Should there be a trial of home versus hospital delivery in the United Kingdom?

We received a letter from Dowswell and colleagues on the feasibility of conducting a trial to compare the effects of birth at home and in hospital. We asked a midwife, an epidemiologist, a general practitioner, the director of the National Childbirth Trust, and an obstetrician for their comments.

Measuring outcomes other than safety is feasible

T Dowswell, JG Thornton, J Hewison, RJL Lilford

Two recent expert groups[1 2] have concluded that the evidence for the relative safety of home compared with hospital delivery[3] does not justify a general recommendation for hospital delivery. Although the evidence has been disputed,[4] safety is not testable in a randomised controlled trial because of the numbers required and will have to be assessed as well as possible by other methods. Nevertheless, another uncertainty underlying the debate is the effect of place of delivery on psychological outcomes and infant feeding.[5] The hypotheses that home birth results in less anxiety and higher rates of breast feeding are testable in a randomised controlled trial of only modest size. For example, if breast feeding rates were 50% in hospital a trial of 100 women per group would have the power to exclude a 20% increase among women offered home delivery (alpha 0.05). Most experts we consulted told us, however, that women would decline being randomly allocated to home or hospital delivery in such a trial, and so we performed a small feasibility study.

"I was surprised when he mentioned home birth. It wasn't anything I had thought of."

Mother being offered entry to trial

Seventy one multiparous women who were judged by a consultant obstetrician (JGT) to be at low obstetric risk and likely to have suitable home support and home circumstances were informed about the trial by the consultant personally and given an information leaflet during their first hospital visit. During the trial period of one year from January 1994 about 500 women booked for pregnancy care with that obstetrician. At a subsequent visit 11 women agreed to take part, gave written consent, and were allocated either to delivery at home or to delivery in hospital. Randomisation was in the ratio 1:1 in balanced blocks of eight and performed by opening the next in a series of numbered opaque sealed envelopes containing the trial allocation.

Six women were allocated delivery in hospital and five delivery at home. One woman allocated to delivery at home was withdrawn from the study 24 hours after randomisation because she was then found to have had a postpartum haemorrhage in a previous pregnancy. She had a normal delivery in hospital, without opiate or epidural analgesia and without tearing of the perineum. She bottle fed the baby.

The remaining 10 participants were interviewed at 34 weeks' gestation about their health, attitudes to the birth, and experience of the pregnancy. The mode of delivery, complications, interventions, including methods of pain relief, and whether the baby was breast fed were recorded for the 11 women who agreed to take part (intention to treat analysis; table 1).

Table 1—*Outcomes in women randomly allocated delivery at home or in hospital**

	Home birth (n=5)	Hospital delivery (n=6)
Normal vaginal delivery	5	6
Perineal sutures	2	3
Anaesthesia during labour:		
Nitrous oxide and oxygen	4	4
Pethidine	0	1
Baby breast fed	4	4

*Intention to treat analysis.

The four women allocated home birth who delivered at home were pleased with the allocation. However, four of the six women allocated delivery in hospital were disappointed, though one husband stated that he was relieved.

Some of the 60 women who declined to participate expressed themselves strongly, declaring that there was no chance or no way that they would take part. Others consulted their partners, relatives, and midwives before declining, and at least one woman declined after having given the matter much thought. Thirteen of the women who declined preferred a home birth and the remainder preferred delivery in hospital.

Although the trial was too small to draw any conclusions about the effect of home birth, the recruitment rate of 11 out of 71 women offered entry to the study, or 11 out of 500 women booking for delivery, shows that the trial is theoretically possible. Recruitment by a consultant is unrealistic for a larger trial, so we now plan to recruit women through midwives to a more feasible trial.

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BMJ 1996;312:753-7

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Evidence from US suggests that trials will not alter obstetric behaviour

Jeanne Raisler

Home births are currently rare and controversial in the United States. The most recent national figures show that in 1992 only 0·6% of infants were born at home.[1] The attendants for these 25 923 births were certified nurse-midwives (11·5%), physicians (18·1%), other midwives (31·9%), and others (38·5%). In many areas it is difficult or impossible to find a trained attendant for a home delivery, and hospital back up is almost non-existent. Mother and birth attendant often encounter suspicion and hostility if an obstetric problem necessitates transfer to hospital. Physicians and nurse-midwives who attend home births may be denied malpractice coverage or have hospital admitting privileges revoked. Lay midwives increasingly face arrest and prosecution for practising without a state licence. In this atmosphere, home delivery is not a viable option for most American mothers.

> ***"I like taking part in studies because it's for the greater good, like giving blood."***
>
> Mother being offered entry to trial

Home births evoke strong emotions among health professionals, and attitudes are rarely based on research data. Proponents argue that home deliveries for women who are at low risk of complications during pregnancy and delivery have perinatal outcomes as good as or better than hospital births. Opponents, including the American College of Obstetrics and Gynecology, argue that unexpected complications may arise during any labour, making hospital delivery a safer option for all women. Studies have compared the safety of home and hospital births in Missouri,[2] Tennessee,[3] North Carolina,[4] Kentucky,[5] and Washington State.[6] Neonatal morbidity and mortality did not differ between planned home deliveries and hospital births when care included continuous risk assessment and a qualified birth attendant. However, studies of home births have had methodological problems, which have weakened their findings. These flaws included lack of randomisation, selection bias, inadequate sample sizes, confounding, and incomplete data.[7] As Dowswell and colleagues note, the safety of home birth is not likely to be established by a randomised controlled trial because most women would probably refuse to be randomly allocated a birth place and a large sample size would be required to detect adverse outcomes. Nevertheless, safety remains a paramount consideration, and descriptive and case-control studies of perinatal outcomes must continue.

The proposed randomised controlled trial of the effect of birth setting on maternal anxiety and breast feeding could illuminate important aspects of the experience of home birth that have received little attention. In a similar vein, nurse-midwives in California recently proposed that research on home birth should expand beyond morbidity and mortality to study women's subjective birth experiences, the appropriate use of technology in home deliveries, and the influence of the birth environment on labour.[8] Soft outcomes such as empowerment, satisfaction, and family bonding also warrant study, although they are difficult to measure.

Methodologically sound research alone is unlikely to change obstetric thinking about home delivery, even if psychological and health benefits are shown. In recent decades the findings of randomised controlled trials have rarely moderated the increasing application of obstetric technology to childbirth. Examples include the use of routine ultrasonography and electronic fetal monitoring despite findings that these measures do not improve outcomes. In addition to scientific studies, the consumer movement and social forces such as the drive to decrease health care costs may be important in determining birth options in the future.

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Trial would not answer key question, but data monitoring should be improved

Alison Macfarlane

To ask whether there should be a trial of home versus hospital delivery puts the cart before the horse, by proposing a method before deciding on the question that needs to be answered.

Comparisons between the settings are hampered by the lack of unique and universal definitions of home birth and hospital birth, the differences relating not only to the characteristics of the locations but to the roles of the midwives, general practitioners, and hospital doctors who are giving care. Even within the United Kingdom, care for home births can be given by NHS or independent midwives, with varying participation of general practitioners and hospital doctors and varying contact with hospital maternity units.

> ***"Disappointed that I had got the hospital."***
>
> Mother after allocation to hospital

Similarly, hospitals, which range from cottage hospitals to large specialist centres, vary widely in the extent to which they offer full facilities for emergencies and in the part played by midwives, obstetricians, and general practitioners in providing care.[1]

It follows that the results of a large scale trial would be meaningless unless it was designed to compare highly specific aspects of the care given in, or characteristic of, different settings. Despite this, small trials might be useful to answer local questions, given sufficient statistical power. It is highly unlikely, however, that their results could be applied to other places and times. In discussing possible outcome measures the proposal rightly rejects safety on the grounds of the numbers required.[2,3] It is disappointing that

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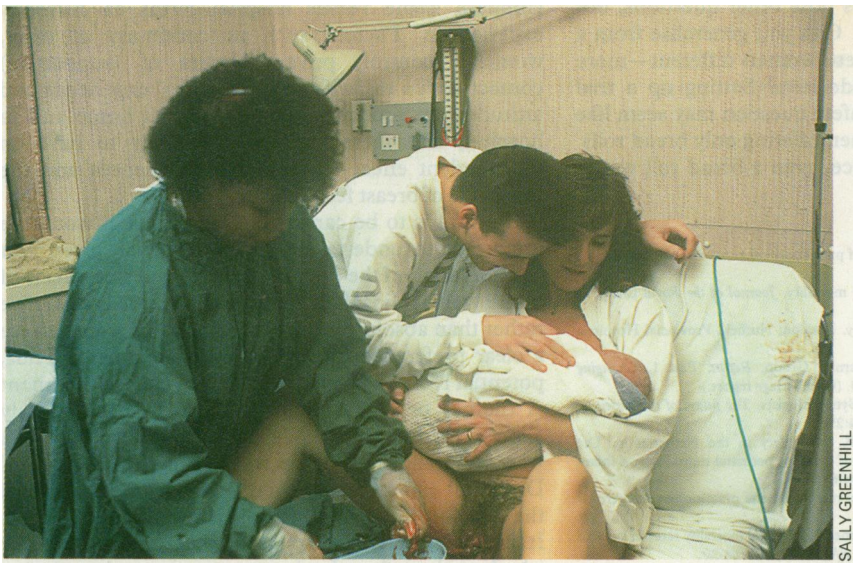

SALLY GREENHILL

Some people consider it unsafe to give birth anywhere other than a hospital with full back up

instead of basing their proposals on their own experiences in Leeds, they cite an unimpressive paper from a country with a different health care system and culture.[1] In addition, if the outcome measures were psychological, results from women who agree to be randomly allocated their place of delivery may not apply to the majority who do not.

In fact, the key question is safety. Some people consider it unsafe to give birth anywhere other than a hospital with a consultant unit, while others fear the iatrogenic effects of care given in such settings. Although unbiased comparisons are impossible, recent trends point to a need for monitoring data. Figure 1, based on birth registration data, shows a small but steady rise in the proportion of births in England and Wales that occurred at the mother's usual place of residence. It rose from the all time low of 0·89% of all maternities in 1987 to 1·8% in 1984.[4]

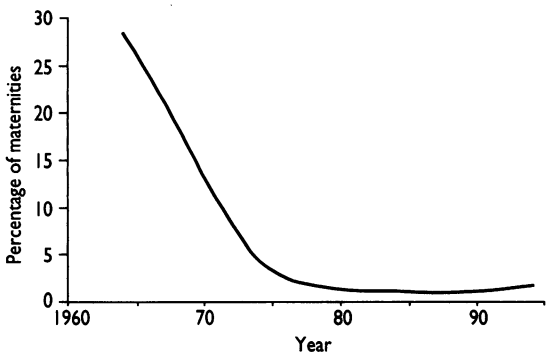

Fig 1—*Percentages of registered maternities in England and Wales in which delivery was at home, 1964-94*[4]

It should be possible to monitor the safety of births in different settings, by using these data together with those from other sources, but each needs improvement. The maternity hospital episode system and its Welsh equivalent should monitor how many births outside hospital are unplanned and how many women who planned home births were transferred to hospital in labour. So far, the data have been incomplete and of poor quality,[5] but a new computer system offers scope for improvement in England.[6] The data from the confidential inquiry into stillbirths and deaths in infancy are uninterpretable because, despite advice to the contrary, neither controls nor interviews with bereaved parents are used, except in two special projects.[7] Controls were used in the National Birthday Trust's survey of planned home births in 1994, although the selection of the births was ambiguous, and its results are awaited with interest.

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Uncertainty is likely to persist, but some knowledge would be better than none

Gavin Young

We do not know whether birth at home is safer or less safe than birth in hospital. This ignorance will surprise pregnant women, who are presented with strong opinions, usually against home birth but occasionally for. Neither side is able to provide much useful evidence to support its case.

A randomised controlled trial could have been carried out in the 1950s. Austin Bradford Hill had shown the way.[1] Alas, it was not. Government reports over the next 30 years indicated that the government knew hospital was best. The evidence for its confident assertions was that maternal and perinatal death rates had fallen at a time when rates of home birth had also fallen. Anecdotes of chloroform and Keilland's in the kitchen persuaded any doubters, apart from a few brave people such as Marjorie Tew, who presented evidence pointing towards greater danger of specialist care,[2] and Archie Cochrane, whose staple diet was healthy scepticism.[3]

The most recent government report, with unusual and stimulating honesty, accepts that we do not know the answer,[4] and the Royal College of Obstetricians and Gynaecologists has also moved from its previously entrenched position to state: "Home birth is an acceptable option and appropriate information should be provided."[5]

The problem is that appropriate information on safety can at present be based only on data from the Netherlands[6] or from rural units run by general practitioners and midwives in the United Kingdom.[7,8]

"I think I was secretly relieved . . . I think I wanted to go into hospital."

Mother after allocation to hospital

All such studies are likely to suffer from selection bias. Even the Northern region's home birth study of 1993 and the National Birthday Trust survey of 1994, both to be published soon, will not answer the question—only a randomised controlled trial can do this. However, Lilford has already shown that such a randomised controlled trial would require hundreds of thousands of pregnant women.[9] The safety question will remain unanswered.

Dowswell and colleagues pose other questions, but even here I have concerns. Can you generalise from a sample of just 2%? Are these women different—more open minded, or more indecisive? Setting up a trial that does not answer the safety question may seem like arranging a banquet and then offering only bread rolls. Given our present ignorance, even a bread roll would be welcome.

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Such a trial should not limit the choices of women who already have a preference

Mary Newburn, Rosemary Dodds

The crucial question is: What would be the purpose of a randomised controlled study of home versus hospital birth? It could be argued that more information about the outcomes associated with home birth would increase the opportunity for women to make informed choices about their care. However, the questions that women and their partners have about home birth centre on issues of safety and how to arrange a home birth in the face of opposition. While they would be interested to hear about breast feeding and psychological outcomes, those who are doubtful are concerned about the risks and those who are keen to have a home birth tend to believe already that it would be a positive experience for themselves and their family.

A trial could be designing the study in such a way as to minimise the effect of intervening variables or compare home versus hospital births as currently experienced. Factors such as continuity of carer, women's control, privacy, hours of (supportive) contact with a midwife, and midwives' experience and attitudes are probably not the same at home and in hospital, and these variables are likely to have an independent effect on women's experiences and the incidence of breast feeding.

If a trial is to be carried out we believe it would be important to undertake a preference trial, given that consideration of the putative benefits and side effects of home versus hospital birth point towards effective rather than absolute equipoise,[1] and some women have a clear preference for one or other treatment. Thus, potential recruits would be invited to choose treatment A (home) or B (hospital) or agree to be randomly allocated a treatment.[1] We note that all four women who were allocated home birth in the pilot study of Dowswell and colleagues were pleased, whereas four of the six allocated delivery in hospital were disappointed. It is not clear when they said this, and we wonder whether they thought it was a true option during pregnancy to ask for a home birth. As they were all multiparous women of low obstetric risk, they should all have been offered this choice.

Prejudice against home birth or lack of confidence among midwives and doctors could seriously jeopardise successful recruitment and treatment as intended, even in a preference trial. For this reason, we suggest any trial should be conducted in an area that already has a higher than average rate of home births. However, our main concern is ensuring access to home birth for all women who want it. No trial should be conducted at the expense of limiting choice among women who have a preference, given that there is no evidence to suggest that all births should take place in hospital.[2]

We think that resources would be better spent evaluating patterns of midwifery care specifically aimed at providing continuity of carer, choice of place of birth, and empowerment in hospital and at home.[3] There is currently a gap between what is known to be effective and what is provided. For example, there are well documented ways of supporting women who wish to breast feed,[4,5] but in the United Kingdom only two maternity units fully meet Unicef's baby friendly criteria.[6]

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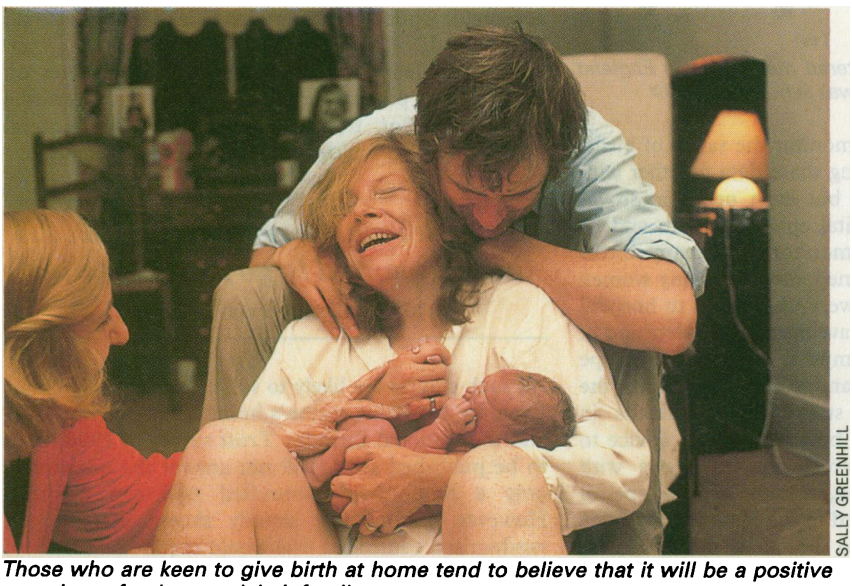

SALLY GREENHILL

Those who are keen to give birth at home tend to believe that it will be a positive experience for them and their family

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Mortality is still important, and hospital is safer

R S Settatree

In the 1993 United Kingdom (except Scotland) inquiry into intrapartum related mortality with a weight at birth of at least 2500 g there were 367 deaths among the 666 204 babies born in hospital (1:1815) and 21 among the 10 588 babies born at home (1:504). However, only nine of the 21 babies who died and were born at home were planned home births. Over this time an unknown proportion of women who planned a home delivery would have been transferred before birth on the

Table 2—*Intrapartum mortality with weight at birth of at least 2500 g in United Kingdom (excluding Scotland) in 1993*

	No of deaths	No of survivors	Ratio of deaths to survivors	Total
Planned and actual delivery at home	9	7826	1:869	7835*
Delivery in hospital plus unplanned delivery elsewhere	379	668 578	1:1764	668 957*
All births	388	676 404	1:1744	676 792

*Assumes that 2753 of the 10 588 (26%) actual home births were not planned home births; 2753 has been subtracted from the total number of home births and added to the total number of deliveries in hospital and elsewhere.

basis of some predicted risk or emergency to hospital, where some of their babies would have died, adding to the mortality for hospital deliveries. Furthermore, a proportion of successful births at home, variously estimated at between 10% and 60% were planned to take place in hospital, but did not quite make it. In a two by two table comparing the number of babies dying who were both planned to be delivered at home and were actually delivered at home with all the other deaths (regardless of place of birth) the relative risk becomes significantly greater than 1 if at least 26% of the women who delivered at home were intending to deliver in hospital (relative risk 2·03 (95% confidence interval 1·05 to 3·92), P=0·049 by Fisher's exact test) (table 2). An analysis on the basis of originally intended place of delivery would obviously lead to a higher relative risk of death in the home intention group.

Many important obstetric skills have to be exercised at extremely short notice. Shoulder dystocia, cord prolapse, and resuscitation of an unresponsive baby would be examples requiring immediate action. Other problems give more warning, and a tendency to overdiagnose fetal compromise in a hospital setting may well lead to unnecessary caesarean sections and assisted deliveries, but at least some of these difficult interventions are likely to have been beneficial. At the same time there is room for improvement as the confidential inquiry of 1993 also suggested that optimum care, judged by hospital standards, might have rescued a further 42% of the 388 babies who died.[1]

The Royal College of Obstetricians and Gynaecologists recently stated that home was an accepted place to plan to have a baby but warned that it would never be possible to reproduce in the home the same standard of response and equipment that is available in hospital.[2] The findings of the confidential inquiry outlined above are disturbing because they suggest that in 1993 the chances that a mother at presumed low risk would lose her baby from intrapartum causes during planned delivery at home were higher than the chances that she would lose her baby from all risks during delivery in hospital. If all national data show only four or five unexpected deaths from planned home deliveries in one year, then the chances of a randomised controlled trial detecting a difference, with current home delivery rates of 1·6%, must be infinitesimal. It would be interesting to see whether the professions, the public, and ethics committees would tolerate randomised trials if these findings are confirmed in later years. Of course mortality should not be the only outcome measure considered, but it must be one of the most important ones.

"The trial made my mind up . . . and if I had been chosen for hospital I would have been disappointed."

Mother after allocation to home birth

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A PAPER THAT CHANGED MY PRACTICE

The manipulative patient

Most patients are not manipulative but those who are can produce strong feelings of anger and hostility in doctors who treat them. George Murphy and Samuel Guze's paper, "Setting limits: the management of the manipulative patient," is the perfect antidote.[1] If you can suspend your prejudices against the facts that the authors are psychotherapists and that they wrote the article at the dawn of the permissive era you will be rewarded with a completely jargon free, well written, and commonsense guide on how to recognise and manage manipulative patients.

The examples used come from a psychotherapy setting, but the situations described will be familiar to any doctor who treats patients with chronic illnesses or gives second opinions. Many of the vignettes will make you cringe with recognition: for example, patients who telephone the doctor repeatedly between appointments, demands for medication, requests for reassurance or promises of help, quoting what other doctors have said, and attempts to intrude on the doctor's personal life.

The true value of the article comes from the fact that all the examples are based on real cases.

One is the familiar story of a patient repeatedly asking for reassurance. "Early in therapy the patient . . . asked the therapist repeatedly whether she would ever get well. Throughout her illness up to that time she had asked the same question many times and of many people, and showed no signs of being reassured by a positive answer. Quite to the contrary, upon being told she would get well, she demanded to know how, when, what others were doing about it, how the [therapist] could be sure, etc. Aware of this behavior, the therapist adopted and repeated the rather painfully truthful reply that he hoped she would get well but thought it was quite possible that she would not. Gradually this behavior decreased and then stopped."

This example shows that the paper is not an exercise in patient bashing or being cruel to be kind but a demonstration that a humane approach does not necessarily equate with acquiescing to the patient's wishes. At times setting limits and not reinforcing maladaptive behaviours are important.

Rereading this paper brought back a flood of memories of a small number of patients who had successfully manipulated me early on in my psychiatric training. Their behaviour and my reactions had led to a lot of bad feeling on both sides. But at the same time I was surprised at how much of the advice had become part of my routine practice.

Although written 35 years ago, the article remains relevant. Like an account of the conquest of the north face of Everest it could have been written only by someone who has been there and experienced the hardships.—JOHN DUNN *is a visiting researcher in psychiatry in São Paulo, Brazil*

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