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Care prior to and during subsequent pregnancies following stillbirth for improving outcomes

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To assess the effects of different interventions or models of care prior to and during subsequent pregnancies following stillbirth on maternal, fetal, neonatal and family health outcomes, and health service utilisation.

BACKGROUND

Description of the condition

Stillbirth is a devastating event with enduring psychosocial consequences for parents, including anxiety and depression, guilt, complicated grief, social isolation, and relationship breakdown (Heazell 2016). Stillbirth also has profound economic impacts on parents, families, and the wider community (Heazell 2016; Ogwulu 2015). Globally, around 2.6 million babies are stillborn in the third trimester each year (Lawn 2016). While data-capture issues persist in many parts of the world, it is known that the vast majority of these deaths (98%) occur in low- and middle-income countries, and that over 40% occur in the intrapartum period - often associated with obstetric emergencies (Lawn 2016). Wide variation exists across and within countries, with stillbirth rates estimated to be below five per 1000 births in some high-income countries (Flenady 2016), compared with approximately 32 per 1000 in sub-Saharan Africa and South Asia (Lawn 2016).
There are many maternal and fetal conditions potentially associated with stillbirth. These conditions often co-exist, and include maternal infections, non-communicable diseases, nutrition and lifestyle factors, malaria, fetal growth restriction and advanced maternal age (Lawn 2016). In low- and middle-income countries,

limited access to skilled birth attendants and low rates of caesarean section are also believed to be important. Maternal undernutrition is prevalent in many low-income countries, and contributes to various adverse pregnancy outcomes including fetal growth restriction (Black 2008a), which is an important risk factor for stillbirth. In high-income countries, common risk factors for stillbirth include maternal overweight and obesity, advanced maternal age, primiparity and smoking (Flenady 2011).

A recent systematic review of stillbirth recurrence in high-income countries including over three million women, reported an almost five-fold increase in risk of stillbirth in the pregnancy following stillbirth from all causes (Lamont 2015). However, predicting recurrence risk in a specific pregnancy is difficult, as the risk depends on a variety of factors, particularly the aetiology of the index stillbirth. Where the death was related to placental insufficiency or a pre-existing maternal condition, the recurrence risk is likely to be higher. Conversely, recurrence is unlikely for isolated events, such as maternal injury leading to placental abruption (Robson 2001). When the cause of stillbirth is unexplained, the risk of recurrence is unclear (Lamont 2015). It is possible that recurrence following truly unexplained stillbirth is no higher than that of the general population (Onwude 2006; Robson 2001). While this may be reassuring for some women and their families, a history of stillbirth has been shown to be associated with higher frequencies of other complications in the next pregnancy, including increased rates of induced labour, elective and emergency caesarean birth, instrumental birth and other adverse outcomes, such as preterm birth, low birthweight, placental abruption, pre-eclampsia, gestational diabetes (Black 2008b; Heinonen 2000; Robson 2001), chorioamnionitis, and neonatal death (Getahun 2009). Some of these outcomes may be in part due to care providers' and women's hypervigilance rather than inherent biological risk (Robson 2006). Previous stillbirth is also commonly associated with intense anxiety and fear in the next pregnancy, with some women feeling a lack of confidence in their capacity to maintain a healthy pregnancy (Mills 2014). The fear of experiencing another loss may further increase risk, as stress during pregnancy has been associated with adverse pregnancy outcomes, such as preterm birth (Van den Bergh 2005) and low birthweight (Baibazarova 2013; Su 2015; Van den Bergh 2005), possibly mediated by placental function (O'Donnell 2009). Anxiety and fear may also prompt some parents to refrain from attachment to their baby (Mills 2014). Disorganised attachment has been observed in infants born subsequent to stillbirth, which may in turn increase these infants' risk of psychological and behavioural problems in childhood (Hughes 2001).

The global reduction in stillbirth rates has not matched that for maternal or neonatal mortality (Lawn 2016). A persisting issue facing providers of maternity care is therefore how to manage the next and subsequent pregnancies after a woman and her family experience a stillbirth. An Australian study of women who experienced an unexplained stillbirth found that women wanted high levels of surveillance and early birth in their next pregnancy (Robson 2009). Similarly, a survey of Australian obstetricians found that many health professionals were likely to recommend close surveillance and early delivery (Robson 2006). While early birth has some potential to reduce the rate of stillbirth, it may also be associated with iatrogenic (caused by treatment or diagnostic procedures) complications as alluded to earlier, including prematurity (and its associated adverse outcomes), failed induction, instrumental birth, emergency caesarean birth and postpartum haemorrhage (Paull 2013).

Description of the intervention

The care and management of women in the next and subsequent pregnancies following stillbirth may be different to the care of women who have never been pregnant, or who have never had a complicated pregnancy. It is possible that a number of management decisions will be required; some guided by causes, circumstances or risk factors associated with the prior stillbirth (Monari 2010; Paull 2013; Reddy 2007; Robson 2010; Saade 2011). Therefore, while individual interventions may be assessed to care for women in the next and subsequent pregnancies following stillbirth, it is also likely that interventions assessed may include the use of different management algorithms, protocols, guidelines, or models of care, combining multiple interventions in order to optimise care and improve outcomes.

Care prior to subsequent pregnancies might first focus on counselling on stillbirth recurrence risk for parents considering a subsequent pregnancy after stillbirth, to provide information and decision-making support on:

- interpregnancy interval; pre-conception health.

Alternatively, or in addition, care prior to or during subsequent pregnancies might focus on managing/addressing specific defined causes and/or circumstances of the index stillbirth, such as interventions to treat, manage or address:

- diabetes; hypertensive disorders; thyroid disorders; acquired or inherited thrombophilia; systemic lupus erythematosus; blood group antibodies; hyperhomocysteinaemia; chronic infectious conditions (toxoplasmosis, syphilis); periodontal disease; preterm labour; and cervical insufficiency.

Care could also be focused on addressing the presence of modifiable high-risk behaviours or risk factors, such as interventions to reduce:

- obesity; smoking; alcohol use.

In the case of unexplained stillbirth and also where causes, circumstances or risk factors have been identified, care may focus on fetal surveillance and timing and mode of birth, such as:

- maternal assessment of fetal movements; regular non-stress testing; early and/or regular ultrasound surveillance (to assess fetal growth, placental size or structure amniotic fluid index, Doppler assessment of uterine or umbilical flow); and/or

- elective induction of labour; elective caesarean birth; early birth; intrapartum monitoring.

Care prior to or during subsequent pregnancies might also focus on specific psychosocial needs, such as:

- specialised antenatal classes for bereaved parents; peer-support programs and grief counselling; and additional antenatal visits and/or therapies to address anxiety, depression, and maternal-infant attachment.

How the intervention might work

Interventions for care prior to and during subsequent pregnancies following stillbirth are likely to be highly diverse, addressing a range of risk factors, conditions, and aspects of care. First, counselling on stillbirth recurrence risk may facilitate informed decision-making for parents considering a pregnancy subsequent to stillbirth (Paull 2013). Such counselling may include information on interpregnancy interval, preconception-health, and the costs and benefits of delaying a subsequent pregnancy in each unique case. For some parents, delaying conception may enable additional time to deal with grief before entering another pregnancy, and may reduce anxiety in the subsequent pregnancy (Davis 1989; Hughes 1999). For women who do become pregnant, understanding the cause of the index stillbirth (if known) will enable the development of an individualised management plan in the subsequent pregnancy to directly address the cause and therefore reduce the likelihood of recurrence. For pre-existing maternal conditions that are likely to recur (e.g. diabetes), stabilisation of the condition may reduce stillbirth recurrence risk. Cessation of smoking and pre-conception interventions addressing maternal overweight and obesity may also reduce risk (Monari 2010). Where no cause of death for the index stillbirth has been identified, frequent monitoring may enable early detection of developing complications and may prompt expedited birth where appropriate (Robson 2010). Interventions designed to improve maternal mental health may reduce stress in pregnancy, lessening the likelihood of adverse effects such as low birthweight and preterm birth, while also enhancing maternal-fetal attachment. Additional antenatal visits, for example, may provide parents with more opportunities for reassurance, and have been welcomed by parents in pregnancies subsequent to stillbirth or neonatal death (Mills 2014).

Why it is important to do this review

Despite the known stillbirth recurrence risk and far-reaching impacts of stillbirth on subsequent pregnancies and beyond, there is a paucity of information on care prior to and during these pregnancies to improve health outcomes. Women pregnant subsequent to stillbirth comprise a small but unique group who require specialised and individualised care both clinically and psychosocially.

OBJECTIVES

To assess the effects of different interventions or models of care prior to and during subsequent pregnancies following stillbirth on maternal, fetal, neonatal and family health outcomes, and health service utilisation.

METHODS

Criteria for considering studies for this review

Types of studies

We plan to include randomised controlled trials, quasi-randomised controlled trials and cluster-randomised trials. Cross-over trials will be excluded. We plan to include studies published as abstract only, provided there is sufficient information to allow us to assess study eligibility and risk of bias.

Types of participants

Women who have experienced a stillbirth of 20 weeks' gestation or more who are pregnant or considering attempting a subsequent pregnancy.

Types of interventions

We will include any single intervention, combination of interventions or tailored model of care/algorithm/guideline/protocol for improving health outcomes in subsequent pregnancies following stillbirth, compared with no intervention or standard care.

We will also include studies where one intervention/combination of interventions/tailored model of care is compared with another. Interventions may include, for example, targeted management to address previous causes or circumstances of prior stillbirth (e.g. diabetes, hypertensive disorders); care to address high-risk behaviours/risk factors (e.g. obesity, smoking); care focused on fetal surveillance and timing and mode of birth; and care to address specific psychosocial needs (See above Description of the intervention for further details).

We will include studies where the intervention/model of care commenced pre-pregnancy, in early pregnancy, late pregnancy or during birth.

Types of outcome measures

The following outcomes will be assessed.

Primary outcomes

- Stillbirth
- Neonatal death
- Adverse perinatal outcome (composite outcome including stillbirth, neonatal death, and major neonatal morbidity)
- Adverse maternal psychological effects (anxiety and/or depression/complicated grief)

Secondary outcomes

Fetal, neonatal and childhood outcomes

- Perinatal mortality
- Preterm birth (any preterm birth; very preterm birth; late preterm birth)
- Birthweight, low birthweight, small-for-gestational age
- Apgar score less than seven at five minutes
- Respiratory distress syndrome
- Neonatal jaundice
- Psychological and behavioural problems in childhood
- Anxiety and/or depression in childhood
- Long-term neurodevelopmental and educational outcomes
- Quality of life

Maternal outcomes

- Adherence with the intervention (process outcomes) (i.e. smoking cessation; lifestyle changes - changes in diet, physical activity, weight loss) (pre-pregnancy and during pregnancy)
- Caesarean birth (elective; emergency)
- Induction of labour
- Instrumental vaginal birth
- Placental abruption
- Pre-eclampsia
- Gestational diabetes
- Chorioamnionitis
- Postpartum haemorrhage
- Satisfaction with care
- Serious maternal outcome (death; cardiac arrest; respiratory arrest; admission to intensive care)
- Breastfeeding
- Maternal-infant attachment
- Quality of life

Health service utilisation

- Antenatal care attendance
- Maternal antenatal admission
- Duration of maternal hospital stay (days)
- Duration of neonatal hospital stay (days)
- Admission to the neonatal intensive care unit
- Duration of neonatal intensive care unit stay (days)
- Antenatal ultrasound scans
- Cost

Other outcomes

- Partner anxiety and/or depression/complicated grief
- Partner quality of life
- Relationship breakdown/disharmony

Search methods for identification of studies

The following methods section of this protocol is based on a standard template used by the Cochrane Pregnancy and Childbirth Group.

Electronic searches

We will search the Cochrane Pregnancy and Childbirth Group's Trials Register by contacting their Information Specialist.
The Register is a database containing over 21,000 reports of controlled trials in the field of pregnancy and childbirth. For full search methods used to populate the Pregnancy and Childbirth Group's Trials Register including the detailed search strategies for CENTRAL, MEDLINE, Embase and CINAHL; the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service, please follow this link to the editorial information about the Cochrane Pregnancy and Childbirth Group in the Cochrane Library and select the '***Specialized Register***' section from the options on the left side of the screen.
Briefly, the Cochrane Pregnancy and Childbirth Group's Trials Register is maintained by their Information Specialist and contains trials identified from:

1. monthly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);
2. weekly searches of MEDLINE (Ovid);
3. weekly searches of Embase (Ovid);
4. monthly searches of CINAHL (EBSCO);
5. handsearches of 30 journals and the proceedings of major conferences;
6. weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts.

Search results are screened by two people and the full text of all relevant trial reports identified through the searching activities described above is reviewed. Based on the intervention described, each trial report is assigned a number that corresponds to a specific Pregnancy and Childbirth Group review topic (or topics), and is then added to the Register. The Information Specialist searches the Register for each review using this topic number rather than keywords. This results in a more specific search set that will be fully

accounted for in the relevant review sections (Included, Excluded, Awaiting Classification or Ongoing).
In addition, we will search ClinicalTrials.gov and the WHO International Clinical Trials Registry Platform (ICTRP) for unpublished, planned and ongoing trial reports using the term 'stillbirth'.

Searching other resources

We will search the reference lists of retrieved studies.
We will not apply any language or date restrictions.

Data collection and analysis

The following methods will be used for assessing studies identified by the search.

Selection of studies

Two review authors will independently assess for inclusion all the potential studies we identify as a result of the search strategy. We will resolve any disagreement through discussion or, if required, we will consult a third author.
We will create a Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) study flow diagram to map out the number of records identified, included and excluded (Liberati 2009).

Data extraction and management

A purpose-built electronic form will be designed to manage data extraction. For eligible studies, two review authors will extract the data using the agreed form. Discrepancies will be resolved through discussion or, if required, referred to a third author. We will enter data into Review Manager software (RevMan 2014) and check for accuracy. When information regarding any of the above is absent or unclear, we will attempt to contact authors of the original reports to provide further details.

Assessment of risk of bias in included studies

Two review authors will independently assess risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We will resolve any disagreement by discussion or by involving a third assessor.
The following domains will be assessed:

(1) Random sequence generation (checking for possible selection bias)

We will describe for each included study the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.
We will assess the method as:

- low risk of bias (any truly random process, e.g. random number table; computer random number generator);
- high risk of bias (any non-random process, e.g. odd or even date of birth; hospital or clinic record number);
- unclear risk of bias.

(2) Allocation concealment (checking for possible selection bias)

We will describe for each included study the method used to conceal allocation to interventions prior to assignment and will assess whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment.
We will assess the methods as:

- low risk of bias (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes);
- high risk of bias (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth);
- unclear risk of bias.

(3.1) Blinding of participants and personnel (checking for possible performance bias)

We will describe for each included study the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. We will consider that studies are at low risk of bias if they were blinded, or if we judge that the lack of blinding would be unlikely to affect results. We will assess blinding separately for different outcomes or classes of outcomes.
We will assess the methods as:

- low, high or unclear risk of bias for participants;
- low, high or unclear risk of bias for personnel.

"Partial" blinding will be noted if identified.

(3.2) Blinding of outcome assessment (checking for possible detection bias)

We will describe for each included study the methods used, if any, to blind outcome assessors from knowledge of which intervention a participant received. We will assess blinding separately for different outcomes or classes of outcomes.
We will assess methods used to blind outcome assessment as:

- low, high or unclear risk of bias.

(4) Incomplete outcome data (checking for possible attrition bias due to the amount, nature and handling of incomplete outcome data)

We will describe for each included study, and for each outcome or class of outcomes, the completeness of data including attrition

and exclusions from the analysis. We will state whether attrition and exclusions were reported and the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information is reported, or can be supplied by the trial authors, we will re-include missing data in the analyses which we undertake.

We will assess methods as:

- low risk of bias (e.g. no missing outcome data; missing outcome data balanced across groups);
- high risk of bias (e.g. numbers or reasons for missing data imbalanced across groups; 'as treated' analysis done with substantial departure of intervention received from that assigned at randomisation);
- unclear risk of bias.

(5) Selective reporting (checking for reporting bias)

We will describe for each included study how we investigated the possibility of selective outcome reporting bias and what we found. We will assess the methods as:

- low risk of bias (where it is clear that all of the study's pre-specified outcomes and all expected outcomes of interest to the review have been reported);
- high risk of bias (where not all the study's pre-specified outcomes have been reported; one or more reported primary outcomes were not pre-specified; outcomes of interest are reported incompletely and so cannot be used; study fails to include results of a key outcome that would have been expected to have been reported);
- unclear risk of bias.

(6) Other bias (checking for bias due to problems not covered by (1) to (5) above)

We will describe for each included study any important concerns we have about other possible sources of bias. We will assess whether each study was free of other problems that could put it at risk of bias:

- low risk of other bias;
- high risk of other bias;
- unclear whether there is risk of other bias.

(7) Overall risk of bias

We will make explicit judgements about whether studies are at high risk of bias, according to the criteria given in the *Handbook* (Higgins 2011). With reference to (1) to (6) above, we will assess the likely magnitude and direction of the bias and whether we consider it is likely to impact on the findings. We will explore the impact of the level of bias through undertaking sensitivity analyses - *see* Sensitivity analysis.

If cluster-randomised controlled trials are identified, risk of bias will be assessed according to the criteria given in the *Handbook* (Higgins 2011).

Assessment of the quality of the evidence using the GRADE approach

Quality of the evidence will be evaluated using the GRADE approach as outlined in the GRADE handbook. The GRADE approach uses five considerations (study limitations, consistency of effect, imprecision, indirectness and publication bias) to assess the quality of the body of evidence for specific outcomes. The evidence can be downgraded from 'high quality' by one level for serious (or by two levels for very serious) limitations, depending on assessments for risk of bias, indirectness of evidence, serious inconsistency, imprecision of effect estimates or potential publication bias. In this review we will use the GRADE approach to assess the following outcomes:

- stillbirth;
- neonatal death;
- perinatal mortality;
- adverse perinatal outcome (composite outcome including stillbirth, neonatal death, and major neonatal morbidity);
- adverse maternal psychological effects (anxiety and/or depression/complicated grief);
- preterm birth (any preterm birth; very preterm birth; late preterm birth);
- maternal-infant attachment.

We will use GRADEpro Guideline Development Tool to import data from Review Manager 5.3 (RevMan 2014) in order to create a 'Summary of findings' table. A summary of the intervention effect and a measure of quality according to the GRADE approach will be presented in a 'Summary of findings' table for each of the above outcomes.

Measures of treatment effect

Dichotomous data

For dichotomous data, we will present results as summary risk ratio with 95% confidence intervals.

Continuous data

For continuous data, we will use the mean difference if outcomes are measured in the same way between trials. We will use the standardised mean difference to combine trials that measure the same outcome, but use different methods.

Unit of analysis issues

Cluster-randomised trials

We will include cluster-randomised trials in the analyses along with individually-randomised trials. We will adjust their sample sizes using the methods described in the *Handbook* (Higgins 2011) using an estimate of the intracluster correlation co-efficient (ICC) derived from the trial (if possible), from a similar trial or from a study of a similar population. If we use ICCs from other sources, we will report this and conduct sensitivity analyses to investigate the effect of variation in the ICC. If we identify both cluster-randomised trials and individually-randomised trials, we plan to synthesise the relevant information. We will consider it reasonable to combine the results from both if there is little heterogeneity between the study designs and the interaction between the effect of intervention and the choice of randomisation unit is considered to be unlikely.

We will also acknowledge heterogeneity in the randomisation unit and perform a sensitivity analysis to investigate the effects of the randomisation unit.

We plan to include multi-armed trials, ensuring analyses are independent. If multi-armed trials are included, we will split the 'shared' group into two or more groups with smaller sample size, and include two or more (reasonably independent) comparisons. Alternatively, we will combine groups to create a single pair-wise comparison.

Cross-over trials

We will exclude cross-over designs as these are unlikely to be a valid study design for Pregnancy and Childbirth reviews.

Dealing with missing data

For included studies, we will note levels of attrition. We will explore the impact of including studies with high levels of missing data in the overall assessment of treatment effect by using sensitivity analysis.

For all outcomes, we will carry out analyses, as far as possible, on an intention-to-treat basis, i.e. we will attempt to include all participants randomised to each group in the analyses, and all participants will be analysed in the group to which they were allocated, regardless of whether or not they received the allocated intervention. The denominator for each outcome in each trial will be the number randomised minus any participants whose outcomes are known to be missing.

Assessment of heterogeneity

We will assess statistical heterogeneity in each meta-analysis using the Tau², I² and Chi² statistics. We will regard heterogeneity as substantial if an I² is greater than 30% and either the Tau² is greater than zero, or there is a low P value (less than 0.10) in the Chi² test for heterogeneity.

Assessment of reporting biases

If there are 10 or more studies in the meta-analysis, we will investigate reporting biases (such as publication bias) using funnel plots. We will assess funnel plot asymmetry visually. If asymmetry is suggested by a visual assessment, we will perform exploratory analyses to investigate it.

Data synthesis

We will carry out statistical analysis using the Review Manager software (RevMan 2014). We will use fixed-effect meta-analysis for combining data where it is reasonable to assume that studies are estimating the same underlying treatment effect: i.e. where trials are examining the same intervention, and the trials' populations and methods are judged sufficiently similar. If there is clinical heterogeneity sufficient to expect that the underlying treatment effects differ between trials, or if substantial statistical heterogeneity is detected, we will use random-effects meta-analysis to produce an overall summary, if an average treatment effect across trials is considered clinically meaningful. The random-effects summary will be treated as the average of the range of possible treatment effects and we will discuss the clinical implications of treatment effects differing between trials. If the average treatment effect is not clinically meaningful, we will not combine trials.

If we use random-effects analyses, the results will be presented as the average treatment effect with 95% confidence intervals, and the estimates of Tau² and I².

Subgroup analysis and investigation of heterogeneity

If we identify substantial heterogeneity, we will investigate it using subgroup analyses. We will perform subgroup analyses, where possible, for the following subgroups:

- cause(s) of previous stillbirth: known recurrent cause(s) versus known non-recurrent cause(s) versus unexplained stillbirth;
- setting: low- or middle-income country versus high-income country;
- psychosocial support: included in intervention versus not included (for interventions not primarily focused on psychosocial support);
- timing of commencement or duration of the intervention: pre-pregnancy versus during pregnancy versus during delivery.

Subgroup analyses will be limited to the primary outcomes.

We will consider whether an overall summary is meaningful, and if it is, use random-effects analysis to produce it. We will assess subgroup differences by interaction tests available within RevMan

(RevMan 2014). We will report the results of subgroup analyses quoting the Chi² statistic and P value, and the interaction test I^2 value.

Sensitivity analysis

We will carry out sensitivity analyses to explore the effects of high attrition rates with studies showing attrition greater than 20% excluded from the analyses in order to assess whether this makes any difference to the overall result. We will also carry out sensitivity analyses to explore the effect of trial quality (including for quasi-randomised trials), assessed by random-sequence generation and concealment of allocation, with studies assessed as high or unknown risk of bias on these domains being excluded from the analyses. Where ICCs are used, we will carry out sensitivity analyses to explore the effects of variation in ICC values and in the randomisation unit (i.e. individual versus cluster). Sensitivity analyses will be limited to the primary outcomes.

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* *Indicates the major publication for the study*

CONTRIBUTIONS OF AUTHORS

Vicki Flenady, Philippa Middleton, and Aleena Wojcieszek designed the review with contribution from all authors. Aleena Wojcieszek led the drafting of the protocol with contribution from Emily Shepherd, Vicki Flenady and Philippa Middleton. Philippa Middleton, Vicki Flenady, Emily Bain and Zohra Lassi provided a methodological perspective, David Ellwood and Alexander Heazell provided a clinical perspective (obstetrics), Trish Wilson provided a clinical perspective (midwifery).

DECLARATIONS OF INTEREST

Aleena M Wojcieszek: none known

Emily Bain: none known

Philippa Middleton: none known

Zohra S Lassi: none known

Trish Wilson: none known

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Vicki Flenady: none known

David Ellwood has received sitting fees from the Australian Medical Council but this work is not related to this Cochrane review. He has received payment for providing expert witness reviews for medico-legal cases - these cases are in no way related to the topic under review. He has also applied for an NHMRC Centre for Research Excellence award - this centre is related to stillbirth and will cover all aspects of research on this topic.

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External sources

- National Health and Medical Research Council (NHMRC), Australia.