrases, ideas, concepts, relationships and themes in the original texts; undertake reciprocal and refutational translations to establish how far the themes arising from the included studies are similar, or different; then synthesise the themes arising from the preceding steps (Noblit and Hare, 1988). To minimise reductionism, the final themes were broad and supported by extensive quoted material.

Figure 2 1: Paper Selection



2.3 RESULTS & DESCRIPTION OF STUDIES

The initial search identified 5,733 unique citations (after duplicates removed). After title, author and journal review, this was reduced to 267 due to inclusion criteria not being met. After all abstracts were reviewed, the number left was 15. The full texts of these were reviewed and another four were discarded because they did not fulfil the inclusion criteria after close examination (Figure 2 1) (Crabtree, 2004, Hunt and Symonds, 1995, Hunter, 2003), or they failed the quality appraisal mechanism (Watts et al., 2003). This left 11 papers that were included in the meta-synthesis (Annandale, 1987, Annandale, 1988, Berg et al., 1996, Coyle et al., 2001a, Coyle et al., 2001b, Esposito, 1999, Pewitt, 2008, Thorgen and Crang-Svalenius, 2009, Walker et al., 1995, Walsh, 2006a, Walsh, 2006b).

The eleven papers report eight research studies (three of the studies published two papers each). The included studies comprised five ethnographies, two based on grounded theory, one phenomenological and three broadly described as qualitative descriptive/interpretive. Four of the studies were from the USA, four were from the UK, two from Australia and one from Sweden. Seven were sited in FSBCs, three in IBCs and one in both.

2.4 QUALITY ASSESSMENT OF INCLUDED STUDIES

The use of quality criteria for qualitative studies is controversial (Dixon-Woods et al., 2007). A quality assessment tool based on a synthesis of eight existing checklists (Walsh and Downe, 2005) was adopted (Table 2.1). The criteria included the following aspects: appropriateness of the sampling strategy and analysis, evidence that the interpretation of the findings is based on the data, full discussion of limitations, full reflexive accounting, an appropriate ethical approach, and evidence of relevance and transferability. A summary of the quality features of included studies is given in Table 2 1. Following on from Downe et al.(2007), papers were graded from A to D. Papers graded 'D' were excluded as these were judged to have significant flaws likely to compromise the credibility and transferability of findings. In general, the quality of the papers was fair.

Most failed to detail a comprehensive literature review but may have been restricted by the word limits of their host journals. Only two authors explicitly reported the theoretical perspective of their work (Berg et al., 1996, Walsh, 2006a, Walsh, 2006b). Annandale (1987, 1988) appeared to take a socio-political and constructionist perspective. It was not possible to deduce the perspective taken by the other authors. Esposito (1999) refers to her ethnography as seeking to explore contextual meaning, positioning her broadly within the theoretical framework of interpretivism.

Sampling strategy, data collection methods and analytical approaches were generally well described. However, while 10 out of the 11 studies gave good accounts of their analytic strategy, only one (Annandale, 1987) provided an audit trail of how the data analysis evolved through worked examples. Researcher reflexivity was poorly addressed by all but one author (Walsh, 2006a, Walsh, 2006b), demonstrating that this criterion remains a neglected one for qualitative researchers. In general, the claims made by the authors appeared to be supported by verbatim quotes.

The earlier studies give scant attention to ethical issues. This is probably a reflection of the accepted approach to the ethics of research at the time. Even in one of the later studies, however, covert data collection is reported (Esposito, 1999). Despite this, the intent in all the studies appeared to have been for fair dealing with the participants, within the context of the ethical standards that were applicable at the time.

All studies give a good description of the setting and context, though only one of them ((Walker et al., 1995) gives a reasonable overview of staffing and the context of care-giving.

In summary, these studies are all at least of fair quality, despite the fact that none of them address all the quality issues specified in the criteria list. The most significant deviations were in the quality of the literature reviews, ethical considerations and the reflexive accounting for the pre-existing views and beliefs of the researchers.

A description of all the studies is provided in Table 2.2 (see page 29).

2.5 FINDINGS

The analytic process and distilling of key concepts by the authors are presented in Table 2.3 (see page 30). The first two columns of Table 2.4 (see page 32) enables the researcher to compare and contrast metaphors, phrases, ideas, concepts, relationships and themes from the original papers. Columns three and four from this table record the reciprocal and refutational translations to establish how far the themes arising from the included studies are similar, or different. Using Noblit and Hare's (1988) guidance, reciprocal translations occur when themes across papers resonate, coalesce or overlap in meaning whilst refutational translations tend to contradict, contrast or diverge in their meanings. Column five synthesises the themes arising from the preceding steps.

2.5.1 THEMES ARISING FROM ANALYSIS

The three central themes to emerge from the meta-synthesis were:

- Relationally-mediated benefits for women: increased agency, more empathic care
- Problematic interface with host units: clash of models and culture
- Greater agency for midwives in midwifery led models, though bounded by the relationship with the host maternity unit

2.5.2 RELATIONALLY-MEDIATED BENEFITS FOR WOMEN

Ten of the 11 papers involved in-depth interviewing of women (Annandale, 1987, Annandale, 1988, Berg et al., 1996, Coyle et al., 2001a, Coyle et al., 2001b, Esposito, 1999, Pewitt, 2008, Walker et al., 1995, Walsh, 2006a, Walsh, 2006b), both in IBC's and FSBC's. Women's accounts in birth centres/MLUs were replete with the language of compassionate, sensitive, and nurturing care, which was mediated through relationships. The centrality of these relationships emerged as fundamental to a positive experience of care during labour and birth. The critical characteristics of these relationships were empathic relating by the professionals and retaining agency (autonomy) by the women users.

Empathy was demonstrated when midwives had time to both be available and emotionally present. In fact, physical presence was not essential but was available when needed. Attentiveness and connection to women is encapsulated by the notion of emotional presence.

'She was able to stay in the background without letting slip of us… I never felt deserted, it felt someone was always there' (Swedish woman, IBC) (Berg et al., 1996).

'they were just outside...it's quite nice because if somebody was there you might feel sort of pressured.. nice to have the choice whether you want somebody or not' (UK, FSBC midwife) (Walsh, 2006b).

Empathic relating was enhanced when women knew their midwives already.

'You build a relationship with them..it sort of made us more friends. I was lucky because when I came in, she was actually the one that actually did everything..it meant that I relaxed a lot more. (UK women, FSBC) (Walker et al., 1995).

Empathetic care facilitated personal agency in the women. Agency, in this context, refers to the expression and perception of autonomy in the individual (Nettleton, 2006). In these studies, 'control' was often used by women and midwives as a proxy for agency. For women, there were paradoxical meanings attached to this. Empathetic care enabled them to 'give in' to the physicality of the labour (relinquish control over body processes that are in the main involuntary anyway) whilst retaining psychological comfort.

'To be advised but not forced..she encourages at the right time and she believed that I was able to manage' (Australian woman, IBC) (Coyle et al., 2001b).

'What enormous power! One can't control the contractions, just follow, merely drift and try to navigate a boat in a storm' (Swedish woman IBC) (Berg et al., 1996).

Esposito (1999:123-124), writing in the USA context, specifically comments on this:

'women no longer needed to work at guarding their environment and were able to give themselves over to their births. Giving up control freed their minds to join with their bodies, allowing the women to go with the birth'.

Berg et al's (1996)study demonstrated the empowering nature of the midwives' approach:

'Even if I received expert help…it wasn't the intention of someone else that dominated, but my own desire'. (Swedish woman, IBC).

Pewit's (2008) study in particular, demonstrated the profound effect of empowerment:

'I am pretty much convinced if I could go through that, I can do anything. I grew wings; I'll go as high as I want to..and if it wasn't for the midwives, I would not believe that because they helped me believe that. They supported me on it, they were my backbone… I feel more powerful.' (USA woman, FSBC).

2.5.3 PROBLEMATIC INTERFACE WITH HOST UNITS: CLASH OF MODELS AND CULTURE

Nine of the eleven studies commented on the differences between midwife-led settings and conventional labour wards. A number gleaned this through interviews with women who had birthed in both environments, some through the reflections of authors who had experience of working or observing care in both settings or through midwives' interviews. There emerged clear demarcations in both the physical space, the attitude of carers, the culture enacted through institutional and bureaucratic effects and the interface between birth centres and host maternity hospitals.

Home-like metaphors arose from women's interviews in birth centres. ' a B & B', 'my bedroom' were recorded by Walsh (2006b) while women in Esposito's (1999:119) study spoke about the lack of privacy in hospitals: 'people don't realise how my privacy was invaded in hospital.. a whole bunch of lights, they put your legs up..'

Attitudes of staff working in midwifery led units to women were frequently commented on in a positive manner:

'She treated me with respect, not looking down from a superior position but on the same level' (Swedish women, IBC) (Berg et al., 1996).

'They don't do anything without asking you..they're not suddenly going to do something to you but not let you know what it is' (UK woman, FSBC) (Walker et al., 1995).

It appeared the culture in hospital labour wards was dominated by risk and fear of pathology. Risk was ubiquitous and manifested at the interface of transfer from birth centre to hospital, called 'risking out' by some birth centre midwives and women whose labours started in birth centres (Annandale, 1988). It was a point of tension and disagreement. Midwives in Thorgen & Crang-Svalenius' (2009) study believed doctors 'don't know what normal births are, haven't seen them'. They were therefore critical of transfer decisions made in MLUs. The same tensions emerged in Walsh's (2006b) study where one midwife stated labour ward staff reacted to transfers with comments such as 'the only time we see you is when we are sorting out your disasters'.

Risk had a symbiotic relationship with the discourse of medicalisation in hospital labour wards, where mutual reinforcement occurred. Observations and interviews of women and midwives who had experience in these settings consistently commented on birth interventions, predicated on 'safety first':

'they (midwives) talked about drugs but they did not talk about how you can control your pain without this. They focus on the intervention, what would happen if you had a caesarean? What would happen if you needed stitches? I think it is important to say these things may happen but they shouldn't be the focus' (Australia women, labour ward) (Coyle et al., 2001b).

'they kept putting me on this heart monitor and said the baby was in distress…they shoved that consent paper at me to sign for an emergency caesarean section and I said, No! (US women, labour ward) (Esposito, 1999).

Hospital labour wards were criticised by women and midwives as 'baby factories' (Walsh, 2006a) where the organisational imperative to 'process' women who were admitted in labour dominated priorities. Institutionalisation aided and abetted this priority by regulating practices and behaviours within the environment. Many midwives felt this militated against forming meaningful relationships with women and women spoke of depersonalisation, disassociation from their labour experiences and even self-blame when labour did not conform to their expectations.

'At the consultant unit, you felt like almost like you were on a conveyer belt and all the nurses (sic) were a bit robotic towards you' (UK woman, previous labour ward birth) (Walsh, 2006a).

'I was just sitting there…no one to talk to, no-one really cares, you are just a patient' (Australian woman, labour ward (Coyle et al., 2001a, Coyle et al., 2001b).

In birth centres the absence of a need to 'process' women through a busy labour ward impacted on how time was viewed and on how midwives interpreted their role. Clock time did not dominate and regulate midwives' activities. Staff could be actively 'present' to women in labour. Coyle et al (2001a, 2001b) summarised these effects as collaborative relationships (equality), accumulative care interactions (continuity of relationship) and women-tailored care structures.

'I felt they (midwives) took my measure and let me be what I needed to be, does that make sense, rather than treating people routinely. Or I need to tell you this because that's the policy' (Australian woman, IBC) (Coyle et al., 2001a).

'I know about a 'processing mentality' in maternity hospitals and I am very critical of it so why does it feel so strange to be in a place where processing is not in the vocabulary. I can see already that the quality of the interactions among the staff, and between the staff and the women is different.' (UK midwife researcher, FSBC) (Walsh, 2006a).

2.5.4 GREATER AGENCY FOR MIDWIVES

The most obvious effect on midwives from working in birth centre/MLUs was increased autonomy (agency). Six studies either interviewed or observed midwives. Thorgen & Crang-Svalenius (2009) placed it as their principal theme distilled from five categories. The following statement illustrates this:

'Your freedom and your autonomy of practice is something I very much value and very much enjoy'' 'I can't see myself doing anything else now…that's what I think a midwife is and that's what I am' (FSBC midwife, UK)

Organisational autonomy was apparent in Walsh's (2006a) account of a FSBC where midwives took charge of decorating the birth centre, including the fund raising:

'she's been heavily involved with raising money for the unit and in the early 90's she and Flo raised £39,000 in 3 months..' (FSBC midwife, UK)

Excerpts from Walsh's (2006b) parallel paper show midwifery clinical autonomy in flexible approaches to assessing labour. The story details how a multiparous woman came into the birth centre in advanced labour, having gone into labour in the supermarket. Because her contractions had subsided somewhat, she went back and completed her shopping before returning later to birth her baby.

Autonomy is thrown into even greater relief when comparing care in hospital that is clearly more regimented and prescriptive. Midwives' practice may be more regulated and monitored in these settings (Annandale, 1988, Coyle et al., 2001a).

2.6 DISCONFIRMING DATA

Three papers problematise birth centre care. They were Annandale's USA birth centre study (Annandale, 1987, Annandale, 1988)and Thoren & Crang-Svalenius' (2009) UK study. Annandale discusses ambivalence in birth centre midwives' attitude to risk in their interactions with the host maternity hospital. Changes in criteria for transfer during labour imposed by the host hospital lead to a lowering of the threshold. The midwives consciously reduced the likelihood of transfer by employing what Annandale terms 'ironic intervention' (Annandale 1988). This included the use of castor oil to induce labour in the case of one woman who had reached 42 weeks gestation, and who was therefore liable to transfer for induction of labour. In effect, they were invoking a professional hegemony, reducing choice for women, out of self-protection.

In Annandale's other paper (1987), she suggests that women sublimate the notion of control about labour decisions to control of self when they encounter restrictive behaviours from birth centre staff. In this sense their agency is inverted and compromised. She argues that women do this because of their ambivalence around choosing to give birth in a birth centre in the first place and because of the political environment surrounding birth centres and the maternity services. Specifically, this led the birth centre midwives to be very defensive and protective of their own practice and of the birth centre model.

Thoren & Crang-Svalenius (2009) found that some birth centre staff lamented losing skills in high risk care and were concerned about burnout in a high demand service. Their study was unique in examining 3 birth centres (2 FSBCs and 1 IBC) with the negative comments coming from the latter site where workloads and sickness rates were higher.

These papers present a counter narrative to the prevailing direction of findings in birth centres and hospital labour wards. Interestingly, it could be argued that Annandale, a sociologist, had no professional interest in propagating the stock of midwives and her criticisms problematise their work within the local birthing culture. She was the only author of papers included in this review who was not a midwife. Thoren & Crang-Svalenius (2009) examined 3 settings and this comparative element is probably more likely to demonstrate particular advantages of some models over others.

2.7 DISCUSSION

It is important to note as a precursor to discussion that ten of the papers included in this review were by midwives, and, although reflexive disclosure was absent from all papers, it is more likely that midwifery authors favoured birth centre settings than conventional labour wards. Nevertheless, verbatim quotes from women users dominate the papers and many of the criticisms of labour wards come from their voices. Their reflections come from comparisons they are making with previous experiences of birth with current births in midwife-led settings.

The overarching theme that can be synthesised from nearly all papers is one of agency and empowerment. This applies to birthing women in the first instance. Agency and empowerment are mediated primarily through relationships. Many papers over the past twenty years have noted the importance of control (Green et al., 2003, Green, 1999, Hodnett, 1989) and choice (Kirkham, 2004, Newburn and Singh, 2004) for women and this has been conceptualised as agency here. It includes the attributes of autonomy and empowerment, the latter being explicated, mentioned in many of the papers in this review. That relationships are the primary conduit for these effects resonates with a plethora of midwifery research, with a timely summation by Hunter et al (2008) recently. They suggest that because childbirth experiences are the endpoint of a sequence of complex interventions involving systems of care, attitudes and medical interventions, then it makes sense to identify the 'weave that holds them all together'. They mount a powerful argument that relationships provide this weave. This meta-synthesis supports that analysis.

However, relationships exist within a care system that can help or hinder their expression as empathy and empowerment. Coyle et al. (2001a, 2001b) illustrate this best with their findings of contrasting care interactions and care structures between a birth centre and labour ward. Walsh's paper (2006b) on institutionalised, bureaucratised settings (hospital) compared with a small scale, informal, entrepreneurial birth centre highlight the effects of scale. Thorgen & Crang-Svalenius (2009) also hint at scale effects in their study of FRBCs and IBCs with the latter generating more negative comments from midwives. These papers demonstrate that the culture of a setting impacts on the relationships that are formed and enacted there. Price & Johnson's (2006) ethnographic study of a small maternity hospital labour ward, not included in this review because there was no midwife-led provision, showed that empathy and empowerment could manifest is this setting, suggesting the power of scale effects. By way of contrast, a plethora of sociological and feminist studies critique institutional birth in hospitals and professional hegemony as expressed in these settings, that appear to strip women of dignity and agency (Baker et al., 2005, Keating and Fleming, 2009, Martin, 2003).

Agency and empowerment have reciprocal effects on midwives working in midwifery led models. Through observations and interviews of midwives across six studies, this is apparent. Evidence already exists in the United Kingdom that midwives have greater job satisfaction, and employers experience better retention and recruitment to these settings (Kirkham et al., 2006). Parallel research into caseload models, which share many of the characteristics of midwifery-led models as defined here, also support this finding (Sandall, 1997). Significantly, the opportunity to form meaningful relationships with women, shines through recent evaluations of caseload models, suggesting that relationship mediated effects work reciprocally between women and midwives (Finlay and Sandall, 2009, Kemp and Sandall, 2010).

Tension between BC/MLUs and host maternity hospitals, apparently arising out of the contrasting cultures of each setting, should also be mentioned. This matters because of the important overlap between them when transfers are required. Evidence suggests that around 20% of labouring women are transferred out of BCs. A number of reports argue that poorer outcomes in the maternity services are related to poor communication or territorial disputes between professional groups (Healthcare Commission, 2006, Healthcare Commission, 2008, Lewis, 2007). This remains an area of challenge and one that research and service development initiatives should address with some urgency.

2.8 CONCLUSION

In the introduction to this meta-synthesis, the aspiration of exploring why BCs/MLUs reduce labour and birth interventions was stated. Through an exploration of qualitative papers of these settings, a number of contextual differences to traditional models of maternity care have been discussed. It is likely that these contribute significantly towards the better outcomes in these settings. It is already known that relationship effects are powerful in influencing clinical outcomes or labour and birth. What this meta-synthesis adds is the suggestion that these effects work primarily by increasing agency and a sense of empowerment in women. In addition, midwives facilitate this more effectively in MLUs because of their own enhanced sense of autonomy and agency. They also benefit from the relationships they share with women in these settings.

Certain characteristics of the settings, what could be broadly termed 'culture', contribute to all of the above. Smallness of scale is dominant among these, though others include an orientation towards normality. Smallness of scale crucially allows time for relationship and time for availability. This has been intuited from a number of studies that have focused on the centrality of relationship without mentioning time and smallness of scale (Berg et al., 1996, Coyle et al., 2001a, Coyle et al., 2001b, Esposito, 1999, Pewitt, 2008, Walker et al., 1995). In the light of Walsh's (2006a, 2006b) findings, scale effects are a common thread shared across all studies and a distinctive organisational characteristic of midwifery led models. This is a key difference with host maternity hospitals where there is a propensity towards increasing the size of provision as smaller maternity units are rationalised.

The current configuration of maternity services in a number of countries in the Western world is dominated by the large maternity hospital model. In the UK, 93% of births occur in the hospital labour ward model with just 3% in alongside birth centres, 2% in free-standing birth centre and 2% at home (Walsh, 2007). This review indicates that women and midwives are discontent with this model and strongly suggests that birth centres provide a welcome alternative to hospital labour wards, albeit restricted to low risk women. Our findings suggest that current trends in centralisation of birthing facilities could be detrimental to the experience and outcomes of care unless birth centres or their characteristics are introduced alongside this centralised provision.

Table 2.1: Quality Appraisal

Author/Date	Thorgen (2009)	Walsh (2006a)	Walsh (2006b)	Walker (1995)	Coyle (2001a)	Coyle (2001b)	Annandale (1987)	Annandale (1986)	Esposito (1999)	Berg (1996)	Pewit (2008)
Clear statement of aims appropriate to question	√	√	√	√	√	√	√	√	√	√	√
Literature review thorough and appropriate	√	X	X	X	X	X	√	√	X	X	X
Theoretical perspective and design clear/ appropriate	X	√	?	?	?	?	?	?	?	√	?
Sampling strategy explained and appropriate	X	√	X	√	√	√	√	X	√	√	√
Data collection described and justified	X	√	X	√	√	√	√	√	√	√	√
Analysis adequately described	X	√	X	√	√	√	?	X	X	√	√
Findings reflect data	√	√	√	√	√	√	√	√	√	√	√
Researcher reflexivity demonstrated	X	X	X	X	X	X	√	X	X	√	X
Study carried out ethically	√	√	√	√	√	√	?	?	√	√	√
Transferability discussed (setting and context adequately described)	√	√	√	√	√	√	√	√	√	√	√
Relevance and usefulness addressed	√	√	√	√	√	√	√	√	√	√	√
Quality Rating	C	B	C	B	B	B	B	C	C	A	B

Key to Quality Rating

A: No flaws or few flaws. The study credibility, transferability, dependability and confirmability is high

B: Some flaws, unlikely to affect the credibility, transferability, dependability and confirmability of the study

C: Some flaws which may affect the credibility, transferability, dependability and confirmability of the study

D: Significant flaws which are very likely to affect the credibility, transferability, dependability and confirmability of the study – Exclude

Symbols:

√= yes

X = no

? = unclear

Table 2.2: Description of Included Studies

Study	Scope and purpose	Design, methods	Sampling strategy /participants	Analytic strategy
Annandale (1987) (USA)	Explores the phenomenon of patient (sic) control in a FSBC FSBC	Ethnographic (fieldwork, interviews, document review) though not stated; also some quantitative	38 women interviewed 3 times, non-participant observation, notes review of 900 women who used birth centre, Demographics given	Triangulation of data sources and findings
Annandale (1988) (USA)	How midwives in a birth centre sought to structure their work around labour and delivery FSBC	Ethnographic (fieldwork, interviews, document review) though not stated; also some quantitative	38 women interviewed 3 times, non-participant observation, notes review of 900 women who used birth centre	Content analysis of notes, nothing else mentioned
Berg (1996) (Sweden)	To describe the encounter between the birthing woman and the midwife during childbirth IBC	Qualitative, interpretative using phenomenological, life-world approach, tape recorded unstructured interviews 2-5 days postnatally	18 women (6 primiparous, 12 multiparous) in hospital setting, some demographic detail	Meaning units distilled, thematic analysis, essential structure formulated
Coyle (2001a,b) (AUS)	To describe women's perceptions of care in birth centres following a previous hospital birth (Australia) IBC	Exploratory, qualitative (broadly interpretative), modified grounded theory, in-depth interviews	Robustly described (inclusion criteria, recruitment until saturation achieved), 17 multiparous women from 3 birth centres, demographic data given	Coding, categories, content analysis, thematic distillation (Burnard, 1991)
Esposito (1999) (USA)	Describe and interpret the culture of a unique birthing centre. (USA) FSBC	Ethnography with interviews and participant observation over 14 month	Opportunistic sample of 29 women, 5 midwives and 6 staff members of birth centre, participant observation 24 hrs and 7 days, 'marginalised' women	Indexing, grouping, categorising, reanalysis
Pewitt (2008) (USA)	To describe women's experience of care and satisfaction at a FSBC	'Qualitative description', semi-structured interviews of primiparous women	Purposive sampling, 6 women who gave birth in FSBC, interview within 12 months of birth	Van Manen procedure, thematic, interpretative
Thorgen & Crang-Svalenius (2009) UK	To investigate midwives' views and experience of working in birth centres in the UK FSBC, IBC	Qualitative open interview of midwives	Snowball sample of 9 midwives	Thematic distillation using Burnard's (1991) method
Walker (1995) (UK)	To elucidate the experience of labour for those receiving care in midwife-led unit. FSBC/MLU	'Qualitative approach', used to gain an 'emic' (insider perspective) via in-depth interviews	Purposive sampling of 32 women including some who were transferred out in labour and 6 partners	Grounded theory
Walsh (2006a) (UK)	To explore the culture, beliefs, values, customs and practices around the birthing process within a free-standing birth centre (UK) FSBC	Ethnography (broadly constructionist), fieldwork and in-depth, unstructured interviews of staff and women	15 visits over 9 months, opportunistic sample of 30 women, purposive sample of 10 midwives and 5 health care assistants	Coding, categories, thematic analysis, tentative theory development
Walsh (2006b) (UK)	To explore the culture, beliefs, values, customs and practices around the birthing process within a free-standing birth centre (United Kingdom) FSBC	Ethnography, fieldwork and in-depth, unstructured interviews of staff and women	Fieldwork over 9 months, opportunistic sample of 30 women, purposive sample of 10 midwives and 5 health care assistants	Not mentioned

Key abbreviations used in table
FSBC - Free Standing Birth Centre l MLU -Midwifery Led Unit l IBC - integrated birth centres

Table 2.3 Summary of how themes emerged from individual papers

Authors	Themes, first iteration	Themes, final iteration	Core concepts
Annandale (1987)	Chose birth centre because: • reaction against hospital • midwives and women providers preferred over male obstetrician • consumerist behaviour as expression of their needs Control mediated by patient ambivalence over risk, BC v hospital competition	Control constructed by women as self-preparation antenatally, influenced by midwives' emphasis on normality Not control over labour events which the midwives retained in their desire to avoid transfer	Control in labour dictated by midwives out of self-protection Women complicit in this, feeling guilty when transferred Reflects badly on BC/host relationship – women becomes pawns in a game Relationally mediated solidarity
Annandale (1988)	Birth centre ideology: woman-directed natural birth Obstetric context: professional control over midwives – resisted by midwives Ambivalence in women between natural and medical birth affected by contact with midwives and loyalty to them Midwives used ironic intervention (standardise birth) to retain clients, in opposition to women sometimes	Opposing notions of birth between BC and hospital Women caught in between Midwives driven by desire to retain clients and standardise care to do this	Midwives invoke medical model to protect midwifery model Greater surveillance by host unit impacted on birth centre care
Berg (1996)	To be seen as an individual To have a trusting relationship To be guided and supported on one's own terms Easier to dare to be themselves by being seen as they are	Midwifery presence, not 'absently present' For genuine dialogue to occur there must be a certain openness, a receptivity, readiness or availability – the open or available person reveals herself as present	To be actively 'present' Good care and experience mediated through relationship
Coyle, (2001a&b)	Birth Centre: • women believed birth was a natural process and midwives reflected this view by non-intervention • women wanted equality with carers and midwives encouraged them to lead on decisions • women felt at ease with carers and were known by them • care was personalised, sincere and same midwife present throughout Hospital: • hospital staff viewed birth as a disease process and consequently intervened more • health professionals authoritarian and women more passive in decision-making • lack of rapport with carers, not previously met • care systematised and routine, more than one carer in labour	Contrasting beliefs about birth between birth centre and hospital staff :birth as normal life event v birth as disease process) Contrasting approaches to power dynamics in relationship between women and providers (collaborative relationship v provider dominated relationship) Contrasting experiences of care interactions (accumulative versus non-accumulative) Contrasting care structures (women-tailored v institution-oriented)	Social model typical of birth centre, biomedical model in hospital Relationally mediated care that was individualised, respectful, 'being known' v fragmented, system-centred care

Table 2.3 continues on next page

Table 2.3 Summary of how themes emerged from individual papers *(continued from previous page)*

Authors	Themes, first iteration	Themes, final iteration	Core concepts
Esposito (1999)	Birth Centre; • Accessible, privacy • Treated with respect • Strong interpersonal connection with midwives • Able to give herself over to the birth, no mind/body separation • sense of control Hospital: • inaccessible, lack of privacy • not respected, judged (racism, stereotyping) • lost control , disempowering • not humanistic • had to dissociate from body to cope • rat in a cage	Control the birth environment Interpersonal connection, valued as a person v impersonal, part of a system Treated with dignity and respect Marginalised women already but empowered through birth centre experience	Primacy of relationship in birth centre experience Marginalised women especially benefited Give up control to labour in supportive environment, struggle to retain control of labour in non-supportive setting 'My body – the hospital takes it away, the birth centre gave it back'
Pewit (2008)	Achievement, accomplishment, self-confidence, self-esteem, strength, security, inspiration Anticipatory anxiety about motherhood alleviated, knew what baby went through, felt better prepared for motherhood Friendship with midwives, spouse greater respect for her, family impressed by midwives and midwifery	Empowerment Sense of motherhood Establishing and strengthening friendship with midwives	Relationship mediated empowerment and growth
Thorgen & Crang-Svalenius (2009)	• practise all aspects of midwifery • continuity of care • losing skills in other areas • independence, confidence • instinctual • variety • working hours • impact on family life • busy, stressful, demanding • staff shortages • isolation • close proximity to consultant delivery suite • co-operation with medical staff	• midwifery aspects • professional development • flexibility and work demand • independence • interprofessional relationships	Autonomy of practice by practising and promoting normal midwifery
Walker (1995)	Wanted availability of midwife but not necessarily present Need to feel informed, able to make choices and decisions about their care Friendliness rather than nice decor Supportive environment Continuity resulted in greater confidence Were not prepared by complications	Balance of perceived control and perceived support Lost control when transferred, break in continuity	Control and support mediated by relationship and availability
Walsh (2006a)	Women being intuitively drawn to birth centre on first visit because of environment and 'vibe' Staff had major focus on perfecting the birth environment Birth centre care was mother-like toward women, seen in care for staff as well	Nesting instinct aroused in women and expressed through staff priorities Linked to broader understanding of safety Matrescent care nurtures the becoming mother	Instinctive, nurturing care relationally mediated
Walsh (2006b	Different sense of time, flexibility with labour stages Deregulated routines – more 'being with' than 'doing to' Non-bureaucratic administration, non-institutional methods	Opposite of Fordism and Taylorism Post bureaucratic organisational processes released entrepreneurial activity Consequence of small scale	Birth centre run more like a home, related to scale Informal, personal

Table 2.4 Meta-synthesis Stages

Authors	Compare and contrast metaphors, phrases, ideas, concepts, relations and themes	Reciprocal and refutational translations	Supported by (Author year)	Synthesis
Annandale, 1987 **1988**	Control in labour dictated by midwives out of self-protection Women complicit in this, feeling guilty when transferred Reflects badly on BC/host relationship – women become pawns in a game Relationally mediated solidarity Midwives invoke medical model to protect midwifery model Greater surveillance by host unit impacted on birth centre care	Relationally-mediated benefits for women: increased agency, more empathic care	Berg 1996, Coyle 2001a, Coyle 2001b, Esposito 1999, Pewitt 2008, Walker 1995, Walsh 2006a, Walsh 2006b	Agency and empowerment are mediated principally through relationships but also the culture of midwifery-led environments. These have reciprocal effects on women and midwives
Berg 1996	To be actively 'present' Good care and experience mediated through relationship	Problematic interface between models, clash of cultures	Annandale 1987, Annandale 1988, Coyle 2001b, Thorgen & Crang-Svalenius 2009, Walsh 2006b, Walker 1995, Esposito 1999	
Coyle, 2001a&b	Social model typical of birth centre, biomedical model in hospital Relationally mediated care that was individualised, respectful, 'being known' v fragmented, system-centred care	Greater agency for midwives and women in birth centres, though bounded by relationship with host unit	Thorgen & Crang-Svalenius 2009, Walsh 2006a, Walsh 2006b, Annandale 1987, Annandale 1988	
Esposito 1999	Primacy of relationship in birth centre experience Marginalised women especially benefited Give up control to labour in supportive environment, struggle to retain control of labour in non-supportive setting 'My body – the hospital takes it away, the birth centre gave it back'			
Pewitt 2008	Relationship mediated empowerment and growth			
Walker 1995	Control and support mediated by relationship and availability			
Walsh 2006a & b	Instinctive, nurturing care relationally mediated Birth centre more run like a home, related to scale Informal, personal			
Thorgen & Crang-Svalenius 2009	Autonomy of practice by practising and promoting normal midwifery			

SECTION 3

Assessment of the cost-effectiveness of midwife-led care

3.1 INTRODUCTION

The prevailing model of maternity care in the United Kingdom (UK) is one of consultant-led care[2]. It is acknowledged that there may exist some degree of efficiency gain through modifying the roles and responsibilities of doctors and midwives (e.g. Bellanger and Or, 2008, Twaddle and Young, 1999). This section of the report analyses the existing evidence on the cost-effectiveness of midwife-led care[3] compared with consultant-led care. The potential for cost savings accruing from an expansion of midwife-led care in the UK is estimated.

3.2 LITERATURE REVIEW

The search strategy used to identify relevant papers is described earlier in the report. Papers relating to the costs of care were then selected and subjected to the following inclusion criteria to determine their suitability for inclusion in calculating the potential cost differential between midwife-led care for eligible maternities and consultant-led care. Costing studies that were relevant to the research question but did not meet the criteria below are analysed in Section 3.2.3.

3.2.1 INCLUSION CRITERIA

1. Consider costs as well as outcomes
2. Compare midwife-led model of care with consultant-led care
3. Randomised controlled trial
4. United Kingdom or a setting generalisable to the United Kingdom

3.2.2 INCLUDED STUDIES

Four studies met all the inclusion criteria listed in section 3.2.1. These are analysed in the following table using a format based on the quality guidelines devised by Drummond and Jefferson (1997).

[2] Consultant-led care includes shared care in which the consultant and midwife are part of a team and midwives may provide most or all of the maternity care
[3] In which care is provided entirely by midwives for eligible maternities, with strict protocols for referral to consultant-led care.

Table 3.1: Included studies

	(Hundley et al. 1995)	(Begley et al. 2009)	(Flint et al. 1987)	(Young et al. 1997a)
STUDY DESIGN				
Perspective of study	Hospital health care provider	Health service	Health service	Society (Young et al. 1997b) deals with costs to women)
Economic study type	Cost Effectiveness analysis	Cost Effectiveness analysis	Cost Effectiveness analysis	Cost Effectiveness analysis
Study setting	Aberdeen, Scotland	Cavan and Drogheda, Republic of Ireland	London, England	Glasgow, Scotland
Study sample	2,844 women	1,653 women	49 (costs were only analysed for a subgroup of the 1,001 RCT participants)	1,299 women
DATA COLLECTION METHODS				
Source of effectiveness data	RCT (Randomised Controlled Trial)	RCT	RCT	RCT
Source of cost data	Prospective costing of effectiveness sample data	Charts and prospective questionnaire of effectiveness sample data	Sub-sample of effectiveness data	Women's records from effectiveness sample data
Effectiveness results	Midwife-led unit is as safe, effective as medical-led care and provides a lower rate of intervention	Safe, effective alternative, with lower rate of intervention	More babies born to intervention group died neonatally (4 compared to 2), but sample size too small to examine statistical significance (pp 151)	Clinically safe and efficacious
Validity of measure of benefit*	Limited measure of benefit	Limited measure of benefit	Limited measure of benefit (Sample size adequate for examining patient satisfaction, feasibility and cost implications, but inadequate for examining obstetric outcome)	Limited measure of benefit
Validity of estimate of cost	No discounting required as less than 1 year [4] . Only short-term costs were considered			
	Average costs only reported (no incremental). Postnatal costs not included (calculated separately). Capital costs analysed.	Capital calculated but not included as considered equal (except birthing pools). Incremental cost, not average cost.	Limited to costs of antenatal admissions, epidural analgesia, perceived costs of consultations during antenatal period	Capital costs excluded, except equipment used during continuous electronic fetal heart rate monitoring in the intrapartum period. Average costs reported
Indirect costs/ productivity changes reported	No. Community health care costs not analysed. Indirect family costs considered similar for alternatives	No	No	Yes (in Young, Shields 1997) £148.42 versus £160.03 (cost saving of £11.61 for the midwife-led group (2010 prices))

Table 3.1 continues on next page

[4] Discounting involves adjusting costs or benefits that occur at different points in time into a common timeframe, usually the present.

Table 3.1: Included studies *(continued from previous page)*

	(Hundley et al. 1995)	(Begley et al. 2009)	(Flint et al. 1987)	(Young et al. 1997a)
ANALYSIS AND INTERPRETATION OF RESULTS				
Statistical analysis of costs	No	Yes. Standard deviations	No	Yes. T-tests, Mann-Whitney U-tests for median
Sensitivity analysis	Yes (e.g. no change in staffing levels, no conversion costs)	Yes (e.g. increase midwife visits after birth, shorten postnatal hospital stay)	No	Median caseload increased from 29 to 39
Average cost of a normal birth [5,6]	No	Normal: UK£437.25 (MLU) V UK£480.91	No	No
Average cost, ITT analysis (intention to treat)**	Varies depending on Scenario: **Base case:** UK£687 In midwifery led unit UK£621 in consultant led unit (UK£66 increase in costs) **Scenario with no increase in staff costs:** Saving: UK£9.50 **Postpartum:** Savings of UK£21.74 per woman)	UK£1,937.76 V UK£2,191.14 (saving = UK£253.38 with midwife-led care)	antenatal care 20% to 25% more expensive for control group (i.e. cost savings with midwife-led care)	**29 caseload per midwife:** Antenatal, intrapartum: No statistically significant difference. Postnatal: intervention median, UK£687.56 V UK£514.94 (control group less costly by UK£172.63) **39 caseload per midwife:** Antenatal: UK£431.55 v UK£400.83 Intrapartum, unchanged. Postnatal: UK£591.01 V UK£514.94 (control group less costly by UK£45.35)
Currency of original study	£ Sterling	€ euro	£ Sterling	£ Sterling

*measures of benefit were not combined into an incremental cost effectiveness ratio or incremental net benefit in these papers.

Hundley et al.(1995) conducted a cost effectiveness analysis within the context of a randomised controlled trial in Scotland (Hundley et al., 1994). The costs of intranatal care were examined for 2,844 low-risk women in a midwife-led unit within a hospital setting in a standard year, compared to a consultant-led unit (CLU). The midwife-led unit was staffed by midwives who rotated into the CLU according to clinical need. Analysis was by intention to treat, which minimises bias associated with non-random loss of participants.

Costs increased by £66 per maternity in the midwife-led unit versus the CLU, as shown in the table above. However, a scenario analysis investigated the impact of varying key parameters such as increased midwife staffing levels and the capital costs of converting a section of the traditional delivery suite into a midwife managed unit, with results ranging from a cost saving of £15.64 to a cost increase of £71.01 per woman (2010 prices[7]). The principal cost driver in intranatal care in the midwife-led unit was an increase in midwife staffing levels, while conversion costs and midwife promotions also accounted for some of the increase (Hundley et al., 1995).

The MidU Study (Begley et al., 2009) was a pragmatic randomised trial conducted in the Republic of Ireland comparing an alongside midwife-led unit with consultant-led unit for healthy women without risk factors, on rate of interventions, maternal satisfaction, costs and neonatal/maternal outcomes. Antenatal care was shared between midwives and general practitioners, while intra- and postnatal care was provided by midwives. Capital costs such as buildings and medical equipment were not included as they were considered equivalent in each unit, with the exception of birthing pool costs. The breakdown between ante, intra, and postnatal care cost savings is shown in Table 3.2.

[5] Normal birth is defined as a birth that does not require either temporary or permanent transfer to consultant-led care at any stage
[6] All costs have been standardised to £ Sterling, year 2010
[7] This means that prices were inflated from the year of the study to 2010 to account for medical inflation and increase comparability with other included studies

Table 3.2: Breakdown of cost savings from midwife-led care in the MidU study

Stage of pregnancy	Cost saving per maternity * (cost increase = negative value)
Antenatal (excluding length of stay)	81.03
Antenatal length of stay	177.13
Intranatal	-1.47
Postnatal	-3.31

* UK£ (2010 values). Source: Begley et al. 2009

Overall, costs were significantly less for midwife-led care, and the bulk of cost savings occurred in the antenatal stage. The implications of this are outlined in the discussion section of this section of the report.

Young and colleagues conducted an economic analysis (Young et al., 1997a) based on a randomised trial in Glasgow, Scotland that compared midwife-led care with shared care (Turnbull et al., 1996). A team of twenty midwives used birth rooms within the hospital setting, with a specific midwife assigned to each woman. If that midwife was unavailable, care was provided by another midwife from the team.

An "individual patient-based costing" approach was used to explore the impact of caseload size per midwife on the results. Capital costs were not included, except for equipment used for intranatal continuous electronic fetal heart rate monitoring. The intervention group recorded significantly lower rates of antenatal visits, inductions, and postnatal daycare attendances, with a mean of 9.4 antenatal visits compared to 10.2 for the shared care patients. These figures are similar to current antenatal care guidelines, which recommend that ten visits should suffice for nulliparous uncomplicated maternities, and that seven visits should suffice for parous uncomplicated pregnancies (National Collaborating Centre for Women's and Children's Health, 2008).

When the median caseload was assumed to be 29 maternities per midwife, no significant difference was found in the cost of ante and intranatal care, but the cost of postnatal care was higher in the midwife-managed group. These increased costs for midwife-led care occurred as (i) more senior (and thus more expensive) midwives were deemed necessary for midwife-managed care, (ii) the control group postnatal ward benefited from scale economies due to its larger capacity and (iii) the caseload in the midwife-led unit was lower than expected due to a number of factors including some of the women referred to the hospital being ineligible for inclusion as they lived outside the study catchment area. When an assumption of 39 women per midwife was used (this was achieved by the midwife with the highest caseload), the cost differential decreased but still favoured consultant-led care (see Table 3.1) (Young et al., 1997a).

A separate paper examined indirect costs to women (Young et al., 1997b). The personal cost to women of attending antenatal clinics was found to vary widely among different settings. Women attending midwife-led antenatal care had lower costs than those receiving shared care, the implications of which are explored in the sensitivity analysis in Section 4.

Flint et al.(1987) conducted a randomised trial involving over 1,000 women comparing midwife-led care to traditional shared care, and reported significant benefits in terms of continuity of carer and maternal satisfaction. Some costing was carried out, however this was limited to a small subgroup of women (n=49) and pertained solely to antenatal care. Each group had similar numbers of antenatal consultations, but the intervention group had a higher proportion with midwives than with doctors. The intervention group was reported to be 20-25% less expensive than the shared care group, apparently due to reduced staffing costs.

Following discharge, women randomised to the midwife-led group were visited more often in the home, implying that postnatal costs may have been greater for the midwife-led group (Flint et al. 1989). However, there has been little evaluation of the clinical and cost-effectiveness of current postnatal care patterns, and there is little knowledge on current levels of postnatal care provision. It is recommended that postnatal care be tailored to individual needs (Demott et al., 2006).

Hundley et al. (1995), by contrast, reported cost saving in the postnatal period resulting from a shorter length of stay due to different modes of delivery. This underlines the heterogeneity of published findings and the difficulty in drawing firm conclusions as to the economic impact of midwife-led care. It is worth noting that a systematic review found insufficient evidence to discern any difference in maternal and neonatal outcomes between early and standard discharge (Demott et al., 2006:56).

It is important to note the limitations of the literature on the cost-effectiveness of midwife-led care. Many studies exhibit similar limitations such as a lack of generalisability to other settings, no measure of benefit, capital costs or indirect societal costs. Furthermore, micro-costing of the care processes and detailed information regarding the package of care received by the control group are often absent from the published literature.

3.2.3 EXCLUDED STUDIES

A number of studies investigated the cost-effectiveness of midwife-led services outside Europe and were thus deemed ineligible for inclusion. In Australia, Rowley et al. (1995) found that care provided by a midwife team improved maternal satisfaction with services and reduced costs. Costing was restricted to acute inpatient services and was measured using Diagnosis Related Groups (DRGs), which likely reduced the accuracy of results[8]. Another Australian study also reported lower costs in a midwife-led model of care (Homer et al., 2001),

[8]This is because DRGs are based on average costs across hospitals, rather than the costs of the individual hospital under investigation

while one small Australian study found no significant difference in costs or clinical outcomes between midwife-led intranatal birth centre care versus traditional care delivered mainly by a midwife who liaised with a doctor (Byrne et al., 2000).

A number of studies conducted in North America have suggested that (midwife-led) free standing birth centres (FBCs) are a safe, effective alternative to CLUs for a normal birth. Stone et al.(2000a) examined the cost-effectiveness of FBCs for low-risk women in the USA. They reported significantly lower costs in FBCs than in the medical model of care (US$6,087 versus US$6,803, intention to treat analysis, n = 146). Observational evidence of lower costs was reported by Walker and Stone (1996).

An observational study conducted in Canada found reductions in costs associated with midwife-led services (CAN$2,294 v CAN$3,020, with CAN$90 the smallest differential when parameters such as prices and consumption of services were adjusted in a sensitivity analysis) (Reinharz et al., 2000). Staffing differences and length of stay accounted for much of the difference in costs. This study has a number of weaknesses, including the possibility of selection bias, Hawthorne effect (midwives knew they were being observed whereas physicians did not), and underreporting of the amount of services provided by some midwives.

Selection bias is likely to have been a problem in non-randomised studies as noted by Henderson and Petrou (2008), as women who choose to deliver outside the traditional hospital setting may differ in terms of characteristics such as their preparation for birth. Because of this, studies such as the non-randomised evaluation of the Edgeware Birth Centre (Saunders et al., 2000), which reported lower costs in the midwife-led group, were excluded from this analysis.

A number of maternity costing studies were excluded as they did not compare a midwife-led model with consultant-led care (e.g. Henderson et al., 2001, Hendrix et al., 2009, Petrou and Glazener, 2002, Turnbull et al., 2004). Useful data on midwifery services in the UK was gathered by Piercy et al. (1996) and Beake et al. (2001) but these were excluded as they did not compare the costs of the intervention versus the control. A useful overview of many of the complex issues surrounding the economic analysis of maternity services is offered by Twaddle and Young (1999).

The greatest scope for improved cost-effectiveness may be in altering the roles of different health care workers in antenatal care (Twaddle and Young 1999). The statistically significant reductions in resource use associated with midwife-led intrapartum care, such as a reduction in antenatal hospitalisation and intrapartum analgesia (Hatem et al. 2008), suggest this also is a promising source of potential cost savings, although evidence to support this from the small number of published economic evaluations is lacking.

There is some evidence to suggest there may be scope for reduced length of postnatal stay and increased contribution from midwives in the community (Brooten et al., 1994, Petrou et al., 2004, Stewart et al., 2004b). However, if antenatal care was partially shifted to community setting, cost savings to the health service may be limited in the short run due to the fixed or semi-fixed nature of most hospital costs (Twaddle and Young 1999). In the longer term a shift to community level care could potentially result in significant efficiency gains. The greater part of the cost savings resulting from increased community care may be gained by the women attending the service, for example, due to reduced travel costs.

The economic impact of reducing the number of antenatal care (ANC) visits for low-risk maternities was examined by Henderson et al. (2000). "Standard care" aimed for 13 ANC visits but in practice achieved an average of 11 visits. The reduced visit model aimed for 7 visits for nulliparous women and 6 for multiparous women, but in practice achieved an average of 9 visits (Carroli et al., 2001). Overall, no significant difference in costs were reported. A decrease did occur in resource use, but this was offset by an increase in neonatal admissions to special care, and women reported poorer psychosocial outcomes (Henderson et al. 2000). The number of ANC visits was broadly similar to current guidelines recommending that ten and seven visits should suffice for uncomplicated nulliparous and uncomplicated parous maternities respectively (National Collaborating Centre for Women's and Children's Health, 2008).

3.3 METHODOLOGY

3.3.1 LITERATURE REVIEW

The search strategy used to identify relevant papers has been outlined earlier in the report. The inclusion criteria used for the economic analysis are outlined in Section 3.2.

3.3.2 ECONOMIC EVALUATION

This study broadly used the methods specified by the National Institute for Health and Clinical Excellence (NICE) to assess the cost-effectiveness of midwife-led care (2009). The stated objective of the Institute is to maximise health gains from available resources. The measure of health gains used is

the quality-adjusted life year (QALY). The QALY is a generic and single index criterion, capturing both reductions in mortality and morbidity. It thus satisfies the need for a consistent but sufficiently sensitive measure that can be used across clinical decisions (Sculpher and Claxton, 2005).

The NICE framework is based upon an understanding that there are two simultaneous but conceptually distinct decisions facing any collective health care system: whether a health technology should be adopted based on current evidence; and whether additional evidence is required to support the adoption of a technology.

The decision to adopt or reimburse an alternative (j) is based on expected costs (Cj), expected outcomes – specified in QALYs (Qj), and an exogenous budget threshold (λ). The budget threshold can represent either

(i) the value of health gains foregone with adoption of j due to the displacement of existing technologies;

or

(ii) (ii) the cost per additional QALY that could be achieved with an augmentation of the health budget.

Costs and outcomes occurring in different periods are adjusted into the present timeframe using the discount rate of 3.5% per year. The cost-effectiveness of j can then be expressed in terms of net benefit (Phelps and Mushlin, 1991, Stinnett and Mullahy, 1998):

$$NB_j = Q_j\lambda - C_j$$

However, there will of course be some uncertainty in NBj, dependent upon the uncertainty over model parameters (θ).With current information, the decision rule should then be to choose the intervention with the maximum expected net benefit:

$$max_j E_\theta NB(j, \theta)$$

It can be noted that decisions are based on mean net benefit, irrespective of any notions of statistical significance. This is because failure to adopt an intervention with a positive but uncertain mean net benefit would impose opportunity costs, of health gain foregone, on those who could benefit from the estimated optimal treatment (Claxton, 1999).

The NICE framework recommends the use of value of information (VOI) analysis to guide the second decision on whether additional evidence is required to support a recommendation. This study did not use VOI analysis, but instead simple one-way sensitivity analysis was undertaken to examine the robustness of findings. Some recommendations for further research are drawn.

3.4 COST-EFFECTIVENESS RESULTS

This section describes current birth patterns in the UK, and the potential benefits and costs of shifting towards midwife-led care for eligible women. The basis for the assumptions employed is elaborated in Sections 3.4.1and 3.4.2.

3.4.1 EPIDEMIOLOGY: BIRTHS IN UK

Regarding the configuration of maternity services in the UK, it is estimated that 16% (National Childbirth Trust, 2008) of pregnant women used a midwife-led unit, which equates to 124,954 from a total of 780,965 (General Register Office for Scotland (GROS), 2010, Northern Ireland Statistics and Research Agency, 2010a, Northern Ireland Statistics and Research Agency, 2010b, Office for National Statistics, 2010). The following table shows the assumptions used in estimating the total number of pregnant women accessing consultant-led services who are eligible and may choose to avail of midwife-led care.

Table 3.3: Eligible pregnant women

% of all pregnant women eligible for midwife-led care	40%
Number of pregnant women eligible but not currently receiving midwife-led care	187,432
Those who would choose midwife-led care	93,716

Assuming that 40% of all pregnant women are eligible for midwife-led care, approximately 187,432 maternities that are eligible for midwife-led care are currently being led by consultant obstetricians. Current guidelines states that women with uncomplicated pregnancies should be permitted to make an informed choice of midwife-led care or obstetrician-led care (National Collaborating Centre for Women's and Children's Health, 2008, National Collaborating Centre for Women's and Children's Health, 2007). Undoubtedly some women would prefer not to avail of midwife-led care, assumed to be 50% based on the published literature (Begley et al., 2009, Donaldson et al., 1998, Ryan et al., 1996).

3.4.2 BASIS FOR EPIDEMIOLOGICAL ASSUMPTIONS

Number of births

There were approximately 780,965 maternities[9] in the four constituent countries of the United Kingdom in 2009 (General Register Office for Scotland (GROS), 2010, Northern Ireland Statistics and Research Agency, 2010a, Northern Ireland Statistics and Research Agency, 2010b, Office for National Statistics, 2010).

[9] Maternities refer to the number of pregnancies ending in stillbirths or live births with multiple births counted once

Preferences of women
Two studies used willingness-to-pay methods to gauge the preferences of women for consultant-led or midwife-led antenatal care. Ryan et al.(1996) reported no difference in preference, while Donaldson et al., (1998) reported that 55% of women preferred the midwife-led option. For the purposes of this analysis it was assumed that 50% of women would opt for midwife-led services were it available. Another paper which investigated this issue was deemed insufficiently generalisable to be included in this study as it was conducted in a remote area of rural Scotland (Pitchforth et al., 2008).

Current configuration of maternity services
Official figures indicate that roughly 7% of births occur in midwife-led units (Healthcare Commission, 2008). However, it has been reported elsewhere that this figure may underestimate the true amount due to incomplete data sources and obsolete classification categories, and that a more accurate estimate may be that 16% of maternities are currently using midwife-led services or units (National Childbirth Trust, 2008:4). This paper uses the latter figure, which gives a more conservative estimate of the potential for increasing midwife-led care beyond current levels.

Eligibility for midwife-led services:
A 2008 report by the Commission for Healthcare Audit and Inspection stated that "low-risk" pregnancies leading to normal births (i.e. without medical intervention) "should usually experience midwife-led care, even in an obstetric unit".
The report noted also that 40% of births were reported as normal by the median trust, while "a quarter of trusts reported 32% or less" (Healthcare Commission, 2008). The target rate of 60% has been suggested as a realistic objective by the Maternity Care Working Party (Maternity Care Working Party, 2007). Taking into account the 16% of maternities currently led by midwives, it was assumed that 24% of total annual maternities (187,432 in table 2 above) are eligible for switching to midwife-led care from medical-led services.

3.4.3 COSTS:

The following table outlines estimated savings associated with a shift to midwife-led care from CLU.

Table 3.4: Cost savings

Estimated saving per birth	£12.38
Estimated aggregate annual saving	£1,160,072

These figures were attained by calculating the mean cost saving (or increase) in three of the included studies (Hundley et al., 1995, Begley et al., 2009, Young et al., 1997a). A fourth study (Flint et al., 1987), which met the inclusion criteria, was excluded from the calculation as the costing data furnished was less detailed than the other studies and pertained only to antenatal care.

3.4.4 OUTCOMES:

The difference in mortality outcomes for midwife-led care versus other models of care was assumed to be zero, based on the best available evidence presented in Section 1 of this report. The reduction in overall fetal loss and neonatal death is not statistically significant at the 95% level. For all studies comparing these models of care, the risk ratio (RR) is 0.93 (95% confidence interval (CI) 0.79 to 1.09). For studies that only included low-risk status women the RR is 1.03 (95% CI 0.82 – 1.30). When analysed by subgroups based on whether the event occurred before or after 24 weeks gestation the findings remained consistent, with risk ratios in each case overlapping with 1.00.[10]

3.4.5 COMBINING COSTS AND OUTCOMES:

The cost-effectiveness measure selected for use is the incremental net benefit (INB). This can be expressed in two forms: the net monetary benefit (NMB) and net health benefit (NHB). The NMB represents the funding that is released to achieve equivalent health gain, and can be invested elsewhere in the health system, while the NHB represents the number of QALYs estimated to be gained as a result of more efficient use of health sector funding. The rationale for using these outcome measures is presented in the methods section along with a fuller explanation of their role in the discipline of health economics.

Table 3.5: Incremental net benefit

Mean net monetary benefit	UK £12.38
Mean net health benefit	QALY 0.0004

This implies that the mean benefit per maternity is equivalent to just over UK£12 using the assumptions outlined previously, which can also be expressed as an average of 0.0004 QALYs gained per maternity. When this is multiplied by the estimated total number of maternities switching to midwife-led care per year the aggregate NMB is £1.16 Million, while the aggregate NHB is 37.5 QALYs gained per year.

3.4.6 SENSITIVITY ANALYSIS

It is difficult to draw firm conclusions on the cost-effectiveness of midwife-led services for eligible maternities due to the sparse nature of the evidence base. To address this, a range of sensitivity analyses

[10] **All studies:** i) Fetal loss and neonatal deaths prior to 24 weeks gestation (RR 0.88, 95% CI 0.73 – 1.05); ii) Fetal loss and neonatal deaths equal to or after 24 weeks gestation (RR 1.16, 95% CI 0.81 – 1.66). **Low-risk women only:** i) Fetal loss and neonatal deaths before 24 weeks gestation (RR = 1.01 [95% CI: 0.78, 1.31]). ii) Fetal loss and neonatal deaths equal to or after 24 weeks gestation (RR = 1.10 [95% CI: 0.69, 1.76])

were conducted to explore the sensitivity of the results to variations in the assumptions employed for cost savings per maternity, the risk ratio of overall fetal loss and neonatal death, and uptake of midwife-led maternity services.

3.4.6.1 Sensitivity Analysis 1: Systematically varying the estimated cost savings

The impact of varying the cost savings is examined in eight scenarios, which are based on the particular features of the three studies used to calculate the cost savings. These scenarios are described below.

Scenarios

i) Scenario 1 is the "base case", meaning assumptions are unchanged.
ii) Improved operational efficiency scenario. First, in (Young et al., 1997a): zero additional staffing costs as these are assumed to be offset by a reduction in consultant-led unit staffing. Second, Hundley et al., (1995): caseload of 39 maternities per midwife assumed, rather than 29 maternities)
iii) Societal perspective (including indirect costs from (Young et al., 1997b)
iv) Combining Scenarios 2 and 3
v) Only Begley et al., (2009) included (the most cost-effective study)
vi) Only the two least cost-effective studies included (i.e. excluding Begley et al., (2009))
vii) Combining Scenarios 2 and 6 (i.e. optimistic outlook for the two least cost-effective studies)
viii) Combining Scenarios 3 and 6 (i.e. optimistic outlook for the two least cost-effective studies, and indirect costs included)

The following table outlines the cost effects per maternity of each of these scenarios.

Table 3.6: Systematically varying the estimated cost savings[11]

Scenario	Mean cost saving (£)	Mean NMB (UK£)	Mean NHB (QALYs)
i)	12.38	12.38	0.0004
ii)	79.76	79.76	0.0027
iii)	23.99	23.99	0.0008
iv)	91.37	91.37	0.0030
v)	253.38	253.38	0.0084
vi)	-108.12	-108.12	-0.0036
vii)	-7.06	-7.06	-0.0002
viii)	4.56	4.56	0.0002

Cost effects per maternity vary from a saving of UK£253.38 to a cost increase of UK£108.12 depending on the assumptions used. The aggregate net monetary benefit ranges across a moderately narrow range in this analysis, from a cost saving of UK£23.75 million to a cost increase of UK£10.13 million (see Appendix F). The assumptions employed in the three included studies clearly have a critical bearing on findings; for example, in Scenario 2 when the caseload is increased towards target levels in Hundley et al., (1995) and an incremental cost approach is employed for capital costs in Young et al., (1997a), the mean cost saving per maternity increases from £12.38 to £79.76. Including indirect costs from Young et al., (1997b) (Scenario 3) increases cost savings by over £11 per patient. The major influence of Begley et al., (2009), the most recent study, is shown by its sizeable cost saving when examined alone in Scenario 5.

3.4.6.2 Sensitivity Analysis 2: Systematically varying the risk ratio for overall fetal loss and neonatal death

This analysis deals with overall fetal/neonatal death in studies comparing midwife-led care to consultant-led care. The following table outlines the effects of systematically varying the risk ratio in studies that include only low-risk status women, based on the 95% confidence interval of 0.82 to 1.30 (as presented in Section 1 of this report).

Table 3.7: Systematically varying the risk ratio, studies that include only low-risk status women

Risk ratio	Mean NMB (£ million)	Mean NHB (QALYs)
1.03	12.38	-1,798
0.82	324	10,787
0.92	144	4,795
1.10	-180	-5,993
1.20	-360	-11,986
1.30	-539	-17,979

Varying the risk ratio has a dramatic impact on results. The aggregate net monetary benefit ranges extremely widely in this analysis, from a saving of £324 million[12] o a loss of £539 million, a difference of over £850 million. The net health benefit ranges from an annual gain of 10,787 QALYs to a loss of 17,979 QALYs. This underlines the relative importance of the assumed change in mortality compared to the assumed cost savings. The expected risk ratio of 1.03 for low-risk status maternities (see Section 1 of this report) would imply an increase of one fetal loss/ neonatal death for every 1,150 low-risk maternities that use midwife-led care rather than consultant-led care.

The following table outlines the effects of varying the risk ratio based on the results of studies that include high and low-risk women. The risk ratio for

[11]It may cause confusion among some readers that the cost saving for scenario 1 does not equal the sum of scenarios 5 and 6. This is because mean values are used in Scenarios 1 and 6 (i.e. divide by three and two respectively) whereas no division occurs in Scenario 5.
[12]The QALYs gained (30,856) are converted into ST£ at the NICE threshold of £30,000 per QALY, then added to the projected annual cost savings of £1.16 Million.

overall fetal/neonatal death was systematically varied based on the 95% confidence interval of 0.79 to 1.09 (see Section 1 of this report).

Table 3.8: Systematically varying the risk ratio, studies that include women in all risk categories

Risk ratio	NMB (£)	NHB (QALY)
1.00	12.38	0.0004
0.79	472 Million	15,723
0.86	314 Million	10,482
0.93	157 Million	5,241
1.09	-202 Million	-6,738

As before, the aggregate net monetary benefit ranges extremely widely in this analysis, from a gain of £472 million to a loss of £202 million, a difference of £674 million. The net health benefit ranges from an annual gain of 15,723 QALYs to a loss of 6,738 QALYs. The expected risk ratio of 0.93 equates to a number needed to treat of 394 (i.e. inverse of the absolute risk reduction, 0.25%), meaning that for every 394 maternities switching to midwife-led care, on average, one fewer fetal or neonatal death would be expected to occur.

3.4.6.3 Assumptions for altering the risk ratio for overall fetal loss and neonatal deaths

1.3.7.1.1 The change in overall fetal loss and neonatal deaths

To estimate the change in overall fetal loss and neonatal death, the absolute risk in the control group (assumed to be the prevailing model of maternity care) was calculated for low-risk maternities and mixed maternities using the data in the first two rows of Table 3.9. Results are shown in the third row of Table 3.9.

Table 3.9: Estimating absolute risk for total fetal loss/neonatal death

Risk ratio	NMB (£)	NHB (QALY)
Number of events (control group)	282	127
Total maternities (control group)	7,771	4,372
Absolute risk in consultant-led care	3.63%	2.90%
Risk ratio*	0.93 (95% CI 0.79 to 1.09)	1.03 (95% CI 0.82 to 1.30)

*midwife-led versus other models of care (see Section 1 of this report)

The absolute risk reduction from switching to midwife-led care was then calculated by multiplying the absolute risk by [1 – risk ratio], and the change in overall fetal loss and neonatal deaths per year was calculated by multiplying the absolute risk reduction by the assumed number of maternities annually switching to midwife-led care (93,716). This was then converted to the mean net health benefit and mean net monetary benefits figures shown in Table 3.7and Table 3.8, with the risk ratios systematically varied within their 95% confidence intervals.

1.3.7.1.2 Estimating Quality Adjusted Life Years gained or lost

To estimate the total health loss or gain from fetal losses and neonatal deaths requires estimating the mean future number of Quality Adjusted Life Years (QALYs) for each infant born. The QALY measures time in terms of quantity (years) and quality (health-related quality of life).

Life expectancy in the United Kingdom for 2006 – 2008 was 79.5 years, at 77.4 years for males and 81.6 years for women (Office for National Statistics, 2009). In an earlier paper, Williams (1997) noted the average quality adjusted life expectancy (QALE) at birth was 61.5 QALYs across all social groups. Factoring in the increase in life expectancy between then and now (Office for National Statistics, 2006, Office for National Statistics, 2009), the current mean QALE at birth is estimated at 62.97.[13] This figure was then multiplied by the change in overall fetal loss/ neonatal death, taking into consideration the discount rate adopted by NICE of 3.5%, to estimate the number of QALYs gained or lost as a result of using midwife-led maternity services in place of consultant-led care.

3.4.6.4 Sensitivity Analysis 3: Systematically varying the assumed uptake of midwife-led maternity services

In the main set of results it was estimated that 24% of total maternities are eligible for midwife-led services and are not currently receiving it. When constructing the economic model it was assumed that half of these, 12% of total annual maternities, would opt to switch to midwife-led services. In this sensitivity analysis, this proportion was systematically varied to gauge its impact on aggregate annual net monetary benefit (NMB) and net health benefit (NHB). It is assumed that the mean cost saving per maternity does not vary from £12.38, but the total annual saving is altered by the number of women who switch to midwife-led services. For this reason, aggregate NMB and NHB figures are shown in Table 3.10.

[13]The percentage increase in QALE over this period was assumed to equal the percentage increase in life expectancy (2% increase).

Table 3.10: Systematically varying the percentage of maternities switching to midwife led care

% Switching	Total net monetary benefit (NMB)	Total net health benefit (NHB)
12%	1,160,072	38.67
17%	1,643,435	54.78
22%	2,126,799	70.89
8%	773,381	25.78
3%	290,018	9.67

The level of uptake by women is influenced by a number of factors, including individual preferences, the particular eligibility criteria applied, and the extent of rollout or availability of the service. There are no universally applied criteria, as these vary among hospitals. The base case assumes 24% of all maternities will shift from medical-led care to midwife-led care (i.e. 40% eligible, subtract the estimated 16% of all maternities currently receiving midwife-led care). An upper bound of 60% eligible births (additional 44% uptake) was used as this has been set as a realistic objective for UK maternity services (Maternity Care Working Party, 2007).

3.5 DISCUSSION

3.5.1 COST-EFFECTIVENESS RESULTS

It is clear that the evidence base for the cost-effectiveness of different models of maternity care, including midwife-led services, is sparse. The paucity of high quality economic evaluations as well as the broad range of estimated costs per birth makes it difficult to draw unambiguous conclusions regarding cost effectiveness (Begley et al., 2009). Based on existing evidence, the mean cost saving for each eligible maternity was estimated at £12.38. If midwife-led services were expanded to 50% of all eligible maternities in the UK, as assumed in the main set of results, this would result in an aggregate cost saving of £1.16 Million per year (equivalent to an annual aggregate health gain of 37.5 QALYs).

Caution is essential when interpreting these findings due to the limited nature of the evidence base. Of the four studies that met the inclusion criteria, two are from the 1990s and another (from the 1980s) was limited to costing antenatal care. The MidU study in Ireland offers the most recent thorough costing analysis of midwife-led care versus consultant-led care in a relevant setting, and its results were the most favourable for midwife-led care (saving of £253.38 per maternity). However, these savings occurred in the antenatal care stage and thus may not be applicable to the UK setting as much antenatal care here is already provided by midwives.

A sensitivity analysis was conducted to ascertain the robustness of the results to changes in key parameters. This demonstrated that the fetal loss and neonatal death rate has a profound bearing on the findings, while results are affected to a much lesser extent by varying the percentage of maternities who switch to midwife-led services and the estimated cost savings per case. When the risk ratio for fetal loss and neonatal death is systematically varied within the two 95% confidence intervals for low-risk and mixed maternities, the net monetary benefit ranging from a gain of £472 million to a loss of £539 million. These sums should not be confused with actual financial savings (which are far smaller as previously noted, at UK£1.16 million). Rather, they represent in monetary terms the magnitude of the gain or loss in QALYs from expanding midwife-led care for eligible maternities; for example, the £472 million figure represents a health gain equivalent to that gained from investing £472 million sterling at £30,000 per QALY, which is commonly taken to represent the NICE threshold.

The findings of subgroup analysis between trials containing mixed and low risk maternities are consistent with the main results in this analysis as the risk ratios for overall fetal loss and neonatal death overlap with 1.00. Similarly, sub-group analyses for trials both with and without the provision of antenatal care also overlap with 1.00.

The mean cost differential between midwife-led care and consultant-led care is a critical determinant of cost-effectiveness, despite its relatively minor impact on incremental net benefit compared to changes in fetal loss and neonatal death. In the sensitivity analysis, the estimated cost-effectiveness increased significantly when numbers of women accessing services was increased (Sensitivity Analysis 1, Scenario 2). This highlights that value for money in midwife-led services is contingent on appropriate planning and effective management of services to ensure satisfactory numbers of women accessing services and operational efficiency.

In the third sensitivity analysis, it was assumed that the mean cost saving per maternity (£12.38) was not affected by changes in the total number of women switching to midwife-led care per year. (The impact on total cost savings per year (a function of the mean cost saving per woman and the total number of women switching per year) is shown in Table 3.10.) In practice, however, the operational efficiency of midwife-led services is influenced by the level of uptake, therefore this could in fact have an important bearing on mean cost-effectiveness.

It is worth highlighting that the results of the MidU study (Begley et al., 2009) are substantially more cost-effective than either Hundley et al., (1995) or Young et al., (1997a) due to cost savings in antenatal length of stay and antenatal visits to the health care facilities. These cost savings are supported by another randomised trial (Flint et al., (1987) that met the inclusion criteria and which reported 20 to 25% higher costs in the control group compared to midwife-led care during the antenatal period. Nonetheless, findings from the MidU Study (Begley et al., 2009) may not apply to the current UK context, as mentioned previously, as much antenatal care in the UK is already being delivered by midwives.

It was not possible to develop more detailed costing models for midwife-led care according to the different care trajectories of women giving birth (meaning those who require transfer to consultant-led services versus those who do not require transfer) due to the sparse nature of the evidence base. There is a clear need for further economic evaluations in the UK context to guide the better use of scarce resources. It was also not possible to estimate lifetime costs saved/incurred within the constraints of this study, therefore only short term costs are included in the analysis.

3.5.2 ASSUMPTIONS REGARDING STAFFING AND CAPITAL EXPENDITURE

Begley et al., (2009) argue that Hundley et al., (1995) overestimated costs due to the assumption that additional midwives are required to establish a MLU (midwife-led unit). They propose that this is because midwife-led care is an alternative to medical-led care for suitable women in which case the midwife-led workload would be offset by a commensurate reduction in the medical-led workload. The demand for maternity services can be increased by normal demographic increases, but not by a greater supply of services. Taking this into consideration, Begley and colleagues (2009) opted to analyse incremental costs and outcomes. A similar approach was adopted by Young et al., (1997a) who excluded most capital costs from their analysis.

Central to this argument, however, is that the number of women accessing a particular service of sufficient magnitude to achieve acceptable value for money for the service. An increase in numbers of women accessing services levels can allow a better spread of fixed costs and hence greater efficiency. Low numbers of women accessing services and hence potentially over-staffed units are likely to be less cost-effective (O'Sullivan and Tyler, 2007). This is demonstrated, for example, by the work of Young et al., (1997a) and Chamberlain et al., (1998) who described how a minimum of 25 births are needed for a midwife-managed community birthing centre to be cost-effective. However, higher caseloads must be weighed against the potential costs of burnout and non-sustainability (Stewart et al., 2004a). Thus, the supply of maternity services must be matched carefully with demand (including women's preferences) if optimal efficiency levels are to be achieved. The value for money of each proposed midwife-led unit should be considered on an individual basis.

Staff mix is a significant predictor of cost of care (Stone et al., 2000b). In some studies, more senior midwives were employed in birth centres than in consultant-led units, which offsets other potential cost savings (Young et al., 1997a, Henderson and Petrou 2008).

In the MidU study (Begley et al., 2009), most capital costs were excluded from the study as they are equally necessary for a consultant-led facility (birthing pools were the only item included). This incremental approach may yield a more valid estimate of cost-effectiveness than studies that include all capital costs as costs additional to the consultant-led alternative.

3.5.3 THE CHALLENGE OF GENERALISABILITY

Caution is required when interpreting results and estimating the potential impact of the midwife-led model of care in the UK. There are issues surrounding the generalisability of findings, particularly due to the limited number of economic evaluations that deal with this issue. The heterogenous nature of published findings makes it difficult to draw firm conclusions, and the limitations of the available evidence have been outlined earlier.

The operational efficiency of any unit is a critical determinant of its cost-effectiveness, and a poorly managed unit is unlikely to offer value-for-money regardless of whether it is consultant- or midwife-led. A trial setting is not necessarily comparable to usual midwife-led care, as greater motivation levels of participants and the possibility of the Hawthorne effect cannot be excluded. Economies of scale can increase the efficiency of units that are part of a larger hospital through the sharing of overheads. However, some commentators have argued that lower caesarean rates in smaller hospitals, as well as lower MRSA rates, may contribute to lower costs of birth centres (O'Sullivan and Tyler, 2007).

Although there are no statistically significant differences in mortality for either mother or neonate when comparing midwife-led services with usual care patterns, the sensitivity analysis demonstrated the major impact of varying this assumption within a plausible range. In some instances a hypothesised improvement in fetal loss and neonatal mortality resulted in a major gain in net health benefit and

net monetary benefit. It is important to note that these gains can only be hypothesised to occur if care is delivered in the same way as in the trials in the review, meaning by a small team or caseload with a certain degree of continuity. It could not be assumed that they would be achieved simply by a midwife providing maternity care.

3.5.4 OUTCOMES

For maternal death, Hatem et al., (2008) found that it was not possible to assess relative risk in the published literature due to its low incidence. The consensus, however, is that this is very low for "low-risk" maternities (Stone and Walker 1995), and it was assumed to be equal for each model of care.

It is noteworthy that the process of care has been found to differ between midwife-led and consultant-led care, with women in the former category experiencing better continuity of carer and reporting a greater sense of control during labour and birth. A lower rate of interventions has been reported in midwife-led care in numerous studies. For example, Flint et al., (1987) and Begley et al., (2009) report less use of epidurals, which is noteworthy because women who use this form of pain relief are at increased risk of having an instrumental delivery (Anim-Somuah et al., 2005), and the frequent use of expensive technology in the hospital setting has been noted in the USA also (Stone et al., 2000).

These findings are supported by the meta-analysis reported in section 1 and a Cochrane Systematic Review (Hatem et al., 2008), the latter reporting that women randomised to midwife-led care "were less likely to experience antenatal hospitalisation, the use of regional analgesia, episiotomy and instrumental delivery, and more likely to experience spontaneous vaginal birth, no intrapartum analgesia/anaesthesia", although no differences were found in caesarean birth rates. As noted previously these variations imply that midwife-led intranatal care could be less costly than consultant-led care, however there is little evidence from economic evaluations to support this. This could be due to insufficient quantity and/or quality of trials conducted, or alternatively due to these savings being offset by changes in other variables that increase costs.

3.5.5 TRANSFERS TO CONSULTANT-LED CARE

It is important in any analysis to consider the proportion of women eligible for midwife-led care that are transferred subsequently to consultant-led care. This can occur on a temporary or permanent basis, with important ramifications for costs. The high rate of transfer from midwife-led to medical-led care found in many studies demonstrates that 'risk' assessment criteria are unable to identify all women who will develop complications during pregnancy and labour (Hundley et al., 1994). It is also important to note that a high transfer rate may reflect strict criteria for transfer and appropriate transfer when such criteria develop.

One early study reported that 32.8% of women were transferred from midwife-led care on a permanent basis, and a further 32.8% transferred on a temporary basis (Turnbull et al., 1996). A relatively recent literature review reported that antenatal transfer rates ranged from 8% to 38%, intranatal rates from 12% to 30%, and total transfers from 15.8% to 64% (Stewart et al., 2004:14). In the (intention-to-treat analysis) MidU study (Begley et al., 2009) almost half of the women (44.7%) transferred permanently to consultant-led care in the antenatal period.

The importance of this was investigated in the American setting by Walker and Stone (1996). A freestanding birth centre (FBC) was compared with traditional hospital-based obstetric practice for women at low risk. The total cost per low-risk birth was calculated at US$3,385 for the FBC, substantially less than US$4,673 for the hospital. A sensitivity analysis varied the likelihood of transfer to the consultant-led unit from 0% to 100%. Interestingly, this revealed that even when the probability of transfer to consultant-led care was 100%, the FBC remained less costly than hospital care due to less use of costly technological interventions. When the transfer rate exceeded 62%, however, the FBC was no longer the most cost-effective care model for low-risk women (Walker and Stone 1996), illustrating the cost implications of the transfer rate.

3.5.6 THE VALUE OF FURTHER RESEARCH

The expected differences in costs and outcomes are very small between the two models of care, but much uncertainty prevails around these estimates. This is reflected in the wide variations in net health benefit and net monetary benefit in the one-way sensitivity analyses.

Value of information (VOI) represents the value of conducting future research to reduce the uncertainty surrounding input parameters and can be used to inform research funding decisions (Chalabi et al., 2008). A full VOI analysis was not undertaken as part of this study, although the one-way sensitivity analyses suggest this could be very valuable to inform improved decision-making in future years.

Based upon the one-way sensitivity analyses we may suspect that the input parameters for which additional evidence would be most valuable are the risk ratio for fetal loss and neonatal death, and the cost differential between midwife-led care for eligible maternities and consultant-led care.

3.6 CONCLUSION

This paper assessed the potential cost-effectiveness of midwife-led maternity care in the UK and of increasing its use. The evidence base contained only a handful of the studies that met the inclusion criteria, highlighting the need for thorough and up-to-date economic evaluations of midwife-led maternity services in the UK.

Results of this analysis indicate that financial savings are possible by shifting to midwife-led care for maternities that meet the specified eligibility criteria. The principal finding of this study is a cost saving of £12.38 per maternity, or an annual aggregate cost saving of £1.16 million (equivalent to 37.5 QALYs gained per year). The limited evidence base, however, means caution is needed when interpreting these findings. Three economic analyses were used in the synthesis of the potential cost saving from increasing the use of midwife-led services (Hundley et al., 1995, Begley et al., 2009, Young et al., 1997a). A fourth randomised controlled trial (Flint et al., 1987) was not used in the calculation due to the limited nature of its results, but its sizeable reported decrease in antenatal costs for midwife-led care lends support to the findings of Begley et al., (2009), who reported the most favourable cost-effectiveness estimates from this group of studies.

There are of course challenges associated with the generalisability of these findings. The numbers of women accessing individual services and operational efficiency would strongly influence the cost-effectiveness of any shift toward midwife-led care. The extent of economies of scale is another crucial determinant of cost-effectiveness, and these are more likely in larger units or units thatare part of a larger hospital.

Expanding midwife-led maternity services for eligible maternities may offer a means of reducing costs compared to the current leading model of care. In any model of maternity care, it is imperative that safety standards are not compromised as this would not be justified by any cost differential that might emerge. Expanding midwife-led care, including models that have and do not have an antenatal component, in the UK is a course of action that merits further attention from policy makers, and for which further evidence is required.

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APPENDIX A
Search strategies

Database: Ovid MEDLINE(R)

01. exp Midwifery/og, st, sn [Organization & Administration, Standards, Statistics & Numerical Data]
02. exp Nurse Midwives/og, st, sn [Organization & Administration, Standards, Statistics & Numerical Data]
03. 1 or 2
04 exp Hospitals/
05. 3 and 4
06. exp "Continuity of Patient Care"/
07. exp "Delivery of Health Care, Integrated"/
08 6 or 7
09. 8 and 3
10. midwi$ or maternity).tw.
11. 8 and 4 and 10
12. *Maternal-Child Health Centers/
13. (12 and 10) or (12 and 3)
14. 12 and 4
15. *perinatal care/ or *prenatal care/ or *postnatal care/ or expLabor, obstetric/ or exp Parturition/
16. 15 and 4 and 10
17. 15 and 3 and 4
18. *models, organizational/
19. (10 or 3) and 18
20. (midwi$ adj2 team$).tw.
21. (midwi$ adj model$).tw.
22. (midwi$ adj led).tw.
23. (midwi$ adj2 manage$).tw.
24. ((caseload or case-load or "case load") and (midw$ or prenatal or antenatal or perinatal or postnatal or postpartum)).mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]
25. integrated.tw.
26. 3 and 25
27. 15 and 25
28. 12 and 25
29. or/20-24
30. ("birthing centre$" or "birthing center$").mp.
31. *Midwifery/
32. *Nurse Midwives/
33. 31 or 32
34. 30 and 33
35. 5 or 9 or 11 or 13 or 14 or 16 or 17 or 19 or 26 or 27 or 28 or 29 or 34

Database: HMIC

01. (midwi* adj2 led).ti,ab
02. (midwi* adj2 team*).ti,ab
03. (midwi* adj2 model*).ti,ab
04. (integrated adj2 midwi*).ti,ab
05. ((caseload OR case-load OR case ADJ load) AND (midwi* OR antenatal OR perinatal OR postnatal OR postpartum)).ti,ab
06. ((midwi* OR antenatal OR perinatal OR postnatal OR postpartum)).af
07. MATERNAL CARE/ OR PREGNANCY/
08. CHILDBIRTH/
09. TEAMWORK/
10. MIDWIFERY SERVICES/
11. (team* OR led OR model* OR integrated OR caseload* OR case-load OR "case load").ti,ab
12. 10 OR 12
13. 1 OR 8 OR 9 OR 11
14. 13 AND 14
15. 2 OR 3 OR 4 OR 5 OR 6 OR 15
16. SHARED ANTE NATAL CARE/
17. (midwi$ adj2 managed).ti,ab
18. 2 OR 3 OR 4 OR 5 OR 6 OR 15 OR 17 OR 19

Database: EMBASE

01. (midwi* adj2 team*).af
02. (midwi* adj2 model*).af53 .
03. (midwi* adj2 led).af
04. (integrated adj2 midwi*).af
05. ((caseload OR case-load OR case ADJ load) AND (midwi* OR antenatal OR perinatal OR postnatal OR postpartum)).
06. exp MIDWIFE/
07. exp DELIVERY/
08. INTRAPARTUM CARE/
09. exp PERINATAL CARE/
10. exp POSTNATAL CARE/
11. exp PUERPERIUM/
12. exp PRENATAL CARE/
13. NONBIOLOGICAL MODEL/
14. exp PATIENT CARE/
15. exp HEALTH CARE ORGANIZATION/
16. exp HEALTH CARE DELIVERY/
17. 13 OR 14 OR 15 OR 16
18. exp PREGNANCY/
19. 7 OR 8 OR 9 OR 10 OR 11 OR 12 OR 18
20. 6 AND 17 AND 19
21. 1 OR 2 OR 3 OR 4 OR 5 OR 20

Databases:

Cochrane Database of Systematic Reviews (CDSR)
Cochrane Central Register of Controlled Trials (CENTRAL)
Database of Abstracts of Reviews of Effects (DARES)
Health Technology Assessment Database
NHS Economic Evaluation Database (NHSEED)
Cochrane Methodology Register

#1 MeSH descriptor Nurse Midwives explode all trees #2 MeSH descriptor Midwifery explode all trees
#3 MeSH descriptor Hospitals explode all trees
#4 MeSH descriptor Continuity of Patient Care explode all trees
#5 MeSH descriptor Delivery of Health Care explode all trees
#6 MeSH descriptor Maternal-Child Health Centers explode all trees
#7 MeSH descriptor Models, Organizational explode all trees
#8 MeSH descriptor Perinatal Care explode all trees
#9 MeSH descriptor Prenatal Care explode all trees
#10MeSH descriptor Postnatal Care explode all trees
#11midwi* near team*
#12midwi* near model*
#13midwi* near led
#14midwi* near unit*
#15midwi* near integrated
#16(caseload or case-load or case next load) and (midwi* or prenatal or antenatal or perinatal or postnatal or postpartum)
#17(#1 OR #2 OR #8 OR #9 OR #10)
#18(#3 OR #4 OR #5 OR #6 OR #7)
#19(#17 AND #18)
#20(#11 OR #12 OR #13 OR #14 OR #15 OR #16)
#21(#19 OR #20)

Database: ASSIA vis CSA Illumina

Search query

(((led or team* or caseload* or model*) and((DE=("midwifery" or "midwives")) or(AB=midwi* or TI=midwi*))) or(((DE=("midwifery" or "midwives")) or(AB=midwi* or TI=midwi*)) and(DE="maternal health care"))) or(DE=("birth centres" or "maternity units")) or(DE="midwife led")

Database: Midwives Information and Resource Service (MIDIRS)

01. (midwi* adj2 caseload*).ti,ab.
02. (midwi* adj2 led).ti,ab.
03. (midwi* adj2 managed).ti,ab.
04. (midwi* adj2 model*).ti,ab.
05. Models - midwifery.de.
06. "Models of care".de.
07. midwi*.mp.
08. 6 and 7
09. "Midwife led care".de.
10. "Midwife Led Care ".ss.
11. "Case Load and One to One Midwifery ".ss.
12. "Caseload practice".de.
13. (midwi* adj2 team*).ti,ab.
14. Team midwifery.de.
15. 1 or 2 or 3 or 4 or 5 or 8 or 9 or 10 or 11 or 12 or 13 or 14

Database: CINAHL

01. exp MIDWIFERY SERVICE/
02. exp CONTINUITY OF PATIENT CARE/
03. HEALTH CARE DELIVERY, INTEGRATED/
04. 2 OR 3
05. 1 AND 4
06. midwi* OR matern*).ti,ab
07. 4 AND 6
08. MATERNAL HEALTH SERVICES/
09. ALTERNATIVE BIRTH CENTERS/
10. *PERINATAL CARE/ OR *PRENATAL CARE/ OR *POSTNATAL CARE/ OR *INTRAPARTUM CARE/
11. (midwi* adj2 team*).ti,ab
12. (midwi* adj2 model*).ti,ab
13. (midwi* ADJ led).ti,ab
14. (midwi* ADJ manage*).ti,ab
15. ((case-load OR caseload OR "case load") AND (midwi* OR antenatal OR prenatal OR perinatal OR postnatal OR postpartum)).ti,ab
16. integrated.ti,ab
17. 10 AND 17
18. 8 AND 17
19. 6 AND 17
20. 5 OR 7 OR 9 OR 11 OR 12 OR 13 OR 14 OR 15 OR 18 OR 19 OR 20

APPENDIX B
References to included studies

Biro 2000
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APPENDIX C
Characteristics of included studies

Begley 2009	
Methods	**Study design:** RCT **Duration of study:** 2004-2007
Participants	**Setting:** Health Service Executive, Dublin North-East, Republic of Ireland **Inclusion criteria:** Women were eligible for trial entry if they were: (a) healthy with an absence of risk factors for complications for labour and delivery as identified in the 'Midwifery-led Unit (Integrated) Guidelines for Practitioners' (at http://www.nehb.ie/midu/guidelines.htm); (b) aged between 16 and 40 years of age; and (c) within 24 completed weeks of pregnancy. **Exclusion criteria:** Women with risk factors **Participants randomised:** 1,101 midwife-led care, 552 to consultant-led care
Interventions	**Experimental:** Women randomised to consultant-led care (CLU) received standard care: antenatal care provided by obstetricians supported by the midwifery and medical team; intrapartum and postpartum care (two to three days in hospital) provided by midwives, overseen by consultants. Women were discharged into the care of Public Health Nurses. **Control:** Women randomised to midwife-led care (MLU) received antenatal care from midwives and, if desired, from their GPs for some visits. Where complications arose, women were transferred to CLU based on agreed criteria. Intrapartum care was provided by midwives in a MLU with transfer to CLU if necessary. Postnatal care was by midwives in the MLU for up to two days, with transfer of women or neonates to CLU if necessary (and back, as appropriate). On discharge, MLU midwives visited at home, and/or provided telephone support, up to the seventh postpartum day.
Outcomes	Outcomes considered in the review and reported in or extracted from the study: 5-minute Apgar score below or equal to 7 Admission to special care nursery/neonatal intensive care unit Amniotomy Antenatal hospitalisation Antepartum haemorrhage Augmentation/artificial oxytocin during labour Breastfeeding initiation Caesarean Birth Duration of postnatal hospital stay (days) Episiotomy Fetal loss/neonatal death before 24 weeks Fetal loss/neonatal death equal to/after 24 weeks Induction of Labour Instrumental vaginal birth (forceps/vacuum) Intact perineum Low birth weight (<2500g) Mean labour length Mean length of neonatal hospital stay (days) Neonatal convulsions (as defined by trial authors) No intrapartum analgesia/anaesthesia Opiate analgesia Overall fetal loss and neonatal death Perineal laceration requiring suturing Preterm birth (< 37 weeks) Postpartum haemorrhage (as defined by trial authors) Regional analgesia (epidural/spinal) Spontaneous vaginal birth (as defined by trial authors)
Notes	Women were randomised to MLU or consultant-led unit (CLU) in a 2:1 ratio

Biro 2000	
Methods	**Study design:** RCT **Duration of study:** 1996-1998
Participants	**Setting:** Public tertiary hospital, Monash Medical Centre, Melbourne, Australia. **Inclusion criteria:** Participants included women at low and high risk of complications. Exclusion criteria: Women who requested shared obstetric care, needed care in the maternal-fetal medicine unit, were > 24 weeks' gestation, did not speak English. **Participants randomised:** 502 team midwifery, 498 to standard care.
Interventions	**Experimental:** Team of 7 full-time midwives who provided antenatal, intrapartum, and some postnatal care in hospital in consultation with medical staff. Doctors and team midwife jointly saw women at 12-16, 28, 36, 41 weeks. Women at high risk of complications had individual care plan. **Control:** Various options of care including shared care between GPs in the community and hospital obstetric staff, shared care between midwives in a community health centre and hospital obstetric staff, care by hospital obstetric staff only, and less commonly, care by hospital midwives in collaboration with obstetric staff. Women within these options experienced a variable level of continuity of care during their pregnancy, from seeing the same midwife or doctor at most visits to seeing several doctors and midwives.
Outcomes	Outcomes considered in the review and reported in or extracted from the study: 5-minute Apgar score below or equal to 7 Admission to special care nursery/neonatal intensive care unit Attendance at birth by known midwife Augmentation/artificial oxytocin during labour Duration of postnatal hospital stay (days) Episiotomy Fetal loss/neonatal death before 24 weeks Fetal loss/neonatal death equal to/after 24 weeks Induction of Labour Intact perineum Instrumental vaginal birth(forceps/vacuum) Mean length of neonatal hospital stay (days) No intrapartum analgesia/anaesthesia Overall fetal loss and neonatal death Perineal laceration requiring suturing Preterm birth (< 37 weeks) Regional analgesia (epidural/spinal) Spontaneous vaginal birth (as defined by trial authors)

Byrne 2000	
Methods	**Study design:** RCT **Duration of study:** 1993-1995
Participants	**Setting:** Women's and Children's Hospital, Adelaide, Australia. Inclusion criteria: Normal, uncomplicated pregnancy and gave informed written consent. Exclusion criteria: Any pregnancy risk factors, or presentation to the antenatal clinic later than 30 weeks gestation. **Participants randomised:** 100 midwife-led (birth centre care) : 101 shared care (delivery suite care).
Interventions	**Experimental:** Birthing centre care (No antenatal care). Women cared for by a midwife who was committed to the normality of the birth process. Women encouraged during their pregnancy to attend two designated classes related to birthing and the birthing centre. Home like surroundings. Partners and support persons encouraged to take an active role in both physical and emotional support. Pethidine, bathing, hot towels, movement and massage available as pain relief measures. Midwives cared for women and their families during the antenatal period, intrapartum and postpartum for up to 12 hours. At the time of the study, the women may have seen a different midwife antenatally to the midwife in the birthing centre. Control: Delivery suite care. Women under the care of both a midwife and a doctor. Midwife was the main care-giver who liaised with the doctor. Fetal monitoring, intravenous fluids and pharmacological pain relief were used at the doctor's, midwife's and mother's discretion. Progress in labour was monitored according to the hospital protocol.
Outcomes	Outcomes considered in the review and reported in or extracted from the study: 5-minute Apgar score below or equal to 7 Caesarean Birth Episiotomy Instrumental vaginal birth (forceps/vacuum) Intact perineum No intrapartum analgesia/anaesthesia Opiate analgesia Opiate analgesia Regional analgesia (epidural/spinal) Spontaneous vaginal birth (as defined by trial authors)

Chambliss 1992	
Methods	**Study design:** RCT **Duration of study:** 1993-1995
Participants	**Setting:** Los Angeles, California, USA. Inclusion criteria: Age 16-45 years, singleton, vertex presentation, 36-42 completed weeks gestation, fetal weight estimated clinically between 2500---4000g. Women with a previous caesarean delivery were eligible if the scar was known to be a low transverse uterine incision or if a women with an unknown scar type had a previous successful vaginal delivery after caesarean. Women with diet controlled gestational diabetes were also included if they had normal fasting glucose levels and did not require insulin. Women exhibiting uterine activity with rupture of membranes were eligible if the liquor was clear and no meconium was seen. Women with no prenatal care and hematocrit greater than 30% were also included. **Exclusion criteria:** Women were excluded if they had oral temperatures of >1000F, spontaneous rupture of membrane without labour, station - 3 or higher, or a significant maternal or fetal complication (i.e. poorly controlled diabetes, hypertension, preeclampsia, or fetal growth retardation. **Participants randomised:** 234 midwife-led (birth centre care) : 253 shared care (delivery suite care)
Interventions	**Experimental:** Normal birth centre (No antenatal care): Located on separate floor. Women cared for by certified nurse-midwives with physician consultation as needed. No oxytocin or regional anaesthesia. Liberal use of ambulation, varied positions for delivery and a support person as an integral part of labour management. **Control:** Physician-managed delivery service: Women rarely able to ambulate. Epidural anaesthesia. Lithotomy position for delivery. Support person not available as an integral part of labour management.
Outcomes	Outcomes considered in the review and reported in or extracted from the study: 5-minute Apgar score below or equal to 7 Caesarean Birth Duration of postnatal hospital stay (days) Episiotomy Instrumental vaginal birth (forceps/vacuum) Spontaneous vaginal birth (as defined by trial authors

Flint 1989	
Methods	**Study design:** RCT, Zelen design **Duration of study:** 1983-1985
Participants	**Setting:** Tertiary hospital and community settings, St George's Hospital, London, UK. Inclusion criteria: Low risk of complications who booked at the study hospital and were likely to receive all their antenatal care at that hospital. **Exclusion criteria:** Under 5 feet tall, serious medical problems, previous uterine surgery, past obstetric history of > 2 miscarriages/TOP/SB/NND, Rh antibodies. **Participants randomised:** 503 team-midwifery, 498 to standard care (shared care)
Interventions	**Experimental:** Team of 4 midwives who provided antenatal, intrapartum and postnatal care in hospital, and postnatal care in the community for women in predefined geographic area. Obstetrician seen at 36 and 41 weeks as appropriate. **Control:** standard antenatal, intrapartum and postpartum care provided by assortment of midwives and obstetricians.
Outcomes	Outcomes considered in the review and reported in or extracted from the study: 5-minute Apgar score below or equal to 7 Admission to special care nursery/neonatal intensive care unit Amniotomy Antenatal hospitalisation Augmentation/artificial oxytocin during labour Caesarean Birth Episiotomy Fetal loss/neonatal death before 24 weeks Fetal loss/neonatal death equal to/after 24 weeks High perceptions of control during labour and childbirth Induction of Labour Intact perineum Instrumental vaginal birth(forceps/vacuum) Low birthweight (< 2500g) No intrapartum analgesia/anaesthesia Opiate analgesia Overall fetal loss and neonatal death Postpartum haemorrhage (as defined by trial authors) Regional analgesia (epidural/spinal) Spontaneous vaginal birth (as defined by trial authors)
Notes	At baseline, more Asian women in control group (18% vs 10%) and more smokers in experimental group (30% vs 22%). Sub-analysis of case notes found that 98% of experimental group and 20% of standard group had previously met midwife attending labour. Discrepancy in instrumental birth data. Date taken from report and not published paper

Harvey 1996	
Methods	**Study design:** RCT **Duration of study:** 1992-1994
Participants	**Setting:** Range of city hospitals and community settings in Alberta, Canada. **Inclusion criteria:** Women at low risk of complications who requested and qualified for nurse-midwife led care. **Exclusion criteria:** Past history of caesarean section, primigravidas< 17 or > 37, > 24 weeks' gestation at time of entry to study. **Participants randomised:** 109 team-midwife led care, 109 to standard care (Physician care)
Interventions	**Experimental:** Team of 7 nurse-midwives who provided antenatal and intrapartum care in the hospital and postnatal care in the community. Obstetrician seen at booking and at 36 weeks. **Control:** Physician care (family practice or obstetrician) which women chose from a range of city hospitals following usual process.
Outcomes	Outcomes considered in the review and reported in or extracted from the study: 5-minute Apgar score below or equal to 7 Admission to special care nursery/neonatal intensive care unit Amniotomy Antepartum haemorrhage Attendance at birth by known midwife Augmentation/artificial oxytocin during labour Caesarean Birth Caesarean Birth Episiotomy Episiotomy Fetal loss/neonatal death before 24 weeks Induction of Labour Instrumental vaginal birth (forceps/vacuum) Intact perineum Opiate analgesia Overall fetal loss and neonatal death Postpartum haemorrhage (as defined by trial authors) Regional analgesia (epidural/spinal) Regional analgesia (epidural/spinal) Spontaneous vaginal birth (as defined by trial author)

Hicks 2003	
Methods	**Study design:** RCT **Duration of study:** Not stated
Participants	**Setting:** Tertiary hospital and community, City not stated but UK. **Inclusion criteria:** Women at low risk of complications. **Exclusion criteria:** Not stated **Participants randomised:** 100 team-midwife led care, 100 to standard care (shared care)
Interventions	**Experimental:** Team of 8 midwives who provided antenatal, intrapartum and postnatal care 24 hours a day, 7 days a week in both hospital and community. The team was attached to a GP practice. Referral to obstetrician as necessary. **Control:** Shared care between community and hospital midwives and GPs and obstetricians when necessary. Women delivered by hospital midwife or community midwife if under domino scheme (1 midwife provides care for a woman throughout pregnancy, accompanies her into hospital for birth and returns home with her and baby a few hours after the birth, and care in postnatal period).
Outcomes	Outcomes considered in the review and reported in or extracted from the study: Induction of Labour Instrumental vaginal birth (forceps/vacuum) Intact perineum Opiate analgesia Overall fetal loss and neonatal death Postpartum haemorrhage (as defined by trial authors) Regional analgesia (epidural/spinal) Regional analgesia (epidural/spinal) Spontaneous vaginal birth (as defined by trial authors)
Notes	71% of experimental group and 14% of standard group had previously met midwife attending labour

Homer 2001	
Methods	**Study design:** RCT, Zelen design **Duration of study:** 1997-1998
Participants	**Setting:** Public tertiary hospital and community, Sydney, Australia. **Inclusion criteria:** Women at low and high risk of complications **Exclusion criteria:** Women more than 24 weeks' gestation at their first visit to the hospital, women with an obstetric history of 2 previous caesareans or a previous classical caesarean and medical history of significant maternal disease. **Participants randomised:** 640 team-midwife led care, 643 to standard care (shared care)
Interventions	**Experimental:** Two teams of 6 midwives sharing a caseload of 300 women a year/team. Antenatal care in outreach community-based clinics. Intrapartum and postpartum hospital and community care. Obstetrician or obstetric registrar did not see women routinely, but acted as a consultant and reviewed women only as necessary. Women who developed complications during their pregnancy continued to receive care from the same group of carers. **Control:** Standard care provided by hospital midwives and doctors in hospital-based antenatal clinic, delivery suite and postnatal ward. Woman at high risk of complications were seen by obstetrician or registrar. Low-risk women were seen by midwives and shared care with GPs in a shared model of care.
Outcomes	Outcomes considered in the review and reported in or extracted from the study: 5-minute Apgar score below or equal to 7 Admission to special care nursery/neonatal intensive care unit Antenatal hospitalisation Antepartum haemorrhage Attendance at birth by known midwife Augmentation/artificial oxytocin during labour Caesarean Birth Episiotomy Fetal loss/neonatal death before 24 weeks Fetal loss/neonatal death equal to/after 24 weeks Induction of Labour Instrumental vaginal birth (forceps/vacuum) Opiate analgesia Overall fetal loss and neonatal death Postpartum haemorrhage (as defined by trial authors) Regional analgesia (epidural/spinal) Spontaneous vaginal birth (as defined by trial authors)
Notes	63% of experimental group and 21% of standard group had previously met midwife attending labour.

Hundley 1994	
Methods	**Study design:** RCT **Duration of study:** 1991-1993
Participants	**Setting:** Aberdeen, MaternityHospital, Grampian, Scotland **Inclusion criteria:** Low risk women **Exclusion criteria:** Pre-existing maternal disease, infertility, a complicated obstetric history (for example, previous caesarean section, difficult vaginal delivery, or poor obstetric outcome), height < 150 cm, maternal age > 35 years, or multiple pregnancy. **Participants randomised:** 1900 team-midwife led care, 944 to standard care (shared care)
Interventions	**Experimental:** Midwives unit (No antenatal care): Separate unit, of five single rooms, located 20 yards from the consultant led labour ward. Midwives take total responsibility for the care delivered. Fetal heart rate is monitored with a Pinard stethoscope or hand held Doppler Active labour is encouraged, and there is minimal intervention. Staffed and run by hospital midwives. There is no input to the midwives unit by medical staff. **Control:** Consultant-led labour ward
Outcomes	Outcomes considered in the review and reported in or extracted from the study: Admission to special care nursery/neonatal intensive care unit Augmentation/artificial oxytocin during labour Caesarean Birth Episiotomy Fetal loss/neonatal death before 24 weeks Fetal loss/neonatal death equal to/after 24 weeks Induction of Labour Instrumental vaginal birth (forceps/vacuum) Intact perineum Maternal Death No intrapartum analgesia/anaesthesia Opiate analgesia Overall fetal loss and neonatal death Preterm birth (< 37 weeks) Regional analgesia (epidural/spinal) Spontaneous vaginal birth (as defined by trial authors)
Notes	2:1 randomisation ratio in favour of midwives unit

Kenny 1994	
Methods	**Study design:** RCT **Duration of study:**
Participants	**Setting:** Westmead public hospital, NSW, Australia. **Inclusion criteria:** Women at low and high risk of complications **Exclusion criteria:** Women requiring use of the 'Drug use in pregnancy service' or booked after 16 weeks gestation **Participants randomised:** 213 team-midwife led care, 233 to standard care (shared care)
Interventions	**Experimental:** Team of 6.8 WTE midwives sharing a caseload. Provided antenatal and intrapartum care in hospital and postnatal care in hospital and community. Obstetrician saw all women at first visit and 32 weeks, and after 40 weeks, and as appropriate. Team midwife was on call for out of hours care. **Control:** Low-risk women seen in midwives' hospital antenatal clinics, and all other women seen by medical staff. Women received intrapartum care from delivery suite midwives, and postnatal care from midwives on postnatal ward and community postnatal care.
Outcomes	Outcomes considered in the review and reported in or extracted from the study: 5-minute Apgar score below or equal to 7 Admission to special care nursery/neonatal intensive care unit Amniotomy Antenatal hospitalisation Attendance at birth by known midwife Augmentation/artificial oxytocin during labour Breastfeeding initiation Caesarean Birth Episiotomy Fetal loss/neonatal death equal to/after 24 weeks Induction of Labour Instrumental vaginal birth (forceps/vacuum) Intact perineum Mean labour length Mean Number of antenatal visits No intrapartum analgesia/anaesthesia Opiate analgesia Overall fetal loss and neonatal death Perineal laceration requiring suturing Postpartum haemorrhage (as defined by trial authors) Regional analgesia (epidural/spinal) Spontaneous vaginal birth (as defined by trial authors)
Notes	96% of experimental group and 13% of standard group had previously met midwife attending labour. Randomisation before consent to participate.

Law 1999	
Methods	**Study design:** RCT **Duration of study:** 1994-1995
Participants	**Setting:** Hong Kong, Prince of Wales Hospital (PWH), a tertiary referral centre. **Inclusion criteria:** Mixed risk. Spontaneous labour between 36-42 weeks gestation, maternal height > 148cms, no medical complications, only one previous operative delivery or caesarean section, no evidence of fetal distress on admission. **Exclusion criteria:** Not stated **Participants randomised:** 563 Midwife 'managed' care (intrapartum), 487 to shared care
Interventions	**Experimental:** Midwife 'managed' care (No antenatal care): Women were entirely cared by midwives during labour, delivery, repair of episiotomies or tears, and postpartum observation until they were discharged to the postnatal 'wards one hour after delivery. Obstetricians were consulted only when the midwives decided that they were necessary or when a medical procedure was required in cases like the insertion of intravenous infusion, application of a fetal scalp electrode, or repair of severe tears, etc. Care transferred to obstetricians if fetal distress or maternal distress, when the women requested epidural anaesthesia, if the active phase of the first stage exceeded 12hrs or if the second stage exceeded 2 hours. Universal electronic fetal monitoring was applied to all women according to the unit policy and this allowed for central monitoring. **Control:** Shared care. Women seen regularly by obstetricians, with midwives monitoring on the progress of labour and alerting the obstetricians when complications arose. Obstetricians perform routine ward rounds.
Outcomes	Outcomes considered in the review and reported in or extracted from the study: 5-minute Apgar score below or equal to 7 Admission to special care nursery/neonatal intensive care unit Amniotomy Augmentation/artificial oxytocin during labour Caesarean Birth Episiotomy Instrumental vaginal birth (forceps/vacuum) Opiate analgesia Perineal laceration requiring suturing Postpartum haemorrhage (as defined by trial authors) Regional analgesia (epidural/spinal) Spontaneous vaginal birth (as defined by trial authors)

MacVicar 1993	
Methods	**Study design:** RCT, Zelen design **Duration of study:** 1989-1991
Participants	**Setting:** Tertiary hospital and community in Leicester, UK. **Inclusion criteria**: Women at low risk of complications. **Exclusion criteria:** Women who had a previous caesarean section or difficult vaginal delivery, a complicating general medical condition, a previous stillbirth or neonatal death, or a previous small-for-gestational-age baby, multiple pregnancy, Rhesus antibodies, and a raised level of serum alpha-feto protein. **Participants randomised:** 2304 team midwifery, 1206 to standard care (shared care).
Interventions	**Experimental:** Team of 2 midwifery sisters assisted by 8 staff midwives provided hospital-based antenatal, intrapartum (in hospital-based 3 room home-from-home unit (no EFM or epidural) and hospital postnatal care only. All the staff were volunteers. Antenatal midwife-led hospital clinic with scheduled visits at 26, 36 and 41 weeks' gestation. Intervening care shared with GPs and community midwives. Referral to obstetrician as appropriate. At 41 weeks mandatory referral to consultant. Postnatal care in community provided by community midwife and GP. **Control group:** Shared antenatal care with GP and midwife. Intrapartum care provided by hospital staff.
Outcomes	Outcomes considered in the review and reported in or extracted from the study: Admission to special care nursery/neonatal intensive care unit Augmentation/artificial oxytocin during labour Caesarean Birth Episiotomy Fetal loss/neonatal death before 24 weeks Fetal loss/neonatal death equal to/after 24 weeks Induction of Labour Intact perineum Instrumental vaginal birth (forceps/vacuum) Low birth weight (< 2500g) No intrapartum analgesia/anaesthesia Opiate analgesia Overall fetal loss and neonatal death Perineal laceration requiring suturing Postpartum haemorrhage(as defined by trial authors) Preterm birth (< 37 weeks) Regional analgesia (epidural/spinal) Spontaneous vaginal birth (as defined by trial authors)
Notes	2:1 randomisation ratio in favour of midwife-led care. 189/2304 (8%) women opted out of team-midwife care post-randomisation. Analysis by intention-to-treat analysis. Level of continuity not reported.

North Stafford 2000	
Methods	**Study design:** RCT, cluster randomisation **Duration of study:** Not stated
Participants	**Setting:** Tertiary hospital and community, UK. **Inclusion criteria:** 'All-risks' **Exclusion criteria:** Not stated **Participants randomised:** 770 midwife-led caseload care, 735 standard care (shared care)
Interventions	**Experimental:** Caseload midwife-led care. Three geographic areas with 21 WTE midwives working in 3 practices offering a caseload model of care. Each midwife was attached to 2-3 GP practices and cared for 35-40 women. Midwives worked in pairs/threesomes. Caseload midwives were existing community midwives, plus new midwives recruited from community and hospital resulting in a mix of senior and junior staff. Monthly antenatal care in the community, intrapartum and postnatal care in hospital and postnatal care in the community provided. **Control:** Shared care in the community between GPs, community midwives and obstetricians. Each community midwife cared for 100/150 women each.
Outcomes	Outcomes considered in the review and reported in or extracted from the study: 5-minute Apgar score below or equal to 7 Admission to special care nursery/neonatal intensive care unit Attendance at birth by known midwife Augmentation/artificial oxytocin during labour Caesarean Birth Episiotomy Fetal loss/neonatal death equal to/after 24 weeks Induction of Labour Instrumental vaginal birth (forceps/vacuum) Intact perineum Low birth weight (< 2500g) Overall fetal loss and neonatal death Perineal laceration requiring suturing Preterm birth (< 37 weeks) Regional analgesia (epidural/spinal)
Notes	95% of experimental group and 7% of standard group had previously met midwife attending labour.

Rowley 1995	
Methods	**Study design:** RCT **Duration of study:** 1991-1992
Participants	**Setting:** John Hunter hospital, Newcastle, NSW, Australia. Inclusion criteria: Women booked for delivery at hospital of low and high risk. Exclusion criteria: Women who had chosen shared antenatal care with their GP or had a substance abuse problem. Participants randomised: 405 team care, 409 standard care (shared care)
Interventions	**Experimental:** Team of 6 experienced and newly graduated midwives provided antenatal care, intrapartum care, and postnatal care in hospital. Women at low risk had scheduled consultations with an obstetrician at 12-16, 36, 41 weeks and additional consultations as needed. Women at high risk had consultations with an obstetrician at a frequency determined according to their needs. Control: Antenatal care from hospital physicians and intrapartum and postnatal care from midwives and doctors working in the delivery suite, and the postnatal ward. Women were usually seen by a doctor at each visit. Control-group midwives were also a mix of experienced and newly qualified midwives.
Outcomes	Outcomes considered in the review and reported in or extracted from the study: 5-minute Apgar score below or equal to 7 Admission to special care nursery/neonatal intensive care unit Antenatal hospitalisation Augmentation/artificial oxytocin during labour Caesarean Birth Episiotomy Fetal loss/neonatal death before 24 weeks Fetal loss/neonatal death equal to/after 24 weeks Induction of Labour Instrumental vaginal birth(forceps/vacuum) Low birth weight (< 2500g) Opiate analgesia Overall fetal loss and neonatal death Perineal laceration requiring suturing Preterm birth (< 37 weeks) Regional analgesia(epidural/spinal) Spontaneous vaginal birth (as defined by trial authors)
Notes	Degree of continuity not reported.

Turnbull 1996	
Methods	**Study design:** RCT **Duration of study:** 1993-1994
Participants	**Setting:** Glasgow Royal Maternity Hospital, Scotland, United Kingdom. **Inclusion criteria:** Women at low risk of complications **Exclusion criteria:** Women booking after 16 weeks of pregnancy, not living in catchment area or with medical/obstetric complications **Participants randomised:** 648 caseload, 651 standard care (shared care)
Interventions	**Experimental:** Caseload midwifery provided by 20 midwives who volunteered to join the MDU. Each pregnant woman had a named midwife whom she met at her first booking visit who aimed to provide the majority of care. When the named midwife was not available, care was provided by up to 3 associate midwives. Women were not seen by medical staff at booking. Antenatal care was provided at home, community-based clinics or hospital clinics. Intrapartum care was in hospital (MDU - 3 rooms with fewer monitors and homely surroundings) or main labour suite. Postnatal care was provided in designated 8-bed MDU ward and community. A medical visit was scheduled where there was a deviation from normal. **Control:** All women seen by medical staff at booking. Shared antenatal care with from midwives, hospital doctors and GPs/ family doctors. Intrapartum care from labour ward midwife on labour suite. Postnatal care on postnatal ward and community by community midwife
Outcomes	Outcomes considered in the review and reported in or extracted from the study: 5-minute Apgar score below or equal to 7 Admission to special care nursery/neonatal intensive care unit Antepartum haemorrhage Augmentation/artificial oxytocin during labour Caesarean Birth Episiotomy Fetal loss/neonatal death before 24 weeks Fetal loss/neonatal death equal to/after 24 weeks Induction of Labour Instrumental vaginal birth(forceps/vacuum) Intact perineum Low birth weight (< 2500g) Mean labour length Neonatal convulsions (as defined by trial authors) No intrapartum analgesia/anaesthesia Opiate analgesia Overall fetal loss and neonatal death Perineal laceration requiring suturing Postpartum depression Postpartum haemorrhage (as defined by trial authors) Preterm birth (< 37 weeks) Regional analgesia (epidural/spinal) Spontaneous vaginal birth (as defined by trial authors)
Notes	Women in the intervention group saw 7 fewer care providers across antenatal, labour and postnatal periods and 2 fewer providers during labour.

Waldenstrom 1997	
Methods	**Study design:** RCT. **Duration of study:** 1989-1993
Participants	**Setting:** Stockholm, Sweden **Inclusion criteria:** At least one partner in each expectant couple had to be Swedish-speaking. A history of low birth weight, preterm birth, perinatal death, or a difficult vaginal delivery did not preclude participation. Women with a previous caesarean section were accepted if their last delivery was vaginal. There were no preconditions regarding maternal age or height. A minimal requirement for inclusion was one antenatal visit. **Exclusion criteria:** Women with a complicating general condition (e.g. diabetes or hypertension), drug abusers, and women who continued to smoke during the present pregnancy were excluded from the trial. Women were encouraged to enrol in the trial as early in pregnancy as possible, although they were allowed to join throughout pregnancy. **Participants randomised:** 928 birth centre care, 932 standard care (shared care but women usually saw same midwife during antenatal period)
Interventions	**Experimental:** Birth centre care in this study included integrated antenatal. Intrapartum and postpartum care. Parents cared for by the same team of midwives. and in the same premises from the outset of pregnancy, throughout the birth, and up to the final visit two months after the birth. The women gave birth at the centre between 37 and 43 weeks gestation. Pharmacological pain relief, induction, augmentation of labour and electronic fetal monitoring were available only after transfer to the hospital's standard delivery ward located one storey above the centre. During pregnancy a woman could be referred for EFM or ultrasound scanning on specific medical grounds and then continues with birth centre care, provided the unit's medical criteria were still fulfilled. The midwives assisted women in labour without the presence of a doctor. They made their own decisions about transfer in labour, according to medical guidelines set up by the obstetrician having medical responsibility for the centre. **Control:** Usual form of public maternity care offered to women in the Greater Stockholm area. Women could make their own choice of antenatal clinic and hospital for the birth, but usually attended those located nearest their homes. Different teams of midwives took care of women during pregnancy, labour and birth and postpartum, and in different premises. However, the pregnant woman usually sees the same midwife throughout her pregnancy. Doctor at hand during labour.
Outcomes	Outcomes considered in the review and reported in or extracted from the study: 5-minute Apgar score below or equal to 7 Admission to special care nursery/neonatal intensive care unit Amniotomy Augmentation/artificial oxytocin during labour Breastfeeding initiation Caesarean Birth Episiotomy Fetal loss/neonatal death before 24 weeks Fetal loss/neonatal death equal to/after 24 weeks Induction of Labour Instrumental vaginal birth (forceps/vacuum) Low birth weight (< 2500g) Mean labour length Neonatal convulsions (as defined by trial authors) Opiate analgesia Overall fetal loss and neonatal death Postpartum haemorrhage (as defined by trial authors) Prolonged backache (as defined by trial authors) Regional analgesia (epidural/spinal)
Notes	Antenatal care was provided by team of midwives in both arms. This midwifery dominant care for the antenatal component of both arms places this trial somewhere in between the two distinct sub-group comparisons of (i) antenatal and intranatal with or without postnatal care and (ii) intranatal with or without postnatal care. We have included it in the main analysis in subgroup (ii).

Waldenstrom 2001	
Methods	**Study design:** RCT **Duration of study:** 1996-1997
Participants	**Setting:** Royal Women's Hospital, Melbourne, Australia. Inclusion criteria: Women at low risk of complications Exclusion criteria: Non-English speaking women, women > 25 weeks gestation at booking, women with high-risk criteria including previous obstetric complications, preterm delivery, IUGR, PET, previous fetal loss, significant medical disease, > 3 abortions, substance addiction, infertility > 5 years. Participants randomised: 495 team-midwife care, 505 standard care (combination of different models of care)
Interventions	**Experimental:** Team midwife care provided by team of 8 midwives who provided hospital-based antenatal, intrapartum (delivery suite or family birth centre) and some postnatal care in collaboration with medical staff. **Control:** Standard care included different options of care being provided mostly by doctors, care mainly by midwives in collaboration with doctors (midwives clinics), birth centres and shared care between general practitioners and hospital doctors.
Outcomes	Outcomes considered in the review and reported in or extracted from the study: 5-minute Apgar score below or equal to 7 Admission to special care nursery/neonatal intensive care unit Antenatal hospitalisation Antepartum haemorrhage Attendance at birth by known midwife Augmentation/artificial oxytocin during labour Caesarean Birth Duration of postnatal hospital stay(days) Episiotomy Fetal loss/neonatal death before 24 weeks Fetal loss/neonatal death equal to/after 24 weeks Induction of Labour Instrumental vaginal birth (forceps/vacuum) Intact perineum Mean length of neonatal hospital stay (days) Opiate analgesia Overall fetal loss and neonatal death Perineal laceration requiring suturing Postpartum haemorrhage (as defined by trial authors) Preterm birth (< 37 weeks) Regional analgesia (epidural/spinal) Spontaneous vaginal birth (as defined by trial authors)
Notes	65% and 9% of experimental (team) and control (standard) group participants had previously met midwife attending labour.

APPENDIX D
Characteristics of excluded studies

Study	Reason for exclusion
Berglund 1998	Before and after study investigating effects of a new routine antenatal care programme.
Berglund 2007	Comparative study of risk assessment by midwives and doctors of women at initial booking.
Chapman 1986	Compares same model of care across two different birth settings.
Eide 2009	Controlled before-after study (CBA) comparing midwife-led with shared model of care. Antenatal component of both models of care had similar characteristics. Fewer than two intervention sites and two control sites therefore did not meet design inclusion criteria.
Giles 1992	Randomised trial comparing antenatal care provided by registered midwives with antenatal care provided by obstetricians.
Heins 1990	Randomised trial comparing prenatal interventions (multiple) provided by nurse-midwives and nurses under their supervision with standard high-risk prenatal care provided by obstetricians
Klein 1984	Randomised trial comparing birth room with conventional setting. Model of care not focus.
Lenaway 1998	Controlled before-after study (CBA) study comparing a 'Public-Private Certified Nurse-Midwife Maternity Program for Indigent Women' with standard care. Study states quasi-experimental design comparing one intervention county with 2 non-intervention control counties. However, no randomisation and method of allocation unclear. Fewer than two intervention sites and two control sites therefore did not meet design inclusion criteria.
Marks 2003	Randomised trial comparing continuous midwifery care with standard care on rates of postnatal depression for women with a history of depression. Model of midwifery care is not midwife-led.
Runnerstrom 1969	Compared effectives of nurse-midwife interns without clinical experience post qualification under medical supervision with care provided by medical residents. Neither model was midwife-led.
Slome 1976	Randomised trial comparing nurse-midwife care with medical-led care. Very large exclusion and loss to follow up after randomisation (combined = 66.5% in the nurse-midwife group and 63.5% in the control group).

APPENDIX E
Risk of bias tables for included studies

Begley 2009		
Item	**Judgement**	**Description**
Adequate sequence generation?	Yes	Computer generated allocation sequence
Allocation concealment?	Yes	'...independent telephone randomisation service (TRS)'
Blinding?	No	**Participants:** No **Personnel:** No **Outcome assessors:** No
Incomplete outcome data addressed?	Yes	Loss to follow up = 5 midwife-led care, 1 consultant-led care
Free of selective reporting?	Yes	**Outcome reporting:** All outcomes stated in the methods section were adequately reported or explained in results

Biro 2000		
Item	**Judgement**	**Description**
Adequate sequence generation?	Yes	'Allocations were computer generated...'
Allocation concealment?	Yes	Randomisation on presentation at antenatal clinic by midwife who telephoned records staff to select an opaque envelope containing the randomised allocation.
Blinding?	Unclear	**Participants:** Not stated **Personnel:** Not stated **Outcome assessors:** Not stated
Incomplete outcome data addressed?	Yes	Loss to follow up = 14 team care, 18 standard care.
Free of selective reporting?	Yes	**Outcome reporting:** All outcomes stated in the methods section were adequately reported in results

Byrne 2000		
Item	**Judgement**	**Description**
Adequate sequence generation?	Yes	'Randomisation numbers were prepared using balanced variable blocks with stratification for parity by a clerical officer not involved in the study.'
Allocation concealment?	Yes	'The researcher telephoned a manager in a separate office to enter women into the trial. Eligibility criteria were checked, then allocation to one of the two treatment groups by the clerical officer was made by opening the next in a series of opaque sealed envelopes.'
Blinding?	No	**Participants:** Not stated **Personnel:** Not stated **Outcome assessors:** No. 'Outcome data were collected from case notes by the chief researcher.'
Incomplete outcome data addressed?	Yes	Loss to follow up = 0 Birthing centre care, 1 Delivery suite care
Free of selective reporting?	Yes	**Outcome reporting:** All outcomes stated in the methods section were adequately reported in results

Chambliss 1992		
Item	**Judgement**	**Description**
Adequate sequence generation?	Unclear	Not stated
Allocation concealment?	Yes	'random assignment was accomplished by drawing a sealed envelope which determined the service to which the patient would be assigned.'
Blinding?	No	**Participants:** Yes. Women were not asked to participate in the study and consent was not obtained so likely blinded. **Personnel:** Yes. The provider who managed the labour was unaware and unable to determine whether a patient was a study participant. **Outcome assessors:** No. 'Outcome data were collected from case notes by the chief researcher.'
Incomplete outcome data addressed?	Yes	Loss to follow up = 0 Normal birth centre, 0 Physician-managed delivery service. However, denominators as low as 222 and 246 respectively.
Free of selective reporting?	Yes	**Outcome reporting:** All outcomes stated in the methods section were adequately reported in results

Flint 1989		
Item	**Judgement**	**Description**
Adequate sequence generation?	Unclear	Not stated
Allocation concealment?	Yes	'randomised into two groups by pinning sealed envelopes on their notes containing either the motto KNOW YOUR MIDWIFE or CONTROL GROUP'
Blinding?	Unclear	**Participants:** Not stated **Personnel:** Not stated **Outcome assessors:** Not stated
Incomplete outcome data addressed?	Yes	Loss to follow up = 15 team care, 19 standard care.
Free of selective reporting?	Yes	**Outcome reporting:** All outcomes stated in the methods section were adequately reported in results

Harvey 1996		
Item	**Judgement**	**Description**
Adequate sequence generation?	Yes	'...computer-generated random allocation.'
Allocation concealment?	Yes	'using a series of consecutively numbered, sealed, opaque envelopes...'
Blinding?	Unclear	**Participants:** Not stated **Personnel:** Not stated **Outcome assessors:** Not stated
Incomplete outcome data addressed?	Yes	Loss to follow up = 8 team care and 16 standard care.
Free of selective reporting?	Yes	**Outcome reporting:** All outcomes stated in the methods section were adequately reported in results

Hicks 2003		
Item	**Judgement**	**Description**
Adequate sequence generation?	Yes	Enveloped '...had been shuffled previously by an individual not involved in the recruitment process, and then numbered consecutively.'
Allocation concealment?	Yes	'Allocation was undertaken by giving each woman a sealed envelope containing one of the care options.'
Blinding?	Unclear	**Participants:** Not stated **Personnel:** Not stated **Outcome assessors:** Not stated
Incomplete outcome data addressed?	Yes	Loss to follow up = 19 team care and 8 standard. Due to non-response to questionnaires.
Free of selective reporting?	Yes	**Outcome reporting:** All outcomes stated in the methods section were adequately reported in results

Homer 2001		
Item	**Judgement**	**Description**
Adequate sequence generation?	Yes	...computer-generated random numbers...'
Allocation concealment?	Yes	'...group allocation was not revealed until the woman's details were recorded by the administrative assistant.'
Blinding?	Unclear	**Participants:** No (states 'unblinded') **Personnel:** No (states 'unblinded') **Outcome assessors:** No (states 'unblinded')
Incomplete outcome data addressed?	Yes	Loss to follow up: Team care 46, standard care 42
Free of selective reporting?	Yes	**Outcome reporting:** All outcomes stated in the methods section were adequately reported in results

Hundley 1994		
Item	**Judgement**	**Description**
Adequate sequence generation?	Yes	'The randomisation was done in a simple, unstratified manner.' Assumed to mean simple random sequence generation.
Allocation concealment?	Yes	'...consecutive sealed opaque envelopes which contained the place for delivery.'
Blinding?	Unclear	**Participants:** Not stated **Personnel:** Not stated **Outcome assessors:** Not stated
Incomplete outcome data addressed?	Yes	Loss to follow up: Midwives unit 34, Consultant-led labour ward 9
Free of selective reporting?	Yes	**Outcome reporting:** All outcomes stated in the methods section were adequately reported in results

Kenny 1994		
Item	**Judgement**	**Description**
Adequate sequence generation?	Unclear	'...allocated a numbered randomisation envelope (the number was recorded by the booking-in midwife on a list of women booked in the session).'
Allocation concealment?	Yes	'Allocated a numbered randomisation envelope (the number was recorded by the booking-in midwife on a list of women booked in the session). When each woman returned for her first visit to the doctor at the antenatal clinic she was approached in the waiting room by a program midwife, reminded about the research and asked to sign a consent form. If the woman agreed to join the study, the randomisation envelope was opened and the woman informed of the type of care she was to receive and the appropriate future appointments made.'
Blinding?	Unclear	**Participants:** Not stated **Personnel:** Not stated **Outcome assessors:** Not stated
Incomplete outcome data addressed?	Yes	Loss to follow up = 19 team care and 22 standard who either moved or had a miscarriage.
Free of selective reporting?	Yes	**Outcome reporting:** All outcomes stated in the methods section were adequately reported in results

Law 1999		
Item	**Judgement**	**Description**
Adequate sequence generation?	Yes	'...computer-generated random numbers...'
Allocation concealment?	Unclear	Not stated
Blinding?	Unclear	**Participants:** Not stated **Personnel:** Not stated **Outcome assessors:** Not stated
Incomplete outcome data addressed?	Yes	Loss to follow up = 0 midwife care, 0 shared care
Free of selective reporting?	Yes	**Outcome reporting:** All outcomes stated in the methods section were adequately reported in results

MacVicar 1993		
Item	**Judgement**	**Description**
Adequate sequence generation?	Yes	'...by a random sequence...'
Allocation concealment?	Yes	'...sealed envelope...cards could not be read through the envelopes. Each envelope was numbered, and unused envelopes were not reallocated...'
Blinding?	Unclear	**Participants:** Not stated **Personnel:** Clinical staff were unaware whether a particular woman was in the control group or was not in the study. No information given for women in intervention arm. **Outcome assessors:** Not stated
Incomplete outcome data addressed?	Unclear	No information given on losses to follow-up
Free of selective reporting?	Yes	**Outcome reporting:** All outcomes stated in the methods section were adequately reported in results

North Stafford 2000		
Item	**Judgement**	**Description**
Adequate sequence generation?	Unclear	'Randomisation was undertaken by one of the principal investigators...who had no prior knowledge of the area or medical and midwifery staff involved.'
Allocation concealment?	Unclear	No information given about allocation concealment.
Blinding?	Unclear	**Participants:** No **Personnel:** No **Outcome assessors:** Not stated
Incomplete outcome data addressed?	Unclear	Loss to follow up: not reported but appears complete
Free of selective reporting?	Yes	**Outcome reporting:** All outcomes stated in the methods section were adequately reported in results

North Stafford 2000		
Item	**Judgement**	**Description**
Adequate sequence generation?	Unclear	'Randomisation was undertaken by one of the principal investigators...who had no prior knowledge of the area or medical and midwifery staff involved.'
Allocation concealment?	Unclear	No information given about allocation concealment.
Blinding?	Unclear	**Participants:** No **Personnel:** No **Outcome assessors:** Not stated
Incomplete outcome data addressed?	Unclear	Loss to follow up: not reported but appears complete
Free of selective reporting?	Yes	**Outcome reporting:** All outcomes stated in the methods section were adequately reported in results

Rowley 1995		
Item	**Judgement**	**Description**
Adequate sequence generation?	Yes	'Allocation to either team care or routine care was done by computer-generated random assignments:'
Allocation concealment?	Unclear	Not stated
Blinding?	No	**Participants:** No **Personnel:** No **Outcome assessors:** No
Incomplete outcome data addressed?	Unclear	Loss to follow up not reported (appears minimal)
Free of selective reporting?	Yes	**Outcome reporting:** All outcomes stated in the methods section were adequately reported in results

Turnbull 1996		
Item	**Judgement**	**Description**
Adequate sequence generation?	Yes	'...random number tables...'
Allocation concealment?	Yes	'The research team telephoned a clerical officer in a separate office for care allocation for each woman.'
Blinding?	Unclear	**Participants:** Not stated **Personnel:** Clinical staff were unaware whether a particular woman was in the control group or was not in the study. No information given for women in intervention arm. **Outcome assessors:** No
Incomplete outcome data addressed?	Yes	Loss to follow up: 5 team care and 16 shared care.
Free of selective reporting?	Yes	**Outcome reporting:** All outcomes stated in the methods section were adequately reported in results

Waldenstrom 1997		
Item	**Judgement**	**Description**
Adequate sequence generation?	Unclear	No information given
Allocation concealment?	Yes	Women asked to pick an '...opaque envelope from a box...' '...envelopes were mingled, and it was not possible for any member of the research team, or the woman herself to predict the group allocation.'
Blinding?	Unclear	**Participants:** Not stated **Personnel:** Not stated **Outcome assessors:** Not stated
Incomplete outcome data addressed?	Unclear	Loss to follow-up: 2 in standard care. Birth centre care not stated.
Free of selective reporting?	Yes	**Outcome reporting:** All outcomes stated in the methods section were adequately reported in results

Waldenstrom 2001		
Item	**Judgement**	**Description**
Adequate sequence generation?	Unclear	No information given
Allocation concealment?	Yes	'The research midwife rang a clerk at the hospital's information desk who opened an opaque, numbered envelope that contained information about the allocated group.'
Blinding?	Unclear	**Participants:** Not stated **Personnel:** Not stated **Outcome assessors:** Not stated
Incomplete outcome data addressed?	Yes	Lost to follow up: 11 team care and 9 standard-care group.
Free of selective reporting?	Yes	**Outcome reporting:** All outcomes stated in the methods section were adequately reported in results

APPENDIX F
Systematically varying the cost savings (detailed)

Systematically varying the cost savings (detailed)

Mean Cost saving	Aggregate NMB	Aggregate NHB	Mean NMB	Mean NHB
12.38	1,160,072.39	38.67	12.38	0.000412621
79.76	7,474,475.16	249.15	79.76	0.002658561
23.99	2,248,650.26	74.96	23.99	0.000799812
91.37	8,563,053.03	285.44	91.37	0.003045752
253.38	23,745,790.95	791.53	253.38	0.008446029
-108.12	-10,132,786.89	-337.76	-108.12	-0.003604083
-7.06	-661,182.73	-22.04	-7.06	-0.000235173

APPENDIX G

1.3 RESULTS

1.3.2 RISK OF BIAS IN INCLUDED STUDIES

Figure 1.1:
Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

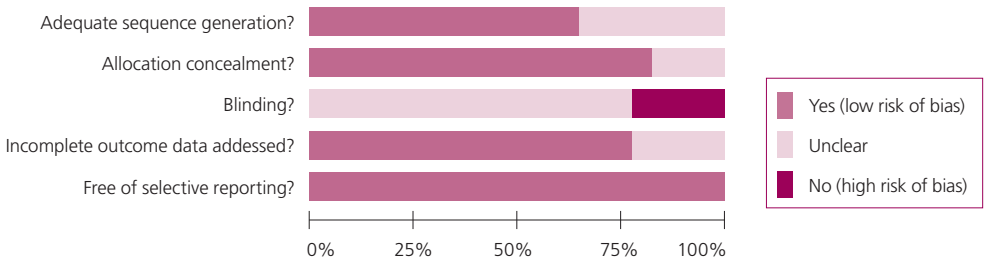
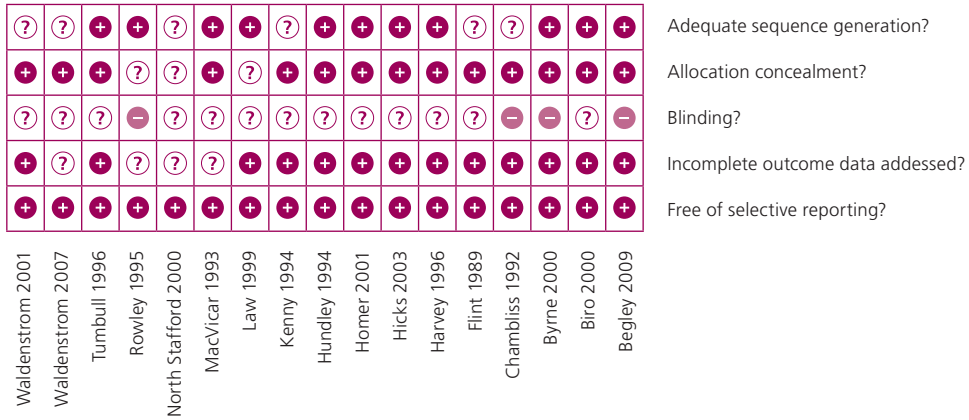


Figure 1.2:
Risk of bias summary: review authors' judgements about each risk of bias item for each included study.



1.3.4.1 Antenatal outcomes

Figure 1.3:
Forest plot of comparison: Mean number of antenatal visits

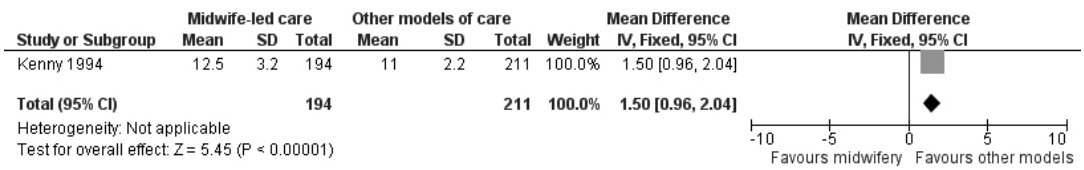


Figure 1.4:
Forest plot of comparison:
Antenatal hospitalisations

Study or Subgroup	Midwife-led care Events	Total	Other models of care Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI	Year
Flint 1989	123	484	146	475	16.8%	0.83 [0.67, 1.01]	1989
Kenny 1994	29	194	38	211	4.2%	0.83 [0.53, 1.29]	1994
Rowley 1995	114	393	135	405	15.2%	0.87 [0.71, 1.07]	1995
Waldenstrom 2001	190	484	185	496	20.9%	1.05 [0.90, 1.23]	2001
Homer 2001	53	594	72	601	8.2%	0.74 [0.53, 1.04]	2001
Begley 2009	487	1101	229	552	34.8%	1.07 [0.95, 1.20]	2009
Total (95% CI)		**3250**		**2740**	**100.0%**	**0.96 [0.89, 1.03]**	
Total events	996		805				

Heterogeneity: Chi² = 9.85, df = 5 (P = 0.08); I² = 49%
Test for overall effect: Z = 1.11 (P = 0.27)

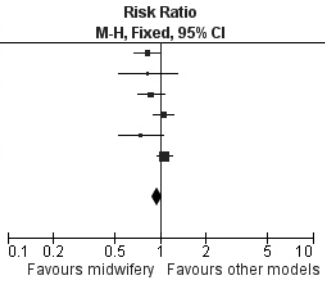


Figure 1.5:
Forest plot of comparison:
Antepartum Haemorrhage

Study or Subgroup	Midwife-led care Events	Total	Other models of care Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI	Year
Harvey 1996	4	105	5	97	5.0%	0.74 [0.20, 2.67]	1996
Turnbull 1996	45	643	57	635	55.5%	0.78 [0.54, 1.13]	1996
Homer 2001	9	594	14	601	13.5%	0.65 [0.28, 1.49]	2001
Waldenstrom 2001	14	484	7	496	6.7%	2.05 [0.83, 5.03]	2001
Begley 2009	27	1101	15	552	19.3%	0.90 [0.48, 1.68]	2009
Total (95% CI)		**2927**		**2381**	**100.0%**	**0.87 [0.66, 1.14]**	
Total events	99		98				

Heterogeneity: Chi² = 4.37, df = 4 (P = 0.36); I² = 8%
Test for overall effect: Z = 1.00 (P = 0.32)

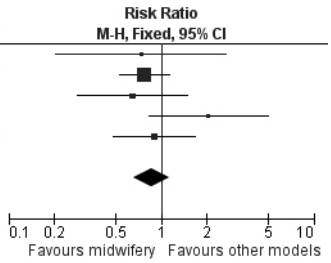


Figure 1.6:
Forest plot of comparison:
Fetal loss/neonatal death before 24 weeks

Study or Subgroup	Midwife-led care Events	Total	Other models of care Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI	Year
Flint 1989	11	488	8	479	3.4%	1.35 [0.55, 3.33]	1989
MacVicar 1993	24	2304	15	1206	8.2%	0.84 [0.44, 1.59]	1993
Hundley 1994	35	1866	13	935	7.2%	1.35 [0.72, 2.54]	1994
Rowley 1995	9	398	19	413	7.8%	0.49 [0.23, 1.07]	1995
Harvey 1996	4	105	4	97	1.7%	0.92 [0.24, 3.59]	1996
Turnbull 1996	20	613	24	603	10.1%	0.82 [0.46, 1.47]	1996
Waldenstrom 1997	16	933	14	936	5.8%	1.15 [0.56, 2.34]	1997
Biro 2000	32	500	36	493	15.1%	0.88 [0.55, 1.39]	2000
Waldenstrom 2001	23	486	27	500	11.1%	0.88 [0.51, 1.51]	2001
Homer 2001	44	597	64	608	26.4%	0.70 [0.49, 1.01]	2001
Begley 2009	17	1101	6	552	3.3%	1.42 [0.56, 3.58]	2009
Total (95% CI)		**9391**		**6822**	**100.0%**	**0.88 [0.73, 1.05]**	
Total events	235		230				

Heterogeneity: Chi² = 7.88, df = 10 (P = 0.64); I² = 0%
Test for overall effect: Z = 1.44 (P = 0.15)

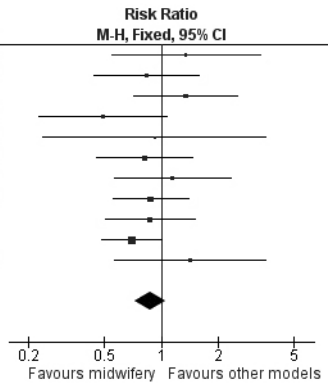
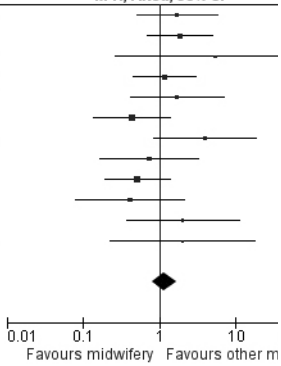


Figure 1.7:
Forest plot of comparison:
Fetal loss/neonatal death equal to/after 24 weeks

Study or Subgroup	Midwife-led care Events	Total	Other models of care Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI	Year
Flint 1989	7	488	4	479	7.1%	1.72 [0.51, 5.83]	1989
MacVicar 1993	18	2304	5	1206	11.6%	1.88 [0.70, 5.06]	1993
Kenny 1994	2	197	0	214	0.8%	5.43 [0.26, 112.40]	1994
Hundley 1994	14	1866	6	935	14.1%	1.17 [0.45, 3.03]	1994
Rowley 1995	5	398	3	413	5.2%	1.73 [0.42, 7.19]	1995
Turnbull 1996	4	613	9	603	16.0%	0.44 [0.14, 1.41]	1996
Waldenstrom 1997	8	933	2	936	3.5%	4.01 [0.85, 18.85]	1997
Biro 2000	3	500	4	493	7.1%	0.74 [0.17, 3.29]	2000
North Stafford 2000	6	770	11	735	19.9%	0.52 [0.19, 1.40]	2000
Waldenstrom 2001	2	486	5	500	8.7%	0.41 [0.08, 2.11]	2001
Homer 2001	4	597	2	608	3.5%	2.04 [0.37, 11.08]	2001
Begley 2009 (1)	4	1101	1	552	2.4%	2.01 [0.22, 17.90]	2009
Total (95% CI)		**10253**		**7674**	**100.0%**	**1.16 [0.81, 1.66]**	
Total events	77		52				

Heterogeneity: Chi² = 12.83, df = 11 (P = 0.30); I² = 14%
Test for overall effect: Z = 0.83 (P = 0.41)

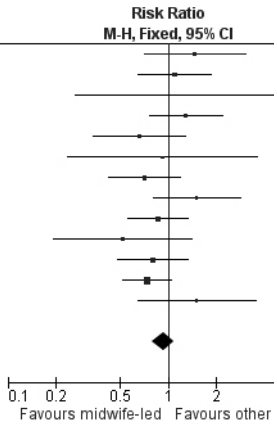


(1) MLU [Fetal loss > 24 weeks = 1, plus 3 NND > 24 weeks] CLU [Fetal loss > 24 weeks = 0, plus 1 NND > 24 weeks]

Figure 1.8:
Forest plot of comparison:
Overall fetal loss and neonatal death

Study or Subgroup	Favours midwife-led Events	Total	Other models of care Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI	Year
Flint 1989	18	488	12	479	4.1%	1.47 [0.72, 3.02]	1989
MacVicar 1993	42	2304	20	1206	8.8%	1.10 [0.65, 1.86]	1993
Kenny 1994	2	197	0	214	0.2%	5.43 [0.26, 112.40]	1994
Hundley 1994	49	1866	19	935	8.5%	1.29 [0.77, 2.18]	1994
Rowley 1995	14	398	22	413	7.3%	0.66 [0.34, 1.27]	1995
Harvey 1996	4	105	4	97	1.4%	0.92 [0.24, 3.59]	1996
Turnbull 1996	24	613	33	603	11.2%	0.72 [0.43, 1.20]	1996
Waldenstrom 1997	24	933	16	936	5.4%	1.50 [0.80, 2.81]	1997
Biro 2000	35	500	40	493	13.6%	0.86 [0.56, 1.33]	2000
North Stafford 2000	6	770	11	735	3.8%	0.52 [0.19, 1.40]	2000
Waldenstrom 2001	25	486	32	500	10.6%	0.80 [0.48, 1.34]	2001
Homer 2001	48	597	66	608	22.0%	0.74 [0.52, 1.06]	2001
Begley 2009	21	1101	7	552	3.1%	1.50 [0.64, 3.52]	2009
Total (95% CI)		**10358**		**7771**	**100.0%**	**0.93 [0.79, 1.09]**	
Total events	312		282				

Heterogeneity: Chi² = 13.66, df = 12 (P = 0.32); I² = 12%
Test for overall effect: Z = 0.88 (P = 0.38)



1.3.4.2 Labour

Figure 1.9:
Forest plot of comparison:
Amniotomy

Study or Subgroup	Midwife-led care Events	Total	Other models of care Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Begley 2009	228	1101	169	552	18.3%	0.68 [0.57, 0.80]
Flint 1989	247	474	270	462	22.2%	0.89 [0.79, 1.00]
Harvey 1996	17	105	28	97	2.4%	0.56 [0.33, 0.96]
Kenny 1994	90	194	102	211	7.9%	0.96 [0.78, 1.18]
Law 1999	287	563	236	487	20.6%	1.05 [0.93, 1.19]
Waldenstrom 1997	209	912	351	910	28.6%	0.59 [0.51, 0.69]
Total (95% CI)		**3349**		**2719**	**100.0%**	**0.80 [0.75, 0.85]**
Total events	1078		1156			

Heterogeneity: Chi² = 47.53, df = 5 (P < 0.00001); I² = 89%
Test for overall effect: Z = 6.91 (P < 0.00001)

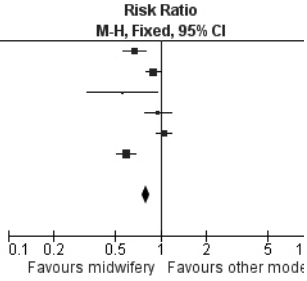
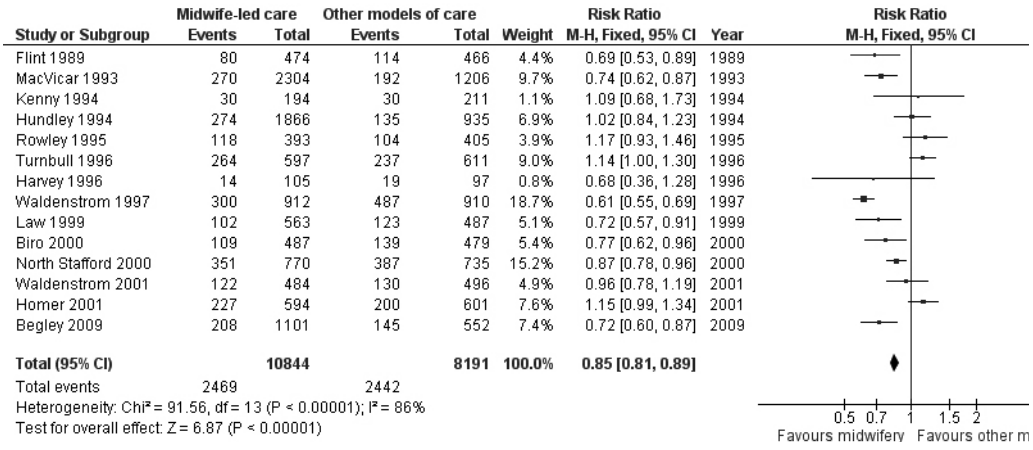


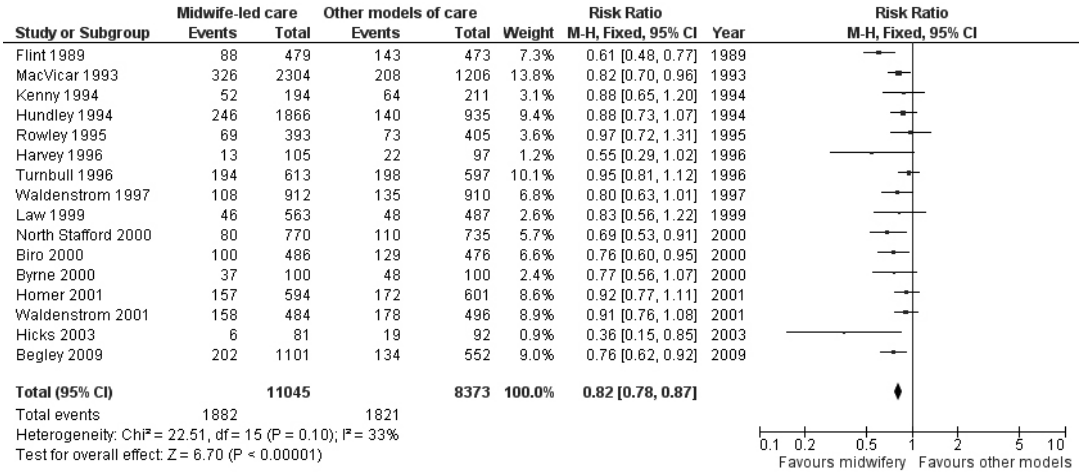
Figure 1.10:
Forest plot of comparison:
Augmentation/artificial oxytocin during labour



Study or Subgroup	Midwife-led care Events	Total	Other models of care Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI	Year
Flint 1989	80	474	114	466	4.4%	0.69 [0.53, 0.89]	1989
MacVicar 1993	270	2304	192	1206	9.7%	0.74 [0.62, 0.87]	1993
Kenny 1994	30	194	30	211	1.1%	1.09 [0.68, 1.73]	1994
Hundley 1994	274	1866	135	935	6.9%	1.02 [0.84, 1.23]	1994
Rowley 1995	118	393	104	405	3.9%	1.17 [0.93, 1.46]	1995
Turnbull 1996	264	597	237	611	9.0%	1.14 [1.00, 1.30]	1996
Harvey 1996	14	105	19	97	0.8%	0.68 [0.36, 1.28]	1996
Waldenstrom 1997	300	912	487	910	18.7%	0.61 [0.55, 0.69]	1997
Law 1999	102	563	123	487	5.1%	0.72 [0.57, 0.91]	1999
Biro 2000	109	487	139	479	5.4%	0.77 [0.62, 0.96]	2000
North Stafford 2000	351	770	387	735	15.2%	0.87 [0.78, 0.96]	2000
Waldenstrom 2001	122	484	130	496	4.9%	0.96 [0.78, 1.19]	2001
Homer 2001	227	594	200	601	7.6%	1.15 [0.99, 1.34]	2001
Begley 2009	208	1101	145	552	7.4%	0.72 [0.60, 0.87]	2009
Total (95% CI)		**10844**		**8191**	**100.0%**	**0.85 [0.81, 0.89]**	
Total events	2469		2442				

Heterogeneity: Chi² = 91.56, df = 13 (P < 0.00001); I² = 86%
Test for overall effect: Z = 6.87 (P < 0.00001)

Figure 1.11:
Forest plot of comparison:
Regional analgesia



Study or Subgroup	Midwife-led care Events	Total	Other models of care Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI	Year
Flint 1989	88	479	143	473	7.3%	0.61 [0.48, 0.77]	1989
MacVicar 1993	326	2304	208	1206	13.8%	0.82 [0.70, 0.96]	1993
Kenny 1994	52	194	64	211	3.1%	0.88 [0.65, 1.20]	1994
Hundley 1994	246	1866	140	935	9.4%	0.88 [0.73, 1.07]	1994
Rowley 1995	69	393	73	405	3.6%	0.97 [0.72, 1.31]	1995
Harvey 1996	13	105	22	97	1.2%	0.55 [0.29, 1.02]	1996
Turnbull 1996	194	613	198	597	10.1%	0.95 [0.81, 1.12]	1996
Waldenstrom 1997	108	912	135	910	6.8%	0.80 [0.63, 1.01]	1997
Law 1999	46	563	48	487	2.6%	0.83 [0.56, 1.22]	1999
North Stafford 2000	80	770	110	735	5.7%	0.69 [0.53, 0.91]	2000
Biro 2000	100	486	129	476	6.6%	0.76 [0.60, 0.95]	2000
Byrne 2000	37	100	48	100	2.4%	0.77 [0.56, 1.07]	2000
Homer 2001	157	594	172	601	8.6%	0.92 [0.77, 1.11]	2001
Waldenstrom 2001	158	484	178	496	8.9%	0.91 [0.76, 1.08]	2001
Hicks 2003	6	81	19	92	0.9%	0.36 [0.15, 0.85]	2003
Begley 2009	202	1101	134	552	9.0%	0.76 [0.62, 0.92]	2009
Total (95% CI)		**11045**		**8373**	**100.0%**	**0.82 [0.78, 0.87]**	
Total events	1882		1821				

Heterogeneity: Chi² = 22.51, df = 15 (P = 0.10); I² = 33%
Test for overall effect: Z = 6.70 (P < 0.00001)

Figure 1.12:
Forest plot of comparison:
Opiate analgesia

Study or Subgroup	Midwife-led care Events	Total	Other models of care Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI	Year
Flint 1989	114	479	128	473	4.2%	0.88 [0.71, 1.09]	1989
MacVicar 1993	812	2304	477	1206	20.5%	0.89 [0.82, 0.97]	1993
Kenny 1994	45	194	40	194	1.3%	1.13 [0.77, 1.64]	1994
Hundley 1994	1063	1866	498	935	21.7%	1.07 [1.00, 1.15]	1994
Rowley 1995	53	393	127	405	4.1%	0.43 [0.32, 0.57]	1995
Turnbull 1996	253	613	262	597	8.7%	0.94 [0.83, 1.07]	1996
Harvey 1996	16	105	17	97	0.6%	0.87 [0.47, 1.62]	1996
Waldenstrom 1997	33	912	120	910	3.9%	0.27 [0.19, 0.40]	1997
Law 1999	210	563	209	487	7.3%	0.87 [0.75, 1.01]	1999
Biro 2000	188	486	208	476	6.9%	0.89 [0.76, 1.03]	2000
Byrne 2000	33	100	29	100	0.9%	1.14 [0.75, 1.72]	2000
Homer 2001	159	594	136	601	4.4%	1.18 [0.97, 1.44]	2001
Waldenstrom 2001	215	484	248	496	8.0%	0.89 [0.78, 1.01]	2001
Begley 2009	345	1101	172	552	7.5%	1.01 [0.86, 1.17]	2009
Total (95% CI)		**10194**		**7529**	**100.0%**	**0.92 [0.88, 0.95]**	
Total events	3539		2671				

Heterogeneity: Chi² = 95.77, df = 13 (P < 0.00001); I² = 86%
Test for overall effect: Z = 4.38 (P < 0.0001)

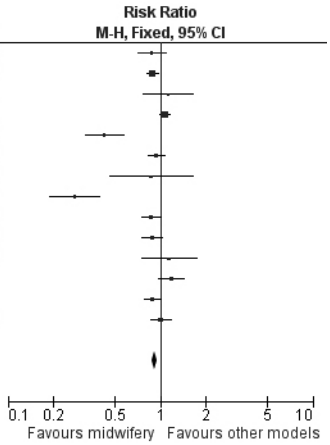


Figure 1.13:
Forest plot of comparison:
No intrapartum analgesia/anaesthesia

Study or Subgroup	Midwife-led care Events	Total	Other models of care Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI	Year
Flint 1989	246	479	180	473	27.6%	1.35 [1.17, 1.56]	1989
MacVicar 1993	270	2304	127	1206	25.4%	1.11 [0.91, 1.36]	1993
Kenny 1994	53	194	62	211	9.1%	0.93 [0.68, 1.27]	1994
Hundley 1994	32	1866	14	935	2.8%	1.15 [0.61, 2.14]	1994
Turnbull 1996	76	613	69	597	10.7%	1.07 [0.79, 1.46]	1996
Byrne 2000	32	100	26	100	4.0%	1.23 [0.80, 1.91]	2000
Biro 2000	62	486	57	476	8.8%	1.07 [0.76, 1.49]	2000
Begley 2009	136	1101	57	552	11.6%	1.20 [0.89, 1.60]	2009
Total (95% CI)		**7143**		**4550**	**100.0%**	**1.17 [1.07, 1.28]**	
Total events	907		592				

Heterogeneity: Chi² = 6.81, df = 7 (P = 0.45); I² = 0%
Test for overall effect: Z = 3.31 (P = 0.0009)

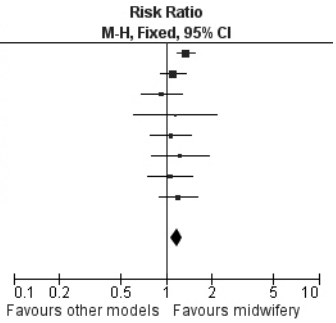


Figure 1.14:
Forest plot of comparison:
Length of labour

Study or Subgroup	Midwife-led care Mean	SD	Total	Other models of care Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI	Year
Kenny 1994	6.1	3.9	194	5.7	4	211	9.0%	0.40 [-0.37, 1.17]	1994
Turnbull 1996	7.9	4.9	612	7.7	5	597	17.1%	0.20 [-0.36, 0.76]	1996
Waldenstrom 1997	15	11.6	912	14	9.9	910	5.4%	1.00 [0.01, 1.99]	1997
Begley 2009	4.56	3.27	1101	4.03	2.41	552	68.5%	0.53 [0.25, 0.81]	2009
Total (95% CI)			**2819**			**2270**	**100.0%**	**0.49 [0.26, 0.72]**	

Heterogeneity: Chi² = 2.19, df = 3 (P = 0.53); I² = 0%
Test for overall effect: Z = 4.14 (P < 0.0001)

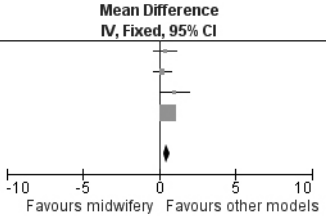
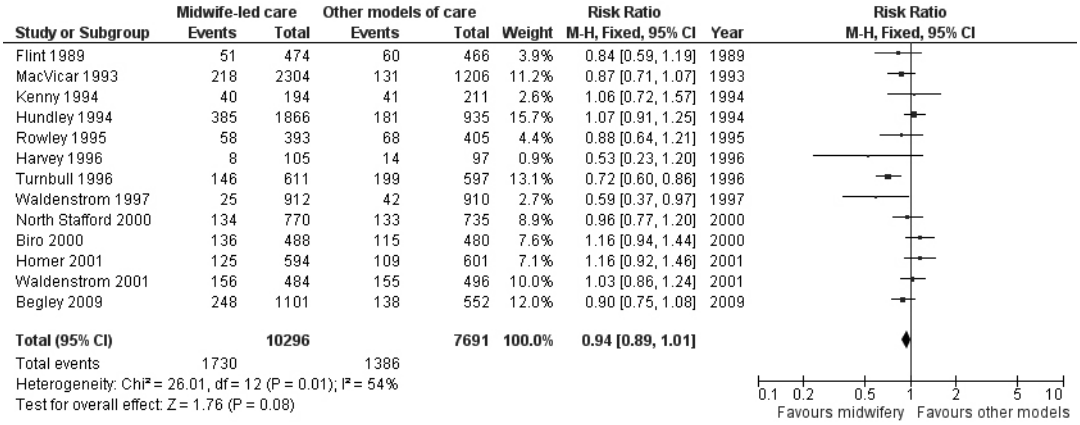


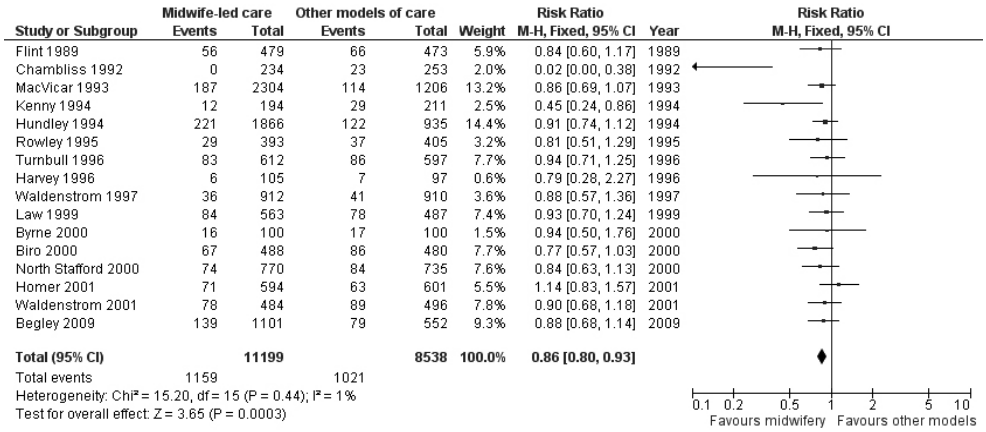
Figure 1.15:
Forest plot of comparison:
Induction of labour



Study or Subgroup	Midwife-led care Events	Total	Other models of care Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI	Year
Flint 1989	51	474	60	466	3.9%	0.84 [0.59, 1.19]	1989
MacVicar 1993	218	2304	131	1206	11.2%	0.87 [0.71, 1.07]	1993
Kenny 1994	40	194	41	211	2.6%	1.06 [0.72, 1.57]	1994
Hundley 1994	385	1866	181	935	15.7%	1.07 [0.91, 1.25]	1994
Rowley 1995	58	393	68	405	4.4%	0.88 [0.64, 1.21]	1995
Harvey 1996	8	105	14	97	0.9%	0.53 [0.23, 1.20]	1996
Turnbull 1996	146	611	199	597	13.1%	0.72 [0.60, 0.86]	1996
Waldenstrom 1997	25	912	42	910	2.7%	0.59 [0.37, 0.97]	1997
North Stafford 2000	134	770	133	735	8.9%	0.96 [0.77, 1.20]	2000
Biro 2000	136	488	115	480	7.6%	1.16 [0.94, 1.44]	2000
Homer 2001	125	594	109	601	7.1%	1.16 [0.92, 1.46]	2001
Waldenstrom 2001	156	484	155	496	10.0%	1.03 [0.86, 1.24]	2001
Begley 2009	248	1101	138	552	12.0%	0.90 [0.75, 1.08]	2009
Total (95% CI)		**10296**		**7691**	**100.0%**	**0.94 [0.89, 1.01]**	
Total events	1730		1386				

Heterogeneity: Chi² = 26.01, df = 12 (P = 0.01); I² = 54%
Test for overall effect: Z = 1.76 (P = 0.08)

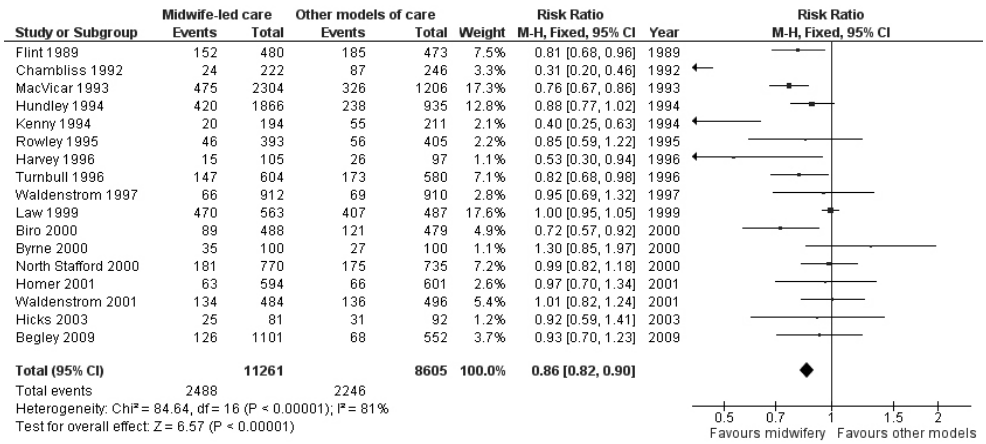
Figure 1.16:
Forest plot of comparison:
Instrumental vaginal birth (forceps/vacuum assisted birth)



Study or Subgroup	Midwife-led care Events	Total	Other models of care Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI	Year
Flint 1989	56	479	66	473	5.9%	0.84 [0.60, 1.17]	1989
Chambliss 1992	0	234	23	253	2.0%	0.02 [0.00, 0.38]	1992
MacVicar 1993	187	2304	114	1206	13.2%	0.86 [0.69, 1.07]	1993
Kenny 1994	12	194	29	211	2.5%	0.45 [0.24, 0.86]	1994
Hundley 1994	221	1866	122	935	14.4%	0.91 [0.74, 1.12]	1994
Rowley 1995	29	393	37	405	3.2%	0.81 [0.51, 1.29]	1995
Turnbull 1996	83	612	86	597	7.7%	0.94 [0.71, 1.25]	1996
Harvey 1996	6	105	7	97	0.6%	0.79 [0.28, 2.27]	1996
Waldenstrom 1997	36	912	41	910	3.6%	0.88 [0.57, 1.36]	1997
Law 1999	84	563	78	487	7.4%	0.93 [0.70, 1.24]	1999
Byrne 2000	16	100	17	100	1.5%	0.94 [0.50, 1.76]	2000
Biro 2000	67	488	86	480	7.7%	0.77 [0.57, 1.03]	2000
North Stafford 2000	74	770	84	735	7.6%	0.84 [0.63, 1.13]	2000
Homer 2001	71	594	63	601	5.5%	1.14 [0.83, 1.57]	2001
Waldenstrom 2001	78	484	89	496	7.8%	0.90 [0.68, 1.18]	2001
Begley 2009	139	1101	79	552	9.3%	0.88 [0.68, 1.14]	2009
Total (95% CI)		**11199**		**8538**	**100.0%**	**0.86 [0.80, 0.93]**	
Total events	1159		1021				

Heterogeneity: Chi² = 15.20, df = 15 (P = 0.44); I² = 1%
Test for overall effect: Z = 3.65 (P = 0.0003)

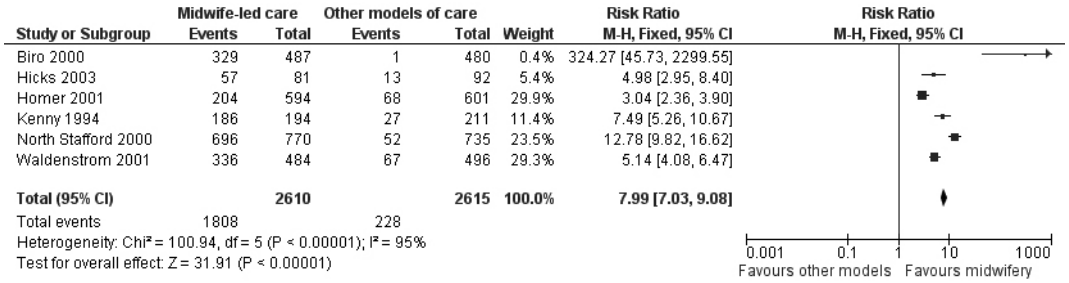
Figure 1.17:
Forest plot of comparison:
Episiotomy



Study or Subgroup	Midwife-led care Events	Total	Other models of care Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI	Year
Flint 1989	152	480	185	473	7.5%	0.81 [0.68, 0.96]	1989
Chambliss 1992	24	222	87	246	3.3%	0.31 [0.20, 0.46]	1992
MacVicar 1993	475	2304	326	1206	17.3%	0.76 [0.67, 0.86]	1993
Hundley 1994	420	1866	238	935	12.8%	0.88 [0.77, 1.02]	1994
Kenny 1994	20	194	55	211	2.1%	0.40 [0.25, 0.63]	1994
Rowley 1995	46	393	56	405	2.2%	0.85 [0.59, 1.22]	1995
Harvey 1996	15	105	26	97	1.1%	0.53 [0.30, 0.94]	1996
Turnbull 1996	147	604	173	580	7.1%	0.82 [0.68, 0.98]	1996
Waldenstrom 1997	66	912	69	910	2.8%	0.95 [0.69, 1.32]	1997
Law 1999	470	563	407	487	17.6%	1.00 [0.95, 1.05]	1999
Biro 2000	89	488	121	479	4.9%	0.72 [0.57, 0.92]	2000
Byrne 2000	35	100	27	100	1.1%	1.30 [0.85, 1.97]	2000
North Stafford 2000	181	770	175	735	7.2%	0.99 [0.82, 1.18]	2000
Homer 2001	63	594	66	601	2.6%	0.97 [0.70, 1.34]	2001
Waldenstrom 2001	134	484	136	496	5.4%	1.01 [0.82, 1.24]	2001
Hicks 2003	25	81	31	92	1.2%	0.92 [0.59, 1.41]	2003
Begley 2009	126	1101	68	552	3.7%	0.93 [0.70, 1.23]	2009
Total (95% CI)		**11261**		**8605**	**100.0%**	**0.86 [0.82, 0.90]**	
Total events	2488		2246				

Heterogeneity: Chi² = 84.64, df = 16 (P < 0.00001); I² = 81%
Test for overall effect: Z = 6.57 (P < 0.00001)

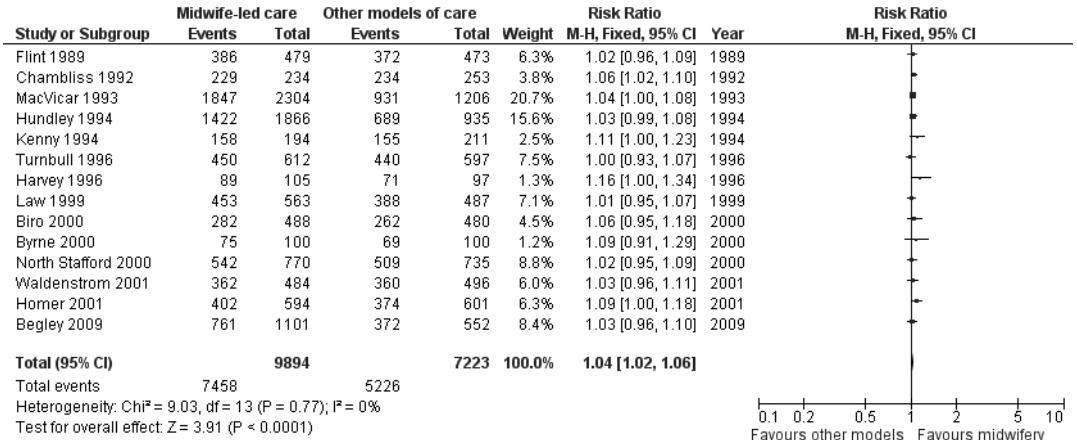
Figure 1.18:
Forest plot of comparison:
Attendance at birth by known midwife



Study or Subgroup	Midwife-led care Events	Total	Other models of care Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Biro 2000	329	487	1	480	0.4%	324.27 [45.73, 2299.55]
Hicks 2003	57	81	13	92	5.4%	4.98 [2.95, 8.40]
Homer 2001	204	594	68	601	29.9%	3.04 [2.36, 3.90]
Kenny 1994	186	194	27	211	11.4%	7.49 [5.26, 10.67]
North Stafford 2000	696	770	52	735	23.5%	12.78 [9.82, 16.62]
Waldenstrom 2001	336	484	67	496	29.3%	5.14 [4.08, 6.47]
Total (95% CI)		**2610**		**2615**	**100.0%**	**7.99 [7.03, 9.08]**
Total events	1808		228			

Heterogeneity: Chi² = 100.94, df = 5 (P < 0.00001); I² = 95%
Test for overall effect: Z = 31.91 (P < 0.00001)

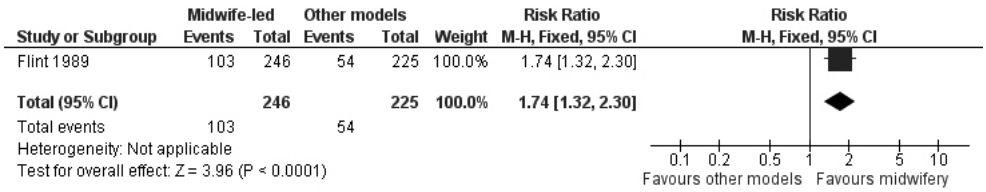
Figure 1.19:
Forest plot of comparison:
Spontaneous vaginal birth



Study or Subgroup	Midwife-led care Events	Total	Other models of care Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI	Year
Flint 1989	386	479	372	473	6.3%	1.02 [0.96, 1.09]	1989
Chambliss 1992	229	234	234	253	3.8%	1.06 [1.02, 1.10]	1992
MacVicar 1993	1847	2304	931	1206	20.7%	1.04 [1.00, 1.08]	1993
Hundley 1994	1422	1866	689	935	15.6%	1.03 [0.99, 1.08]	1994
Kenny 1994	158	194	155	211	2.5%	1.11 [1.00, 1.23]	1994
Turnbull 1996	450	612	440	597	7.5%	1.00 [0.93, 1.07]	1996
Harvey 1996	89	105	71	97	1.3%	1.16 [1.00, 1.34]	1996
Law 1999	453	563	388	487	7.1%	1.01 [0.95, 1.07]	1999
Biro 2000	282	488	262	480	4.5%	1.06 [0.95, 1.18]	2000
Byrne 2000	75	100	69	100	1.2%	1.09 [0.91, 1.29]	2000
North Stafford 2000	542	770	509	735	8.8%	1.02 [0.95, 1.09]	2000
Waldenstrom 2001	362	484	360	496	6.0%	1.03 [0.96, 1.11]	2001
Homer 2001	402	594	374	601	6.3%	1.09 [1.00, 1.18]	2001
Begley 2009	761	1101	372	552	8.4%	1.03 [0.96, 1.10]	2009
Total (95% CI)		**9894**		**7223**	**100.0%**	**1.04 [1.02, 1.06]**	
Total events	7458		5226				

Heterogeneity: Chi² = 9.03, df = 13 (P = 0.77); I² = 0%
Test for overall effect: Z = 3.91 (P < 0.0001)

Figure 1.20:
Forest plot of comparison:
High perceptions of control during labour & childbirth



Study or Subgroup	Midwife-led Events	Total	Other models Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Flint 1989	103	246	54	225	100.0%	1.74 [1.32, 2.30]
Total (95% CI)		**246**		**225**	**100.0%**	**1.74 [1.32, 2.30]**
Total events	103		54			

Heterogeneity: Not applicable
Test for overall effect: Z = 3.96 (P < 0.0001)

Figure 1.21:
Forest plot of comparison:
Caesarean birth

Study or Subgroup	Midwife-led care Events	Total	Other models of care Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI	Year
Flint 1989	37	479	35	473	3.4%	1.04 [0.67, 1.63]	1989
Chambliss 1992	5	234	1	253	0.1%	5.41 [0.64, 45.93]	1992
MacVicar 1993	144	2304	78	1206	9.8%	0.97 [0.74, 1.26]	1993
Hundley 1994	153	1866	92	935	11.7%	0.83 [0.65, 1.07]	1994
Kenny 1994	24	194	27	211	2.5%	0.97 [0.58, 1.62]	1994
Rowley 1995	52	393	59	405	5.6%	0.91 [0.64, 1.28]	1995
Turnbull 1996	79	612	71	597	6.9%	1.09 [0.80, 1.47]	1996
Harvey 1996	4	105	14	97	1.4%	0.26 [0.09, 0.77]	1996
Waldenstrom 1997	65	912	82	910	7.8%	0.79 [0.58, 1.08]	1997
Law 1999	26	563	20	587	1.9%	1.36 [0.77, 2.40]	1999
Biro 2000	100	488	91	480	8.8%	1.08 [0.84, 1.39]	2000
Byrne 2000	9	100	14	100	1.3%	0.64 [0.29, 1.42]	2000
North Stafford 2000	137	770	128	735	12.5%	1.02 [0.82, 1.27]	2000
Waldenstrom 2001	55	484	56	496	5.3%	1.01 [0.71, 1.43]	2001
Homer 2001	73	594	96	601	9.1%	0.77 [0.58, 1.02]	2001
Hicks 2003	9	81	14	92	1.3%	0.73 [0.33, 1.60]	2003
Begley 2009	163	1101	84	552	10.7%	0.97 [0.76, 1.24]	2009
Total (95% CI)		**11280**		**8730**	**100.0%**	**0.94 [0.87, 1.02]**	
Total events	1135		962				

Heterogeneity: Chi² = 17.93, df = 16 (P = 0.33); I² = 11%
Test for overall effect: Z = 1.47 (P = 0.14)

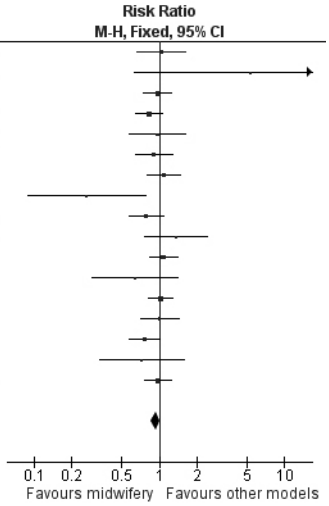


Figure 1.22:
Forest plot of comparison:
Intact perineum

Study or Subgroup	Midwife-led care Events	Total	Other models of care Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI	Year
Flint 1989	107	480	104	473	5.5%	1.01 [0.80, 1.29]	1989
MacVicar 1993	669	2304	308	1206	21.3%	1.14 [1.01, 1.28]	1993
Hundley 1994	394	1866	171	935	12.0%	1.15 [0.98, 1.36]	1994
Kenny 1994	98	194	100	211	5.1%	1.07 [0.87, 1.30]	1994
Harvey 1996	50	105	58	97	3.2%	0.80 [0.61, 1.03]	1996
Turnbull 1996	160	604	120	580	6.5%	1.28 [1.04, 1.58]	1996
North Stafford 2000	370	770	361	735	19.5%	0.98 [0.88, 1.09]	2000
Byrne 2000	20	100	27	100	1.4%	0.74 [0.45, 1.23]	2000
Biro 2000	66	488	77	479	4.1%	0.84 [0.62, 1.14]	2000
Waldenstrom 2001	128	484	107	496	5.6%	1.23 [0.98, 1.53]	2001
Begley 2009	431	1101	225	552	15.8%	0.96 [0.85, 1.09]	2009
Total (95% CI)		**8496**		**5864**	**100.0%**	**1.06 [1.00, 1.11]**	
Total events	2493		1658				

Heterogeneity: Chi² = 20.76, df = 10 (P = 0.02); I² = 52%
Test for overall effect: Z = 2.04 (P = 0.04)

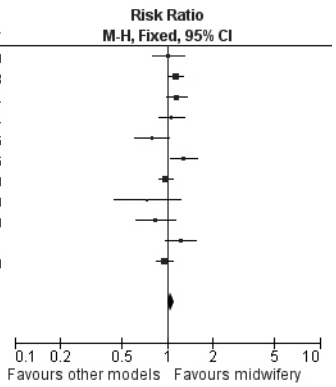


Figure 1.23:
Forest plot of comparison:
Perineal laceration requiring suturing

Study or Subgroup	Midwife-led care Events	Total	Other models of care Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI	Year
MacVicar 1993	1389	2304	743	1206	35.6%	0.98 [0.93, 1.03]	1993
Kenny 1994	107	194	115	211	4.0%	1.01 [0.85, 1.21]	1994
Rowley 1995	141	393	126	405	4.5%	1.15 [0.95, 1.40]	1995
Turnbull 1996	218	604	216	580	8.0%	0.97 [0.83, 1.13]	1996
Law 1999	514	563	443	487	17.3%	1.00 [0.97, 1.04]	1999
Biro 2000	143	488	133	479	4.9%	1.06 [0.86, 1.29]	2000
North Stafford 2000	197	770	180	735	6.7%	1.04 [0.88, 1.24]	2000
Waldenstrom 2001	100	484	135	496	4.9%	0.76 [0.61, 0.95]	2001
Begley 2009	484	1101	287	552	14.0%	0.85 [0.76, 0.94]	2009
Total (95% CI)		**6901**		**5151**	**100.0%**	**0.97 [0.94, 1.01]**	
Total events	3293		2378				

Heterogeneity: Chi² = 18.92, df = 8 (P = 0.02); I² = 58%
Test for overall effect: Z = 1.66 (P = 0.10)

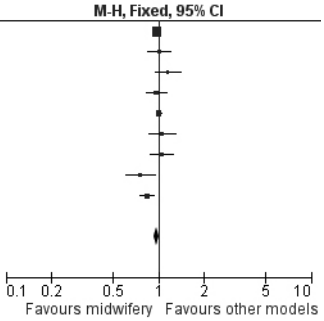
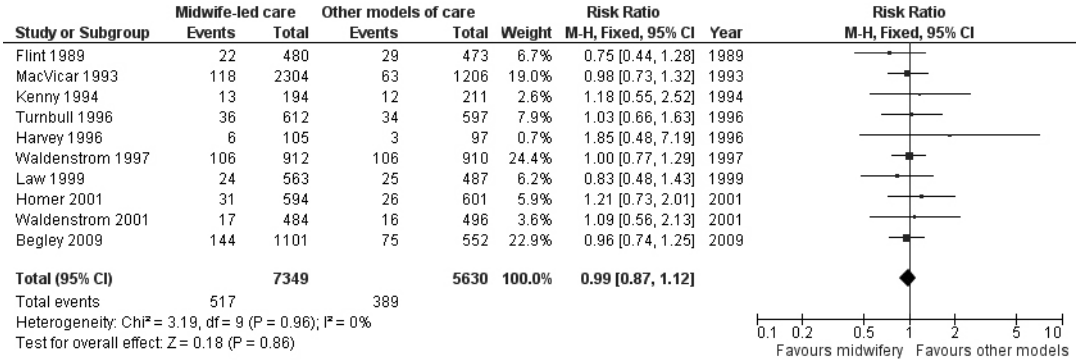


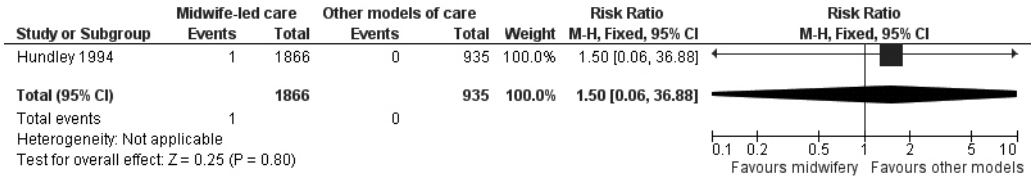
Figure 1.24:
Forest plot of comparison:
Postpartum haemorrhage



Study or Subgroup	Midwife-led care Events	Total	Other models of care Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI	Year
Flint 1989	22	480	29	473	6.7%	0.75 [0.44, 1.28]	1989
MacVicar 1993	118	2304	63	1206	19.0%	0.98 [0.73, 1.32]	1993
Kenny 1994	13	194	12	211	2.6%	1.18 [0.55, 2.52]	1994
Turnbull 1996	36	612	34	597	7.9%	1.03 [0.66, 1.63]	1996
Harvey 1996	6	105	3	97	0.7%	1.85 [0.48, 7.19]	1996
Waldenstrom 1997	106	912	106	910	24.4%	1.00 [0.77, 1.29]	1997
Law 1999	24	563	25	487	6.2%	0.83 [0.48, 1.43]	1999
Homer 2001	31	594	26	601	5.9%	1.21 [0.73, 2.01]	2001
Waldenstrom 2001	17	484	16	496	3.6%	1.09 [0.56, 2.13]	2001
Begley 2009	144	1101	75	552	22.9%	0.96 [0.74, 1.25]	2009
Total (95% CI)		**7349**		**5630**	**100.0%**	**0.99 [0.87, 1.12]**	
Total events	517		389				

Heterogeneity: Chi² = 3.19, df = 9 (P = 0.96); I² = 0%
Test for overall effect: Z = 0.18 (P = 0.86)

Figure 1.25:
Forest plot of comparison:
Maternal death

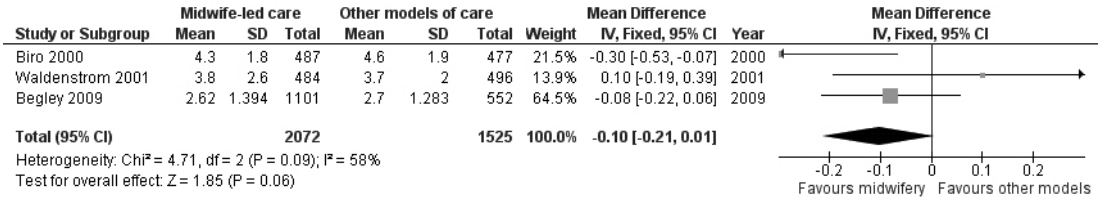


Study or Subgroup	Midwife-led care Events	Total	Other models of care Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Hundley 1994	1	1866	0	935	100.0%	1.50 [0.06, 36.88]
Total (95% CI)		**1866**		**935**	**100.0%**	**1.50 [0.06, 36.88]**
Total events	1		0			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.25 (P = 0.80)

1.3.4.4 Postnatal

Figure 1.26:
Forest plot of comparison:
Duration of postnatal hospital stay



Study or Subgroup	Midwife-led care Mean	SD	Total	Other models of care Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI	Year
Biro 2000	4.3	1.8	487	4.6	1.9	477	21.5%	-0.30 [-0.53, -0.07]	2000
Waldenstrom 2001	3.8	2.6	484	3.7	2	496	13.9%	0.10 [-0.19, 0.39]	2001
Begley 2009	2.62	1.394	1101	2.7	1.283	552	64.5%	-0.08 [-0.22, 0.06]	2009
Total (95% CI)			**2072**			**1525**	**100.0%**	**-0.10 [-0.21, 0.01]**	

Heterogeneity: Chi² = 4.71, df = 2 (P = 0.09); I² = 58%
Test for overall effect: Z = 1.85 (P = 0.06)

Figure 1.27:
Forest plot of comparison:
Postpartum depression

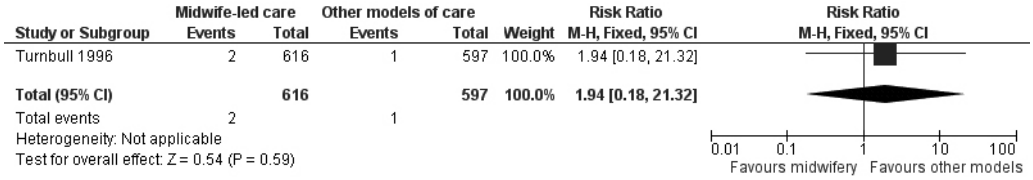


Figure 1.28:
Forest plot of comparison:
Breastfeeding initiation

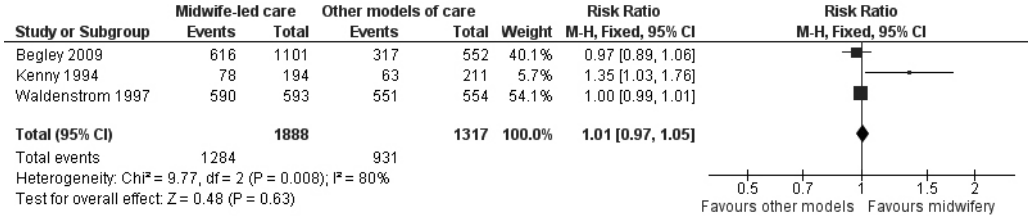
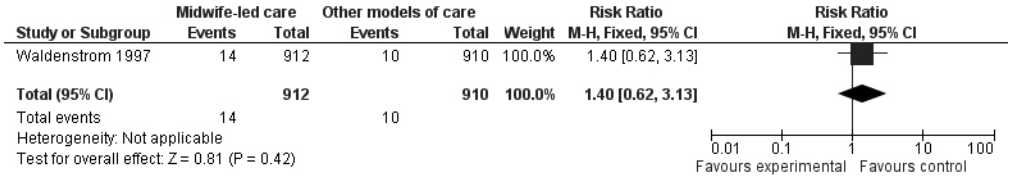


Figure 1.29:
Forest plot of comparison:
Prolonged backache



1.3.4.5 Neonatal

Figure 1.30:
Forest plot of comparison:
Length of neonatal hospital stay

Study or Subgroup	Midwife-led care Mean	SD	Total	Other models of care Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI	Year
Biro 2000	6.8	0.5	89	8.8	0.5	86	91.5%	-2.00 [-2.15, -1.85]	2000
Waldenstrom 2001	11.1	23.2	48	17.2	34	36	0.0%	-6.10 [-19.00, 6.80]	2001
Begley 2009	3.2	4.949	1101	3.18	4.665	552	8.5%	0.02 [-0.47, 0.51]	2009
Total (95% CI)			**1238**			**674**	**100.0%**	**-1.83 [-1.97, -1.69]**	

Heterogeneity: Chi² = 60.97, df = 2 (P < 0.00001); I² = 97%
Test for overall effect: Z = 25.29 (P < 0.00001)

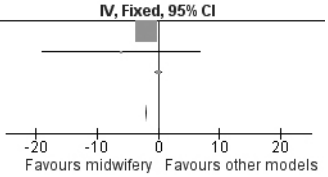


Figure 1.31:
Forest plot of comparison:
Low birth weight

Study or Subgroup	Midwife-led care Events	Total	Other models of care Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI	Year
Flint 1989	31	488	38	479	14.2%	0.80 [0.51, 1.27]	1989
MacVicar 1993	112	2304	59	1206	28.8%	0.99 [0.73, 1.35]	1993
Rowley 1995	28	398	24	413	8.7%	1.21 [0.71, 2.05]	1995
Turnbull 1996	46	613	44	603	16.5%	1.03 [0.69, 1.53]	1996
Waldenstrom 1997	10	933	12	933	4.5%	0.83 [0.36, 1.92]	1997
North Stafford 2000	52	770	51	735	19.4%	0.97 [0.67, 1.41]	2000
Begley 2009	29	1101	16	552	7.9%	0.91 [0.50, 1.66]	2009
Total (95% CI)		**6607**		**4921**	**100.0%**	**0.97 [0.83, 1.15]**	
Total events	308		244				

Heterogeneity: Chi² = 1.63, df = 6 (P = 0.95); I² = 0%
Test for overall effect: Z = 0.32 (P = 0.75)

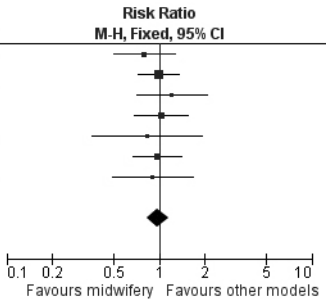


Figure 1.32:
Forest plot of comparison:
Preterm birth (< 37 weeks)

Study or Subgroup	Midwife-led care Events	Total	Other models of care Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI	Year
MacVicar 1993	110	2304	70	1206	29.1%	0.82 [0.61, 1.10]	1993
Hundley 1994	48	1866	27	935	11.4%	0.89 [0.56, 1.42]	1994
Rowley 1995	52	398	54	413	16.8%	1.00 [0.70, 1.43]	1995
Turnbull 1996	30	613	42	603	13.4%	0.70 [0.45, 1.11]	1996
Biro 2000	36	500	42	493	13.4%	0.85 [0.55, 1.30]	2000
Waldenstrom 2001	16	486	12	500	3.7%	1.37 [0.66, 2.87]	2001
Begley 2009	86	1101	29	552	12.2%	1.49 [0.99, 2.24]	2009
Total (95% CI)		**7268**		**4702**	**100.0%**	**0.95 [0.81, 1.11]**	
Total events	378		276				

Heterogeneity: Chi² = 8.64, df = 6 (P = 0.19); I² = 31%
Test for overall effect: Z = 0.68 (P = 0.50)

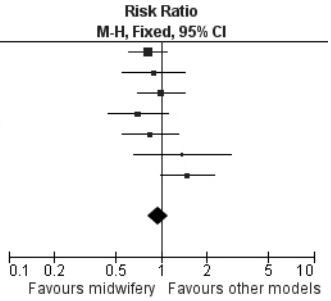


Figure 1.33:
Forest plot of comparison:
5-minute Apgar score below or equal to 7

Study or Subgroup	Midwife-led care Events	Total	Other models of care Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI	Year
Flint 1989	17	480	6	476	5.4%	2.81 [1.12, 7.06]	1989
Chambliss 1992	1	234	0	253	0.4%	3.24 [0.13, 79.21]	1992
Kenny 1994	7	197	1	214	0.9%	7.60 [0.94, 61.25]	1994
Rowley 1995	6	398	7	413	6.1%	0.89 [0.30, 2.62]	1995
Harvey 1996	4	105	4	97	3.7%	0.92 [0.24, 3.59]	1996
Turnbull 1996	24	613	38	603	34.1%	0.62 [0.38, 1.02]	1996
Waldenstrom 1997	11	933	10	936	8.9%	1.10 [0.47, 2.59]	1997
Law 1999	0	563	1	487	1.4%	0.29 [0.01, 7.06]	1999
Biro 2000	13	500	11	493	9.9%	1.17 [0.53, 2.58]	2000
Byrne 2000	2	100	1	100	0.9%	2.00 [0.18, 21.71]	2000
Waldenstrom 2001	9	486	7	500	6.1%	1.32 [0.50, 3.52]	2001
Homer 2001	12	597	13	608	11.5%	0.94 [0.43, 2.04]	2001
Begley 2009	10	1101	9	552	10.7%	0.56 [0.23, 1.36]	2009
Total (95% CI)		**6307**		**5732**	**100.0%**	**1.01 [0.79, 1.31]**	
Total events	116		108				

Heterogeneity: Chi² = 15.67, df = 12 (P = 0.21); I² = 23%
Test for overall effect: Z = 0.11 (P = 0.91)

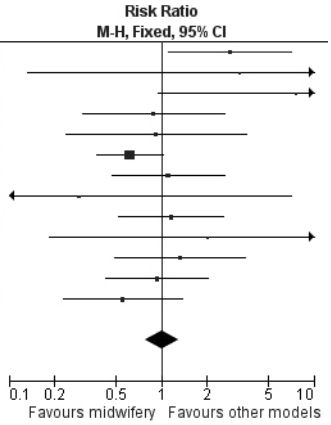


Figure 1.34:
Forest plot of comparison:
Admission to special care/neonatal intensive care unit

Study or Subgroup	Midwife-led care Events	Total	Other models of care Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI	Year
Flint 1989	23	485	21	478	3.0%	1.08 [0.61, 1.92]	1989
MacVicar 1993	31	2304	20	1206	3.8%	0.81 [0.46, 1.42]	1993
Hundley 1994	143	1866	67	935	12.8%	1.07 [0.81, 1.41]	1994
Kenny 1994	15	197	33	214	4.5%	0.49 [0.28, 0.88]	1994
Rowley 1995	17	398	20	413	2.8%	0.88 [0.47, 1.66]	1995
Harvey 1996	8	105	18	97	2.7%	0.41 [0.19, 0.90]	1996
Turnbull 1996	56	613	58	603	8.4%	0.95 [0.67, 1.35]	1996
Waldenstrom 1997	102	933	83	936	11.9%	1.23 [0.94, 1.62]	1997
Law 1999	7	563	10	487	1.5%	0.61 [0.23, 1.58]	1999
North Stafford 2000	45	770	34	735	5.0%	1.26 [0.82, 1.95]	2000
Biro 2000	89	492	87	481	12.6%	1.00 [0.77, 1.31]	2000
Homer 2001	80	597	102	608	14.5%	0.80 [0.61, 1.05]	2001
Waldenstrom 2001	48	486	36	500	5.1%	1.37 [0.91, 2.07]	2001
Begley 2009	128	1101	60	552	11.5%	1.07 [0.80, 1.43]	2009
Total (95% CI)		**10910**		**8245**	**100.0%**	**0.99 [0.90, 1.09]**	
Total events	792		649				

Heterogeneity: Chi² = 21.18, df = 13 (P = 0.07); I² = 39%
Test for overall effect: Z = 0.19 (P = 0.85)

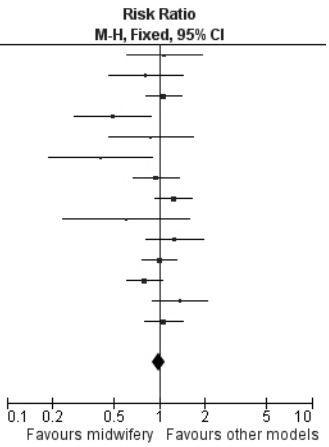
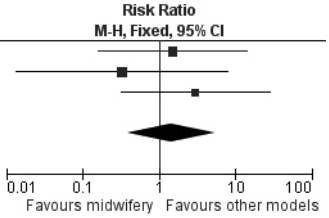


Figure 1.35:
Forest plot of comparison:
Neonatal convulsions

Study or Subgroup	Midwife-led care Events	Total	Other models of care Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Begley 2009	3	1101	1	552	34.7%	1.50 [0.16, 14.43]
Turnbull 1996	0	613	1	603	39.4%	0.33 [0.01, 8.03]
Waldenstrom 1997	3	933	1	936	26.0%	3.01 [0.31, 28.88]
Total (95% CI)		**2647**		**2091**	**100.0%**	**1.43 [0.38, 5.34]**
Total events	6		3			

Heterogeneity: Chi² = 1.23, df = 2 (P = 0.54); I² = 0%
Test for overall effect: Z = 0.53 (P = 0.59)



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