Adverse drug reactions in paediatrics: data of an Italian active monitoring study of adverse drug reactions in emergency departments (MEREAFaPS).

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Introduction and objectives: It is well-known that safety data on the use of drugs in children are lacking and not necessarily deductible from information on adverse drug reactions (ADRs) available from adults, mainly due to deep changes in pharmacokinetics and pharmacodynamics occurring during development and aging. The aim of this study was to determine the prevalence of ADRs reported in the paediatric emergency department (ED) of Meyer Children's Hospital (Florence, Italy), using data derived from the MEREAFaPS project. MERAFaPS is an active pharmacovigilance project promoted by the Italian Agency of Medicines (AIFA), and aims to increase knowledge about drugs and to define their safety profile, to improve treatment quality, and to evaluate their use in clinical practice.

Methods: We analysed all the suspected ADRs reports compiled by monitors between January 2012 and December 2016 in the ED of Meyer Children's Hospital (Florence, Italy). All demographic, clinical and pharmacological data of patients were collected, as well as anatomical therapeutic class (ATC) of suspected and concomitant drugs involved, and seriousness of ADRs, classified according to preferred terms (PT) and system organ class (SOC) classification.

Results: We included 600 reports of ADRs. The majority of them involved infants and children of both gender, and for each ADR the number of suspected drugs was usually <3 (79.5%). Following the ATC classification system of the first level, drugs most implicated belonged to the group of anti-infective agents for systemic use (J class; 72.0%), including both antibiotics (penicillins and macrolides) and vaccines, followed by drugs active on the nervous system (N class; 8.6%) and drugs belonging to the M class (musculoskeletal system; 3.6%). Only few patients were treated with concomitant drugs and only in few cases we observed the use of food supplements. SOCs more reported were "General disorders and administration site conditions" (32.7%), "Gastrointestinal disorders" (23.9%) and "Skin and subcutaneous tissue" (20.8%), with rash, nausea, vomiting and fever as the most reported PTs. The majority of analysed ADRs were not serious and did not required hospitalisation.

Conclusions: ADRs are a serious health issue for Healthcare systems and paediatric population represents a challenge for clinicians and health workers. This study provides an overview of ED admissions related to ADRs in infants and children and describes their seriousness and impact in a representative Italian paediatric ED.

Further studies are still needed in order to improve our knowledge on drug safety, in particular in childhood, for promoting a rationale use of available drugs, taking into account the variability in pharmacokinetics and pharmacodynamics among different ages.