LETTERS

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**Vitamin K deficient bleeding in cystic fibrosis**

We would like to report a female infant (initially breast fed and subsequently formula fed) who had received two 1 mg doses of vitamin K orally, and presented at 9 weeks of age with large haematomas at the sites of her primary immunisations. Her weight had dropped from 2580 g to 90th centile at birth to 2 kg at 2 months. Her haemoglobin was 72 g/l, white blood cell count 13×10⁹/l, platelet count 523×10⁹/l, prothrombin time >10 seconds (normal range 0.8–1.2), activated partial thromboplastin time 109.4 seconds (normal range 24.0–34.0), and fibrinogen 4.5 g/l (normal range 1.7–4.5). She received 1 mg of vitamin K intravenously and repeat coagulation screen was then normal. Sweat osmolality was 110 mmol/l (normal range 17–80) and 105 mmol/l on repeat testing. No chymotrypsin activity was found in the faeces. DNA analysis confirmed homozygosity for delta F508. However, working class parents were seriously under-represented in the study. The results from educated and pre-employment sample from the Oxford region are not applicable to areas like ours. In the Camden and Islington boroughs of London, we work with parents of mostly lower socioeconomic class and of varied ethnicity—from Albania to Zaire—to whom these results are not relevant. We need more studies conducted in these people to know the best evidence.

Thirdly, the intervention effect is seen at 6 months (short term) follow up. We wonder whether the maturational effect seen in the control group will actually decrease the effect of parenting in the intervention group in the long term? Moreover the intervention effect is said to be statistically significant. But is it clinically significant as well? And there is no cost-benefit analysis given.

Does this justify the considerable use of resources, especially in today’s cash strapped, staff depleted (fewer health visitors) NHS? Furthermore, parents in the intervention group might have believed that the parenting programme is efficacious, and consequently feel and perform better than those who were in the control group, as they were aware of group allocation. Also, unblinded study personnel who are measuring and recording outcomes (such as quality of life) may provide different interpretations of trials, which can distort the results. We now know that negative, inconsistent parental behaviour in families with high levels of adversity are associated with emergence of problems in early childhood and later life. Hence, we believe that parenting interventions should be applied in high risk populations. That is parents of children with ECBI scores of 127 or more and not children with 100 and above as included in the study.

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**Improving mental health through parenting programmes: are the results valid?**

We read the article by Patterson et al with interest. Firstly, the percentage of questionnaires returned from the survey should have been 61.8% not 70%, as reported.

Secondly, mental health problems are prevalent in families of parenting in the intervention group in the middle class. Unfortunately, working class parents were seriously under-represented in the study. Results from educated and pre-employment sample from the Oxford region are not applicable to areas like ours. In the Camden and Islington boroughs of London, we work with parents of mostly lower socioeconomic class and of varied ethnicity—from Albania to Zaire—to whom these results are not relevant. We need more studies conducted in these people to know the best evidence.

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**Authors’ reply**

Drs Srinivas, Gada, Shanker, and Kanumakala make a number of useful points about our trial. Firstly, they query our response rate. This rate cannot be calculated using either the number of families or the number of children as the denominator. The rate we quoted 800/1155 is the proportion of families responding. The rate of 61.8% (1105/1788) relates to the proportion of children. Given that this was a trial about parents and parenting we decided that the family based response rate was the most appropriate to report.

Secondly, they point out that this trial was carried out in Oxford and that the socioeconomic mix was somewhat biased towards middle class parents. Although all social groups were well represented in the trial, the point Dr Srinivass and colleagues make is valid. However, behaviour problems are common in all social groups, and because of the distribution of children in each social class, there are considerably more children with behaviour problems in middle class families than there are in families living in social deprivation. An important finding in this trial was that those who consented to take part were more likely than those who did not to have a child with problem behaviour. We feel that this validates our population approach. At the same time, it is true that our results may not be totally transferable to Islington. That does not stop them, however, being both valid and important.

Dr Srinivas says that more studies of programmes with parents from lower socioeconomic groups are needed. In fact, the great majority of trials of parenting programmes have been conducted with high risk groups and we know from these trials that they are valuable with families living in social deprivation. We are currently completing a systematic review of parenting programmes for minority ethnic families and have found no evidence that parenting programmes are less effective with parents from such groups than they are with those from majority ethnic groups.
The authors suggest that the changes we have observed in our trial could be a speeding up of a normal maturational effect. Half of the child outcomes we measured showed changes compatible with this interpretation, but the other half do not. The latter show either continuing improvement in both groups or more change in the intervention than control group at six month follow up. We will be publishing the results of our 12 month follow up.

The authors also ask whether our results are clinically significant. The differences between intervention and control group scores at 6 months represent effect sizes of around 0.3 (of a standard deviation). In clinical terms such changes are regarded as small. However in public health terms a small change in a large group is often more important than a big change in a small group, so these differences are of public health significance.

Dr Srinivas and colleagues also ask about cost effectiveness. We did not undertake a formal economic analysis in this study, but the costs of the intervention were mainly in the staff time. Taking account of time spent in supervision, but not training, the costs fall somewhere between six and ten hours of supervision, but not training, the costs fall beyond the scope of our study but could be estimated and cannot be measured accurately. The evidence that the quality of care matters beyond the scope of our study but could be estimated and cannot be measured accurately.

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Finally, and perhaps most importantly, Dr Srinivas and colleagues also ask about the cost effectiveness. We did not undertake a formal economic analysis in this study, but the costs of the intervention were mainly in the staff time. Taking account of time spent in supervision, but not training, the costs fall somewhere between six and ten hours of supervision, but not training, the costs fall beyond the scope of our study but could be estimated and cannot be measured accurately. The evidence that the quality of care matters beyond the scope of our study but could be estimated and cannot be measured accurately.

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Dr Srinivas and colleagues also suggest that our results may be invalid because they were not collected by researchers blind to intervention group. All our outcomes were based on self-report by parents, so blinding of study personnel is irrelevant. It is unfortunately not possible, in trials of health promoting interventions, to blind participants to the intervention. Although it is theoretically possible to mask the beneficial effects of some of these outcomes, such approaches greatly increase the cost of studies and were not possible with the funding we had available.

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In response to comments by Pearce and Mabin on Professor Russell's editorial on our paper they doubt that our survey underestimated the true scale of the problem. I can inform them that this is not the case. Since our survey was completed we have notified of a further seven cases (five children, two adults). All but one of the children had been taking fluticasone in similar dosages to those reported in our survey. Three of these children were critically ill in intensive care and an 8-year-old girl died due to adrenal crisis. The remaining child was only 20 months old and had been given budesonide in extremely high doses of 2000–8000 mcg/day. Both adults had been taking fluticasone (1000 mcg/day, 2250 mcg/day). Case reporting clearly plays a much greater role than clinical studies in post license surveillance. In an international 20 year study of drug safety discontinuations, nearly all occurred as a result of case reporting. Despite studies the authors concluded that “it is impossible to know fully all the facts concerning the effects both beneficial and harmful at the time of approval.” Further, it is incorrect for Pearce and Mabin to say that “studies show no increased risk of hypothalamic pituitary axis (HPA) suppression with fluticasone than when compared with other inhaled steroids”. There are many studies arguing against this assertion.” Actually, there is a serious disparity between the results of different safety studies involving fluticasone which requires explanation. While the product monograph claims “mean plasma cortisol concentrations remained within the normal range for adults and children demonstrating that, even at high doses (2000 mcg), fluticasone propionate is well tolerated with regard to side effects”, many studies suggest otherwise. For example, as little as 88 mcg/day of fluticasone can produce 10% adrenal suppression and 352 mcg/day can produce 50% adrenal suppression, a considerably greater degree than the equipotent dosage of beclometasone, leading those authors to conclude that increasing the dose beyond this point of maximum efficacy... resulted in increasing systemic effect, especially with fluticasone metered dose inhaler with its CFC propellant—exact what we have reported.

Pearce and Mabin correctly state that “individuals have differing sensitivities to inhaled corticosteroids. Idiosyncratic responses to inhaled corticosteroids may occur even at licensed doses.” I agree, however, such patients “disappear” in large multicentre studies, particularly when the pharmaceutical company will not make available data on individual patients. This is of concern as there is evidence that fluticasone is associated with significantly more individual abnormally low cortisol values than other inhaled steroids. Also, over 75% of patients developed adrenal crisis greater than one year after starting fluticasone, and it is known that length of time taking inhaled corticosteroids is a major factor in determining the frequency of side effects. How many studies of fluticasone have lasted greater than one year? Pearce and Mabin correctly state that in recent years, when paediatricians are often asked whether high doses of inhaled corticosteroids are necessary, more are choosing to prescribe fluticasone propionate. However, they need to explain why only 2 cases of adrenal crisis (1 child, 1 adult) in over 30 years of prescribing inhaled corticosteroids had ever been reported in literature before the introduction of fluticasone propionate allowing Russell to make a claim in 1994 that “there is no firm evidence that any child has ever developed adrenocortical insufficiency as a result of adrenal suppression induced by inhaled corticosteroid therapy.” Further, some cases reported in our survey had previously been taking very high doses of either beclometasone or budesonide but only developed adrenal crisis some time after changing to fluticasone.

Finally, it is unfair to blame doctors for prescribing fluticasone “off label.” A large percentage of all drug prescriptions for children in hospital are either unlicensed or off label. Prescribers have every right to expect a reasonable margin of safety with a drug they decide off label dosages are necessary in children. Bearing in mind that there have now been two reported deaths and many intensive care cases, the risks of prescribing fluticasone off label appear greatly to exceed any possible benefits for patients, and will have serious medicolegal implications for doctors, particularly when there is not a single study showing better efficacy for fluticasone compared with other available inhaled corticosteroids.”

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Cultural representation of newborn feeding

Nicoll and Williams suggested that attitudes to breast feeding need to change: “everyone (not just women) needs to see breast feeding as normal and education needs to start early”. In Italy breastfeeding rates are low. Numerous training initiatives have been set up to heighten awareness with the aim of promoting breastfeeding. These initiatives have been based on implementation of the Baby Friendly Hospital Initiative; three hospitals in the country being nominated “Baby Friendly”.

I was recently invited to discuss the importance of breastfeeding with newborns with two 4th year junior school classes (41 children in total (17 girls and 24 boys), aged between 9 and 10). Before talking to the children, I asked them to draw on a sheet of paper everything they thought was necessary for a baby to grow up healthy. All except four drew a feeding bottle next to a baby; 15 children drew a baby alone with a bottle; only three children drew a baby in his/her mother’s arms, but all these the babies were still holding a bottle. Only two drawings showed the baby with both parents and in without a bottle; the other two drawings without a bottle depicted a scene in the hospital. When I asked how many of them thought that formula milk was the same as mother’s milk, 28 out of 41 raised their hands. I believe this reflects the widespread tendency, also reported in other countries, not only to consider breastfeeding the same as artificial feeding, but “artificial” as “natural”.

In an historic and ever pertinent editorial, the Lancet hoped a warm chain for breastfeeding could be created, and warned about the ambivalent messages often encouraged by the marketing campaigns of formula manufacturers. I feel that the implementation of interventions aimed at supporting breastfeeding should not be limited to the healthcare system, but should cover a wider range of activities, aimed at changing the cultural representation of newborn feeding and at defending breastfeeding.

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Arch Dis Child 2003 88: 553
doi: 10.1136/adc.88.6.553-a

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