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The methodological challenges of attempting to compare the safety of home and hospital birth in terms of the risk of perinatal death

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ABSTRACT

This paper identifies a number of methodological difficulties associated with the comparison of home and hospital birth in terms of the risk of perinatal death, and suggests ways in which these problems can be overcome. A review of recent studies suggests that most available data sources are unable to overcome all of these challenges, which is one of the reasons why the debate about whether perinatal death is more likely if a home birth is planned or if a hospital birth is planned has not been satisfactorily resolved. We argue that the debate will be settled only if perinatal mortality data from a sufficiently large number of maternity care providers over a sufficiently long period of time can be pooled and made available for analysis. The pooling of data will bring about its own difficulties due to variations over time and between providers and geographical areas, which would need to be taken into account when analysing pooled data. However, given the impracticality of a randomised controlled trial and the rarity of home birth in most of the Western world, we argue that more effort should be made to pool data for perinatal mortality and other rare pregnancy outcomes, and share them between health providers and researchers. Thus, high-quality analyses could be conducted, allowing all women to make an informed choice about place of birth. However, pooling data from countries or states with very different maternity care systems should be avoided.

Introduction

Previous research indicates that home birth is of interest to a significant number of women (Department of Health, 1993; Singh and Newburn, 2000), and in areas where maternity care providers make home birth a realistic option, take-up is high (Leap, 1996; Nixon et al., 2003; Leyshon, 2004). Despite this, in most developed countries, the percentage of births taking place at home has changed little in the last 20 years, and very few women in developed countries actually have planned home births. For example, Li et al. (2011) noted that just 0.3% of births in Australia took place at home, and Hutton et al. (2009) reported that 1.6% of births in Ontario, Canada took place at home. In the USA, Martin et al. (2011) reported that 0.7% of births took place at home, but noted that the percentage is beginning to increase in many states. England and Wales are unusual in that there has been a slow but steady increase in the proportion of births taking place at home since the 1980s (Nove et al., 2008), but the proportion currently stands at just 2.7% (Office for National Statistics, 2010), and is showing a small decline for the first time since the 1980s. The Netherlands is the only developed country in which a significant proportion (about 30%) of women give birth at home, but this figure has been in decline since the 1960s (de Jonge et al., 2009).

To some extent, the low incidence of planned home birth in most developed countries may be due to women not being offered the option of a home birth, but there is evidence to suggest that, even when home birth is offered, women tend not to feel equipped to make an informed choice (Care Quality Commission, 2010). This is due in no small part to the lack of reliable, objective evidence about whether or not planned home birth is safe (National Collaborating Centre for Women's and Children's Health, 2007).

In many developed countries, the debate over the relative safety of home and hospital birth has been a long-running, highly emotive and polarised one, involving power struggles, gender politics and workplace politics. For example, the debate in the UK is well summarised by Campbell and Macfarlane (1994), Kirkham and Stapleton (2004), and Kitzinger (2005). Proponents of home birth argue that a planned home birth attended by a competent midwife can maximise the chances of a normal birth and minimise the chances of the birth being a traumatic experience.

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The underlying attitude here is that childbirth is a physiological process which is most likely to go smoothly in an environment where the woman feels relaxed, safe, secure and in control. Proponents of hospital birth argue that, because there is always the potential for unforeseen complications, women should deliver in hospital so that they are close to emergency facilities should the need arise. The underlying attitude is that childbirth is an event that must be closely managed due to the possibility of pathology.

Mortality is perhaps the ultimate yardstick by which safety is measured; unlike most other indicators of safety, mortality is both irreversible and objectively measurable. A fair and robust comparison in terms of perinatal mortality rates is, therefore, the 'holy grail' of those who wish to compare the safety of different birth settings. Studies which make comparisons between birth settings in relation to other outcomes and/or composite outcome variables will leave important questions unanswered.

It is generally accepted that a randomised controlled trial (RCT) would be impossible for this research question, because most women would be unwilling to be assigned randomly to a particular birth setting (Hendrix et al., 2009). We are therefore reliant on observational studies to compare the safety of home and hospital birth. Such studies have claimed that planned home birth is associated with a number of benefits to the labouring woman (Chamberlain et al., 1997; RCOG/RCM, 2007; Birthplace in England Collaborative Group, 2011), and several studies from developed countries have suggested that, for 'low-risk' pregnancies, planned home birth is not associated with increased risk to the safety of the baby (Johnson and Daviss, 2005; Lindgren et al., 2008; de Jonge et al., 2009; Hutton et al., 2009; Janssen et al., 2009). On the other hand, some recent studies have concluded that, whilst home birth is safe in most cases, under some circumstances (e.g. if the mother has not given birth before or the pregnancy is 'high-risk') there is an increased risk of a negative perinatal outcome such as perinatal death or birth injury if the mother attempts a home birth (Pang et al., 2002; Kennare et al., 2010; Birthplace in England Collaborative Group, 2011).

Numerous methodological challenges are inherent in such studies, and most studies have fundamental flaws, with the result that proponents of hospital birth tend to dismiss the findings of research showing that babies whose mothers planned a home birth are at no higher risk of negative perinatal outcomes than babies whose mothers planned a hospital birth, and proponents of home birth tend to dismiss the findings of research showing that home birth is less safe than hospital birth. The contradictory evidence has resulted in a long-running and unresolved debate about the safety of planned home birth, with maternity care providers and pregnant women often unable to make sense of the conflicting findings.

This paper has been produced by researchers who have recently attempted to compare home and hospital birth in terms of the risk of perinatal death, using the North-west Thames database from England (National Centre for Health Outcomes Development, 2011). We discuss ten methodological challenges (see Box 1), suggest how these can be overcome, and set out a number of 'essentials' which must be in place before firm conclusions can be drawn from a study of the safety of planned home birth. This paper will be useful for anyone who wishes to design such a study, and for those asked to review research papers on this topic. Ultimately, we hope it will help to ensure that future generations of childbearing women have access to informed choice on a subject that is important to them (Rogers et al., 2005).

Box 1–The ten methodological challenges discussed in this paper.

1. Whether or not to include high-risk pregnancies.
2. Whether intrapartum transfers from home to hospital should be classified as 'home births' or 'hospital births'.
3. Accurately recording intended place of birth.
4. Avoiding bias due to deaths which would have occurred regardless of place of birth.
5. The rarity of planned home birth and perinatal death in most developed countries.
6. Separate analysis of different types of hospital birth.
7. Controlling for confounding.
8. Differentiating between confounders and mediators.
9. Whether the overall result masks any sub-group variations.
10. Pooling data from different countries.

Challenges inherent when comparing different birth settings in terms of the incidence of perinatal death

1. *Should comparative analysis include high-risk pregnancies?*
   Research into the comparative safety of different birth settings tends to include only low-risk pregnancies, on the grounds that women with 'high-risk' pregnancies tend to be directed into hospital, so there should be few, if any, 'high-risk' pregnancies among those who plan a home birth. For this reason, and because it is generally assumed that 'high-risk' women should not attempt a home birth, the safety of planned home birth for 'high-risk' women is rarely given any consideration. However, there is evidence to indicate that some women with 'high-risk' pregnancies do plan to give birth at home. In the North-west Thames database, 11% ($n=658$) of the planned home births would have been classed as 'high-risk' under the English 2007 guideline (Nove, 2011), and research using more recent data indicates that this practice still occurs (Symon et al., 2010). The fact that women with 'high-risk' pregnancies do sometimes plan a home birth raises the question of whether it is appropriate to exclude 'high-risk' pregnancies from a study of the comparative safety of different birth settings. If a significant number of women with 'high-risk' pregnancies have a preference for home birth, it would be helpful for them to have some empirical evidence (as opposed to opinion) about whether planned home birth is associated with a significantly higher risk of a negative pregnancy outcome for them. Researchers must be clear from the outset about whether or not their study will include 'high-risk' pregnancies, and this decision should be justified based on sound methodological principles and/or research evidence rather than assumptions.
   Whether or not 'high-risk' pregnancies are included in the comparison, it is imperative that the risk status of each pregnancy is defined objectively and in the same way regardless of intended place of birth. This will allow the researchers either to ensure that the 'home' and 'hospital' groups are directly comparable in terms of risk status, or to control for the fact that the hospital group will contain a higher proportion of high-risk pregnancies than the home group. This task is complicated by the fact that there is no universally accepted definition of the term 'high-risk' as it relates to pregnancy. National clinical guidelines on pregnancy risk classification and place of birth apply in two countries: the Netherlands (Obstetric Working Group of the National Health Insurance Board of the Netherlands, 2000) and England (National Collaborating Centre for Women's and Children's Health, 2007). Research conducted in countries without such a guideline must be extremely careful to ensure that pregnancy risk status is defined objectively and in the same way for home and hospital births, and that the method used is described and justified when the results are presented. The process of risk classification is further complicated by the fact that pregnancy risk status can change over the course of an

individual pregnancy, e.g. a 'low-risk' pregnancy may become 'high-risk' if the woman develops a condition such as pre-eclampsia. There must, therefore, be a reliable system for ensuring that pregnancies are classified according to their risk status at the start of labour. Even then, there will be some pregnancies which are 'high-risk' but not diagnosed as such at the start of labour, e.g. undiagnosed breech presentation. These cases must be also identified and analysed appropriately if they are not to introduce bias to the results.

2. *How should intrapartum transfers be classified?*
   If a woman attempts a home birth but experiences labour complications, she will usually be advised to transfer to hospital for the delivery. If the baby is born at home, therefore, in most cases labour and delivery will have been straightforward. A comparison of the risk of perinatal death between babies born at home and babies born in hospital will, therefore, make it seem as though hospital birth is far riskier than home birth because intrapartum transfers from home to hospital will be counted as hospital births. For this reason, intrapartum transfers to hospital must be counted in the 'home birth' group. In order to identify accurately which cases are intrapartum transfers to hospital, the database used for analysis must record whether or not a home birth was intended (see Section 3 for a discussion of why this can be problematic).
   It has been argued (Tew, 1986) that it is inappropriate to categorise intrapartum transfers in the same group as planned home births, because if such cases do result in a negative outcome, we cannot tell whether the attempt at a home birth contributed to the negative outcome (for example, it may have been due to poor care after arrival in hospital or the pregnant woman choosing not to follow the advice of her caregivers). To eliminate the possibility of such a debate, research studies should ideally be set up to allow the possibility of some follow-up research among intrapartum transfers with negative outcomes to ascertain whether the outcome was in any way related to intended or actual place of birth. This approach was taken as part of a recent study in Scotland (Symon et al., 2010).
3. *Is intended place of birth recorded accurately?*
   Previous research has shown conclusively that the risk of a negative pregnancy outcome is far higher for unplanned home births than for planned home births (Campbell et al., 1984; Northern Region Perinatal Mortality Survey Coordinating Group, 1996). A study which classes unplanned home births in the same group as planned home births will, therefore, over-estimate the risk associated with home birth. However, the classification of unplanned home births in the same group as planned hospital births would also be problematic; unplanned home births occur exclusively among women who plan to have a hospital birth, so their inclusion in the 'intended a hospital birth' group would inflate the risks associated with planning a hospital birth. The researcher must therefore decide whether to include unplanned home births within the 'hospital' group, include them as a separate group, or exclude them altogether, and carefully justify this decision.
   In order to identify unplanned home births accurately, there must be an accurate and reliable record of intended place of birth. Whilst this may sound straightforward, it is fraught with practical difficulties. It is relatively common (although by no means universal) to record a woman's *initial* intentions regarding place of birth (e.g. in the UK it is often discussed at the woman's first appointment with a midwife towards the end of the first trimester of pregnancy), but research from the UK (Nove et al., 2011) indicates that some women change their intended place of birth during pregnancy. For example, a woman who initially intends a home birth may change her mind in response to the development or discovery of a 'high-risk' condition such as breech presentation. Because 'high-risk' pregnancies are more likely to have negative outcomes, if such cases are classed as planned home births, a study will over-estimate the risks associated with planned home birth. It is therefore essential to ensure that there is an accurate record of the woman's intended place of birth *at the start of labour*, and that this – rather than her original intention – is used to classify women as having planned a home birth or a hospital birth. In some cases, even this will not be an accurate reflection of a woman's intention, since some midwifery practices encourage women to wait until labour is established before deciding where they wish to give birth (Leyshon, 2004).
   As with unplanned home birth, a woman delivering without a skilled birth attendant is at higher risk of a negative birth outcome. Although this situation is rare in developed countries, it can happen, and it is more likely to happen if the woman has planned a home birth and labours so quickly that the baby arrives before the midwife. Such cases should also be identified, and either treated as a separate group or excluded altogether, to avoid their introducing bias into estimates of the risk associated with planned home birth.
4. *Avoiding bias due to deaths which would have occurred regardless of place of birth*
   If a perinatal death (1) was caused by something that happened prior to the onset of labour and (2) would have occurred regardless of place of birth or quality of care, then it is impossible for that death to be in any way associated with place of birth. If, as seems likely, these deaths are proportionally more common among hospital births than among home births, their inclusion in the comparison will artificially inflate the risk of perinatal death in hospital. Because perinatal death is so rare, even small numbers of 'rogue' observations can affect the conclusions drawn by a statistical comparison, so it is essential to exclude such deaths from the analysis. (They may, of course, be worthy of study in their own right, e.g. to find ways of minimising the risk of their occurring, but they have no place in a fair comparison of home and hospital birth.)
   Table 1 lists the groups which must be excluded from comparisons of the safety of different places of birth, and notes some issues of definition. These groups will make up quite a large proportion of the perinatal deaths in any dataset, so when deciding on an appropriate sample size for quantitative analysis, it is important to calculate the number of perinatal deaths (likely to be) left in the dataset *after* these cases have been excluded.
5. *The rarity of planned home birth and perinatal death in most developed countries*
   Given the attention that this subject has received over recent decades, if there was a very large difference between home and hospital in terms of the risk of perinatal death, it is likely that it would have become apparent by now. The fact that it has not suggests that, if a difference does exist, it is a small one. This has major implications for study design. In all developed countries except the Netherlands, hospital birth is the norm and only a small proportion of women have planned home births. Because planned home birth is unusual and perinatal death is a rare outcome, in most developed countries the number of perinatal deaths among planned home births will be tiny even if the dataset is extremely large, as illustrated by the examples shown in Table 2.
   A major challenge for a researcher is to ensure that the dataset contains enough planned home births for the

incidence of rare outcomes to be compared with hospital births. The researcher must decide between two basic approaches: (1) selecting all available planned home births and a matched sample of planned hospital births or (2) selecting a sample so large that the home birth group will contain sufficient perinatal deaths. Advice from a statistician should be sought to ensure that the sample will contain enough observations in each sub-group of interest to permit robust conclusions to be drawn, given the particular research question under investigation and the planned analysis technique(s).

In most developed countries, planned home birth is so rare that the only practical way to select sufficient planned home births would be to pool data from a number of different maternity care providers. In many countries, this will bring about both practical problems (e.g. if different providers use different computer systems for data collection/storage) and ethical problems (e.g. if providers are unable or unwilling to release their data for pooling because of confidentiality concerns).

Without a sufficiently large number of perinatal deaths in the 'home birth' group, the researcher would be forced to use a composite outcome variable, i.e. compile a list of individual negative pregnancy outcomes and compare home and hospital in terms of the risk of experiencing any of them. For example, the recent UK Birthplace study (Birthplace in England Collaborative Group, 2011) used a composite outcome variable consisting of perinatal death, neonatal encephalopathy, meconium aspiration, brachial plexus injury, fractured humerus or fractured clavicle, and compared different birth settings in terms of the risk of babies experiencing at least one of these outcomes. Whilst composite outcomes can help to assess the relative safety of different birth settings, their use will tend to raise further questions. For example, some outcomes have greater clinical significance than others (e.g. perinatal death would be considered a much more serious outcome than a fractured clavicle), but within a composite outcome variable this variation in severity is not captured; a perinatal death is counted as a negative outcome in the same way as a fractured clavicle. Further, if one of the individual outcomes in the composite list is much more common than the rest, the relationship between that individual outcome and place of birth will tend to determine the relationship between the composite outcome and place of birth. If a rarer individual outcome has a different relationship with place of birth, this information would be 'lost' and it may not make sense to include it within the composite outcome.

On the other hand, it could be argued that a composite outcome variable makes sense in some situations. For example, if a birth setting is associated with a relatively low risk of perinatal death but a relatively high risk of severe infant morbidity, presenting a comparative analysis of either perinatal death or severe morbidity would tell only part of the story and would not be particularly helpful to someone wishing to make an informed choice about place of birth. For complete clarity, however, the ideal study would present the results for individual outcomes separately as well as a single composite result.

6. *Separate analysis of different types of hospital birth*

In many countries, the term 'hospital birth' covers a wide range of different experiences, from midwife-led birth centres which aim to be home-like, to high-technology consultant-led obstetric units. Recent research has indicated that many of the positive outcomes observed among planned home births can also be observed among midwife-led hospital/birth centre births (Hatem et al., 2008; Birthplace in England Collaborative Group, 2011). This suggests that the comparison should not be a simple 'home vs. hospital' one, but that planned home births should be compared with the various different types of hospital birth available. This means that, ideally, the dataset should be large enough so that the number of perinatal deaths is sufficiently high in each type of birth setting to allow a reliable comparison.

7. *Controlling for confounding*

A number of previous studies have highlighted the fact that women who choose home birth are not a random sub-set of the population of pregnant women (Chamberlain et al., 1997); in particular; they tend to have given birth before. Studies from the Netherlands and the UK have identified

Table 1
Deaths which should be excluded from comparisons of home and hospital birth.

Group	Issues of definition
Miscarriages	
Lethal congenital abnormalities	Some congenital abnormalities (e.g. anencephaly, bilateral kidney agenesis) are always fatal (Julian-Reynier et al., 1994), but others are fatal only in some cases. Medical expertise is necessary to identify the cases in which the baby's death was (1) due to the congenital abnormality and (2) not associated in any way with the intrapartum care received. In some cases this judgement will be difficult to make, so decisions should be carefully documented and justified, and if there is a group of deaths for which it is impossible to make the judgement, the analysis should be run both with and without this group to test the sensitivity of the results to their inclusion or exclusion.
Antepartum stillbirths	It is not always possible to determine whether the death occurred before or during labour. If there are any stillbirths for which it is impossible to determine whether the death occurred before or during labour, a sensitivity analysis should be run.
Birth weight too low to be compatible with life	There is no consensus on where this line should be drawn

Table 2
Incidence of perinatal death among those who intended home birth in different datasets.

Country (reference)	Dataset	Year	Total no. of observations	No. of planned home births	No. of perinatal deaths among planned home births*
England (Birthplace in England Collaborative Group, 2011)	Birthplace	2008–2010	64,538	16,553	< 10
England (Nove et al., 2011)	North-west Thames	1988–2000	585,291	7,079	12
Australia (Kennare et al., 2010)	Perinatal statistics	1991–2006	300,011	1,141	9
Canada (Hutton et al., 2009)	Ministry of Health database	2003–2006	25,720	6,947	9
Sweden (Lindgren et al., 2008)	National medical birth register + recruitment	1992–2004	1,122,250	790	1
USA (Pang et al., 2002)	Birth certificate data	1989–1996	21,057	6,052	20

* After the removal of miscarriages, lethal congenital abnormalities, antepartum stillbirths and birth weight below 500 g.

a number of additional characteristics which have an independent association with an intention to give birth at home (Anthony et al., 2005; Nove et al., 2011). These include maternal age, ethnic group, relationship status, social class, obstetric history (e.g. previous caesarean sections, previous miscarriages, previous baby with low-birth weight) and pregnancy risk status. All of these factors can 'confound' the association between intended place of birth and perinatal death. For example, women who have given birth before are more likely than first-time mothers to have a positive pregnancy outcome, and also more likely to plan a home birth. Therefore, a relatively low incidence of perinatal death among those who plan a home birth may be entirely due to the fact that the 'home birth' group contains more parous women than does the 'hospital birth' group.

For the comparison to be a fair one, it is essential to quantify and control for confounders, either through matching on key variables or using multivariable analysis techniques. Intention to give birth at home also varies over time and according to which care provider is being used (Nove et al., 2008), so time and care provider must be held constant if the database contains observations from a wide time period and/or more than one provider.

If the researcher has decided to include 'high-risk' pregnancies (see Section 1), particular care must be taken to control for the fact that the hospital group will contain a higher proportion of 'high-risk' pregnancies than the home group. Analysis of the English North-west Thames database (Nove, 2011) revealed that women with 'high-risk' pregnancies who plan a home birth tend to have different 'high-risk' conditions from women with 'high-risk' pregnancies who plan a hospital birth (e.g. women with multiple pregnancies or previous caesareans nearly all planned a hospital birth, whereas several of those with gestational diabetes or who had had a previous stillbirth/neonatal death went ahead with a planned home birth despite their 'high-risk' condition). The 'high-risk' conditions under which hospital birth was almost universal were 'higher-risk' than the 'high-risk' conditions under which some women opted for home birth. This indicates that, when controlling for pregnancy risk status in a comparison of home and hospital births, it is not appropriate simply to classify pregnancies as 'high-' or 'low-risk'—the difference in detailed risk profile must be taken into account, e.g. by controlling for individual risk factors rather than for overall risk status.

8. *Differentiating between confounders and mediators*

Some variables are known to predict negative pregnancy outcomes as well as being associated with birth setting, and could therefore appear to be confounders of the relationship between intended place of birth and perinatal death. For example, factors such as mode of delivery, type of health professional attending delivery, type of pain relief used in labour and augmentation of labour are associated with place of birth, and also known to predict certain negative pregnancy outcomes (Waterstone et al., 2001; Hatem et al., 2008). To take mode of delivery as an example: caesarean sections are more likely to occur among those who plan a hospital birth (but do occur among those who plan a home birth and transfer to hospital during labour), so should the researcher hold mode of delivery constant when assessing the relationship between intended place of birth and perinatal death?

To answer this question, the researcher must consider whether mode of delivery is a confounder or whether it is, in fact, a mediator. A variable is considered to be a mediator if it is hypothesised to be on the causal pathway between intended place of birth and perinatal death, i.e. if it is thought to explain how or why intended place of birth influences the likelihood of perinatal death (see Babyak (2009) for a more detailed discussion of the difference between confounders and mediators). If a study were to find that those who plan a hospital birth are more likely to have a caesarean section and that babies born by caesarean section are more likely to suffer perinatal death, the possibility should be considered that the relatively high incidence of caesarean sections among those planning a hospital birth is contributing towards the relatively high risk of perinatal death among those planning a hospital birth. If it is contributing, then controlling for mode of delivery would effectively lead to controlling for the association between planned place of birth and perinatal death. This would, of course, be a fatal flaw in a study which aims to establish whether or not there *is* such an association. However, if the researcher decides not to hold mode of delivery constant, it is vital to control for factors which *predict* caesarean section (e.g. malpresentation of the fetus diagnosed in advance of labour), to avoid introducing bias due to women who plan a home birth being less likely to *need* a caesarean.

Note that this paper relates specifically to the methods which should be used to identify whether or not there is an independent association between intended place of birth and perinatal death. If a different research question was to be asked (e.g. *why* is there a particular association between intended place of birth and perinatal death?), then it could well be appropriate to hold mediating factors constant.

9. *Does the overall result mask any sub-group variations?*

As things currently stand, it is impossible to predict which individual pregnancies will have a negative outcome, because negative outcomes can occur even in 'low-risk' pregnancies. This situation has given rise to the central objection to planned home birth, i.e. that at the level of the individual pregnancy, it can be declared safe only after the event, so it is better to be in hospital 'just in case' emergency medical care is required for mother and/or baby. The fact that this argument still holds sway for many clinicians and maternity service users is an indication that previous research has not satisfactorily addressed the problem. It has tended to assess the *overall* safety of planned home birth without addressing the question of whether there are specific situations in which the overall pattern does not apply. It is clear from most previous studies that, for most 'low-risk' women, planned home birth is safe, but there are lingering doubts over whether home birth is as safe as hospital birth if unexpected complications arise during labour or delivery. Unless and until it can be shown that the incidence of severe negative pregnancy outcomes is the same for home and hospital births even when there are unforeseen complications of pregnancy and labour, then the hospital birth lobby will probably not become much more receptive to arguments about the other benefits of planned home birth.

The definitive study of the safety of home birth will, therefore, have the capacity to work out exactly which conditions or situations (if any) are associated with a higher risk of perinatal death if a home birth is attempted. This could be done either by selecting an individual group (e.g. breech presentation) and comparing the incidence of perinatal death between home and hospital births, or by using interaction terms in a statistical model. In either event, a valid result will be possible only if there are sufficient numbers of perinatal deaths in each sub-group (e.g. planned home births with breech presentations). Drilling down this far into the data would require an extremely large number of planned home births to be included in the dataset.

10. *The problems of pooling data from different countries*

As noted above, the relative rarity of planned home birth combined with the need for large numbers of home births in order to conduct the necessary analysis means that, in most

countries, the only way to conduct a successful comparison of home and hospital birth would be to use pooled data from different maternity care providers. In a relatively small country with few home births, even a census of all planned home births may not yield sufficient numbers of perinatal deaths in the home birth group.

This raises the questions of whether research results from one country can be assumed to apply in another, and whether multi-country meta-analysis is an appropriate tool to use to answer this particular research question. We could speculate – as have others (Keirse, 2010) – that the safety of planned home birth is contingent upon factors including geography (ease and speed of access to emergency medical care if required), the maternity care system in place, and ease of access to midwives who are confident and competent to work in the home. Such factors vary between countries, so it would be simplistic to assume that one country's research results will apply in a different country. All that can be inferred from a study from another country is that, under certain circumstances, home birth is or is not safe. By the same token, the results of multi-country meta-analyses (Olsen, 1997; Wax et al., 2010) – which are often quoted by both sides of the home birth debate – are open to question, even if the methodology used for the meta-analysis is otherwise sound.

Summary

Based on the arguments put forward in this article, Table 3 lists a number of attributes which are essential or desirable in any data source which is to be used to make a fair comparison between planned home birth and hospital birth in terms of the risk of perinatal death. An attribute was classed as 'essential' if, based on the arguments put forward in this article, the research team considered that a study without this attribute would be unsuitable for answering the question: is perinatal death more likely if a home birth is planned than if a hospital birth is planned? As attribute was classed as 'desirable' if, based on the arguments put forward in this article, the research team considered that a study without this attribute would allow only cautious conclusions to be drawn about the comparative safety of different birth settings in terms of the risk of perinatal death.

Table 3 indicates whether a number of influential studies published since the year 2000 on the subject of the safety of home birth met these criteria. For most of the attributes in the table, the classifications given to each study are easy to verify with reference to the published research articles. For two, however, it is important to set out the criteria used to classify each study: 'controlled for confounding' and 'did not hold mediating variables constant'.

To be classed as having controlled for confounding, a study must, through the use of multivariate analysis or matching, have controlled for at least four factors which are known to be associated with choice of birth setting (see Section 7), of which two were parity and maternal age. In practice, nearly all of the studies given a 'yes' rating on this measure controlled for several additional confounders, including mother's ethnic group, partner status, and socio-economic status. To be classed as having 'partially' controlled for confounding, a study must have controlled for at least two known confounders, of which one was parity. If neither of these criteria applied, a study was rating as not having controlled for confounding.

To be classed as 'did not hold mediating variables constant', a study must have made no attempt to hold constant: mode of

Table 3
Essential and desirable attributes of a study comparing home and hospital birth in terms of the risk of perinatal death, and extent to which studies published since 2000 met these criteria.

Study	Birthplace (2011)	Kennare et al. (2010)	de Jonge et al. (2009)	Hutton et al. (2009)	Janssen et al. (2009)	Mori et al. (2008)	Lindgren et al. (2008)	Pang et al. (2002)	Johnson & Daviss (2005)	Janssen et al. (2002)
Setting	**England**	**South Australia**	**Netherlands**	**Ontario Canada**	**British Columbia Canada**	**England and Wales**	**Sweden**	**Washington State USA**	**USA and Canada**	**British Columbia Canada**
High-risk pregnancies included?	No*	Yes	No	No	No	Yes	Yes	No	Yes	No
Number of perinatal deaths in 'home' group	<10	9	207	9	<5	96	1	20	11	3
Essential attributes										
'Home' and 'hospital' groups directly comparable vis-a-vis risk status	Yes	No	Yes	Yes	Yes	No	No	Yes	No	Yes
Intrapartum transfers included in 'home' group	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Excluded deaths which could not have been associated with birth setting	Yes	Partially	Yes	Yes	No	Yes	No	No	Yes	Partially
Controlled for confounding	Yes	Yes	Yes	Partially	Yes	No	Partially	Yes	No	Partially
Did not hold mediating variables constant	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Desirable attributes										
Separate analysis of different types of hospital birth, e.g. midwife-led vs. obstetrician-led	Yes	No	No	No	Yes	No	No	No	No	Yes
Attempt to find out if overall results mask key sub-group variations	Yes	No	Yes	No	No	No	No	Yes	No	No
Comparison of infant morbidity as well as perinatal mortality	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
Assessment of 'avoidability' of deaths	No	Yes	No	No	No	No	Yes	No	Yes	Yes
Unplanned home births accurately identified and excluded	Yes	No	No	Yes	Yes	No	Yes	No	Yes	Yes

* Some high-risk pregnancies were captured by the study but they were not deliberately sampled, so most of the analysis focuses on low-risk pregnancies only.

delivery, induction/augmentation of labour or type of pain relief administered in labour (see Section 8). Any study holding at least one of these mediating factors constant was classed as 'no' on this measure.

It is notable from Table 3 that only one study both (1) contained a large number of deaths in the 'home' group and (2) exhibited all of the essential attributes: a Dutch study by de Jonge and colleagues, published in 2009, which concluded that planned home birth in low-risk pregnancy was not associated with an increased risk of perinatal death (but noted that this result could not be generalised to countries with different systems of maternity care). All of the other studies – some of which claimed planned home birth is safe, and some that it is not as safe as hospital birth – lacked a sufficiently large number of perinatal deaths and/or at least one essential characteristic, rendering them unable reliably to answer the question of whether the risk of perinatal death varies according to birth setting. No study had all of the desirable attributes.

Table 3 also makes it clear that the most common problem with this type of study is the small number of deaths in the 'home birth' group. To counteract this fundamental problem, in most developed countries it would be necessary to use data pooled from a number of maternity care providers. This will bring about its own problems, because in some countries there will be wide variations between providers in terms of, for example, case mix and the geography of the surrounding area. If pooled data are to be used, an additional 'essential' characteristic of a study must be to control adequately for such variations. Similarly, the pooling of data from different countries is fraught with difficulties because it cannot be assumed that the geographical, cultural and health system conditions that prevail in one country will apply in another. Unless, therefore, a multi-country study can control adequately for these variations, and ensure that the data pool is not unduly influenced by one or more individual countries, its results will not be convincing.

Conclusions and future steps

There are several significant hurdles which must be overcome if a study is to make a useful contribution to the debate about whether perinatal death is more likely if a home birth is planned or if a hospital birth is planned, and few (if any) readily available data sources can overcome all of these hurdles. These deficiencies have in part led to the continuation of the debate over several decades, and it is unlikely to be brought to a satisfactory conclusion in the foreseeable future. We call for journal editors to take note of the essential characteristics that must be in place for a high-quality study on this subject, and to ensure that any shortcomings are clearly acknowledged in published articles.

The future direction of research into the safety of different birth settings will depend on some extent on whether studies are carried out which overcome all of the hurdles described above. In most countries, it is theoretically possible to do so because the data exist (or could easily be made to exist) in the form of health facility records. However, the financial cost of conducting such a study would be considerable, and would need to be weighed up against considerations such as the number of women and babies who would benefit from the findings and the willingness of politicians, clinicians and the public to engage with empirical research on this subject. However, the fact that the recent Birthplace study in England was funded by central government is an indication that, at least in some countries, value is attached to high-quality research on this topic. It will be interesting to observe the extent to which this translates to action being taken as a result of the study's findings, especially given the Birthplace study's use of a composite outcome variable.

In addition to the question of cost, the practical obstacles for conducting the ideal study are considerable. Any study wishing to compare the risk of perinatal death will need large numbers of perinatal deaths in all sub-groups of interest. In most countries, this will be impossible unless researchers can pool data from a number of maternity care providers. Aside from the cost and time which would be involved, a major obstacle to the pooling of data is concern over the confidentiality of personal data; maternity care providers and/or women may refuse to allow their data to be released for this purpose. Without wishing to detract from the importance of treating people's personal information with care and respect, the question does need to be asked: 'should the right to confidentiality trump the right to informed choice?' Without a satisfactory answer to the question of whether planned home birth is associated with a raised risk of perinatal death, any claims to the provision of informed choice can be no more than rhetoric. It would be interesting to know how women themselves feel about the balance between confidentiality and informed choice, and to what extent they would be willing for their data to be used for this type of research.

Conflict of interest statement

None of the authors has any conflict of interest to declare.

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