months later. Their care over these three months is identical: they have their blood pressure checked monthly, and any women whose blood pressure returns to normal are transferred to the placebo group because they cannot benefit from the new drug. At three months those remaining in the group to have the new drug are treated and all other women have placebo. The outcome is compared on an intention to randomise/treat basis, and it is now clear that such a comparison is invalid because at the start of treatment the groups are no longer comparable.

Hundley and colleagues made the same mistake. They randomised the women some five months before the intervention (to different labour and delivery regimens), transferred women at high risk to consultant led care, and invalidly analysed groups on the basis of their original classification at booking. Such an analysis would have been valid if they were comparing two styles of care from booking onwards.

All is not lost. The study should be reanalysed, with those women in the midwife led group at the onset of labour being compared with those women at low risk at the onset of labour in the consultant led group. Such a comparison would be a valid investigation of midwife led care during labour and delivery versus consultant led care. Such reanalysis would lead to the debate about such care being better informed. I suspect that correct analysis may not show benefits from midwife led care in the biomedical outcome measures used by the authors. I look forward to seeing the assessment of outcome in psychosocial terms that the authors mention, which is to be published elsewhere. Such measures are equally important in assessments of care during pregnancy.

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1 Hundley VA, Cruickshank FM, Lang GD, Glazener CMA, Milne JM, Turner M, *et al.* Midwife managed delivery unit: a randomised controlled comparison with consultant led care. *BMJ* 1994;**309**:1400-4. (26 November.)

Study shows interventionist nature of British obstetrics

EDITOR,—The high rate of antepartum and intrapartum transfer of women from the midwives unit to the labour ward (1030 out of 1900) requires further explanation than V A Hundley and colleagues give in their discussion of the trials of the midwives unit in Aberdeen.[1] Table V shows that there were only 374 medical interventions during delivery if one assumes that all the caesarean sections and forceps and ventouse deliveries come within this category. If one further assumes that placental removal under anaesthesia (n=26) was in addition to these then the total number of women requiring specifically medical intervention and hence transfer to a labour ward was 400. The clinical implication of this may not be that as many as half of low risk women booked into a midwives unit become high risk during pregnancy or labour, as stated in the paper, but that three fifths of these will be transferred unnecessarily.

Table V also shows that 245 (9%) of the 2734 low risk women followed up had a caesarean section—an incredibly high figure when one considers that the rate of caesarean section in a low risk service in the Netherlands was 1·4%[2] and in a teaching clinic in Vienna was 1% between 1976 and 1985.[3] The cumulative frequency of the generally accepted conditions requiring caesarean section in developed countries is estimated to be 6-8%.[4] These figures compare with the overall rates of caesarean section in Aberdeen Maternity Hospital of 13·5%, 14·9%, and 15·6% in 1991, 1992, and 1993 respectively.[5]

There is a widespread belief that Britain has for many years been training midwives only to make them work as obstetric nurses. As a consequence many midwives are thought to have become deskilled and less able to work independently. The high rate of unnecessary transfer in Hundley and colleagues' study, which was necessarily produced within this framework, provides further confirmation of this. The high rate of caesarean section in women initially classified as at low risk indicates the interventionist nature of current British obstetric practice.

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1 Hundley VA, Cruickshank FM, Lang GD, Glazener CMA, Milne JM, Turner M, *et al.* Midwife managed delivery unit: a randomised controlled comparison with consultant led care. *BMJ* 1994;**309**:1400-4. (26 Novembert.)
2 Van Alten D, Eskes M, Treffers PE. Midwifery in the Netherlands. The Wormerveer study; selection, mode of delivery, perinatal mortality and infant morbidity. *Br J Obstet Gynaecol* 1986;**96**:656-62.
3 Rockenschaub A. Technology-free obstetrics at the Semmelweis Clinic. *Lancet* 1990;**335**:977-8.
4 Savage W. Technology-free obstetrics at the Semmelweis Clinic. *Lancet* 1990;**336**:178-9.
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Conclusions are not supported by results

EDITOR,—V A Hundley and colleagues' randomised controlled trial comparing midwife led care with consultant led care[1] is welcome as there have been few such trials in this field.[2] We are concerned, however, at some of the conclusions reached—in particular, the conclusion that midwife led care is as safe as consultant led care is not supported by the results.

The authors do not explicitly define safety in their paper. Although they chose perinatal morbidity as the primary outcome measure, they do not explain the type of morbidity used in the estimation of sample size. To base a trial on an expected baseline morbidity of 30% in a group of women judged to be at low risk of complications of pregnancy suggests that the morbidity of interest was relatively minor; although leading to much distress, this is not life threatening to either the mother or the baby. Severe morbidity, however, occurred in only a small number of babies. For example, 119 (6·6%) babies were admitted to the special care baby unit for more than 48 hours in the midwifery arm of the trial compared with 54 (6%) of babies in the consultant led arm of the trial. To show a difference between these relatively well defined outcomes of perinatal morbidity would require a much larger randomised controlled trial than that undertaken in Abedeen. If, for example, a difference between 8% and 6% of babies being admitted to the special care baby unit was considered to be clinically important then a trial of nearly 6000 women would be required.

This point reflects a much wider issue in many randomised controlled trials: when the primary outcome under investigation is rare, the trial often needs to be too large to be feasible. The amalgamation of several trials with meta-analysis may produce sufficient numbers of events for this question to be answered, but individual randomised controlled trials should be designed so that they can answer the question that they set out to answer. In this example, if the question is one of safety then the trial has to be of a sufficient size that if any clinically important differences in safety measures exist, it can detect them. If that size is impossible in the setting available then the report should state clearly that the study is sized to look at other outcome measures that are important and more common.

Despite our reservations about the ability of the Aberdeen trial to reach conclusions on safety, we welcome its findings on other issues, particularly morbidity that is not life theatening, and look forward to the authors' papers on the other outcomes measured.

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1 Hundley VA, Cruickshank FM, Lang GD, Glazener CMA, Milne JM, Turner M, *et al.* Midwife managed delivery unit: a randomised controlled comparison with consultant led care. *BMJ* 1994;**309**:1400-4. (26 November.)
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Pregnancy and delivery require a joint midwifery and medical approach

EDITOR,—We believe that V A Hundley and colleagues make observations about midwife managed versus consultant led care that are potentially midleading.[1] The assertion that there is no increase in adverse neonatal outcomes associated with midwife managed care is not justified by the neonatal mortality quoted; our calculation of the relative risk of neonatal death in the midwives unit compared with the standard labour ward is 2·2 (confidence interval 0·5 to 10). This confidence interval shows that the data are consistent with a large increase in neonatal mortality in the midwives unit.

Similarly, the incidence of important complications of labour such as shoulder dystocia (1·4% *v* 0·9%), undiagnosed malpresentation (0·7% *v* 0·4%), and third degree tear (0·8% *v* 0·3%) was higher in the midwives unit than the standard labour ward, but confidence intervals are not shown. Other complications of labour showed similar rates of occurrence in the two groups. A much larger study would be required to prove or disprove the authors' conclusion that midwife led care is as safe as standard care in a labour ward.

It is encouraging to note that the midwives unit held clear advantages for women in terms of their mobility and use of natural methods of analgesia. We would emphasise the need for an integrated joint midwifery and medical approach to pregnancy and delivery. This would avoid the largely artificial divide between midwifery led and consultant led delivery units and remove the need for antepartum and intrapartum transfer of women, which in this study was necessary for 54% of the women originally randomised to the midwives unit. The movement of women at such a critical time in their pregnancy is emotionally traumatic and potentially dangerous and must surely be against the spirit of woman centred care.

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1 Hundley VA, Cruickshank FM, Lang GD, Glazener CMA, Milne JM, Turner M, *et al.* Midwife managed delivery unit: a randomised controlled comparison with consultant led care. *BMJ* 1994;**309**:1400-4. (26 November.)