Adverse Reactions to Vaccines Causing Children Admission to the Paediatric Emergency Department: a Single Center Study

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Despite the safety of current vaccination program, mild adverse reaction and in rare cases severe reactions to vaccines may occur. Therefore, surveillance plays an important role in the pediatric population in order to improve vaccination coverage in children.
A retroprospective observational study was conducted at the Paediatric Emergency Department of 'Azienda Ospedaliera Universitaria G. Martino' of Messina, during a 36-months period.
The aim of our study was to assess the incidence of ADR-related hospital admission in children, due to vaccines, and to identify the principal vaccines involved and symptoms.
We collected data of suspected adverse reactions to vaccines, from April 2012 to April 2015. We included in the study only adverse drug reactions (ADRs) with a probable or possible causality assessment, according to the World Health Organization criteria. This report represents a part of a multicentre study on drug safety in children coordinated by the National Institute of Health in Italy.
Over the study period there were 4.233 admissions to the Paediatric Emergency Department. Among the 38 cases of ADR, 25 were serious and led to hospitalization, complete recovery occurred in all cases. The rate of hospital admission due to adverse reactions to vaccines was 0.6%.
Most ADR occurred in children aged 0-15 months with a slight predominance in females (n=13) with respect to males (n=12).
The reported adverse reactions were: neurological disorders (13 cases), dermatological manifestations (9 cases) and multiple symptoms affecting different organs or systems (3 cases). The most frequently implicated vaccines in ADR reports were: coadministered Diphtheria, Tetanus, Pertussis, Hepatitis B, Poliomyelitis, Haemophilus influenzae type b (Hexavalent) vaccine and Pneumococcal 13-valent vaccine (12), Pneumococcal 13-valent vaccine (4), Hexavalent vaccine (2), Diphtheria, Tetanus, Pertussis, Polio vaccine (2), Measles, Mumps, Rubella vaccine (2), Meningococcal Serogroup C Conjgate vaccine (1), concomitant administration of Measles, Mumps, Rubella vaccine and Meningococcal Serogroup C Conjgate vaccine (1) and three coadministered vaccines: Pneumococcal 13-valent vaccine, Hexavalent vaccine and Rotavirus vaccine (1).
Moreover, we wanted to compare the results obtained by the Sicilian Regional Pharmacovigilance Centre, during the same period. 83 reports of serious ADRs to vaccines, that led patients to hospital admission, were collected from all the Sicilian local health structures. Among these events, 25 (30%) derived from our study.
Therefore, according to the literature (Lieber et al., 2012) we suggest the importance of Pharmacovigilance to assure the risks and benefits of vaccination (Gallagher et al., 2012) and support the development of interventions for children at risk (related to genetic disorders or syndromes) in order to promote safety and increase the parent trust in vaccine.

Lieber et al. (2012) *Rev Bras Epidemiol* 15: 265-274.
Gallagher et al. (2012) *PLOS ONE* 7 (12) e50127.