4 Prentice AM, Jebb SA. Obesity in Britain: gluttony or sloth? *BMJ* 1995;311:437-9.

5 Riboli E. Nutrition and cancer: background and rationale of the European prospective investigation into cancer and nutrition (EPIC). *Ann Oncol* 1992;3:783-91.

Long term outcome by method of delivery of fetuses in breech presentation

Policy of planned caesarean section could have appreciable costs

EDITOR,—P J Danielian and colleagues contend that a policy of vaginal breech delivery in selected cases of breech presentation is as safe as elective caesarean section with respect to long term disability.¹ In their editorial in the same issue M Hannah and W Hannah point out the need for a large randomised prospective trial to answer this question but assert that a policy of planned caesarean section for all breech deliveries would not only limit women's choices but give rise to substantial costs.²

Unfortunately, in our litigious society and with claims for compensation for severe disability regularly exceeding £1m when avoidable obstetric causes are found to have occurred, the situation may be murkier. According to Danielian and colleagues' study, one out of 1645 babies (that is, 0.0006 babies) presenting by the breech was born with severe disability "possibly attributable to delivery." A study to detect an increase in possibly avoidable causes of disability (the critical issue) at this level—say, 0.000 in the planned caesarean group versus 0.0006 in the intended vaginal delivery group—with 80% power and 5% significance would require over 26 000 breech births, and so the question remains unanswered. Given the numbers required, it may remain so. It might be argued that this proportion is an unreasonably low one to study, but, as such claims for compensation seem to go in favour of the plaintiff when doubt exists, the extra indemnity premium for a policy of selective vaginal breech delivery could be as much as £900-1000 for each intended vaginal breech delivery. This needs to be borne in mind when the financial costs of a policy of planned caesarean section are considered.

JONATHAN WEST

Consultant obstetrician and gynaecologist

Royal Devon and Exeter Hospital,
Exeter EX2 5DW

1 Danielian P, Hall M, Wang J. Long term outcome by method of delivery of fetuses in breech presentation at term: population based follow up. *BMJ* 1996;312:1451-3. (8 June.)

2 Hannah M, Hannah W. Caesarean section or vaginal birth for breech presentation at term. *BMJ* 1996;312:1433. (8 June.)

External cephalic version at term should be considered

EDITOR,—P J Danielian and colleagues report a 20% rate of long term disability among fetuses delivered by the breech, irrespective of mode of delivery.¹ This raises the key issue of whether there is an inherent abnormality associated with such fetuses. Braun *et al* initially suggested that fetuses with a wide range of morphological and functional damage more commonly present by the breech.² Hyten postulated that neurological deficit in the fetus disrupts normal muscular control, allowing for persistent extension of the legs and preventing the assumption of a normal fetal attitude.³

If it is presentation by the breech in utero or at delivery that puts the infant at greater risk of long term morbidity then external cephalic version at term might be considered. The literature suggests that this has a 65% success rate and significantly reduces the caesarean section rate (37%, compared with 83% in controls).⁴ The procedure is also cost

effective and safe, with a perinatal mortality of <1% and risks of fetomaternal transfusion and entanglement in the cord of 3% and 1%, respectively.⁴ Data suggest that, regardless of birth weight and gestation, fetuses presenting by the breech have a higher perinatal mortality and morbidity rate than fetuses with cephalic presentation.⁵ Furthermore, there are no published data comparing short and long term morbidity between infants delivered by the breech and those delivered by the vertex after spontaneous version or external cephalic version at term.

What is needed, therefore, is a prospective randomised study comparing morbidity rates in infants delivered by the breech and infants delivered by the vertex after external cephalic version at term, irrespective of the mode of delivery. Such a study would help address the important issue of whether the raised morbidity rate is an inherent problem with fetuses that present by the breech at term or purely a function of malpresentation at delivery.

P S BHAL

Clinical research fellow

K ASAAD

Lecturer

A SHARMA

Registrar

R W SHAW

Professor

Department of Obstetrics and Gynaecology,
University Hospital of Wales,
Cardiff CF4 4XN

1 Danielian PJ, Wang J, Hall MH. Long term outcome by method of delivery of fetuses in breech presentation at term: population based follow up. *BMJ* 1996;312:1451-3. (8 June.)

2 Braun FHT, Jones KL, Smith DW. Breech presentation as an indicator of fetal abnormality. *J Pediatr* 1975;86:419-21.

3 Hyten FE. Breech presentation: is it a bad omen? *Br J Obstet Gynaecol* 1982;89:879-80.

4 Zhang J, Bowes WA, Forney JA. Efficacy of external cephalic version: a review. *Obstet Gynaecol* 1993;82:306-12.

5 Brenner WE, Bruce RD, Hendricks CH. The characteristics and perils of breech presentation. *Am J Obstet Gynaecol* 1974;118:700-9.

Outcomes of breech presentations not diagnosed until labour need to be studied

EDITOR,—P J Danielian and colleagues report the long term outcome among infants delivered by the breech at term by the intended mode of delivery.¹ I was surprised that the authors do not mention the group of fetuses in which breech presentation was not diagnosed until the women presented in labour.

The proportion of breech presentations diagnosed in labour varies in the published literature between 9% and 33%^{2,3} and is therefore not insignificant. As the paper does not describe this group separately it can be assumed only that most of the breech presentations that were diagnosed in labour were included in the "intended vaginal delivery" group and therefore that intended vaginal delivery is not the same as planned vaginal breech delivery.

A generally accepted aim of antenatal care is to detect malpresentation in order to offer external cephalic version and to assess the mode of delivery, the commonly held belief being that excess perinatal mortality and morbidity is associated with undiagnosed breech presentation. This belief has been challenged, but only short term outcomes were described.⁴ A study such as that by Danielian and colleagues looking at the long term outcomes in this group is therefore needed.

SARAH VAUSE

Specialist registrar in obstetrics and gynaecology

Leeds General Infirmary,
Leeds LS1 3EX

1 Danielian PJ, Wang J, Hall MH. Long term outcome by method of delivery of fetuses in breech presentation at term: population based follow up. *BMJ* 1996;312:1451-3. (8 June.)

2 Bingham P, Hird V, Lilford RJ. Management of the mature selected breech presentation: an analysis based on the intended method of delivery. *Br J Obstet Gynaecol* 1987;94:746-52.

3 Cockburn J, Cheun Foong, Cockburn P. Undiagnosed breech. *Br J Obstet Gynaecol* 1994;101:648.

4 Nwosu EC, Walkinshaw S, Chia P, Manasse PR, Atlay RD. Undiagnosed breech. *Br J Obstet Gynaecol* 1993;100:531-5.

Evaluation should have included long term follow up of the mothers

EDITOR,—We agree with the recommendations in P J Danielian and colleagues' paper and the accompanying editorial that a large randomised controlled trial is required to determine which is the safest and most acceptable mode of delivery in breech presentation at term.^{1,2} We are concerned, however, that the discussion, particularly in the editorial, does not mention the need for long term follow up of the mother.

The authors of the editorial state that "increased maternal morbidity is an inevitable consequence of abdominal delivery" on the basis of evidence from the Cochrane meta-analysis of two randomised controlled trials that compared the policy of planned caesarean section with that of planned vaginal birth. Both of these trials measured maternal morbidity by short term variables such as blood transfusion, headache after spinal anaesthetic, wound infection, febrile morbidity, and length of stay in hospital.^{3,4} These measures are extremely important, but longer term measures of maternal morbidity, such as urinary incontinence, faecal incontinence, and dyspareunia, should also be included (along with measures of infant morbidity) to evaluate modes of delivery comprehensively.

Few studies have investigated the long term health problems of women after childbirth. Our study of 1010 members of the National Childbirth Trust focused on postnatal sexual health and showed high levels of morbidity up to two years after the birth.⁵ This was significantly associated with the mode of delivery: dyspareunia was most common in women who had had assisted vaginal deliveries and least common in those who had had a caesarean section (table 1). Nearly all the women who had an assisted delivery had an episiotomy (93%); this compared with a rate of episiotomy of 20% in those who had unassisted vaginal deliveries.

Table 1—Number (percentage) of women who had dyspareunia after childbirth by mode of delivery

	Vaginal unassisted delivery (n = 743)	Forceps or ventouse delivery (n = 143)	Caesarean section (n = 122)
Dyspareunia	144 (19)	75 (52)	16 (13)
No dyspareunia	599 (81)	68 (48)	106 (87)

$\chi^2 = 81$, df = 2, $P < 0.0001$.

Vaginal deliveries of babies presenting by the breech are rarely straightforward and therefore may result in considerable maternal morbidity. Any evaluation that does not include long term follow up of the mother will give only a partial perspective on the effect of breech delivery on mothers and children.

GERALDINE BARRETT

Research fellow

CHRISTINA R VICTOR

Senior lecturer

Department of Public Health Sciences,
St George's Hospital Medical School,
London SW17 0RE

1 Danielian PJ, Wang J, Hall MH. Long term outcome by method of delivery of fetuses in breech presentation at term: population based follow up. *BMJ* 1996;312:1451-3. (8 June.)

- 2 Hannah M, Hannah W. Caesarean section of vaginal birth for breech presentation at term. *BMJ* 1996;312:1433-4. (8 June.)
- 3 Collea JV, Chein C, Quilligan EJ. The randomised management of term frank breech presentation: a study of 208 cases. *Am J Obstet Gynecol* 1980;137:235-44.
- 4 Gimovsky ML, Wallace RL, Schiffrin BS, Paul RH. Randomized management of the nonfrank breech presentation at term: a preliminary report. *Am J Obstet Gynecol* 1983;146:34-40.
- 5 Barrett G, Victor CR. Postnatal sexual health. *BMJ* 1994;309:1584-5.

Authors' reply

EDITOR,—We think that Jonathan West's cost calculations are speculative; one would have to take into account the cost of the extra (roughly 600) caesarean sections required to prevent the one possibly avoidable case of severe disability, plus the cost of the resulting increased number of caesarean sections in future pregnancies. Best practice should not be determined by the risk and cost of litigation but should aim to achieve the best outcome for the mother and baby.

We agree with P S Bhal and colleagues that it would be interesting to look at the outcome of cases after external cephalic version, but this is not relevant to the problem of how a fetus presenting by the breech at term should be delivered. External cephalic version in women at term was not used during study.

We also agree with Sarah Vause that a similar study for undiagnosed breech presentations would be of interest. There were no undiagnosed breech presentations in the group with severe disability in our study; we could not ascertain the number in the group with no disability at all, but it is likely to have been too small for separate analysis.

Geraldine Barrett and Christina R Victor are correct to point out that the long term morbidity of the mother should be considered. We think, however, that the data that they quote refer mainly to cephalic presentations (ventouse deliveries are rare in breech presentations); in breech presentations, forceps are most often used to prevent rapid delivery of the head rather than just to provide traction when there is an element of dystocia, as is the case in cephalic presentations. Trauma to the mother may therefore be less severe. Clearly, such trauma will occur in some cases of vaginal breech delivery, but what the long term effects of this are and how they compare with those after cephalic deliveries or caesarean sections is unknown. Hopefully, these questions will be addressed by a prospective randomised trial, as proposed in the editorial by M Hannah and W Hannah.¹

PETER DANIELIAN
Senior registrar
MARION HALL
Consultant

Department of Obstetrics and Gynaecology,
Aberdeen Maternity Hospital,
Aberdeen AB9 2ZA

- 1 Hannah M, Hannah W. Caesarean section of vaginal birth for breech presentation at term. *BMJ* 1996;312:1433-4. (8 June.)

French regulatory medical references are criteria, not clinical guidelines

EDITOR,—Karen Bloor and Nick Freemantle misuse the word "guidelines" when they introduce the subject of the French national contract in their article on international experience in controlling pharmaceutical expenditure.¹ In France doctors must prescribe in keeping with "regulatory medical references" and not extensive guidelines. The regulatory medical references were defined in 1993. They consist of one to three sentences, beginning with the words "*Il n'y a pas lieu de ...*" ("It is inappropriate to ..."). They have been defined as "recognised scientific criteria that make it possible to define inappropriate care and prescriptions, and the frequency at which such care or prescriptions are used by the patient."²

Writing that "147 guidelines are in force" in France may mislead readers. The Agence Nationale pour le Développement de l'Évaluation Médicale (ANDEM) has defined "guidelines" (as have other institutions): "Clinical practice guidelines are systematically-developed statements which aim to assist practitioner and patient decisions about the appropriate health care for specific clinical circumstances. This method of evaluation is generally entrusted to a small group of experts which analyses both the literature and the opinions of health professionals." A guideline is an extensive document containing the positions of a group of experts derived by use of an explicit method. ANDEM has published 48 guidelines, from which 74 regulatory medical references have been extracted.³

Other points need to be emphasised. Firstly, regulatory medical references do not apply to hospital practice; they apply only to the private outpatient sector. This means that the regulatory policy could have a higher impact than the figures given by Bloor and Freemantle suggest. Secondly, ANDEM has published a guideline on drugs prescribed to patients aged over 70, but doctors are not bound by regulatory medical references on this topic. This means that the other ways of providing information to prescribing doctors will bias the results attributed to the implementation of the regulatory medical references. Thirdly, the prescribing practice of 1278 private doctors was inspected over two months before 30 November 1995. A total of 186 had contravened the binding criteria, of whom 75 were fined up to Fr 15 000 (£2000) (these doctors were overprescribers who had already been identified by the local insurance fund).

Finally, it is wrong to say that "as an incentive for following these guidelines, doctors were awarded a 5% increase in their fees." This increase was awarded after negotiations between doctors' unions, social security, and the health ministry. It was a trade off that was related more to the budgetary constraints placed on the rate of increase in outpatient expenditure than to the regulatory medical references.

HERVÉ MAISONNEUVE
Medical references manager
CYRILLE COLIN
Editor in chief, *Journal d'Economie Médicale*
YVES MATILLON
Director

Agence Nationale pour le Développement de l'Évaluation Médicale,
159 rue Nationale,
75640 PARIS Cedex 131,
France

- 1 Bloor K, Freemantle N. Lessons from international experience in controlling pharmaceutical expenditure. II. Influencing doctors. *BMJ* 1996;312:1525-7. (15 June.)
- 2 Arrêté du 25 novembre 1993 portant approbation de la convention nationale des médecins. *Journal Officiel de la République Française* 1993;26 Nov:16297-311.
- 3 Agence Nationale pour le Développement de l'Évaluation Médicale. *Recommandations et références médicales*. Vols 1 and 2. Paris: ANDEM, 1995.
- 4 Lalandrie S. Rôle des caisses d'assurance maladie dans l'élaboration et l'application des références médicales opposables. *Arch Pédiatr* 1996;3(suppl 1):261-2s.

Monitoring oral anticoagulation in primary care

GPs in Wales send blood samples to clinic, get results in post, and decide dose

EDITOR,—D A Fitzmaurice and colleagues' editorial on monitoring oral anticoagulant treatment in primary care exposes a debate that has

been simmering for some time.¹ Our hospital, in a rural area in north east Wales, has never had an anticoagulant clinic. In addition, there is no near patient testing for the control of anticoagulation at present. In our system, blood samples are sent from general practice to the hospital laboratory, where the international normalised ratio is measured. Results are sent by return of post (no specific dose is recommended), and on the basis of these results the general practitioner decides the dose for the patient. Any results outside the range 2.0-4.5 are telephoned to the general practitioner the same day, and any result dramatically outside this range is discussed with the general practitioner immediately.

This system relieves the haematologist of what many of our colleagues are finding to be an arduous clinical commitment. The patient does not have to come to hospital or wait in an anticoagulant clinic, and the general practitioner has the full clinical details of the patient's treatment readily available when he or she decides the dose. Audit of the system has shown that the general practitioners involved show skill in deciding the dose. The down side is the number of tests performed: we have seen a steady increase in requests for measurement of the international normalised ratio from general practice over the past few years. We suspect that much of this may be due to the interval between tests being too short. One solution would be for the anticoagulant laboratory to have a (non-human) expert system to provide advice on the dose and interval between tests. We and our clinical colleagues are extremely satisfied with our present system and would highly recommend it.

D I GOZZARD
Consultant haematologist
ALISON CRAIG
Staff haematologist

Glan Clwyd District General Hospital,
Rhyll,
Clwyd LL18 5UJ

- 1 Fitzmaurice DA, Hobbs FDR, Murray JA. Monitoring oral anticoagulation in primary care. *BMJ* 1996;312:1431-2. (8 June.)

Integrated, proactive laboratory based approach is effective

EDITOR,—We recognise many of the problems outlined by D A Fitzmaurice and colleagues in their editorial on monitoring oral anticoagulant treatment in primary care but think that they are unlikely to be resolved in primary care.¹ Lack of consistency is not limited to outpatient anticoagulant treatment; it extends to hospital inpatients and the interface between hospitals and the community. Problems include variation in practice between clinical teams, a dangerously long interval between inpatient induction and the first outpatient appointment for measurement of the international normalised ratio, and changes being made to the dose of warfarin or concurrent interacting drugs without the anticoagulant clinic being told.

These problems have contributed to a fragmented and in many instances inefficient service. Our approach has been to devise a laboratory based anticoagulant management system that ensures full integration of care—that is, from inpatient induction to oral anticoagulation to outpatient monitoring as well as anticoagulant treatment during any subsequent readmissions to hospital.

The system is based on a computerised decision support system (4S Business Technology) for drug doses and for recalling patients. The target therapeutic ranges used are those recommended by the British Committee for Standards in Haematology. There are nine clinic sessions a week and a home phlebotomy service for infirm patients, which provides flexibility of