Surveillance of adverse reactions to vaccines leading children to the Emergency Department

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Pharmacovigilance plays an important role in the pediatric population to improve medication safety in pediatrics. We reported a case series of adverse reactions to vaccines that led children to the Pediatric Emergency Department of 'Azienda Ospedaliera Universitaria G. Martino' of Messina, over a 11-months period. This report represents a part of a multicentre study on drug safety in children coordinated by the National Institute of Health in Italy.
This is a retroprospective observational study. We selected and then analysed in detail all the case reports of suspected adverse reactions to vaccines collected from June 2012 to April 2013. We included in the study only adverse drug reactions (ADRs) with a probable or possible causality assessment, according to the World Health Organization criteria.
Most ADR occurred in children aged 0-15 months with a slight predominance in males (n=6) with respect to females (n=4) .
Among the 10 cases of ADR, all reports were serious and led to hospitalization, complete recovery occurred in all cases. The reported adverse reactions were: dermatological manifestations (3 cases) neurological disorders (5 cases) and multiple symptoms affecting different organs or systems (2 cases). Two of the dermatological reactions were attributed to Pneumococcal 13-valent vaccine, and one to the Hexavalent vaccine. Among case reports presented neurological events, three were ascribed to coadministered vaccines: Hexavalent vaccine and Pneumococcal 13-valent vaccine, one to Pneumococcal 13-valent vaccine and the last one to concomitant administration of Measles, Mumps, and Rubella (MMR) Virus Vaccine and Meningococcal Serogroup C Conjugate Vaccine. Moreover, we reported two cases of vomiting, fever and irritability, one to Pneumococcal 13-valent vaccine, while the other to Hexavalent vaccine concomitantly with Pneumococcal 13-valent vaccine.
Furthermore, we compared the spontaneous reports of suspected ADRs attributed to vaccines received from local health structures and sent to the Sicilian Regional Pharmacovigilance Centre during the same period. Overall 158 ADR reports have been collected, 6,3% of which derived from our study.
Among these reports, 32 (20,2%) described serious ADRs including 21 cases referred to events that led patients to hospital admission. The most frequently implicated vaccines in ADR reports were: co-administered Hexavalent and Pneumococcal 13-valent vaccines (n=40), Pneumococcal 13-valent vaccine (n=16), MMR vaccine (n=14).
According to the literature (Oehme et al., 2012), vaccines or a combination vaccines represent after antibiotics, the most frequent ADRs in children (Lieber et al., 2012). Our reports may be underestimated. The lower number of ADRs causing admission to the Pediatric Emergency Department is related to the difficult to achieve patients charts and to the lack of information of these data.

Lieber et al. (2012) *Rev Bras Epidemiol* 15: 265-274.
Oehme et al. (2012) *PLOS ONE* 7: 1-11.