

Safety of planned home birth: an NCT review of evidence

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This paper provides a review of the evidence on the safety of planned birth at home compared with planned birth in hospital, looking in particular at the evidence for women at low risk of complications during labour. It examines the research papers identified by the NICE Intrapartum Care Guideline Development Group (IPC GDG) for the chapter on place of birth in the NICE Intrapartum Care Guideline.^{1,2} A group of NCT staff and research networkers reviewed the identified papers on home birth, using the NICE methodology for assessing the risk of bias,³ to inform the NCT's position on the NICE guideline and recommendations. The NCT group reached different conclusions from the IPC GDG. This paper, written by two members of the NCT review group, provides the NCT's assessment of the evidence.

The paper addresses the following questions:

- What evidence is available on the comparative safety of planned home birth in terms of babies dying during labour or shortly after birth (perinatal mortality (PNM))?
- How reliable is the evidence?
- What does the evidence tell us about the safety of planned home birth for women at low risk of complications?

This paper does not address important questions about morbidity for either the baby or the mother, nor important questions around well-being and psychological outcomes linked to place of birth. The authors are planning to undertake a full systematic review of home birth addressing a broader range of benefits and risks.

Background

The NICE Intrapartum Care Guideline, published in September 2007, includes a chapter on place of birth which considers the

evidence on the comparative safety of planned home birth and planned hospital birth. The draft guideline was circulated for consultation to stakeholders in June-August 2006¹ and the chapter on place of birth was circulated for a second consultation in March-May 2007.² Staff and volunteers at the NCT decided to review the identified papers on home birth to inform the NCT's position on place of birth, in preparation for publication of the NICE guideline, when the organisation's views would be sought and NCT workers would need guidance.

Ever since the Peel report recommended that '...sufficient facilities should be provided to allow for 100 per cent hospital deliveries', claiming that, '...the greater safety of hospital confinement for mother and child justifies this objective'⁴, there has been controversy over the evidence on 'safety' of home birth. In the 1970s, Marjorie Tew began work which established that studies which assessed comparative perinatal mortality (PNM) were misleading when the home birth group included data for unbooked, unintended home births.⁵ It is now widely accepted that unplanned, particularly unattended, home births have a much higher mortality rate than planned home births⁶⁻¹⁰ and it is, therefore, now acknowledged in the literature on home birth that care needs to be taken in defining terms and distinguishing between planned and unplanned home births.

The NICE IPC guideline

The NICE IPC GDG assessed the evidence on the comparative safety of planned home birth and planned hospital birth. As part of the IPC guideline development process, a literature search of comparative home birth studies published in English was undertaken.¹ This initially identified two systematic reviews^{11,12} and 17 papers from 16 studies.¹³⁻²⁹ All the English language papers contained in

the two systematic reviews were included among the 17 studies identified.

A further paper³⁰ from one of the studies was identified later.² In addition, at the request of the IPC GDG, the National Collaborating Centre for Women's and Children's Health (NCC-WCH) conducted an analysis of data from England and Wales on intrapartum related perinatal mortality (IPPM).³¹ A ten year period of data collection was chosen to provide sufficient power to assess IPPM. As the paper had not been published, it was provided as Appendix D in the second consultation document.²

The IPC GDG reviewed these 19 papers from 17 studies. It assessed each paper in terms of the criteria set by NICE, which assigns research papers an evidence level (EL) according to the type and quality of the study (Figure 1).¹ In addition, the IPC GDG established its own validity criteria, published in Appendix C of the second consultation document (Figure 2)² These are described in more detail below.

There are a number of methodological challenges affecting the study of the safety of home birth, so this grading of evidence is very important. The following section covers how this grading was addressed by the IPC GDG.

NICE and IPC GDG grading of the evidence

When considering the effectiveness of healthcare treatments, interventions or 'packages of care', well-conducted randomised controlled trials (RCTs) are the most reliable way to compare two or more alternatives, because they produce two groups with similar baseline characteristics. RCTs are given a NICE evidence level grade of 1.

For interventions where randomisation is difficult or unethical, non-randomised comparative studies can sometimes be used. However, without randomisation, it is

impossible to achieve groups that are similar in every respect except for the intervention or package of care being studied (in this case, planned home birth and planned hospital birth). Where there are differences - known or unknown - between the groups being studied, these may affect the outcomes in the groups as much, or more than, the different packages of care. These differences may be socio-demographic (e.g. age, education, social class), or clinical (medical or obstetric history). Differences in any of these can introduce 'bias' or 'confounding' which may affect the reliability of the comparison and thus the conclusions of the research.³²⁻⁵ To ensure as much similarity as possible, steps need to be taken to try to balance the background risk factors of the two groups being compared. This is usually attempted by selecting individuals in the group of primary interest (in this case women at low risk of complications choosing a home birth) and matching them with one or more people from the comparative group (in this case women at low risk of complications choosing hospital birth) using a number of key known characteristics. Alternatively, or in addition, sophisticated statistical adjustments can be made according to the variations in risks identified between the two groups.³⁵ Neither of these methods can be relied on to make full adjustment of known confounders, and there is no way of adjusting for any unknown confounders (except through good randomisation), so non-randomised studies, such as these, are given a NICE evidence level grade of 2.

A study's considered susceptibility to bias is recognised in the grading systems by the use of '++', '+', or '-' in the NICE evidence level allocation, with '++' representing studies with very low risk of bias, '+' representing studies with low risk of bias and '-' representing studies with high risk of bias. NICE includes these symbols for evidence levels 1 and 2 to further clarify the quality of the study (Figure 1).

In addition, the IPC GDG devised its own scoring system for overall validity involving a combination of external and internal validity (Figure 2) where 'internal validity' measured the risk of bias in a way similar to the NICE criteria and 'external validity' was related to the relevance of the research to women in the UK. External

validity was graded highest with studies conducted in the UK since 1980, and older studies or those conducted outside high-income countries were ranked lowest. (In the final version of the IPC guideline, published on 26 September 2007,³⁶ this combined internal/external assessment scoring system was replaced with assessment of internal validity only).

Another factor which can affect the reliability of research findings is the size of the study. A large number of 'events' are needed ('an event' being PNM in this case) if any difference in outcomes is to be attributed to one of the packages of care with any degree of certainty in a statistical analysis. Since adverse outcomes are rare for healthy women with a straightforward pregnancy (the group for whom home births are considered most suitable),³⁷ studies have to be sufficiently powered (i.e. large enough) to answer questions about the comparative safety of home birth.^{38,39} In addition, studies may be undertaken retrospectively (collecting data from the past) or prospectively (setting out to collect future data). Prospective studies can more easily gather data on potential confounding factors and so more easily balance the two groups being compared.

Only one very small RCT has ever been published comparing the outcomes for planned home birth with planned hospital birth. This was a small pilot study of 11 women to see if women at low risk of complications would be willing to be randomised in a trial on home birth.²² This concluded that it was unlikely that sufficient numbers of women would be willing to be randomised to assess the comparative PNM adequately. Therefore, most studies comparing the safety of planned home birth with planned hospital birth have been done using non-randomised studies.

Consequently, there are considerable difficulties inherent in conducting and interpreting research on the safety of place of birth. The grading of evidence itself can be subjective and hence the NCT decided to undertake its own review of the evidence relating to the safety of planned home birth for women at low risk of complications.

IPC GDG information on the safety of home birth

The IPC GDG assessed the outcomes from

their included studies. For the first consultation, the main outcome measure to assess safety was PNM. In the UK, PNM is usually defined as the number of stillbirths (after 24 weeks gestation) and early neonatal deaths (those occurring less than seven days after birth) per 1,000 live births and stillbirths.¹⁰ The World Health Organisation (WHO) has a different criteria for registering stillbirths, namely loss occurring after 22 weeks gestation. Thus PNM measured with the WHO definition is greater than that measured with the UK definition.¹⁰ Individual research papers may have used their own definitions.

In the second consultation, a new outcome measure was introduced, the intrapartum-related perinatal mortality (IPPM). This was defined in Appendix C as '...deaths from intrapartum 'asphyxia,' 'anoxia' or 'trauma' derived from the extended Wigglesworth classification⁹... This includes deaths and stillbirths in the first week of life.² This measure is subjective and classification may vary.

The IPC GDG reported in the second consultation document² that six of the 17 studies met the inclusion criteria.^{19,20,23,27,28,31} (there were seven studies in the final published guideline with the paper by Dowswell also included.²²) However, only four of these studies were reported to provide data on PNM and IPPM^{19,23,27,31} although two of the other studies did report the number of babies who died.^{20,28} The inclusion and exclusion decisions in the second consultation document are summarised in Table 1.

Methodology

In February 2007, a group of six NCT staff and research networkers (members of the NCT with an interest in research) agreed to review the research papers on home birth, as published in the first consultation draft of the NICE IPC guideline.¹ Two people assessed each paper independently using the NICE methodology (Figure 1).³ The six people then attended a meeting to discuss the papers and agree the assignment of the type of study and the level of evidence, using the NICE guideline methodology (Figure 1).³ In April 2007, a smaller group met to assess the additional studies identified in the second IPC stakeholder consultation draft.² Overall, the NCT group reviewed and graded the same 19 papers from 17 studies as the IPC GDG.

Outcomes assessed

After grading the 19 papers from 17 studies, the NCT group looked at reported PNM rates in the groups who had planned home births compared with the groups who had planned hospital births. Where available, the IPPM rates were also compared. The group looked, in particular, at the evidence for women at low risk of complications during labour.

Results

Assessment and inclusion of studies

The NCT group assessed the 17 studies differently from the IPC GDG (Table 1). The NCT excluded: two case series studies because they had no comparative data;^{16,21} one study that looked at actual place of birth¹⁴ and also the one small RCT because it did not report PNM.²² In addition, the study by Tew looked at out-of-hospital birth (home births plus GP unit births) compared with in-hospital birth and was, therefore, addressing a slightly different question and so was omitted.²⁶ This left the NCT group with 12 studies for detailed reporting.^{15,17,19,20,23,24,25,27,28,29,30,31} The NCT group further divided these studies based on:

- the assessed level of risk of confounding bias (2++, 2+ or 2-)
- whether they considered women at low risk of complications
- whether they were conducted in the UK.

The four studies considered to have a low risk of bias (but still with some risk of bias, EL 2+) are detailed in Table 2.^{19,24,25,29} Three of these considered women at low risk of complications^{24,25,29} with one study being conducted in the UK.²⁵ The eight studies considered to have a high risk of bias (EL 2-) are detailed in Table 3^{15,17,20,23,27,29,30,31} of which only two considered women at low risk of complications.^{15,20} The studies in Table 3 were included in the NCT review to show the judgements made by the NCT group about the quality of the evidence. However, these eight studies were considered to have too high a risk of bias for the PNM data to be compared.

Findings

Reasonable quality evidence for non-randomised studies - women with low risk of complications

There were three studies of reasonable methodological quality for non-randomised studies (EL: 2+) addressing safety for women at low risk of complications,^{24,25,28} one of which was undertaken in the UK.²⁵ All these studies were underpowered for assessing comparative PNM and still had some risk of bias. They are described in Table 2a.

UK studies

The one UK study of reasonable methodological quality for a non-randomised study (EL: 2+) (which was excluded from the IPC-GDG review) was a prospective cohort study involving just under 8,000 women. It collected data on 61% of all the planned home births in the UK during 1990, and compared outcomes with a matched group of women at low risk of complications planning birth in hospital. Midwives identified women for both groups at 37 weeks gestation, but they often found it hard to find a suitable hospital control for each home birth they booked.²⁵ Matching was considered reasonable for some risk factors but the home birth group had more women of higher social class and more years in full-time education. The NCT group considered this study to have relative methodological strengths in that it was prospective, focused on low-risk women, was carried out in the UK, and had some control for confounders, but it also had some limitations including some imbalances of background risk factors and incomplete data collection. The study found no statistically significant difference in PNM, with five out of 4,665 babies dying in the planned home birth group (1.07 per 1,000) and five out of 3,319 babies dying in the planned hospital birth group (1.51 per 1,000). However, the authors stated: 'We had recognised from the outset that this study did not have the power to detect any differences in perinatal death between women intending home or hospital birth... It is therefore essential that no conclusions are drawn from the figures relating to perinatal death.'

Non-UK studies

The non-UK studies of reasonable methodological quality for non-randomised studies (EL: 2+) were small studies but neither identified any increased risk in terms of PNM or IPPM in women at low risk of complications choosing home birth.^{24,28} The

study in the Netherlands (excluded from the IPC-GDG review) found four out of 1,140 babies died in the home birth group (3.5 per 1,000) and two out of 696 in the planned hospital birth group (2.9 per 1,000).²⁴ In the study from British Columbia, Canada (included in the IPC-GDG review but not used in their assessment of PNM), again there was no significant difference in PNM with three out of 862 babies dying in the planned home birth group (3.5 per 1,000), one out of 743 in the matched planned hospital birth group attended by a physician (1.3 per 1,000) and no babies dying out of 571 in the unmatched planned hospital group cared for by midwives.²⁸

Women with low and increased risk of complications

There was one study of reasonable methodological quality for a non-randomised study (EL: 2+) addressing safety for a combination of women at low and increased risk of complications. This was a small non-UK study carried out in Western Australia, and found no difference in PNM between the two groups though, like the studies above, it was underpowered for assessing this outcome (Table 2b).¹⁹

Unreliable evidence for assessing comparative safety

The remaining eight studies were considered by the NCT group to have a high risk of confounding bias (EL: 2-), mainly because they studied populations of women and did not balance, or adjust, for confounding factors like socio-demographic differences, or medical or obstetric risk factors.^{27,17,15,30,29,23,31,20} Five of these studies were also carried out retrospectively, which often means that less is known about the individual characteristics of the woman involved. In particular, these studies were unable to address the question of the comparative safety of planned home birth for women at low risk of complications compared with a similar low-risk population of women who choose hospital birth, as the risk factors for the women in the studies are not known in any detail. Therefore, these studies are only described briefly, and their PNM and IPPM data is not reported (Table 3).

UK studies

Three of these studies were undertaken in the UK.^{15,23,31} One small study (387 women)

provided no information on how the groups were matched and the study had no balancing for background risk factors (social, medical or obstetric) and they addressed a mixed risk group of women who had planned a home birth.^{23,31} More detail is given for these two larger, more recent, studies as they were included in the IPC GDG review but were not considered of good enough quality by the NCT review group to contribute to the evidence on comparative safety of planned home birth.

The most recent UK study was a retrospective case control study (EL: 2-) (included in the IPC GDG review but unpublished at the time of the second 'place of birth' consultation). This study concluded that the incidence of PNM and IPPM in planned home births is very low, but reported that IPPM appeared to be significantly higher than rates for hospital birth for the period 1999-2003.³¹ This study attempted to estimate the number of planned home births at booking by taking the known number of actual home births and adjusting for an estimate of both unplanned home births and transfers of care. It also relied on data from two different, unlinked, sources (CEMACH and the Office of National Statistics) to calculate the IPPM rate for births in different settings. The NCT review group considered these assumptions and extrapolations to be unreliable. For example, the NCC-WCH study used the assumption that unintended home births are correlated with the number of home births and used the figure of 50% calculated from studies in the Northern Region of the UK.^{23,21} However, Murphy showed that unintended home birth rates are correlated with total birth rates rather than total home birth rates, and are in the region of about 0.3% of all births.⁶ As the home birth rate in the Northern Region was about 0.6%, this alternative assumption is compatible with both studies. Using this new assumption, together with an alternative calculation of transfer rates, IPPM rates in planned home births for 1999-2003 could be shown to be no different from those in planned hospital birth. Given the sensitivity of the analysis to the range of unplanned home births and transfer rates, this study was considered to provide unreliable comparative data.

The UK Northern Regional Health Authority study (EL: 2-) (included in the IPC

GDG review), was also considered to provide unreliable comparative data because of the type of study and the assumptions made.²³ This was a retrospective case control study which took the number of babies who had died in out-of-hospital births, both planned and unplanned, and tried to estimate how many of these had been planned home births and how many planned home births resulted in transfer to hospital. This involved a number of calculations and assumptions all of which carried a considerable range of uncertainty. The authors reported that the number of women planning a home birth was hard to assess and the transfer data even more difficult to assemble. The study concluded: 'All we can say with certainty is that of the 1,890 women who were estimated to have booked for home delivery in this region in the last ten years of the study period, only five lost a baby and intrapartum events were implicated in only one of those deaths.' In addition, because half the women who gave birth outside hospital in this study were not booked for home birth, the authors concluded that: 'A service geared to cope with these unplanned events ought to be able to deal with a proportion of planned low risk deliveries.'

Non-UK studies

Five of the studies of poor methodological quality for comparative assessments of safety (EL: 2-) came from high-income countries other than the UK. There was a high risk of bias because there was no balancing for background risk factors (social, medical or obstetric) and they involved a mixed risk group of women planning home birth, including women with breech babies and twins.^{30,17,27,29,20}

The most recent study was a large prospective cohort study (EL: 2-) (excluded from the IPC GDG review) assessing outcomes for 5,418 planned homebirth in North America in 2000.²⁹ This prospective cohort study reported on a number of characteristics of the women included but not on their medical or obstetric risk factors. This study showed planned home birth in North America to be associated with low PNM (2.0 per 1,000 excluding congenital birth defects and 1.7 per 1,000, excluding congenital birth defects, twins and breech births). The study also reported on timings and reasons for transfer during labour. The

authors stated that the main limitation of their study was '...the inability to develop a workable design from which to collect a national prospective low risk group of hospital births to compare morbidity and mortality directly.'

A retrospective cohort study from the early 1990s, (EL: 2-) (included in the IPC GDG review), assessed the outcomes for 7,002 planned home births in Australia.²⁷ This study had no information on the background risk status of the women participating, made no adjustments for differing risk status in the outcome assessments but did report on the causes of death for the 50 babies who died in planned home births. The study reported a higher PNM for planned home births in Australia (6.4 per 1,000 and IPPM 2.7 deaths per 1,000) compared with planned home births in other high-income countries. The study attributed some of the higher PNM rate to women at increased risk of complications (e.g. twins and breech births) choosing home birth. The study concluded: 'While home birth for low risk women can compare favourably with hospital birth, high risk home birth is inadvisable and experimental.'

One study from Switzerland (excluded from the IPC GDG review) created matched pairs based on background characteristics, but did not report baby deaths by these matched pairs.²⁰ The other two studies^{30,17} (both excluded from the IPC GDG review) were from the USA both looking at mixed risk status with The Farm study by Durand¹⁷ being considered a unique setting not comparable with current UK maternity care systems.

Discussion

Reliability of the evidence

The available evidence on the safety of planned birth compared with planned hospital birth is limited. The lack of rigorous evidence is particularly marked when considering data for women at low risk of complications. In general, the studies are non-randomised observational studies, all of which have risk of bias and are too small to detect differences in PNM and IPPM. Many were undertaken outside the UK where maternity care systems differ considerably from the UK.

Differences in assessment of evidence between the IPC GDG and the NCT review group

There are some significant differences

between the assessment of the evidence by the IPC GDG and the NCT group. The IPC GDG second consultation draft included four studies in its assessment of IPPM,^{19,23,27,31} three of which are identified in this paper as having a high risk of confounding bias because they did not balance for risk factors.^{23,27,31} These included the NCC-WCH analysis of the CEMACH data specifically undertaken for the guideline.³¹ Balancing for background risk factors was one of the criteria for internal validity set by the IPC GDG, so it is unclear why these studies were included in their assessment of the evidence. By contrast, some studies included in the NCT review of the evidence were excluded by the IPC GDG assessment, most notably the large UK study of 1997.²⁵ It could be argued that there was sufficient bias in this study to exclude it, but those criteria would then also exclude three of the studies in the IPC GDG review which had greater risk of bias.^{23,27,31} This would leave only one small study of sufficient quality but assessing a mixed risk population of women, and showing no evidence of greater safety in hospital births.¹⁹

Overall, the NCT review group considered that none of the studies were of high enough quality to be considered as good evidence of the comparative safety of planned home birth and planned hospital birth. However, there were four studies that could be considered of reasonable quality to provide some information about PNM,^{24,25,28,19} of which three looked at women at low risk of complications.^{24,25,28} These studies indicated that PNM was low in both planned home birth and planned hospital birth in women at low risk of complications. None of these studies identified any significant difference in the PNM between women planning a home birth and women planning a hospital birth, though all were underpowered to assess this outcome. Several of the authors themselves stated that their studies were too small to detect any differences.

Therefore, we concluded that there is no evidence to suggest that hospital birth is safer than home birth for low risk women, that is, healthy women with a straightforward pregnancy, when considering PNM or IPPM. If the comparative safety of home birth for women at low risk of complications in the UK is to be properly assessed, more rigorous, good quality prospective data are

needed. The Department of Health has commissioned research to produce better evidence on the safety of out-of-hospital birth (see www.npeu.ox.ac.uk/birthplace). Until good quality evidence about comparative safety is available, the choice a woman makes about where to give birth will have to rely on other factors. However, the likelihood of a baby dying is very low for women at low risk of complications wherever they choose to give birth.

Key points

- The incidence of perinatal mortality (PNM) and intrapartum related perinatal mortality (IPPM) in the UK is very low, with PNM around 8/1000⁴⁰ and IPPM less than 1/1000 births.²
- The quality of the comparative evidence on safety of home birth is poor; however, our assessment suggests that there is no evidence that the risk of a baby dying during or shortly after labour is any higher in women at low risk of complications choosing home birth compared with women at low risk of complications choosing hospital birth.
- Women should be offered a choice of place of birth and should be provided with unbiased, evidence-based information to help them decide what is right for them.
- Women should be supported by a high quality maternity service that meets their needs, irrespective of where they choose to give birth, including good transfer arrangements with the ambulance service and the medical and midwifery staff receiving women at the hospital.
- Unintended home births carry a high risk of mortality for the baby, and hospital trusts and PCTs should provide sufficient community-based midwives with experience in home birth to provide support and care promptly when unplanned home birth occurs.

Glossary

Case control

A study that compares people with a specific disease or outcome of interest (cases) to people from the same population without that disease or outcome (controls).

Case series

A study reporting observations on a series

of individuals, usually all receiving the same intervention, with no control group.

Cohort

An observational study in which a defined group of people (the cohort) is followed over time. Because subjects are not allocated by the investigator to different interventions or other exposures, adjusted analysis is usually required to minimise the influence of other factors (confounders).

Cross-sectional

A study measuring the distribution of some characteristic(s) in a population at a particular point in time.

RCT

An experiment in which two or more interventions, possibly including a control intervention or no intervention, are compared by being randomly allocated to participants.

Glossary entries modified from: Glossary, Cochrane handbook for systematic reviews of interventions, Version 4.2.5, Updated May 2005. Available at: www.cochrane.org/resources/handbook/index.htm

Notes

- Gill Gyte was one of the three 'women's representatives' on the IPC GDG, but resigned in June 2007 as she could not support the methodology used in the systematic review on home birth.
- In June 2007, NCT made a formal complaint to NICE regarding the methodology in this systematic review on home birth in the IPC guidelines. The complaint was partly upheld though the two non-executive directors at NICE asked to investigate the complaint were only able to investigate process and not content.

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Figure 1: Levels of evidence for intervention studies

From NICE Guideline Methodology 1 (reproduced with permission from the Scottish Intercollegiate Guidelines Network [SIGN 2002])

Level of evidence	Type of evidence
1 ⁺⁺	High-quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1 ⁺	Well conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
1 ⁻	Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias*
2 ⁺⁺	High-quality systematic reviews of case control or cohort studies
2 ⁺	High quality case-control or cohort studies with a very low risk of confounding, bias or chance, and a high probability that the relationship is causal
2 ⁻	Well-conducted case-control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal
2 ⁻	Case-control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal*
3	Non-analytical studies (for example, case reports, case series)
4	Expert opinion, formal consensus

***Studies with a level of evidence '2-' should not be used as a basis for making a recommendation (see section 7.4)**

Figure 2: Criteria for strength of validity and inclusion/exclusion of studies for the systematic review comparing planned home and hospital birth
From NICE IPC GDG second consultation 2

	Strength of validity		
	++	+	-
External validity	Conducted in the UK since 1980	Conducted in high-income countries other than the UK since 1980	Any other studies
Internal validity	Adequate randomised controlled design	Any observational study with planned places of birth with additional adequate study design to control background medical and/or obstetric risks of women between places of birth and/or relevant outcome measures	Any other study
Total validity	Any study in which both internal and external validity were ++	Any study in which either internal and external validity were + but neither were -	Any study in which either internal or external validity were -

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Table 1: Studies on home birth

No.	Study	IPC GDG assessment			NCT assessment			
		Type of study	Validity and evidence level (EL) if included	Included/ excluded for safety of home birth	Type of study	Evidence level EL	Detailed assessment carried out Yes/No	Included/ excluded in safety of home birth
1	Mehl 1977 ³⁰ California, USA 1970-1973	Cross-sectional	External 'L' Internal 'L' Total 'L'	Excluded '...these were comparing actual home birth with actual hospital birth with significantly different backgrounds.' Too old, not applicable to the UK.	Retrospective cohort	EL: 2-	Yes NCT felt this study did assess planned place of birth	Excluded No balancing nor adjustment for differing risk factors. Compared with all California births for 1973. Lay midwives involved.
2	Caplan 1985 ¹⁴ UK 1980-1981	Cross-sectional	External 'L' Internal 'L' Total 'L'	Excluded 'Use of actual place of birth populations, rather than planned birth ones, and the lack of any controlling for background risk of these two groups.'	Retrospective cohort	EL: 2-	No Compared actual place of birth, not planned place of birth.	Excluded
3	Shearer 1985 ¹⁵ UK 1978-1983	Cross-sectional	External 'L' Internal 'L' Total 'L'	Excluded 'No control of background obstetric risks was attempted.'	Prospective cohort	EL: 2-	Yes	Excluded High risk of confounding bias as no information on how the groups were matched.
4	Ford 1991 ¹⁶	Case series	External 'L' Internal 'L' Total 'L'	Excluded No control group	Case series	EL: 3	No EL: 3 (no control group)	Excluded
5	Durand 1992 ¹⁷ Tennessee, USA 1971-1989	Cross-sectional	External 'L' Internal 'L' Total 'L'	Excluded '...these were comparing actual home birth with actual hospital birth with completely different backgrounds.' In control group '...low birthweights and fetal deaths were deliberately over sampled.'	Retrospective cohort	EL: 2-	Yes	Excluded High risk of confounding bias due the way the control group was obtained.
6	Woodcock 1994 ¹⁹ Western Australia 1981-1987	Cross-sectional	EL: 3 External 'L' Internal 'L' Total 'L'	Included	Retrospective cohort	EL: 2+	Yes	Included Some balancing of baseline characteristics and adjustment.
7	Ackermann-Liebrich 1996 ²⁰ Switzerland 1898-1992	Cohort	EL: 2+ External 'L' Internal 'L' Total 'L'	Included But PNM not discussed because not reported in matched pairs.	Prospective cohort	EL: 2+	Yes	Excluded Some balancing of baseline characteristics but PNM not assessed by matched pairs.
8	Davies 1996 ²¹	Case series	External 'L' Internal 'L' Total 'L'	Excluded No control group	Case series	EL: 3	No EL: 3 (no control group)	Excluded
9	Dowswell 1994 ²² UK 1994	RCT	External 'L' Internal 'L' Total 'L'	Excluded No relevant outcomes	RCT	EL: 1+	No Did not assess PNM	Excluded
10	NRPMSG 1996 ²³ UK 1981-1994	Cross-sectional population based	EL: 3 External 'L' Internal 'L' Total 'L'	Included	Retrospective case control	EL: 2-	Yes	Excluded No balancing nor adjustment for differing risk factors social, medical or obstetric risk factors.
11	Wiegiers 1996 ²⁴ Netherlands 1990-1993	Cross-sectional	External 'L' Internal 'L' Total 'L'	Excluded Outcome reported was 'perinatal outcome index' defined by authors, and each relevant clinical outcome was not obtained.	Prospective cohort	EL: 2+	Yes	Included Though main outcome was 'perinatal outcome index' did report the numbers of babies who died.

Table 1 (continued):

No.	Study	IPC GDG assessment			NCT assessment			
		Type of study	Validity and evidence level (EL) if included	Included/excluded for safety of home birth	Type of study	Evidence level EL	Detailed assessment carried out Yes/No	Included/excluded in safety of home birth
12	Chamberlain 1997 ²⁵ UK 1994	Population-based cohort	External ⁺⁺ Internal ⁺⁺ Total ⁺⁺	Excluded ‘There were over 1,000 unmatched planned home birth women, but these women were included in the analysis. Moreover, social economic status and obstetric backgrounds of these two groups were reported as statistically significantly different;... No regression analysis was used.’	Prospective cohort	EL: 2+	Yes	Included A prospective matched study of women at low risk of complications. Although the demographics showed some differences, some factors were balanced between the groups.
13	Tew 1998 ²⁶	Cross-sectional	External ⁺⁺ Internal ⁺⁺ Total ⁺⁺	Excluded			No Compared ‘home birth’ + GP units with hospital births	Excluded
14	Bastian 1996 ²⁷ Australia 1985-1990	Cross-sectional population-based	EL: 3 External ⁺⁺ Internal ⁺⁺ Total ⁺⁺	Included	Retrospective cohort	EL: 2-	Yes	Excluded No balancing nor adjustment for differing social, medical or obstetric risk factors.
15	Janssen 2002 ²⁸ Canada 1989-1999	Cross-sectional	EL: 3 External ⁺⁺ Internal ⁺⁺ Total ⁺⁺	Included	Prospective cohort	EL: 2+	Yes	Included Some balancing of baseline characteristics
16	Johnson 2005 ²⁹ North America 2000	Case series	External ⁺⁺ Internal ⁺⁺ Total ⁺⁺	Excluded No control group	Prospective cohort	EL: 2-	Yes Included PNM rates from other birth settings	Excluded No balancing nor adjustment for differing medical or obstetric risk factors.
17	NCC-WCH 2007 ³¹ UK 1994-2003	Cross-sectional population based	EL: 3 External ⁺⁺ Internal ⁺⁺ Total ⁺⁺	Included	Retrospective case control	EL: 2-	Yes	Excluded No balancing nor adjustment for differing social, medical or obstetric risk factors.

IPC GDG inclusion criteria:

Total validity: any study in which both internal and external validity were the most valid was regarded as the most valid, and any study in which either internal and external validity were [+] and neither were [-] was also considered.

Internal validity:
 [++] = good RCT;
 [+] = any study with adequate design to control background medical and/or obstetric risks of women reporting relevant outcomes;
 [-] = study not reporting relevant outcomes and not meeting other validity criteria.

External validity:
 [++] = any study conducted in UK since 1980;
 [+] = any study in high-income country since 1980 where no UK study available;
 [-] = any other study

NCT inclusion criteria: all comparative studies (evidence levels 1 & 2) addressing the question of the safety of homebirth in terms of PNM or IPPM but only those graded as [+] were used to assess the comparative safety of planned home and planned hospital birth.

Table 2: Studies of reasonable quality for non-randomised studies, but still with a risk of confounding bias
a) Women at low risk of complications

Study	Description	Quality of evidence	PNM or IPPM outcome
Chamberlain 1997 ²⁵ UK 1994 Prospective cohort study	<p>Women at low risk of complications planning a home birth at 37 weeks were compared with a matched group of women planning a hospital birth, identified by the midwife during the same time period.</p> <p>Matching was on age, parity and obstetric history. Data on unplanned home births was also collected.</p> <p>There were 4,665 women in the planned home birth group and 3,319 women in the planned hospital group, with data also collected on 1600 unplanned home births.</p>	<p>Graded as evidence level 2+.</p> <p>It was analysed on both intention to treat and by actual place of birth.</p> <p>Sometimes midwives could not find a matched control but were encouraged to collect the data on the home birth anyway. Thus there is a discrepancy between the numbers of planned home births and planned hospital births. Matching was reasonable except for social class where the home birth group included more women of higher social class.</p>	<p>The perinatal mortality rate was no different between the two groups.</p> <p>Home: Five babies died out of 4,665 = 1.07 per 1000. Hospital: Five babies died out of 3,319 = 1.51 per 1000</p> <p>The authors concluded: ‘It is clear that the size of the potential bias arising from incomplete data collection is small where frequently occurring outcomes such as transfers to hospital, induction of labour, CS are concerned. Rare outcomes such as perinatal death are invalidated...We had recognised from the outset that this study did not have the power to detect any differences in perinatal death between women intending home or hospital birth... It is therefore essential that no conclusions are drawn from the figures relating to perinatal death.’</p>

Table 2a (continued):

Study	Description	Quality of evidence	PNM or IPPM outcome
Wiegers 1996 ²⁴ Netherlands 1990-1993	Women at low risk of complications booking home birth with a midwife at the time of booking compared with women choosing hospital birth, controlling for parity and social, medical and obstetric background.	Graded as evidence level 2+. It was analysed by intention to treat.	The perinatal mortality rate was no different between the two groups. Home: Four babies died out of 1,140 = 3.5 per 1000.
Prospective cohort study	In the planned home birth group, there were 471 women having their first baby and 669 having their second or subsequent baby. In the planned hospital group, there were 369 women having their first baby and 327 having their second or subsequent baby. Main outcome was perinatal outcome index consisting of 36 items.	Women were matched using a 'perinatal background index'.	Hospital: Two babies died out of 696 = 2.9 per 1000 The study was small and underpowered to assess perinatal mortality outcomes. The authors concluded: 'The outcome of planned home births is at least as good as that of planned hospital births in women at low risk receiving midwifery care in the Netherlands.'
Janssen 2002 ²⁸ British Columbia, Canada, 1989-1999.	Women at low risk of complications planning home birth with a midwife at 36 weeks were compared with women with similar obstetric risk planning to give birth in hospital with a physician or midwife. Women were matched by age, lone parent status, parity, hospital where the midwife had admitting privileges.	Graded as evidence level 2+. It was analysed on intention to treat and on intended place of birth at the onset of labour.	The perinatal mortality rate was no different between the two groups. Home: Three babies died out of 862 = 3.5 per 1000
Prospective cohort study	There were 862 women in the planned home birth group, 743 women in the planned birth in hospital with a physician group (matched) and 571 women in the planned birth in hospital with a midwife group (unmatched). The study took place during the first two years of implementation of midwifery in British Columbia and authors reported: 'The rugged geography and mixed weather conditions in Canada potentially present unique challenges for home birth.'	There were some variations in the socio-demographic and pregnancy related characteristics, and results were adjusted for confounders. The authors report problems in accessing all the relevant data. The study was small and underpowered to assess PNM.	Hospital with physician [matched]: One baby died out of 743 = 1.3 per 1000 Hospital with midwife [unmatched]: No babies died out of 571 The authors concluded: 'There was no increased maternal or neonatal risk associated with planned home birth under the care of a regulated midwife. The rates of some adverse outcomes were too low for us to draw statistical comparisons, and on-going evaluation of home birth is warranted.'

b) Populations of women with mixed risk of complications

Study	Description	Quality of evidence	PNM or IPPM outcome
Woodcock 1994 ¹⁹ Western Australia 1981-1987.	All women who had planned birth at home, thus mixed risk population, were traced from multiple sources and compared with a matched group of women planning birth in hospital.	Graded as evidence level 2+. It was analysed by intention to treat.	The perinatal mortality rate was no different between the two groups Home: Five babies died out of 976 = 5.1 per 1000
Retrospective cohort study	There were 976 women in the planned home birth group and 2,928 women in the planned hospital birth group. Women were matched by year of birth, parity, previous stillbirth/death of a liveborn child, age, height and marital status. Matching was not possible on socio-economic status, smoking, obstetric and medical history.	However, women were not matched on medical and obstetric risk factors and analyses were subjected to crude adjustment using logistic regression.	Hospital: Twelve babies died out of 2928 = 4.1 per 1000 Crude odds ratios had a wide confidence interval showing the large uncertainty in the results due to small numbers of events in both groups. The study was small and underpowered to assess perinatal mortality. The authors concluded: 'Planned home births in WA appear to be associated with less overall maternal and neonatal morbidity and less intervention than hospital births.'

Table 3: Studies with high risk of confounding bias for a comparative estimate of PNM or IPPM

Study	Description	Quality of evidence	PNM or IPPM outcome
NCC-WCH 2007 ³¹ UK, 1994 - 2003.	For a mixed risk population of women, IPPM for planned home birth at booking was compared with planned hospital birth.	Provided data on IPPM over a ten year period in the UK. Considered a poor quality study for assessing comparative safety because of high risk of confounding bias.	Across the ten year period, there was no statistically significant difference in the IPPM between the planned home births and all births.
Retrospective case control study	There was no assessment of the risk status of women included, and no assessment of the factors involved in any of the baby deaths. There were 96 IPPM events in the planned home birth group and 4,991 IPPM events in the UK across this ten year period. Outcomes were also reported for two five-year periods: 1994-1998 and 1999-2003. The number of women who planned home births was estimated by taking the number of actual home births, subtracting an estimated number of unplanned home births and adding an estimated number of transfers during pregnancy and during labour. The percentage of unplanned home births was estimated from three UK studies all carried out in the Northern region between 1983 and 1993. Transfers were averaged from four UK studies conducted between 1977 to 1994. Weighted means were calculated and sensitivity analysis gave upper and lower ranges.	Graded as evidence level 2-. There was no balancing for risk status or confounding factors. The data used to estimate the % of unplanned home births were taken from small studies, all in one region and over a different time period from the study itself. Also, more importantly, the authors estimated the unplanned home birth as a % of all home births. A more accurate estimate would have been to estimate the % of unplanned home births as a % of all births. This was shown to remain reasonably steady over a 10 year period at around 0.3% of all births regardless of the changing planned home birth rate. ⁶	The latter five year period did show a statistically significant higher IPPM for home birth with the authors' estimates. Using what NCT considered as more appropriate estimates for unplanned home births and transfers, calculations on the same data show no statistically significant difference in IPPM, illustrating the very poor quality of this data to address the safety of planned home birth. Authors concluded: 'Although those women who had intended to give birth at home and did so had a generally good outcome, those requiring transfer of care appeared to do significantly worse...The potential for confounding means the results of the present study must be interpreted with caution.'

Table 3 (continued):

Study	Description	Quality of evidence	PNM or IPPM outcome
NRPMSCG 1996 ²³ UK, Northern Region. 1981-1994 Retrospective case control study	For a mixed risk population of women, stillbirth and neonatal deaths in planned and unplanned out-of-hospital births in the Northern Regional health authority compared with all births in the same health authority. There was no assessment of the risk status of women included. There were 134 baby deaths outside hospital, and the authors reported that data on the number of women who had planned birth at home was hard to assemble, and the estimates of the number of women who had planned home birth but transferred during labour was even more difficult to obtain.	Provided data on IPPM for home and hospital births over a 14 year period in Northern England. Considered poor quality study for assessing comparative safety because of high risk of confounding bias. Graded as evidence level 2-. There was no matching for risk factors and no adjustment for confounders. Assumptions were made and some estimates seemed imprecise.	Over the whole 14 years, the risk of death during delivery or in the first four weeks of life in a baby of normal birth weight and without a lethal malformation was higher in those born to the small group of women who had booked for home delivery. However, during the last ten years of that period, when the midwife was always the community lead professional, mortality in this subgroup was lower in those booking for home delivery. Neither difference was statistically significant. Authors concluded: 'The perinatal hazard associated with planned home birth in the few women who exercised this option (<1%) was low and mostly unavoidable.'
Shearer 1985 ¹⁵ UK, Essex. 1978-1983 Prospective cohort study	Women at low risk of complications planning home birth were compared with women booked for hospital care under a consultant. There were 202 women in the planned home birth group meeting the criteria for low risk of complications compared with 185 women booked for hospital birth.	No adjustment for confounders, therefore, the study was considered to have a high risk of bias. Graded as evidence level 2-. There was no information on how the women were matched, and so it is not possible to assess how good or poor the matching was.	There were no baby deaths reported. The author concluded: 'The results of this study showed no evidence of an increased risk associated with home confinement but indicated that there were fewer problems than were encountered in the deliveries in mothers confined in hospital.'
Johnson 2005 ²⁹ North America 2000 Prospective cohort study	A population of women of unknown risk status planning home birth were compared with hospital births of singleton babies in the vertex position at 37 or more weeks as reported in the National Center for Health Services. There were 5,418 women in the planned home birth group (cared for by a registered midwife) and 3,360,868 hospital births. Intrapartum and neonatal mortality was also compared with other studies on planned out of hospital births and low risk hospital births in North America where at least 500 births were considered.	Provided data on over 5000 home births in North America. Considered a poor quality study for assessing comparative safety because of high risk of confounding bias as recognised by authors. Graded as evidence level 2-. There was no matching on background risk factors, no adjustment for confounders, and so the study was considered to have a high risk of bias for assessing comparative safety of home birth.	The PNM data compared favourably with data from other studies on low risk hospital births. Authors concluded: 'Planned home birth for low risk women in North America using certified professional midwives was associated with lower rates of medical interventions but similar intrapartum and neonatal mortality to that of low risk hospital births in the United States.'
Bastian 1998 ²⁷ Australia. 1985-1990. Retrospective cohort study.	A mixed risk population of women who had planned home birth at the beginning of labour compared with all women giving birth in Australia over the same period. There were 7002 women in the home birth group and 1,502,756 in the hospital birth group. The population of women choosing home birth included some women with increased risk, for example, women with breech babies and women with twins.	Provided data on over 7000 home births. Considered a poor quality study for assessing comparative safety because of high risk of confounding bias. Graded as evidence level 2-. There was no balancing of the differing demographic characteristics or varying risk status of the two populations of women, and no adjustment for confounders so this study was considered to have a high risk of bias.	Perinatal mortality was lower in the home birth group but intrapartum related perinatal mortality was higher. The paper reported on the factors associated with the baby deaths in the planned home birth group, and identified a number of women at increased risk choosing to give birth at home. Authors concluded: 'The death rate in Australian home births was higher than comparable births nationally and home births in other countries...While home birth for low risk women can compare favourably with hospital birth, high risk home birth is inadvisable and experimental.'
Ackerman-Liebrich 1996 ²⁰ Switzerland 1981-1992 Prospective cohort study	Women at low risk of complications choosing a home birth at the start of pregnancy were compared with a hospital cohort, matched on age, parity, medical history, partner situation, social class and nationality. There were 489 women in the planned home birth group, 385 women in the planned hospital group and 214 matched pairs.	Graded as evidence level 2+ except PNM not reported by matched pairs. It was analysed on intention to treat and reported findings for both matched and unmatched pairs. However, there was a small sample size, there were some differences in the matched pairs (home birth group weighed less) and there was no adjusting for confounders. Outcomes were reported for the matched and unmatched pairs separately. However, PNM was only reported by the unmatched pairs.	The perinatal mortality rate was no different between the two groups. Authors concluded: 'The study does not have sufficient power to exclude differences in rare events...Most indicators suggest that home delivery does not pose a higher risk than hospital delivery and that it reduces some of the additional risks of interventions.'
Mehl 1977 ³⁰ USA, California. 1970-1973. Retrospective cohort study	A mixed risk population of women who had planned home birth were compared with births across California over the same time period.	Considered a poor quality study for assessing comparative safety because of high risk of confounding bias. Graded as evidence level 2-. There was no matching of background risk factors, no balancing of nor adjustment for confounders, therefore the study was considered to have high risk of bias.	There was no statistically significant difference in PNM between the groups. Authors concluded: 'These figures demonstrate that in a self-selected, medically screened, low-risk population, home delivery with medical facility back-up can be a reasonable alternative to hospital delivery.'
Durand 1992 ¹⁷ USA, Tennessee. 1971-1989. Retrospective cohort study	A mixed risk population of women who chose home birth with a lay midwife were compared with a probability sample of national data for the whole of the US during 1980 for women attended by a physician. The women choosing home birth were of mixed risk, women laboured without analgesia but with emotional support from midwives and family. There were 1,707 women in the planned home birth group and 14,033 women in the planned hospital birth group. A hospital with surgical facilities was located a 20 minute drive from the community.	This was the largest comparative study of a cohort of home births at the time. Considered a poor quality study for assessing comparative safety because of high risk of confounding bias. Graded as evidence level 2-. There were concerns around the differences in characteristics between the home birth and hospital groups. Although weighted coefficients were used to compensate for differential sampling and each outcome was examined via multiple logistic regression equations, there was concern about the possible high risk if bias, graded as evidence level 2-.	There was no statistically significant difference in PNM between the groups. The perinatal deaths in the planned home birth group included lethal congenital malformations, complications relating to prematurity and death in utero before the onset of labour. Authors concluded: 'For relatively low-risk pregnancies, home birth with attendance by lay midwives is not necessarily less safe than conventional (hospital-physician) delivery...it is possible that unfamiliar setting and the presence of unfamiliar personnel, the limited presence and role of family members, and the restricted freedom of movement of the labouring woman may all create an atmosphere at a hospital birth that undermines self-confidence and encourages passivity on the part of the labouring woman, diminishing her ability to deliver spontaneously.'