

The authors reply:

In their letter, Acharya et al. have raised 2 important issues regarding our paper^[1] which we would like to address. These relate to the inclusion of references to previous published reports of the safety of lamotrigine in children.

Our publication was not intended as a review of the literature but rather a presentation of the overall Glaxo Wellcome clinical trial experience with lamotrigine in children and a comparison of this experience with the previously published experience in adult patients.^[2] As such the report included all of the data presented in the paper by Besag et al.^[3] (n = 285) with the addition of considerably more experience gained since that paper was published (n = 1096). We certainly agree that it would have been appropriate to cite the Besag paper as an historically important document that provided the first presentation of the Glaxo Wellcome paediatric clinical trial experience. However, we decided it was appropriate to present a single and more updated paediatric lamotrigine database.

With respect to the reference to Drug Safety Research Unit (DSRU) reports,^[4,5] these are indeed very important publications. However, we did not intend this report to be a literature review but rather a complete disclosure of the Glaxo Wellcome clinical trial experience with lamotrigine. Other publications regarding lamotrigine have provided a review of rash data from multiple sources including the important work of the DSRU.^[6]

Our purpose in limiting our discussion to the clinical trial data was to represent the very detailed

and systematic collection of safety data that occurs in centrally co-ordinated clinical trials and the opportunity this provides to present, with reasonably large numbers of cases, incidence estimates for adverse events. While a literature review would have added to the presentation and certainly would have included references to the DSRU data as well as other sources, this was not the intended purpose of the publication.

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