

## LETTERS TO THE EDITOR

### Prevention of intraventricular haemorrhage in preterm infants in Britain and Ireland

EDITOR,—Intraventricular or periventricular haemorrhage is a potential cause of morbidity and mortality in preterm infants. Many potential treatments have been studied but three in particular have influenced practice in the British Isles: vitamin E<sup>1</sup>; ethamsylate<sup>2</sup>; and fresh frozen plasma.<sup>3</sup>

Meta-analysis has shown no consistent benefit for any postnatal preventive treatment.<sup>4</sup> We were aware that the use of prophylaxis against intraventricular haemorrhage varied in different units and we wished to gain a picture of the pattern of prophylaxis use throughout Britain and Ireland.

A short postal questionnaire was sent to each neonatal unit asking whether prophylaxis was used and what criteria were used

Type of prophylaxis used	Number of neonatal units	Percentage total replies (n=254)
Vitamin E	46	18.1
Ethamsylate	53	20.9
Fresh frozen plasma	33	13
Other*	3	1.2

\*Of those units using other than ethamsylate, vitamin E, or fresh frozen plasma, two units used routine volume expansion with human albumin solution and one unit is using routine phenobarbitone.

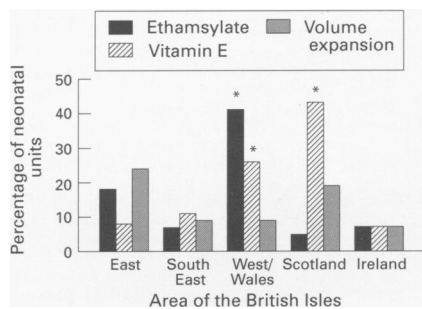
to decide on the requirement for prophylaxis. Statistical analysis was done using  $\chi^2$  analysis.

Ninety nine point two per cent of units responded, giving a total of 254 replies. Ninety four (37%) units use a prophylactic treatment for the prevention of intraventricular haemorrhage in preterm infants (table). Sixteen point two per cent of neonatal units are using more than one type of prophylaxis.

Eighty five point one per cent of the 94 units using prophylaxis used a gestational age criterion, most often less than or equal to 32 weeks of completed gestation; 69.1% of units used a birthweight criterion, most often less than or equal to 1500 g birth weight. Eight point five per cent of units used other criteria, such as the ventilatory requirement of the baby; 62% use a combination of birthweight and gestational age criteria.

There was no significant difference in prophylaxis use between regional subregional or district general hospitals. There was, however, a noticeable difference between different geographical areas of the country. Vitamin E was used much more often in the west of England and in Scotland. Routine volume expansion with fresh frozen plasma was most often used in the east of England. Ethamsylate was most often used in the west of England and in Wales (figure).

Our survey clearly shows that most neonatal units in the United Kingdom and Ireland remain unconvinced of the effectiveness of some or all of these treatments. Notably there is no difference in prophylaxis use between hospitals with neonatal intensive care units of different sizes; this observation



\*  $p < 0.05$ ; significant difference within type of prophylaxis between areas.

#### Regional variations in prophylaxis use.

was of particular interest in view of the recent trend for more preterm infants to be managed in smaller units. Our results seem to show that the single factor most likely to influence the use of prophylaxis for intraventricular haemorrhage is the geographical area of the British Isles into which the baby is born. There are many possible reasons for this, but we note that the areas of highest use of a particular treatment correspond to those areas in which the trials of the respective treatments were carried out.<sup>1-3</sup> Either two thirds of babies at risk of intraventricular haemorrhage in Britain and Ireland are not getting a potentially life saving treatment or one third of at risk infants are getting unnecessary, expensive, and potentially harmful interventions. Clearly, further work is required to provide the evidence that is needed for a consensus to be achieved in this area of neonatal medicine.

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#### Clinical trials and neonatal intensive care

EDITOR,—Neena Modi raises important questions about methods of obtaining assent from parents for the participation of their sick child in a clinical trial, and rightly points out that these methods deserve further scrutiny.<sup>1</sup>

There is a dearth of empirical evidence about how parents actually feel in such circumstances. Usually, clinicians or researchers have to make assumptions about this. In a number of randomised controlled trials with which we have been involved, members of parents' groups and other voluntary organisations involved in maternity care have worked with us on the trial protocols and written information for parents. There are very few examples, however, in which the parents concerned have actually been asked for their views.<sup>2,3</sup>

The Wellcome Trust has recently granted us funds for a one year project to begin to investigate this further. Part of this work will include a case study within the United Kingdom Collaborative Neonatal ECMO Trial.<sup>4</sup> A working group consisting of members of relevant voluntary organisations has collaborated closely in the design of this trial. An early meeting of this group discussed the possibility of post randomisation consent for the experimental arm of the trial using a Zelen design,<sup>5</sup> as advocated by Dr Modi. Although this was felt to have major advantages, the weight of opinion came down against this approach. There was concern that parents might become distressed and angry to learn that their child had been randomised to a particular treatment option without their prior knowledge. It is also scientifically worrying if, in a trial which depends crucially on continued contact with these parents, more parents in one arm of the trial than another might opt in or out. Hence the trial uses pre-randomisation consent procedures, and parents who participate are being asked for their views about this and other aspects of the trial.

Equally there is little empirical work about the views of clinicians who are participating in trials.<sup>6</sup> As well as asking for the views of the parents, therefore, the study will also explore methods for ascertaining the views of such clinicians in this and other trials.

The overall aim of the study is to explore ways in which the process of participation in trials can be made less stressful. This is important both in itself and as a means of increasing recruitment to such trials. This would in turn lead to earlier and more generalisable answers about treatment options.

If readers wish to help in this exercise, we would be very interested to hear from you. Any replies of a personal nature will be treated in confidence.

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#### Audit of neonatal intensive care transport

EDITOR,—Two articles concerning transport of the critically ill neonate and child appear in the July issue of the journal.<sup>1,2</sup> Seventy five per cent of 56 children transported had adverse clinical events.<sup>2</sup> This is an extremely high rate. A report of complications during transport of 614 patients in North Carolina reported complications in the neonate of 3.1% and 1.5% in paediatric patients less than 1 year old. Beyond 1 year no