

# Epidemiological monitoring of adverse drug reactions in paediatric emergency department.

S.Stabile, L.Prestini, F.Di Sessa, R.Chittolina, F.Rotondo, G.Vighi.  
A.O. Niguarda Ca'Granda, Milan, Italy

## Background:

Drugs utilization in children presents several problems regarding safety and tolerability, mainly due to lack of information about the risk-benefit profile in real conditions of use. Pharmacovigilance could ensure a safer drug therapy especially in the most vulnerable people as paediatric patients or over-65.

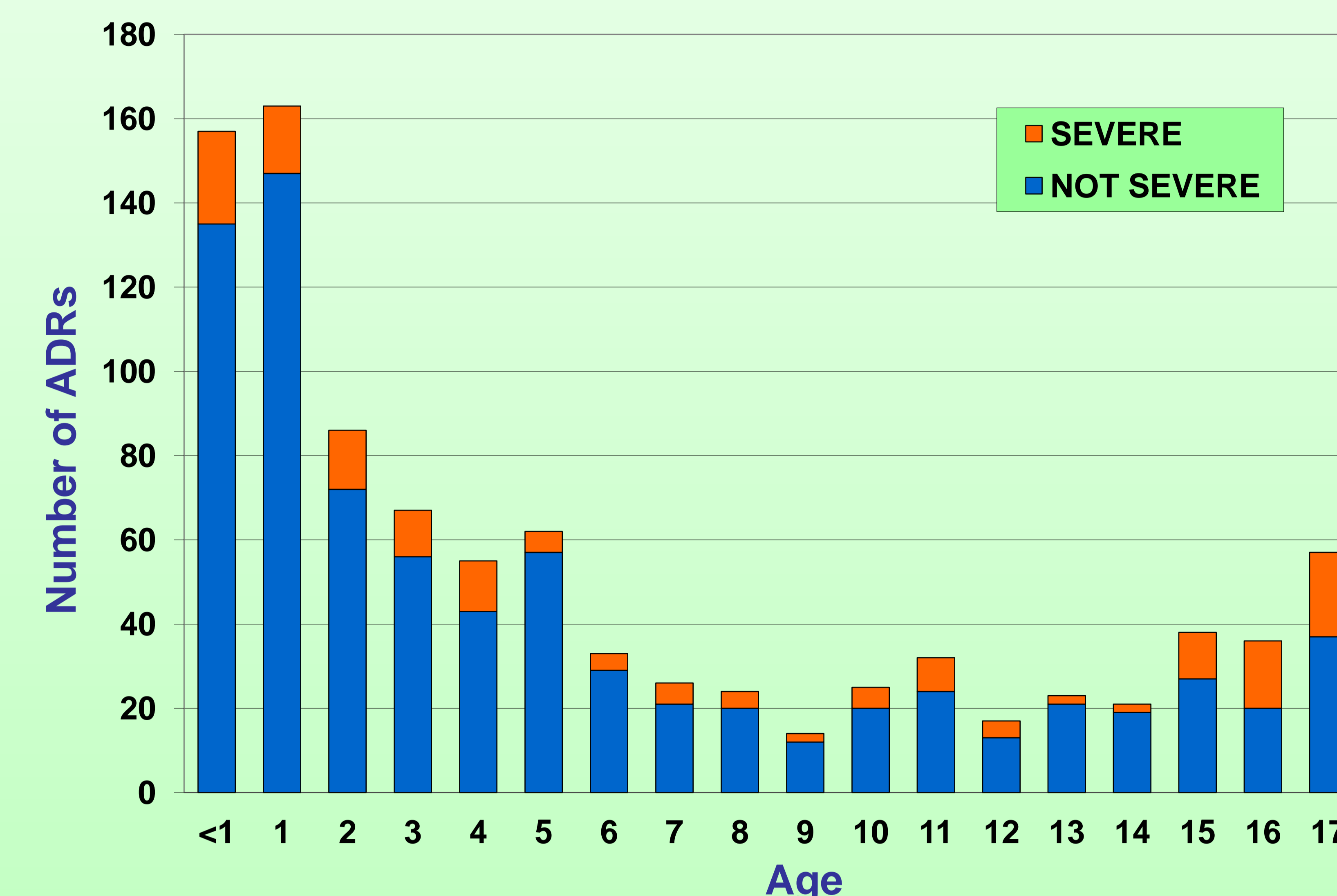
## Purpose:

The aim of this study is to analyze the impact of adverse drug reactions (ADRs) on paediatric patients visited in emergency departments (ED)

## Material and Methods:

In this study we consider ADRs reported in the project database MEREAFaPS (epidemiological monitoring of adverse drug reactions in ED) collected in 16 hospitals of Lombardy from 1st July 2009 to 31th December 2011. The ADRs were coded by MedDRA dictionary. All the potential ADRs among patients <18 years old were reported and analysed by seriousness, suspected drugs, resolution, preventability and type of adverse reactions.

Age distribution of suspected Adverse Drug Reactions



## Results:

During the observation period we collected 10885 reports: over-65 patients represented 40,78% of the total ADRs and paediatric population (<18yr) was 8,60%. The 43,37% of paediatric ADRs concern patients with less than 2 yr with a clear prevalence of non serious reactions than severe ones. The incidence of ADRs evaluated on ED access was 1,5/1000 ED paediatric visits. The System Organ Classification (SOC) most frequently reported was skin and subcutaneous reactions (59,74%), while the SOC with the highest proportion of severe reactions were psychiatric disorders (73,33% ratio) and nervous system diseases (53,73% ratio). The most frequently reported drug was amoxicillin/clavulanic acid (22,80%), followed by amoxicillin alone and acetaminophen. Adverse vaccine reaction represented 12,18% of overall cases: the hexavalent vaccine was the most reported (4,65% overall).

## Conclusion:

This study underlines the importance of pharmacovigilance in paediatric population and the need of more careful drug use especially in early childhood. Moreover the attention of specialists on these issues should be increased with training initiatives on problems related to drug therapy and, above all, education for spontaneous reporting.

	<i>Suspected Active Ingredient (ATC)</i>	<i>ADRs .N°</i>	<i>Cases %</i>	<i>Cumulative %</i>
1	Amoxicillin / clavulanic acid (J)	245	22,79	22,79
2	Amoxicillin (J)	118	10,98	33,77
3	Acetaminophen (N)	62	5,77	39,54
4	Hexavalent vaccine	50	4,65	44,19
5	Clarithromycin (J)	48	4,47	48,66
6	Ibuprofen (M)	45	4,19	52,85
7	Measles, mumps and rubella vaccine (J)	37	3,44	56,29
8	Cefaclor (J)	35	3,26	59,55
9	ketoprofen lysine salt (M)	26	2,42	61,97
10	Azithromycin (J)	23	2,14	64,11
-	Other	386	35,90	100%

TABLE: first 10 active ingredients most signaled for suspected ADRs in paediatric patients.