

How objective are the supporters of the Haemoglobin Colour Scale?

Editor – The authors of the letter (1) criticising my paper (2) on the Haemoglobin Colour Scale do not declare any conflicts of interest, yet two of them effectively designed the Colour Scale (3). Concerns as to the effect this might have on their impartiality are heightened by their penultimate paragraph comparing me to Marie-Antoinette — a comparison that does nothing to assure the reader of the authors' ability to assess evidence impartially and objectively.

Far from being an "innovative" analysis, the Bland-Altman method is accepted as being the appropriate and best method for comparing two assays. The fact that the papers, quoted by the authors of the letter, use a variety of other statistical methods does not disguise the fact that none of them use the appropriate test. Nonetheless, as the authors point out, the results of my study are comparable with those of other studies, and much of the difference lies in the interpretation of the data. In my study over a fifth (22.79%) of the Colour Scale results differed by more than 2g/dl from the reference. In another study (4), and one quoted by the authors of the letter, a third (33%) of results differed by more than 2g/dl. Of greater importance than their statistical significance is that these results are *clinically* significant; implying that if the Colour Scale is relied on, between a fifth and a third of patients will have wildly inaccurate assessments of their haemoglobin levels. Beyond the rigorous confines of a clinical trial, results with the Colour Scale might be expected to be less accurate and I stand by my conclusion that the poor accuracy of the Haemoglobin Colour Scale renders its use questionable. ■

J.J. Paddle¹

Conflicts of interest: none declared.

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Further clarity on vaccine-associated paralytic polio in India

Editor – We appreciate the comments by T.J. John in response to our article on vaccine-associated poliomyelitis (VAPP) in India (1). He highlights some of the methodologic challenges in deriving risk estimates of this type and correctly points out that interest is now shifting from risk estimation to estimation of VAPP burden in terms of numbers of children paralysed because of exposure to oral poliovirus vaccine (OPV).

The primary purpose of our analyses was to provide risk estimates of VAPP in India — under conditions of massive use of OPV — by applying established methods of calculating VAPP risk (2–4). We used exactly the same methods and definitions outlined in reference 2 to allow risk calculations that would be comparable among different populations.

Our findings demonstrate that the risk of VAPP is lower in India compared to previous analyses in Latin America (2) or in industrialized countries (3, 4). Since we reported our findings, surveillance data from India for 2000 and 2001 have become available. These data show a decreasing trend in the total number of VAPP cases from 181 in 1999, to 129 in 2000, and 109 in 2001, suggesting

that the 1999 data (and associated risks) were not stable. Massive exposure to more than 750 million doses of OPV in India in 1999 alone probably resulted in a "catch-up phenomenon" exposing many children to the first "immunizing" dose of OPV, with the associated increased risk of VAPP. Only data from subsequent years will allow calculation of a more precise VAPP estimate under conditions approximating a steady state in India.

Thus, we are confronted with a situation where the risk is exceedingly small, but the total number of VAPP cases is increasingly of concern. We believe that the established methods of calculating VAPP risk estimates will continue to have their utility, and should not be abandoned. However, the total number of VAPP cases that communities will have to bear in an increasingly polio-free world (5) may be driving polio vaccination policy decisions to a much greater degree. To assist the process, The World Health Organization is committed to preparing an estimate of the global VAPP burden in the near future. ■

Kathryn A. Kohler,² Kaushik Banerjee,³ & Roland W. Sutter⁴

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¹ Anaesthetic Specialist Registrar, Department of Anaesthesia, Royal Cornwall Hospital, Truro TR1 3LJ, England. (email: jpaddle@doctors.org.uk).

² Epidemiologist, Polio Eradication Branch, Global Immunization Division, National Immunization Program, Centers for Disease Control and Prevention, Atlanta GA 30333, USA (email: kik9@cdc.gov). Correspondence should be addressed to this author.

³ Medical Officer, World Health Organization Regional Office for South East Asia, New Delhi, India.

⁴ Medical Officer, Vaccine Assessment and Monitoring, Vaccines and Biologicals Department, World Health Organization, Geneva, Switzerland.