Beyond Morecambe Bay

1) Maternity services should focus on safe, clinically effective care which leads to a positive, experience for the woman, her baby and her family.

2) This is not the focus in every unit. Instead some services have become embroiled in a struggle where normality and caesarean reduction have become the aim rather than the physical and emotional wellbeing of all women and babies. This problem was identified on the first page of the Morecambe Bay Investigation Report: ¹

   ..Midwifery care in the unit became strongly influenced by a small number of dominant individuals whose over-zealous pursuit of the natural childbirth approach led at times to inappropriate and unsafe care. One interviewee told us that “there were a group of midwives who thought that normal childbirth was the… be all and end all… at any cost… yeah, it does sound awful, but I think it’s true – you have a normal delivery at any cost”. Another interviewee “… was aware that there were certain midwives that would push past boundaries”. A third told us that there were “… a couple of senior people who believed that in all sincerity they were processing the agenda as dictated at the time… to uphold normality…”

   However, the normality agenda is part of the philosophy of modern maternity services and is deeply entrenched in its culture. There needs to be paradigm shift in attitudes to maternity services so that it serves the needs of ALL women and babies.

3) Intervening in straightforward labour when those interventions are unwelcome and provide no benefit to the mother and baby is clearly wrong and we would support all efforts to see these interventions eliminated. Reducing the incidence of complications by helping women feel supported and respected, by ensuring adequate staffing, communicating well and by providing one to one care in labour is common sense. This is implicit in the aspiration to provide safe, clinically effective care which results in positive experiences.

   However too much focus on ‘promoting normality’ can lead to a pressure to treat labour with significant risks as normal when it clearly is not. This is important in view of the growing risk factors amongst the female population; women having babies at a greater age, more IVF, more obesity, more diabetes and a significant and unexplained increase in the birth weight of babies. ²a,b

4) Thought also needs to be given to the psychological impact of labelling births ‘normal’ and describing women as ‘achieving normal birth’. The corollary of normal is abnormal. A very significant proportion of women will not have a normal birth and it would be healthier to

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¹ Morecambe Bay Investigation https://www.gov.uk/government/publications
encourage all women to feel that the birth of a baby is an achievement regardless of how it is born.

5) Quality services need to be listening services. Women have a diverse range of attitudes, fears and expectations about birth. Some women will have a strong desire to give birth naturally, while others will not feel safe without neonatal services, epidurals and doctors close at hand. It is important that services are respectful of the diversity of women's needs and not focused on ‘promoting’ choices that suit professional preferences. This respect needs to be enshrined in the training of health professionals.

Dissatisfaction is occurring in both directions particularly in respect of place of birth; pressure to give birth in the community when the woman does not want this or, conversely, pressure to give birth in hospital when the woman has no risk factors and wants to give birth at home. The following posts are from the parenting site Mumsnet:

"I am considered low risk, and I don't feel I'm being offered a choice - it's being assumed that I'll want to give birth in a midwife led unit. I'm happy with the idea of gas and air as pain relief, but I think I would feel much more relaxed in the labour ward than in a midwife led unit.” 3.12.14

"Had a HB planned (bought pool and everything), then when my waters broke I rang the community MW team to be told "we're busy - you'll have to go to hospital". 19.3.13

6) Choice requires that accurate, robust information is communicated in a comprehensible and consistent way by all maternity service health care professionals. Professionals also need to be honest about uncertainties in the evidence and careful not to impose their own beliefs and values on women. Efforts to ‘promote’ choices beyond a balanced discussion of risks and benefits are misplaced. Choices are made; they should never be directed. This applies as much to place of birth as mode of birth. Pregnant women’s right to be properly informed and engaged in decisions about their care has been strengthened by the recent landmark Montgomery versus Lanarkshire 2015 case:

A small framed diabetic woman with a large baby expressed concern about the forthcoming birth to her doctor. According to the judge, the doctor seemed to believe that vaginal birth was ‘morally superior’ and therefore failed to discuss the possibility of a section with Ms Montgomery. The baby was starved of oxygen and suffered brain damaged during the subsequent traumatic vaginal birth. The negligence claim was upheld.³

7) The following are examples where normality and good outcomes conflict:

a) High risk women and their babies

Women are having babies later in life, babies are increasing in size, women are bigger, leading more sedentary lives and there is more IVF. This is leading to a significant

increase in obstetric complications and many women have no prospect of ‘normal’ birth. It is clearly inconsistent to have the main profession caring for women so focused on normal birth when it is not relevant to so many women or their babies. The maternity services need to focus on the needs of ALL women ensuring all have a positive experience regardless of how the baby will be born.

b) Tokophobia

Tokophobic women have extreme fear of childbirth and expecting a baby is a time of terror: they feel the birth impending like a ticking time bomb. Many sufferers cannot eat or sleep. As each day goes by the anxiety and terror increase until in many cases they become unable to function.

Some want to overcome their fear and give birth vaginally, others need immediate assurance they can have a caesarean. Instead, many are cajoled to consider vaginal birth. This causes incalculable distress and often leads to postnatal mental breakdown particularly where the women is eventually refused her caesarean. Charities deal with the fallout of this ill treatment. This is not individualised care - it is unforgivable cruelty; the doctrine of ‘normality’ prioritised at the expense of women’s health.

c) Breech Birth

National guidance and Royal College of Obstetricians and Gynaecologists Green-top Guidance make it clear that all women with a breech baby should be offered caesarean section because it reduces perinatal mortality and morbidity. Women are rightly at liberty to reject this advice but the option should be offered and the risks must be explained.

This, however, was a quote from the RCM website ‘Campaign for normal birth’ reference to breech birth

“Even though many babies presenting by the breech can and should be born normally, caesarean section is currently the most common mode of delivery (irrespective of clinical indicators”

Advising a woman that her breech baby ‘should be born normally’ is grounds for clinical negligence (failure to inform); indeed we understand this was cited in recent cases of a widely publicised breech birth fatality:

http://www.dailymail.co.uk/news/article-3253702/Parents-baby-died-panic-delivery-room.html#comments

The maternity services need to operate as a single cohesive partnership where midwives and obstetricians agree on risk and provide women with consistent advice. This cannot happen where one part of the service is focused on risk and the other on ‘promoting normality’.

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Epidurals

Normal birth is defined on the RCM website as birth without interventions such as epidurals.

Failure to provide adequate pain relief is a frequent complaint and NICE guidance makes it clear, that after explanation of risks and benefits, requests for epidurals should not be refused. Despite this more than a third of women in the recent NPEU Maternity Survey said they did not get the pain relief they wanted.\(^5\)

A Post on Mumsnet in 2011 entitled ‘Anyone else tricked out of epidurals’\(^6\) was bombarded with so many responses in a short space of time that it was reported in the Times.

We cannot have a service focused on promoting a definition of ‘normal birth’ when it leaves women dissatisfied and sometimes traumatised; it is inconsistent with respect for choice and a positive patient experience.

8) There is a lack of consistent policy documents and policy confusion. A myriad of documents, produced by the NHS and professional organisations, recommend ‘targets’ or aspirational levels for interventions such as caesarean and for normal birth. Unlike NICE & the Green-tops, some of these documents are notable in providing no robust evidence whatsoever for the safety of the ‘targets’ to which they aspire.

a) Some of these, such as the NHS document entitled ‘Focus on normal birth and reducing caesarean rates’ advocate dangerous practices. As an example of good practice, it advocated augmenting labour in women attempting vaginal birth after a previous section in exactly the same way as women who had never had a section.\(^7\) This is clinically negligent, risks uterine rupture and is contrary to RCOG Green-top guidance. With the help of a well respected obstetrician, charities were able to get this document withdrawn but it is unacceptable that such oversight should be the responsibility of user groups.

b) The NCT, RCOG and RCM ‘Consensus on Normal Birth’ document called for a 60% aspirational target for ‘normal birth’.\(^8\) No evidence is provided for how this figure was arrived at. It included, as ‘normal births’, women who suffered perineal trauma, haemorrhage or whose baby was admitted to special care but excluded those who used epidural pain relief. Despite vociferous objection from user groups, the obstetric anaesthetists association\(^9\) and neonatologists, it remains in circulation.

c) The Department of Health, NHS England and health services need to be much more focused on ensuring some of these non-evedenced based documents are removed from circulation and that no more public money is wasted on producing them.

d) Interventions need to be offered when they are clinically appropriate, recognising women need to be fully informed and may reject interventions that are offered. Clinical

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\(^5\) Safely Delivered A national survey of women’s experience of maternity care NPEU 2014
\(^6\) http://www.mumsnet.com/Talk/childbirth/1147361-Anyone-else-tricked-out-of-epidural/AllOnOnePage
\(^7\) Focus on Normal birth and reducing caesarean rates NHS NII 2008 (withdrawn).
\(^8\) Making Normal Birth a Reality
\(^9\) http://www.aa-anaes.ac.uk/UI/Content/Content.aspx?id=143
appropriateness can be judged by clinical audit with reference to RCOG Green-tops and NICE guidance. Where parties feel that too many interventions are being carried out, they need to produce the evidence to NICE and the RCOG and get the guidance changed.

9) Training of maternity professionals needs to be much more integrated so that midwives, obstetricians, neonatologists and anaesthetists undergo some of their training together. This would both improve team working and ensure that all women get consistent rather than contradictory information. Many midwives provide outstanding empathetic care to women despite the pressure under which many work. However, some seem let down by their training which seems insufficiently focused on what matters: the health and physical and emotional safety of women and babies. One university based Midwifery School describes its Midwifery BSC Honours thus:

The main focus of the course is the promotion of normality i.e. the framing of childbirth as a normal physiological process which the majority of women will undergo in their lifetime.

This is completely wrong; the focus of midwifery is to provide safe, clinically effective care that results in a positive experience for ALL mothers and babies. Midwives need to be kind, sympathetic and supportive when caring for women with straightforward births but also able to recognise complications and respond not only appropriately but quickly. The promotion of normality as the focus of midwifery care is dangerous in this respect; it risks midwives being blind to clinical indications and tardy in reacting appropriately.

10) Some junior doctors are also clearly working beyond their skill level on obstetric wards particularly in the case of instrumental deliveries. Some comment they feel ‘marked down’ if they call for senior help too frequently. Senior obstetricians need to take the lead in positively encouraging less experienced doctors to be open about their uncertainties. A single case of brain damage can result in upwards of £8,000,000 in damages taking into account legal costs; for the family it will be devastating. The NHS cannot afford to have doctors fearful for their prospects if they ask for advice.

11) Lack of skills, knowledge and understanding on the part staff has been noted in confidential enquiries as the root cause of many serious outcomes. Parents often remark that they did not feel listened to when they raised concerns which subsequently proved well founded. Thought needs to be given to how parents can directly escalate their concerns and obtain a second opinion about the care they are receiving. More importantly, the wider issue of how to improve the clinical skills and knowledge of maternity staff needs to be addressed.

12) Organisations need to learn lessons rather than apportion blame when things go wrong. Importantly they need to learn to say sorry at an early stage and, in cases of negligence, tell families what efforts they are making to ensure there will be no recurrence.

13) Commissioning of services needs to be based on what women choose not what women can be persuaded to choose. Women are being nudged into community births they do not want and denied homebirths when they request them:


10 Saving Mothers lives Dec 2007 CEMACH
a) The case for home birth, alongside midwifery units and consultant units is well made and there is absolutely no doubt that these are important and valued choices for many women. The popularity of freestanding midwifery units needs further exploration. For 2012/13 the RCM document Trends in Freestanding Midwifery Units (link below) showed that in 2012/13, 3 units opened and 6 closed.


Some units are being built at considerable expense and then closed down shortly after:

http://www.standard.co.uk/news/3m-birthing-centre-closes-after-four-years-6641206.html

The main reasons for closure seem to be that women are not choosing to give birth in freestanding units. As a consequence the ‘per birth’ cost is unsustainable. One clinical commissioning group cites a per birth cost of over £7000 per FMU birth. ^11

b) We would fully support freestanding midwifery units where women are choosing them of their own volition. Where this is resulting in unsustainable costs as a result of low take up, then health services will need to consult local service users. However, women should not be pressured to give birth in unpopular units simply to save them from closure.

c) Most, but not quite all, low risk women in UK are given a choice of birth in the community or birth in a hospital or a unit attached to a hospital. ^12 All women should be offered these choices. The majority of women choose hospital or alongside midwifery units. Reasons include not wanting to transfer in an emergency, access to epidurals, and proximity of neonatal care. As a consequence, individualised care is often poor, particularly in the busiest hospitals. It would seem sensible to ensure that all women receive comparable care and staffing levels wherever they give birth.

d) Some women choose homebirth because their experience of hospital birth was so traumatic. This is not truly a positive choice. The psychological experience of hospital birth needs improvement so that women feel more in control and supported. This is particularly important as some women have risk factors and have no other safe choice of place of birth. The improvement of hospital care has received too little focus. Women who choose homebirth should be doing so because it is their first choice, not simply because the alternative is so awful.

e) For women, the choice of where to give birth, particularly if this is their first child, is not an easy one. They do not know in advance whether they will have a straightforward labour needing minimal medical attention or a difficult one requiring strong pain relief and possible medical intervention. Yet they are expected to make a decision about whether to give birth in the comfortable, relaxed surroundings of home or a midwife-led unit, or in a busy, overstretched consultant-led unit that has easy access to emergency care. Women may feel

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^12 Safely Delivered A national survey of women’s experience of maternity care NPEU 2014
guilty and angry with themselves if they later believe they have made the wrong choice. We firmly believe the environment in which all women give birth should be both comfortable and safe.

f) Thought also needs to be given to choices that might be popular but are not yet generally available; in particular alongside midwife units with an integrated epidural service or making hospital birth more homely and better supported.

14) Policy change and major studies likely to influence policy need to incorporate the views of adverse outcome groups as well as those groups advocating birth in the community. Failure to do this and failure to include sufficient doctors (obstetricians, neonatologists and anaesthetists) on advisory panels has permitted policy to be made on the basis of weak or profoundly flawed data particularly in respect of safety.

15) One example of controversial interpretation of data was the Birthplace Study. There is no doubt the study points to the safety of community birth for low risk women who both choose that setting and are expecting a second or subsequent baby. What it does not confirm is the safety of community birth for first-time mothers or women who are ‘directed’ to that choice.

a) The Birthplace study cost £13 million most of which was paid to individual hospitals to collect data. The study design was very seriously flawed. Not a single user group with detailed knowledge of the root cause of adverse events was invited on the contributor panel for outcomes study. The user group which was involved is a staunch advocate of community birth. There was only one obstetrician and midwives outnumbered obstetricians 3:1.

b) Despite its cost, the Birthplace Study would inevitably be a low quality ‘observational’ study as graded by NICE. A higher quality study would have required randomisation and blinding. Blinding is impossible and randomisation to place of birth would have been unethical since women have strong views on where they want to give birth.

c) Observational studies are subject to multiple biases; the largest of which, in this case, is that women self select. Although the Birth Place study was of women categorised as low risk, this is a misleading term. Within low risk, there is a wide spectrum from women who are very low risk indeed to those who are almost high risk. The Birthplace Study divided these women in 5 groups or ‘quintiles’ based on their risk profile within ‘low risk’. Significantly more women with the highest level of risk factors chose consultant birth. Such was the bias this created that a true comparison with other places of birth was impossible. (Page 202 Birthplace Cohort Study).

d) The best grade an observational study can achieve is a ‘low grade’. However, NICE quite correctly graded the study as ‘very low’ for nearly all the important outcomes. This was unacceptable for such a high-cost study.

e) To produce an observational study strong enough to change policy requires robust evidence and sufficient size to detect important differences.

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13 Birthplace National Prospective Cohort Study
http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0006/84948/SDO_FR4__-08-1604-140_V04.pdf
Flaws in the study are thus:

- **The study was only powered to detect a 90% increase in risk of adverse outcomes between the consultant unit and midwifery units.** Anything below this could be reported as no evidence of increased risk. The study size calculation was independently assessed by a highly qualified epidemiologist who agreed that it was seriously flawed and undermined the conclusions of the study. This independent assessment is available for inspection but not for publication (APPENDIX 1)

- **The cohorts (home birth, midwife-led and consultant unit) needed to be matched. They were not.** In the primary analysis the consultant group contained 20% of women who had complications at the start of labour and these were INCLUDED in the primary analysis. These represented over 40% of the consultant unit adverse outcomes; it was a comparison of apples and pears. There is no credible explanation for this. It was clearly wrong.

- **All the data needed to be collected.** This is vital because the records of greatest interest would be those which were hardest to collect particularly for birth in community settings. Women and babies would have been transferred to a different location or be under review as a serious untoward incident. Tracking the outcomes in these cases would have been much harder but it was absolutely vital for the research team to achieve comprehensive data returns. The Netherlands prospective study of over 37,700 births entitled\textsuperscript{14} had data losses of only 0.02%. No more than 2-3% data losses should have been accepted.

In fact, although many hospitals returned their data efficiently to the Birthplace researchers, others returned less than 85%; how much lower than 85% could not be ascertained from the research team. Random data returns are of no use whatsoever in a study looking at relatively rare but high consequence outcomes.

- **Adverse outcomes were aggregated into ‘composite outcomes’ but these were not comparable.** Death and brain damage were treated as comparable to fractured clavicle and other much less serious outcomes. The obstetric unit – after removing the unmatched 20% of women with risk factors – had a much lower percentage of the grave outcomes but this was hidden in the aggregation.

- **Account needed to be taken of distance to consultant unit for all out of hospital birth units so that a subanalysis of outcomes against transfer time could be assessed.** This was simply not done and is one of the major failings. The advisory team appeared to have insufficient knowledge of the root causes of adverse events in community settings.

\textsuperscript{14} Perinatal mortality and severe morbidity in low and high risk term pregnancies in the Netherlands: prospective cohort study. BMJ 2010; BMJ 2010;341:c5639
The better adjusted data in Table 59 (below) in the Birthplace study clearly shows a statistically significant odds ratio increase in risk for first-time mothers (nulliparous) who give birth in a freestanding midwifery units of 2.29. (FMU – odds ratio (OR) in far right columns). It comes from units which returned over 85% of their data whilst excluding all women who were sent to the obstetric unit because they had complications at the start of labour.

| Primary outcome for babies of 'low risk' women without complications at the start of labour in the Birthplace study (nulliparous) who give birth in a freestanding midwifery unit (FMU) |  

| Events Births n/1000 (%) | Weighted1 n=63732 | Unadjusted1 n=62036 | Adjusted1,2 n=62036 |  

| Planned place of birth |Nulliparous women |  |  |  |  |  

| OU | Home | FMU | AMU | Total |  

| Ov 17 | 5947 | 2.8 | (1.7-4.5) | 1 | - | 1 | - | 1 | - | 1 | - | 2.29 | (2.42-2.92) |  

| Home 35 | 3611 | 10.8 | (7.9-13.6) | 3.05 | (2.12-7.12) | 4.10 | (2.28-7.38) | 4.63 | (2.92-7.32) |  

| FMU 20 | 4074 | 5.2 | (3.3-8.6) | 1.85 | (0.55-6.63) | 1.95 | (0.51-7.35) | 2.29 | (1.17-4.47) |  

| AMU 24 | 3942 | 3.4 | (2.2-9.2) | 1.21 | (0.64-2.29) | 1.29 | (0.69-2.46) | 1.47 | (0.79-2.72) |  

| Total 95 | 19977 | 3.2 | (2.2-4.3) | 1 | - | 1 | - | 1 | - | 1 | - |  

| Multiparous women |  

| Ov 18 | 5555 | 3.2 | (1.6-8.5) | 1 | - | 1 | - | 1 | - | 1 | - |  

| Home 24 | 9990 | 2.2 | (1.5-3.1) | 0.69 | (0.25-1.86) | 0.70 | (0.25-1.86) | 0.78 | (0.40-1.54) |  

| FMU 11 | 4663 | 2.3 | (1.3-4.0) | 0.73 | (0.23-2.10) | 0.79 | (0.26-2.12) | 0.89 | (0.42-1.86) |  

| AMU 17 | 6070 | 2.9 | (1.9-9.3) | 0.91 | (0.39-2.09) | 0.95 | (0.43-2.32) | 1.03 | (0.47-2.37) |  

| Total 70 | 25848 | 3.0 | (2.0-8.1) | 1 | - | 1 | - | 1 | - | 1 | - |  

Adjusted regression test of heterogeneity p-values: Home =< 0.001 ; FMU = 0.07 ; AMU 0.53 ; Overall =< 0.001

1 Weighted to reflect each unit’s duration of participation, the sampling of OUs and to take the clustered nature of the data into account.

2 Restricted to women included in the adjusted analysis.

3 Adjusted for maternal age, ethnic group, understanding of English, marital/partner status, body mass index, index of multiple deprivation score quintile, previous pregnancies >24 weeks, and gestation (completed weeks).

f) How did Birthplace make the claim that there was no risk for first time mothers in free standing midwifery units? As stated earlier, 20% of the obstetric unit cohort were higher risk births as a consequence of complications at the start of labour. Table 24 (below) shows the data and analysis with the 20% high risk group included. The final column of this table shows no statistically significant risk for Free Standing Midwifery Units (FMU). Note the 5.3 adverse outcomes per thousand in the Obstetric Unit which is higher than the FMU’s 4.5. This was the table on which the Birthplace study claimed no evidence of risk.

| Primary outcome for 'low risk' women by parity and planned place of birth |  

| Events Births n/1000 (%) | Weighted1 n=62036 | Unadjusted1 n=62036 | Adjusted1,2 n=62036 |  

| Planned place of birth |Nulliparous women |  |  |  |  

| OU | Home | FMU | AMU | Total |  

| 52 | 20541 | 5.3 | (3.0-7.3) | (6.2-13.1) | 1.75 | (1.08-2.82) | 1.76 | (1.10-2.82) | 1.75 | (1.07-2.86) |  

| Home 30 | 4488 | 9.3 | (6.5-13.1) | 1.75 | (1.08-2.82) | 1.76 | (1.10-2.82) | 1.75 | (1.07-2.86) |  

| FMU 24 | 5158 | 4.5 | (2.8-7.1) | 0.84 | (0.48-1.60) | 0.85 | (0.48-1.68) | 0.91 | (0.52-1.60) |  

| AMU 38 | 8256 | 4.7 | (3.1-7.2) | 0.89 | (0.52-1.60) | 0.90 | (0.53-1.68) | 0.96 | (0.58-1.68) |  

| Total 153 | 28443 | 5.3 | (4.0-7.0) | 1 | - | 1 | - | 1 | - | 1 | - |  

| Multiparous women |  

| OU 20 | 8080 | 3.3 | (2.2-5.0) | 1 | - | 1 | - | 1 | - |  

| Home 31 | 12050 | 2.3 | (1.6-3.2) | 0.70 | (0.41-1.21) | 0.70 | (0.41-1.21) | 0.72 | (0.41-1.27) |  

| FMU 17 | 6025 | 2.7 | (1.6-4.6) | 0.83 | (0.42-1.63) | 0.86 | (0.44-1.69) | 0.91 | (0.46-1.80) |  

| AMU 20 | 8234 | 2.4 | (1.4-4.2) | 0.73 | (0.36-1.50) | 0.77 | (0.38-1.57) | 0.81 | (0.40-1.62) |  

| Total 97 | 35289 | 3.1 | (2.2-4.5) | 1 | - | 1 | - | 1 | - | 1 | - |  

Adjusted regression test of heterogeneity p-values: Home 0.01 ; FMU 0.99 ; AMU 0.69 ; Overall 0.05

1 Weighted to reflect each unit’s duration of participation, the sampling of OUs and to take the clustered nature of the data into account.

2 Restricted to women included in the adjusted analysis.
Table 25 (below) shows the same data but for low risk women in which the higher risk women with complications at the start of labour are removed making the cohorts more comparable. Note however, that the number of adverse outcomes per thousand for the OU is now very different and lower than both the FMU and AMU (alongside midwifery unit). However, the Birthplace Study can still claim ‘no risk’ as the confidence interval does not show a statistically significant increase in risk.

A further difficulty with the data in both Tables 24 and 25 is that they include units that had a less than 85% response rate. Because of the higher likelihood of losing the most important data as a consequence of transfer or serious incident review, the better data would be from the units that returned more than 85%. Although the ‘greater than 85%’ data was published in the Birthplace study and is shown in Table 59 above, the less than 85% data was not. However, it has been generated in this report and is given in Appendix 2. It can be seen that the rate per 1000 for the less than 85% response units is totally different to the better data. The ‘more than 85%’ group is around three quarters of the data yet the effect of the smaller less well collected data set is to completely change the appearance of risk.

It can be argued that the progression from Table 24, to 25 and finally Table 59 refines the accuracy of the data and each time the FMU risk increases with the final table showing a statistically significant increase in risk.

It is notable that the RCOG also disagrees that first-time mothers should be told community birth represents no increased risk:

*Based on these findings (Birthplace), the RCOG advocates that first-time (nulliparous) mothers should be advised of the benefits of delivering in OUs or alongside midwifery units (AMU) unless geography prohibits.* Tony Falconer President RCOG 1.12.2015 BMJ
The information above does not provide evidence that birth in a freestanding midwifery unit is unsafe for first time mothers. The risks are relatively small and a more convincing study involving a much larger, matched cohort of women would be required for this. *What is totally indefensible to claim ‘no evidence of increased risk’ for first-time mothers in free standing midwifery units on the basis of the evidence we have; the consistent trend in the data suggests exactly the opposite. The conclusion must therefore be that we simply do not have sufficient evidence on the safety of freestanding units for first time mothers.*

Several other studies are suggestive of higher risk for first time mothers in community settings 15

16) NICE guidance needs to be independent. The National Collaborating Centre for Women and Children’s Health (NCCWH) is the body responsible for preparing NICE Maternity Guidelines. The Birthplace Study was one of the main sources of evidence used by this by Guideline Group in arriving at their recommendations. It made some unusual decisions in respect of the NICE Intrapartum Guideline Update 2014:

a) It appointed a well qualified obstetrician well known for her advocacy of birth in the community. It was an unusual choice of chair. A more neutral chair would have been expected for such a controversial topic. The NCCWCH has been unable to justify its choice.

b) There were only two mainstream obstetricians

c) Data selection was extremely unusual. In the neonatal deaths and clinical brain damage analysis, the guideline selected the primary analysis data from Birthplace, not the better quality data which was available which excluded the unmatched 20% of women with problems at the start of labour. *This made these adverse outcomes seem nearly 70% higher in obstetric units.* Why did it use this data when better data was available?

Unsurprisingly the RCOG commented on this at considerable length in their response to the guideline and referred to the bias against obstetric units. 16 There was much criticism of the ‘selectivity’ of the data in the medical and wider press (Appendix 3)

17) Given the worrying data from Birthplace, much better data from a much larger sample is needed, identifying, at unit level, all cases of stillbirth, neonatal death and brain damage by final and planned place of birth at the start of labour for women without risk factors. Direct comparison of Obstetric units and other settings is unhelpful. It will always favour out of hospital settings as these have far fewer high risk women and babies. The paucity of data was highlighted in the Morecambe Bay Investigation:

38. Mortality recording of perinatal deaths is not sufficiently systematic, with failures to record properly at individual unit level and to account routinely for neonatal deaths of transferred babies by place of birth. This is of added significance when maternity units rely inappropriately on headline mortality figures to reassure others that all is well. We recommend that recording systems are reviewed and plans brought forward to improve systematic recording and tracking of perinatal deaths. This should build on the work of national audits such as MBRACE-UK, and include the provision of comparative information to Trusts. Action: NHS England.

18) Poor health economic evaluation can result in wasted resources. There are clear anomalies in evaluations e.g. free standing midwife units being closed down on cost grounds when they


have been judged as more cost effective by NICE. Highly expensive surgery for obstetric tract injury is not being costed nor psychological treatment for PTSD 17

The NHS Litigation Authority has an immense body of knowledge of risk, safety and the ‘root cause analysis’ of the 1 in 600 maternity cases that result in a claim but it seems to be rarely actively engaged in policy making. Litigation should not drive care but neither can the NHS ignore it. Health economic evaluations must include a ‘risk’ element as most insurers do.

The costs to the NHS when things go wrong are almost unimaginable. There have been £3,117,649,888 in NHSLA maternity claims in a recent ten year period 18. This does not include unsettled claims pre March 2000, nor claims below the Clinical Negligence Scheme for Trusts threshold, nor claims for injury to the child which have up to 25 years to be registered. Behind every litigation claim is a human tragedy. Health economic evaluations need to be markedly improved so that the real cost of services and their consequences are known.

In conclusion the NHS should:

- Focus on best outcomes for the mother and baby – psychological and physical so that all health care professionals work to the same common goal.
- Ensure that the information on which choices are made is communicated as accurately as possible including uncertainties in evidence.
- Fully engage women in decision making including about where and how they have their baby ensuring information provided is tailored to their individual risk factors.
- Improve the quality of data on which policy decisions are made.
- Provide fewer, consistent and better evidenced policy documents which are formulated with engagement of a wider range of professionals and user groups.
- Ensure more integrated training of midwives, obstetricians, anaesthetists and neonatologists to improve teamwork so that maternity services operate as a single cohesive team.
- Improve overall knowledge & skills of midwives and junior doctors.
- Improve data collection and health economic evaluations so that the true cost of maternity care - not simply the short term costs – can be more accurately estimated. Savings would thereby be generated for the NHS which can be reinvested in improved staffing.
- Reduce the number of adverse events that lead to litigation.

Whilst more robust health economic analysis is needed to understand the true cost of maternity care one thing is certain. The most cost effective birth will always be one that results in a physically and emotionally healthy mother and baby. Perhaps it is time to reflect on this and ensure that when we ‘change childbirth’ in future, we change it for the better.

18 Ten Years of Maternity claims NHSLA
Appendix 1


Reviewer: XXXXXXXX
Scientist (epidemiologist)
XXXXXXXXXXXXXXXXX

Disclaimer: The reviewer has no conflict of interest.

The aim of the study was to compare perinatal outcomes, maternal outcomes, and interventions in labour by planned place of birth at the start of care in labour for women with low risk pregnancies. Comparison birthplace groups were all NHS trusts providing intrapartum care at home (Home), all freestanding midwifery units (FMUs), all alongside midwifery units (AMUs: midwife led units on a hospital site with an obstetric unit), and a stratified random sample of obstetric units (OUs) in England.

The study found that overall, there were no significant differences in the adjusted odds of the primary outcome for any of the non-obstetric unit settings compared with obstetric units. One of the findings of this study was about nulliparous women, for whom the odds of the primary outcome were higher for planned home births (adjusted odds ratio 1.75, 95% CI 1.07 to 2.86) but not for either midwifery unit setting. Based on these findings, authors concluded that women planning birth in a midwifery unit and multiparous women planning birth at home experience fewer interventions than those planning birth in an obstetric unit with no impact on perinatal outcomes.

Concluding equal safety of giving birth in the midwifery units compared to obstetric units based on negative (no difference) findings would be a wrong conclusion if the study does not have enough statistical power to claim so. Therefore, an ad hoc (priori or beforehand) sample size calculation is essential for such kinds of studies to prevent wasting limited resources of health care system and limited research budget as well as avoiding wrong conclusions, especially when we are talking about a serious outcomes, including perinatal mortality, in other words deciding for life or death of babies. Every reviewer would first check whether such an ad hoc sample size calculation has been done for this study or not, and whether this was done in an appropriate way.

Authors of this study claim that they have done sample size calculation and they have provided explanations in the study protocol (appendix 1 on bmj.com). But, there are some fundamental problems in this crucial stage of study design, which arise serious doubts about the validity of the findings and conclusions, especially negative findings:

Firstly, authors stated in the article that “The target sample size was at least 57 000 women overall: 17 000 planned home births, 5000 planned alongside midwifery unit births, 5000 planned freestanding midwifery unit births, and 30 000 planned obstetric unit births (of which we estimated 20 000 would be low risk). Participating units/trusts collected data for varying periods of time within the study period 1 April 2008 to 31 April 2010.” No reason has been provided why and based on what calculations 57 000 was set as the target sample size. In addition, arrangements for number of participants in each unit (17 000 Home, 5000 each midwifery unit) seem quite odd as it has nothing to do with the distribution of birthplace in England as follows: “Of women giving birth in 2007, around 8% gave birth outside an obstetric unit—2.8% at home, around 3% in alongside midwifery units, and just under 2% in freestanding midwifery units.” It is unknown how authors have come up with these 17 000, 5000 and 5000 numbers. Suppose 17 000 is maximum number of participants that will give birth at home during the 2-year period of the study, then estimated number of participants in FMUs would be 18 214 and AMUs 12 143, which are far beyond the suggested 5000 for each. An appropriate sample size calculation to estimate minimum required number of participants in each unit for a meaningful analysable study population could be done based on preset values for statistical power of the study (conventionally 80%), a two-sided level of significance (usually 5%), an estimate of prevalence of outcome in the control group (3.6/1000 in OU as they
estimated), and a clinically significant effect size (e.g. about 50% increase in risk of primary outcome in each type of units compared to risk in the OUs, or odds ratio of 1.5). Using www.openepi.com, Sample Size for Cross-Sectional/Cohort Studies section, at least 21 917 participants in each unit would be needed for a conclusive study. None of the units had this amount of participants.

Secondly, despite the first estimation of 5000 participants in FMUs, the actual sample size for FMUs turned to be 11 282. To be able to conclude lack of evidence for difference in outcome between FMUs and OUs, at least 59 330 controls (participants in OUs) would be needed. Using 19 706 controls in this study is far less than what is required for the conclusions that were inferred from results of this study, especially for midwifery units that had much less participants than needed. Inadequate sample size, which is evident in this study, has influenced the entire study. As effect size for Home (odds ratio 1.59-2.80) was larger than what was preset for sample size calculation (1.5) and the fact that their number of participants (16 840) was closer to minimum required sample size in each unit (21 917), the result for comparison between Home and OUs turned out to be significant, which can be a real association in contrast to association due to random variation (which was the case in under-power part of the study, inadequate sample size in FMUs).

Thirdly, it is evident that sample size calculations stated in the study protocol were post hoc, which means they had been done afterwards instead of beforehand and arise ethical question: “FMUs and AMUs were to be analysed separately when being compared to OUs. With 5,000 women included from each type of midwifery unit, the study would be able to detect an increase in the incidence of the primary outcome from 3.6 per 1,000 births in OUs to 6.8 per 1,000 in midwifery units, with a 5% two sided level of significance and 80% power.” In the appropriate way of sample size calculation, the effect size (odds ratio) is preset along with values for power of the study (conventionally 80%), a two-sided level of significance (usually 5%), an estimate of prevalence of outcome in the control group (3.6/1000 in OU). But in this study as stated in the aforementioned quoted sentence in the study protocol, the sample size, power, significance value, and prevalence had been preset and they found the detectable effect size (clinical difference), which was 6.8/3.6 (roughly equal to odds ratio of 1.9). This means that this study with this sample size would not be able to detect any difference below 1.9. Setting detection of 90% increase in risk is quite unusual, which means any percentage of increase in risk below 90% is not clinically significant. This is far from the reality. Ignoring 50-89% increased risk in outcomes including perinatal mortality would be a huge mistake in the design of such a prospective and probably expensive study. It is also odd to set different effect size for the same problem, e.g. effect size for Home vs. OU was 5.7/3.6 (roughly 1.6). These show that the sample size was already preset rather than calculated. If there was limitation in the maximum number of participants in non-obstetric units, number of controls (participants in OU), which did not have such a limitation, could be increased to compensate the lack of enough statistical power. This was not done in the study.

Finally, the study also suffers from some other biases, such as using midwives as the data collectors who might have conflict of interest and differential low response rate from some units that make it hard to believe the validity of this study. To tackle the bias due to differential response rate, a sensitivity analysis using a worst case scenario (assuming non-respondents as event) seems necessary. The problem with sample size in this study is so serious that expanding other biases seems redundant. Moreover, aforementioned problems in the sample size applies only to overall analyses for all women; this means that minimum required sample size for subgroup analyses should be even larger, making negative results of subgroup analyses for nulliparous women even less conclusive.

In conclusion, as this study apparently suffers from fundamental problems in the design phase, negative results of which should not be considered as valid and conclusive evidences. Therefore, any action (such as calls for midwifery units to be expanded and for low risk women to have to go to them instead of obstetric hospitals) based on negative results of this study would be a dangerous mistake, especially in the context of some evidences from this study showing higher risk for nulliparous women in FMUs when only higher response rate units were analysed. In general, lack of statistically significant difference between two groups in a study with inadequate sample size does not mean that there is no difference. A study with a robust design and much larger sample size is warranted to address the important question of difference in perinatal/maternal outcomes between midwifery units and obstetric units.
Appendix 2

Unadjusted results for units who returned less than 85% of returns for low risk women without complicating conditions at the start of labour.

Nulliparous

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Multiparous

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Birthplace falls short on neutrality

1. nna Lawin O’Brien, subspecialty trainee in maternal and fetal medicine
2. Manju Chandiramani, subspecialty trainee in maternal and fetal medicine
3. Christoph C Lees, head of department of fetal medicine
4. on behalf of Tg Teoh, Tom Bourne, Bryony Jones, Catriona Stalder, Pran Pandya, Shyamaly Sur, Hanine Fourie, Anita Mitra, Maya A-Memar, Tomas Prior, Jasmine Tay, Visha Tailor, Hanine Fourie, Shirin Khanjani, and Srdjan Saso

Author affiliations
1. lawinobrien@doctors.org.uk

The title of the news item on the National Institute for Health and Care Excellence (NICE) guidance on intrapartum care—“Midwife led units safest for straightforward births”—and the guideline itself, belie the evidence. Birth can be considered straightforward only in retrospect—classification beforehand implies a predictive accuracy that neither obstetricians nor midwives possess. It is not immediately obvious from the guideline that “the small increase in risk for nulliparous women” means that complications as grave as stillbirth and neonatal death make up 13% of adverse outcomes, and that the risk for nulliparous women is almost double that for multiparous women. In nulliparous women, serious problems occur at home in 9/1000 births versus 5/1000 births in an obstetric unit. The evidence cited comes from the English Birthplace Study, where morbidity was defined by a heterogeneous composite outcome measure. A fractured clavicle and serious encephalopathy were both component outcomes, but their health impact on the baby is hardly equivalent. The guideline based its statement, “Planning for home births was associated with reduced risk of interventions and complications,” on a study that was too small to make a meaningful statistical comparison of perinatal and neonatal mortality. NICE did not cite a large US meta-analysis that included 500 000 planned homebirths in healthy low risk women, which showed that neonatal mortality tripled with homebirth.

Given the limited evidence on the true risks of homebirth, the guideline’s recommendations rely on the development group’s collective opinion. This may not be apparent to women choosing their birthplace. Only by communicating the uncertainty underlying the evidence can women be at the centre of decision making and make a fully informed choice of birthplace. We believe that the NICE guideline development group has fallen short of a neutral analysis of the available evidence.

Notes
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Footnotes
• Competing interests: None declared.
• Full response at: www.bmj.com/content/349/bmj.g7421/rr/813994.

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1. Torjesen I. Midwife led delivery is safer than a labour ward for low risk pregnancies, says NICE guidance.BMJ2014;349:g7421. (3 December.)

