Letter to the Editor
(Re: Karwowski et al. 2018)

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This manuscript was sent to the editor of Academic Pediatrics but was returned by the editor with the note that the journal does not publish Letters about papers published in the journal. When the editor was asked about other ways to address the scientific flaws in this paper there was no reply. You can read about the editor of Academic Pediatrics here (https://www.uclahealth.org/peter-szilagyi) and come to your own conclusions as to why such a fundamentally flawed paper was published with his support. I also sent the below letter to the lead author of the paper, Alan Woolf, but without any reply.

The Safety of Aluminium Adjuvants in Infants

In a recent paper1, an attempt is made to connect the body burden of aluminium to aluminium exposure through vaccination and how these might impact upon early infant development. The laudable working hypothesis being to establish if exposure to aluminium through vaccination is affecting early infant development. The authors conclude that it is not. I find the research described in this paper at best unconvincing and at worst seriously flawed. The provenance of the major issues is probably a lack of experience and understanding by the authors of aluminium in human health. For example, the authors used two indices of human exposure to aluminium, hair and whole blood, neither of which are widely accepted as reliable indicators of the body burden of aluminium2. Attempts were then made to relate these data with aluminium exposure through vaccines, the latter calculated erroneously as if all adjuvant aluminium administered in a vaccine dissolves into the whole body of an infant equilibrating, presumably, with whole blood and hair3. The authors also appear to assume that adjuvant aluminium will be the only significant source of aluminium to infants, somehow forgetting that infant formulas are heavily contaminated with aluminium4. Indeed breast milk may also be a significant source of aluminium to the infant5.

The data obtained for hair aluminium can largely be discarded as, regardless of numerous published studies, hair aluminium remains to be demonstrated as a useful biological index of human exposure to aluminium. Whole blood, as opposed to serum, may, in the future following robust validation, prove to be useful in estimating the body burden of aluminium but not in this study due to significant issues in relation to its measurement. For example, no details are given as to how blood was collected. Researchers are often unaware that commercially available blood collection devices are heavily contaminated with aluminium leading to significantly higher measured values, as indeed are observed in this study. If, as is suggested in this paper, method blanks employing distilled water were used then, in the first instance, distilled water is not an appropriate blank for these preparations and secondly the method blank data obtained should be reported along with how they were used in any adjustments of
final values. The authors report that they used a blood volume of (as little as) 0.1 mL which following digestion was diluted to a final volume of 5 mL. A dilution factor of 50 which when applied to their median blood aluminium content of 15.4 µg/L means that they were measuring 0.31 µg/L as their median value using an instrument which they suggest had a limit of detection of 0.1 µg/L. The measurement of aluminium in human tissues is fraught with problems and demands the highest levels of quality assurance. Primary data should be adjusted appropriately with representative method blanks and while I cannot say that the data presented in this paper are erroneous much about their provenance and final values suggests that they might not be reliable. The authors also concede as much in their discussion.

One does wonder why the authors believed that whole blood (and hair) would be reliable indicators of infant exposure to aluminium through vaccination? The current consensus is that urinary excretion of aluminium, either 24h or creatinine-corrected spot values, is the best estimate of the body burden of aluminium. Unfortunately, such data are not yet available for infants in the age group of this study. However, it must be debatable if aluminium exposure solely through vaccination would even be discernible using urinary excretion considering infants’ additional and much greater exposure to aluminium through formulas and occasionally breast milk. In addition, the assumption that adjuvant aluminium is metabolised in the body in the same way as that entering the body in feed through the gut seems somewhat far-fetched. The fate of aluminium in the human body is very much governed by the original route of exposure. Adjuvant aluminium is known to be harvested at vaccine injection sites by immune reactive cells many of which are very long lived and are capable of transporting aluminium throughout the body. A recent publication on aluminium in brain tissue in autism demonstrated that the fate of such cells might be the brain.

The authors are not correct in their assertion that the safety of aluminium adjuvants in infants has been well established. No such experiments on the safety of aluminium adjuvants have ever been carried out, nor is there currently any regulatory requirement for such. Paediatric vaccines that include an aluminium adjuvant are tolerated by the majority of recipients, though longer term effects or consequences have not been investigated, while some infants do experience serious adverse events which remain largely unexplained. The authors’ use of ‘internet’ citations (10-12 in the paper) in an attempt to belittle the potential dangers of aluminium adjuvants is unbecoming and should have been questioned during peer review. The authors are correct in their assertion that the safety of aluminium adjuvants in pediatric vaccines demands attention, unfortunately this study achieves very little in this respect.

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References


