

Reply to Letter to the Editor

No epidemiological evidence for infant vaccinations to cause allergic disease [Vaccine 2004;22:3375–85]

In an article recently published in this journal, Koppen and colleagues [1] present the results of a thorough literature review of studies assessing the association between infant vaccination against DPT, measles/MMR and BCG, and allergic diseases, rightly acknowledging and discussing methodological limitations of the studies identified.

Although I subscribe to the critical appraisal of studies made by the authors, I cannot agree with the final statement that “current epidemiological evidence indicates that infant vaccines do not increase the risk of allergic diseases”. . . On the contrary, I argue that current evidence, as described by the authors, is insufficient to either accept or discard the causal or contributing role of vaccines in the development of allergic diseases. First, the methodological weaknesses and conflicting findings of the studies conducted so far (and pointed by the authors) prevent any clear conclusions to be drawn. Second, some studies have non-significant results, and non-significant results do not imply evidence of lack of effect. Moreover, the final statement is not in accordance with passages of the text in which is said “there is no convincing evidence” linking atopic diseases and DT/DPT and measles/MMR vaccines, and “there is insufficient evidence to accept or reject a causal” link with BCG vaccine.

“Evidence of no effect” is not the same as “no evidence of effect” [2], and it seems that the authors used both terms without a clear distinction. Epidemiologic studies of the magnitude required to discard an effect would probably be very large and costly, and, therefore, most of them are unlikely to be feasible [2]. In practical terms, the existence of well conducted epidemiologic studies or a meta-analysis of sev-

eral studies with adequate sample size to detect a significant effect on statistical and public health grounds favours the rejection of a association [3].

Furthermore, although I do agree that development of vaccines to prevent infectious diseases is an important achievement, this certainly should not prevent careful monitoring and scientific examination of possible and unexpected side effects of vaccines. Actually, open discussion and transparency in the investigation of unexpected results is essential to nurture confidence in vaccination programmes and to overcome mistrust [4].

References

- [1] Koppen S, et al. No epidemiological evidence for infant vaccinations to cause allergic disease. *Vaccine* 2004;22:3375–85.
- [2] Costa LJ, Xavier AC, Del Giglio A. Negative results in cancer clinical trials-equivalence or poor accrual? *Control Clin Trials* 2004;25:525–33.
- [3] Stratton KR, Howe CJ, Johnston Jr RB, editors. Causality and evidence, in adverse events associated with childhood vaccines. Evidence bearing on causality. Washington: National Academy Press; 1994. p. 19–33.
- [4] Cunha SS, Dourado I. MMR mass vaccination campaigns, vaccine-related adverse events, and the limits of the decision making process, in Brazil. *Health Pol* 2004;67:323–8.

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