Adverse Events Following Immunization (AEFI) in emergency department: results of MEREAFaPS study

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Introduction: Adverse events following immunization (AEFIs) are untoward events temporally associated with immunization that may have been caused by a vaccine or other immunization processes. AEFIs are generally mild in nature while serious ones are extremely rare.[1] In USA it has been estimated that 15.790 patients every year are admitted to the emergency department (ED) due to vaccine-related problems.[2]
Objective: To analyze ED admissions for potential AEFIs in nine EDs involved in the *Epidemiological Monitoring of Adverse Drug Reactions and Events in First Aid* (MEREAFaPS) study from 1st July 2010 to 31st March 2013.
Methods: The MEREAFaPS study is a prospective cohort, observational, multicentre, no profit study, with the aim of investigating admissions to ED for adverse drug reactions (ADRs) and AEFIs. The MEREAFaPS database retrospectively collects data on patients for which the ED admissions for drug or vaccine-related problems have been suspected by the clinicians operating in the ED. ADRs and AEFIs have been coded using the Medical Dictionary for Regulatory Activities (MedDRA).
Results: The study population included 864.046 ED admissions, with 2920 ADR-related (0.34%) and 166 AEFI-related (0.019%) admissions throughout the study period; about 1061 ADR-year and 60 AEFI-year. The vaccines most frequently involved in AEFIs were: combined diphtheria-tetanus-acellular pertussis, hepatitis B, poliovirus (15.8%); combined measles, mumps, rubella and varicella (12.2%) and conjugate pneumococcal 13-valent (9.3%). AEFIs involved 81 females (48.8%) and 85 males (51.2%). The majority of AEFIs were recorded in children, mainly those belonging to the age group 0-2 years (72.9%). The MedDRA system organ classes most frequently involved in AEFIs were: injury, poisoning and procedural complications (50.5%); gastrointestinal disorders (15.9%); skin and subcutaneous tissue disorders (10.0%); nervous system disorders (9.0%) and respiratory, thoracic and mediastinal disorders (4.0%). AEFI outcomes were distributed as follows: 14 (8.4%) complete recovery; 63 (38.0%) improvements; 89 (53.6%) outcome not available. Among AEFIs, 27 (16.3% of overall patients with AEFIs) had a serious event, which required hospitalization. Most frequently reported serious AEFIs included: pyrexia (26.9%); hyperpyrexia (3.8%); febrile convulsions (3.8%); sleepiness (3.8%); rash (3.8%); ataxia (3.8%); appetite loss (3.8%); dyspnea (3.8%); irritability (3.8%) and vomiting (3.8%).
Conclusions: AEFIs seem to represent an uncommon cause of ED admission in Italy, with a small number of them requiring hospitalization. Our results probably underestimate the actual proportion of AEFI-related ED admissions due to potential misclassification bias. ED physicians and nurses should be educated to an appropriate detection and reporting of AEFIs-requiring ED admissions.

References

1. Bonhoeffer et al. (2002) Vaccine. 21: 298-302.
2. Budnitz et al. (2006) JAMA. 296: 1858-66.