Children adverse drug reactions in Emergency Department: an analysis of MEREAFaPS study national database

N. Lombardi[1], M. Moschini[1], R. Bonaiuti[1], A.M. Calvani[2], L. Innocenti[4], M.C. Lenti[1], E. Lucenteforte[1], V. Maggini[1], F. Mandò Tacconi[3], S. Masi[4], M. Parrilli[3], A. Pugi[1], M. Rossi[5], A. Saporiti[6], G. Vighi[7], C. Blandizzi[6], A. Mugelli[1], M. Tuccori[6], A. Vannacci[1]

[1]Tuscan Regional Centre of Pharmacovigilance, Dept. of Neurosciences, Psychology, Drug Research and Child Health, School of Human Health Sciences, University of Florence, Italy
[2]Hospital Pharmacy Unit, Anna Meyer Children's University Hospital, Florence, Italy
[3]Tuscan Regional Centre of Pharmacovigilance, Local Health Unit N° 10, Florence, Italy
[4]Dept. of Emergency Medicine, Anna Meyer Children's University Hospital, Florence, Italy
[5]Tuscan Regional Centre of Pharmacovigilance, Siena, Italy
[6]Tuscan Regional Centre of Pharmacovigilance, University Hospital of Pisa, Pisa, Italy
[7]Lombardy Regional Centre for Pharmacovigilance, Unit of Clinical Pharmacology and Pharmacovigilance, Niguarda Ca'Granda Hospital, Milan, Italy

Introduction: Adverse drug reactions (ADRs) are an important cause of mortality and morbidity and have a significant impact on health care resources. In western countries, ADRs cause 3% to 5% of all hospital admissions and are responsible for about 5% to 10% of in-hospital costs. In pediatric patients the monitoring of drug use and of ADRs requires careful evaluation, since many drugs are used off-label, due to the lack of registrative studies in this age group.

Aim: Aim of the present study is to give a 'real-life' information on safety profile of drugs used by pediatric patients, information that now is only based on data coming from clinical trials conducted on adult population.

Methods: We analyzed the impact of ADRs on Emergency Department (ED) accesses, using data from a national pharmacovigilance project of ADRs monitoring in ED (*Monitoraggio Epidemiologico di Reazioni ed Eventi Avversi da Farmaci in Pronto Soccorso* - MEREAFaPS) and we focused our attention on children.

Results: This study considered ADR reports form patients with 18 year or less admitted to 94 Italian EDs for a suspected ADR from January 2010 to March 2015. The reports were stored in a structured Italian database called *Niguarda* database. ADRs were classified according to System Organ Class (SOC) of the Medical Dictionary for Regulatory Activities (MedDRA) and were classified serious if they caused or prolonged hospitalization, were life-threatening, resulted in death, or produced permanent malformations or disabilities. In a period of five-years, the number of pediatric admissions to ED due to ADRs was 3839 representing 9% of the total reports records in the MEREAFaPS study. Fifty-one percent of the reports involved female children with a mean age of 6 years (standard deviation 5.9 years). Serious reactions requiring hospitalization represented 14.5% of total ADRs, only 8 being life-threatening; thus, the majority of ADRs were classified as 'not serious'. As expected, the reporters were mainly hospital doctors (62%), followed by pharmacists (36%) and other healthcare professionals including nurses. The 3839 ADR-related ED admissions resulted in 6006 adverse events: 42% involved the skin, 15% the gastrointestinal system, 15% were related to general disorders and administration site conditions and 6% to nervous system disorders. Drugs (n=4761) most frequently involved in the ADRs were vaccines and antibacterials for systemic use.

Conclusions: Results from this study could help minimizing ADRs incidence in the pediatric population and increasing awareness about drug safety.