Monitoring of Adverse Events in Paediatrics (MEAP) Project: preliminary results

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Introduction: The children are highly exposed to the toxic effects of the drugs due to an incomplete maturation of organs and the lack of clinical trials. Therefore, the decision making in paediatric pharmacotherapy has historically been made on the basis of data obtained in adults, even though it is clear that children have different pharmacokinetics and pharmacodynamics . Moreover, the limited availability of clinical trials in children facilitates an off-label use of many drugs with a higher probability of occurrence of Adverse Drug Reactions (ADR). **AIMS:** The Project Monitoring of Adverse Events in Paediatrics (MEAP) was born to encourage spontaneous reporting of ADRs in children and provide paediatricians with a better understanding of the safety profiles of the drugs. Currently, the regions of Italy, that in collaboration with Lombardy (Nationale Coordinating Center of study) have joined the project MEAP, are Tuscany, Apulia and Campania. **Methods:** In Campania, the Regional Centre of Pharmacovigilance and Farmacoepidemiology has been identified as a Local Coordinator Centre of the study. A the beginning, it was involved in the training of hospital referents and territory paediatricians (PLS).The monitors followed the project at all stages, visiting the hospital paediatricians and PLS for the collection of the reports. Each reporting of suspected ADRs was then included in the National Network of Pharmacovigilance (RNF) of Italian Medicines Agency (AIFA) and sent to the National Coordinating Centre of the study, and the feedback containing data from the literature and in-depth insights regarding the reported case for serious ADRs and /or notes were sent to all participants, together with a bi-monthly summary report. **Results**: To date, 767 reports of suspected ADRs deriving from the Campania Region have been included in the the National Network of Farmacovigilance (RNF) of Italian Medicines Agency (AIFA). 30% reports were received from hospital paediatricians, of which 23.5% were from University Hospital Policlinico SUN. Of the total reports, 77% were not serious. The average age of patients (range 0-17 years) was 7.5 years and 54.5% were female. Because each report form may contain more than one ADR and more than one drug, a total of 1232 ADRs for 993 suspected drugs were reported. ADRs referred to gastrointestinal disorders (17.3%), skin and subcutaneous tissue diseases (17%), systemic diseases and administration site conditions (14.3%) and nervous system disorders (11.6%). The antineoplastic and immunomodulating agents were the most often involved in the development of ADRs (40%), and among those, the most frequently reported was vincristine, followed by cytarabine. Other drugs associated with ADRs were drugs of the nervous system (16.5%), in particular risperidone, and the antimicrobial drugs for systemic use (13.6%), in particular amoxicillin-clavulanic acid. ADRs of vaccines were 17.5% of a total, 38% of them occurred following the administration of hexavalent Diphtheria-Hemophilus influenzae B-Pertussis-Tetanus-Polio-B hepatitis vaccine. Most of the reported ADRs resolved with the complete resolution of symptoms or improvement but in 21% of cases the outcome was not available. For all pairs of drug/event the notoriety occurred, and about 85% of ADRs were known and, therefore, predictable. **Conclusions:** The participation of Campania to MEAP study has brought the attention of paediatricians to the ADRs arisen in children during hospitalization or outpatient visits. Fortunately, most of the ADRs reported during the first months of the project in Campania, was not serious, but probably could be prevented, being mainly noted ADR. This indicates that the system of pharmacovigilance in paediatric patients should be strengthened not only to safeguard the health of paediatric patients, but also to reduce health care costs associated with the treatment of ADRs.