Safety and Efficacy of Inactivated Influenza Vaccines in Children

TO THE EDITOR—Cowling and colleagues should be congratulated for doing a prospective, placebo-controlled, influenza vaccine trial in children aged 6–17 years and following them for 3 years [1]. There is a dearth of placebo-controlled studies in children where efficacy vs harms with these vaccines can be examined [2].

We are, however, disappointed that in their publications [1,3], they have still not published complete information on adverse events. They show that using serology, a high proportion of children appear to have acquired infection over the 3-year follow-up period, but make no mention in their abstract that the vaccine appears to be of minimal or no benefit in preventing symptomatic disease [1]. As judged by their polymerase chain reaction results, presumably the only symptomatic infections detected clinically and prevented by the vaccine compared to the placebo group, were 4 episodes of influenza B infection [1].

This trial was registered in 2008 at ClinicalTrials.gov with a final data collection date for primary outcome measures of December 2010 [4]. However, no study results are yet posted there. The Consolidated Standards of Reporting Trials harms extension criteria mandate the reporting of adverse events [5,6]. The only adverse events Cowling and colleagues report were an increase in acute respiratory illness (ARI) in children who received the vaccine compared to those on placebo [1]. A significant increase in symptomatic ARI was also seen in children in Western Australia after receipt of inactive influenza vaccine [7]. It is important to learn what symptomatic effects, such as fever, resulted from the vaccine. The authors should publish all data on harms, along with their trial protocol, so we can understand how adverse events were collected and analyzed. If, overall, the increased number of cases of ARI plus vaccine side effects are much higher than those on placebo, given the low efficacy of the vaccine, then this is a strong argument against current policies advocating routine influenza vaccination of children.

We need much larger, independent, and better-reported prospective studies to be available that clearly demonstrate that benefits of influenza vaccines in children far outweigh harms. This needs to include the demonstrated risk of unexpected side effects in children [8,9] or findings such as an acute increase in other respiratory illness [2,6].

Notes

Financial support. C. D. M. receives grant funds from National Health and Medical Research Council. T. J. has received competitive research grants and is co-recipient of a UK National Institute for Health Research grant (HTA-10/80/01).

Potential conflicts of interest. T. J. receives royalties from his books; is occasionally interviewed by market research companies for anonymous interviews about phase 1 or 2 pharmaceutical products; has acted as an expert witness in a litigation case related to oseltamivir phosphate (Tamiflu, Roche) and in a labor case on influenza vaccines in healthcare workers in Canada; has acted as consultant for Roche, GlaxoSmithKline, IMS Health, and Sanofi-Synthelabo; and is on a legal retainer for litigation on neuraminidase inhibitors. All other authors report no potential conflicts.

All authors have submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Conflicts that the editors consider relevant to the content of the manuscript have been disclosed.

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Clinical Infectious Diseases® 2015;60(3):489
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DOI: 10.1093/cid/ciu835