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The Vaccine-attributable Risk for Febrile Convulsions Following Influenza Vaccine

To the Editors:

n a recent article in The Pediatric Infectious Disease Journal, Wood and colleagues¹ noted that, although the use of influenza vaccine in children who were 6-59 months of age has an excellent safety record over many years, there was an increased association of fever following vaccination with a trivalent inactivated influenza vaccine produced by one manufacturer in Australia in 2010. This follows previous reports of increased rates of fever and febrile convulsions after receipt of this vaccine.^{2,3} Wood et al.¹ noted that no studies had reported the vaccine-attributable risk (VAR) of febrile convulsions after influenza vaccine. We now provide an estimate of the VAR for emergency department presentations coded as a febrile convulsion (International Classification of Diseases, 10th revision, R56.0) in Perth, Western Australia, during 2010, following receipt of the specific influenza vaccine, manufactured by CSL Biotherapies (Parkville, Australia).

We confined our analysis to children who were 6-59 months of age presenting to Perth hospitals for management of a febrile convulsion in the 49 days between March 8, 2010, when the influenza vaccination program commenced, and April 24, 2010, 48 hours after vaccinations for children were suspended.² Using Emergency Department Information System data from 9 Perth hospitals, 99 children presented to emergency departments with febrile convulsions in this period, 39 within 72 hours of receiving an influenza vaccine and 60 who had no evidence of influenza vaccination in the previous 72 hours.² We also determined that 38 of the 39 children who had a febrile convulsion after influenza vaccination had received the 2010 CSL vaccine, Fluvax or Fluvax Junior. The number of children in the Perth metropolitan area estimated to have received Fluvax was

11,963.² Hence, among the estimated population of 104,076 children 6–59 months of age living in metropolitan Perth in 2010, 92,113 (104,076–11,963) would not have been vaccinated or received a different influenza vaccine brand. The 49-day risk of emergency department presentation for a febrile convulsion following Fluvax was 38/11,963 = 32/10,000. The risk in those who had not received Fluvax was 61/92,113 = 7/10,000. The VAR, calculated as the risk difference, is thus estimated as 25/10,000 children. In contrast, the VAR for the same program and corresponding period in 2009 can be estimated as zero.

Unpublished data for the same 9 Perth hospitals between 2002 and 2007 show that, among children who were 1-4 years of age, emergency department presentations for febrile convulsions coded as R56.0 occurred 7 times per week on average outside the influenza season, increasing to an average of 15 times per week during the influenza season (defined as June to October, inclusive). The 60 febrile convulsion presentations we documented in unvaccinated children during March-April 2010 (8.6 per week) is consistent with the out-of-season average of 7 per week. Inclusion of the 39 febrile convulsions associated with influenza vaccination in 2010 increases the average to 14 per week, more in line with the historical influenza season average.

Our estimate of VAR (25/10,000 children vaccinated) provides a missing index in the assessment of a serious adverse event following immunization.1-3 It is far in excess of VAR estimates for the same program in Western Australia in the previous year and 42 times the VAR (0.6/10,000 vaccinated 4-19 year olds) for narcolepsy associated with a different influenza vaccine formulation (Pandemrix) that was recently the subject of safety investigations in Sweden and Finland.⁴ Although it was not reported at the time, the high VAR for febrile convulsions associated with Fluvax in 2010 in Australia further supports the decision to suspend use of this vaccine in young children in that year and subsequently.

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Implementation of Procalcitonin in the Management of Febrile Children

To The Editors:

read with interest the article of Luaces-Cubells et al,¹ about the use of procalcitonin (PCT) to detect invasive bacterial infections in nontoxic-appearing infants with fever.

The authors conclude that PCT is a useful biomarker to predict invasive infections in nontoxic-appearing febrile infants. This article adds to existing literature on the diagnostic value of PCT in febrile children.² But where do we stand? Until now, diagnostic studies in febrile children did not support the implementation of new biomarkers in the routine diagnostic approach of febrile children in emergency care.³ From this perspective, I would like to comment on 2 issues in particular.

First, the authors assign an additional, important role for the duration of disease before presentation. In addition to the duration of disease before presentation, other clinical characteristics may add to discriminate between children with and without serious infections. Laboratory tests constitute a part of the diagnostic approach, but an important role is assigned to the clinical patient evaluation by the clinician. Evaluating a test without clinical information usually overestimates its diagnostic value in practice.⁴ I would challenge the authors to investigate the diagnostic value of PCT in addition to other clinical observations.

Next, the authors assess the diagnostic value of PCT for children with invasive bacterial infections, defined by meningitis, septicemia and occult bacteremia. Although

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^{1.} Wood N, Sheppeard V, Cashman P, et al. Influenza vaccine safety in children less than 5 years

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