PostScript

LETTERS

Rejoinder to Eigenmann PA, Haengelli CA, Food colourings and preservatives—allergy and hyperactivity (*Lancet* 2004;364:823–4) and an erratum

Eigenmann and Haenggeli have commented[1] on a paper we recently published on food additives and hyperactivity in children.[2] This commentary gives a seriously misleading account of the findings of the study. Eigenmann and Haenggeli claim that ''the term hyperactivity seems to be used as synonymous to ADHD''. We deliberately did not use the term ADHD as a criterion for recruitment into the study. This is a diagnostic term requiring a set of explicit criteria to be met and is of doubtful validity when applied to 3 year olds. The definition of hyperactivity we used for this study was one based on the risk of subsequent behavioural difficulties in middle childhood which we had established previously in a longitudinal study of an epidemiologically ascertained sample of 3 years olds.[3 4]

The study used screens for atopy (AT) and for hyperactivity (HA) applied to a total population sample to identify cases for the following design: ''Children were entered into the four group randomised, placebo controlled, double blind, crossover challenge study. The four groups were in a 2×2 between group design with the following groups: HA/AT, non-HA/AT, HA/non-AT, and non-HA/non-AT.''[2] Eigenmann and Haenggeli observe that ''…families interested in hyperactivity seem to be over-represented'' and on this basis conclude that ''…results from this study should not lead to recommendations for the general population''. The presence of hyperactivity was one of the inclusion criteria of the food challenge phase of the study and consequently occurs in about half of the cases. A substantial proportion of children were included in the food challenge phase by design. Full details of participant flow were given in a diagram (fig 1 in our paper) as recommended in the CONSORT statement for reporting randomised trials.[5]

The separate issue of sample attrition through each of the stages of the study was considered carefully and we concluded that the findings from the group completing the food challenge phase would indeed hold for the general population.

The study found significantly greater increases in hyperactive behaviour reported by parents when the children were given the active compared to the placebo challenge. The statement by Eigenmann and Haenggeli that ''parents' observations can be easily explained by their expectations'' is puzzling. The parents, children, and the person collecting the behaviour ratings were blind as to the food challenge being taken by the child over these periods. Consequently ''expectations'' cannot account for the effects we identified based on changes during the active and placebo periods. This does not hold for the reduction in hyperactivity we observed during the withdrawal phase which, as we discussed in the paper, was not blinded and was greater than that for the placebo versus active periods. This would be expected if the withdrawal effect alone was influenced by parental expectations.

The final part of the Eigenmann and Haenggeli commentary is concerned with the use of diet changes as treatments for hyperactivity. Our study showed that the effects of food colourings and the benzoate preservative were not restricted to or more strongly present for children with atopy or hyperactivity. Consequently our conclusions did not relate to the treatment of children with hyperactivity but rather to the preventive public health issue of whether food additives are having a general detrimental effect on children's behaviour. The final conclusion from the paper was ''…if additives have an effect at all, it is via a pharmacological effect which is best exemplified by the non-IgE dependent histamine release. We believe that this suggests that benefit would accrue for all children if artificial food colours and benzoate preservatives were removed from their diet. These findings are sufficiently strong to warrant attempts at replication in other general population samples and to examine whether similar benefits of the removal of artificial colourings and sodium benzoate from the diet could be identified in community samples at older ages.'' We are now conducting just such a replication.

Erratum

While preparing this rejoinder, we have discovered an error in the reporting of the composition of the above mix in the paper. The sentence that reads:

> ''The active drink included 20 mg in total of artificial food colourings (sunset yellow, tartrazine, carmoisine, and ponceau 4R; 5 mg of each) (Forrester Wood, Oldham, UK) and 45 mg of sodium benzoate (J Loveridge, Southampton, UK).''

should have read:

> ''The active drink included 20 mg in total of artificial food colourings (sunset yellow 5 mg, tartrazine 7.5 mg, carmoisine 2.5 mg, and ponceau 4R 5 mg) (Forrester Wood, Oldham, UK) and 45 mg of sodium benzoate (J Loveridge, Southampton, UK).''

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Funding: Jim Stevenson and John Warner are funded to conduct studies on children's food by the Food Standards Agency, UK

Competing interests: none declared

References

1 **Eigenmann PA**, Haengelli CA. Food colourings and preservatives—allergy and hyperactivity. *Lancet* 2004;**364**:823–4.
2 **Bateman B**, Warner JO, Hutchinson E, *et al*. The effects of a double blind placebo controlled artificial food colourings and benzoate preservative challenge on hyperactivity in a general population sample of preschool children. *Arch Dis Child* 2004;**89**:506–11.
3 **Thompson MJJ**, Stevenson J, Sonuga-Barke EJS, *et al*. The mental health of preschool children and their mothers in a mixed urban/rural population: I. Prevalence and ecological factors. *Br J Psychiatry* 1996;**168**:16–20.
4 **Sonuga-Barke EJS**, Thompson M, Stevenson J, *et al*. Patterns of behaviour problems among preschool children. *Psychol Med* 1997;**27**:909–18.
5 **Moher D**, Schulz KF, Altman G, for the CONSORT Group. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials. *Lancet* 2001;**357**:1191–4.

Developmental delay versus developmental impairment

The use of the term delay should be replaced by impairment because of parental perception of the meaning of delay as applied to development.

I would like to draw attention to my experience of parents' perception of the language we use in describing children and their ability.

It is common practice to refer to children who are detected to be significantly behind in achieving developmental milestones to be *developmentally delayed*. In talking to prospective adoptive parents I have become aware of how misleading this phrase is in describing to prospective adopters what we mean.

The general population has a perception of delay to mean something that will get there in the end, rather like a train being delayed, but reaching its destination eventually. It has taught me to use the term *impairment* rather than *delay* so that I do transmit to prospective adopters the true meaning of what I am trying to describe.

I wonder if as a profession we would consider examining our use of this term *delay* and possibly re-educating our profession to use the term *impairment* because it does not suggest that the child will be normal eventually.

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Palivizumab prophylaxis in haemodynamically significant congenital heart disease

Patients with congenital heart disease (CHD) have been reported by many authors to have high rates of hospitalisation, morbidity, and mortality associated with respiratory syncytial virus (RSV) lower respiratory tract illness.[1–3] However, in a recent paper in *Archives of Disease in Childhood*, Duppenthaler *et al* reported a substantially lower incidence of