

# ADVERSE DRUG REACTIONS CAUSING CHILDREN ADMISSION TO THE EMERGENCY DEPARTMENT

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#### INTRODUCTION

Post-marketing surveillance plays an important role in the pediatric population to improve medication safety in pediatrics. We reported a case series of adverse drug reactions (ADRs) that led children to the Pediatric Emergency Department of "Azienda Ospedaliera Universitaria G. Martino" of Messina, over a 28 - months period. This report represents a part of a multicentre study on drug safety in children coordinated by the National Institute of Health in Italy.

### Aim of Study

> To assess the importance and consequences of ADR causing admission to a Pediatric Emergency Department.

#### Methods

This is a retrospective observational study. We selected and then analysed in detail all the case reports of suspected adverse reactions to drugs and vaccines collected from April 2012 to July 2014. We included in the study only adverse drug reactions (ADRs) with a probable or possible causality assessment, according to the Naranjo Algorithm and the World Health Organization criteria.

#### Conclusions

- We suggest the importance of pharmacovigilance with the aim to diminish the incidence of ADR-related admission and support the development of interventions to promote drug safety.
- According to the literature<sup>[1-2]</sup>, antibiotics and vaccines represent the most frequent cause of adverse drug reactions in children.
- Our reports may be underestimated due to the difficult to achieve patients charts and to the lack of information of these data.

#### **References:**

- Lieber NS, Ribeiro E. Adverse drug reactions leading children to the emergency department. Rev Bras Epidemiol 2012: 15(2):265-274
- Oehme AK, Rashed AN, Hefele B, et al. Adverse drug reactions in hospitalised children in Germany are decreasing: results of a nine year cohort-based comparison. PLOS ONE 2012: 7: 1-11

### RESULTS

Over 28 months, April 2012 to July 2014, there were 3132 admissions to the Paediatric Emergency Department. The rate of hospital admission due to ADRs was 1.9% [table 1]. Among the sixty-one cases of ADRs, of these, 72.1% required hospitalization, complete recovery occurred in all cases. Most ADR occurred in children aged 0-15 years with a predominance in females (n=34) with respect to males (n=27). The drugs most frequently involved were antibiotics (n=23), vaccines (n=23), FANS and corticosteroids (n=19), respiratory agents (n=6), antiepileptics (n=2). The reported adverse reactions were: dermatological manifestations (38 cases), neurological disorders (15 cases), haematemesis (3 cases), gastrointestinal symptoms (3 cases), vomiting (2 cases), cardiology symptoms (2 cases). The most frequently ADR reports implicated were: combination of drugs (Amoxicillin/Clavulanate) and co-administered vaccines (Hexavalent and Pneumococcal 13-valent vaccines).

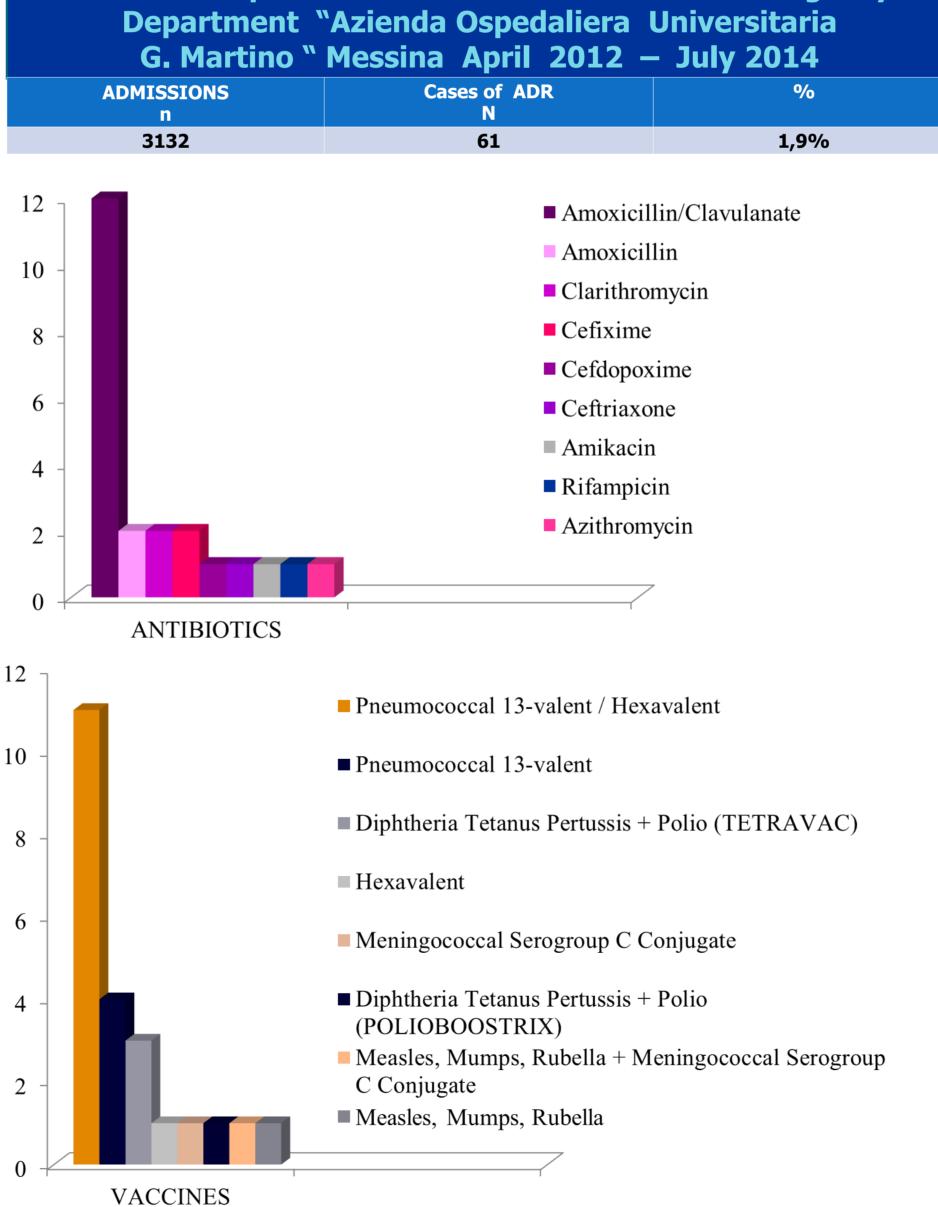
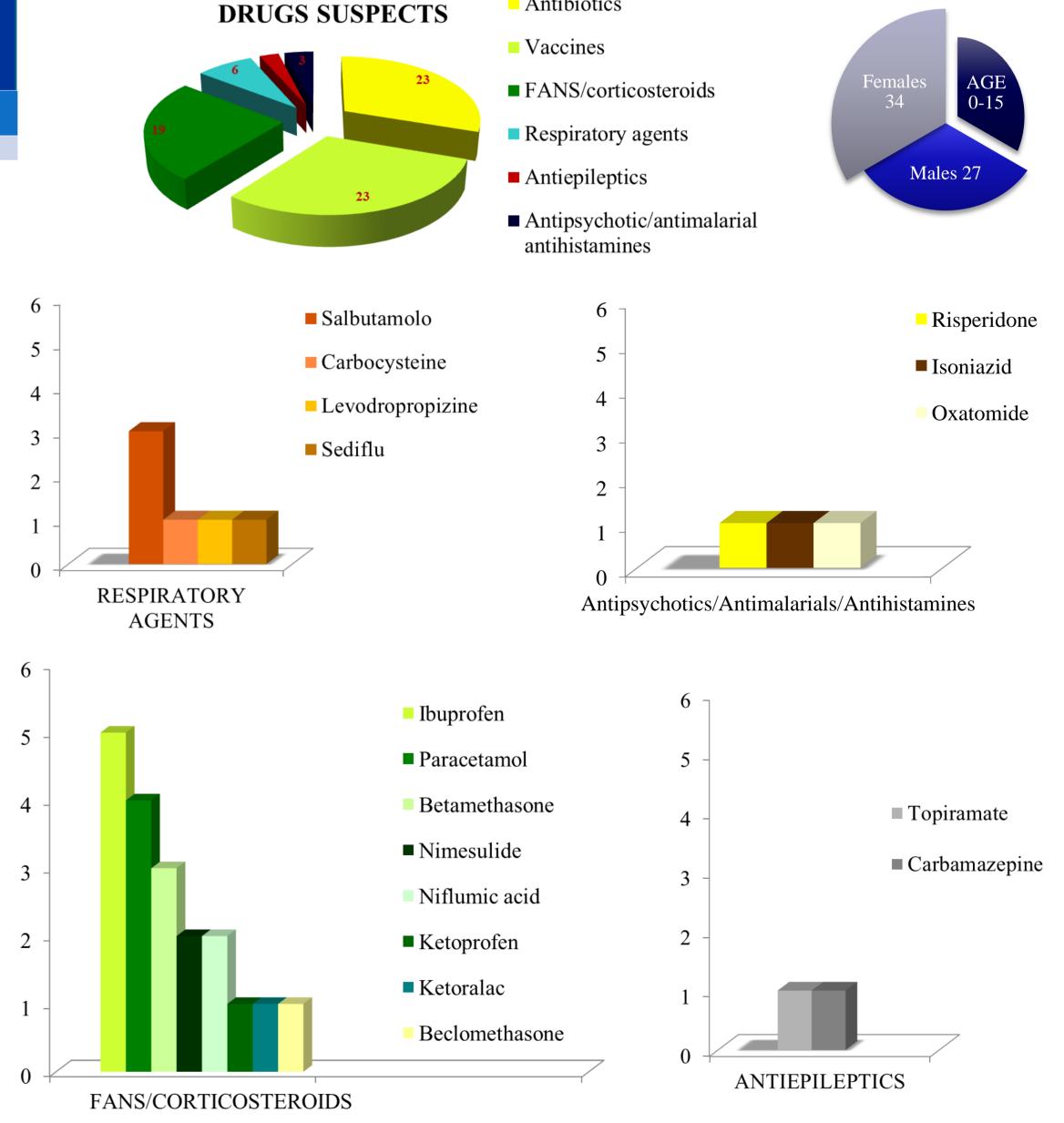


Table 1. Hospitalization for ADR in Pediatric Emergency



Antibiotics