

## A COMMUNITY BASED METHOD TO MONITOR THE FREQUENCY AND NATURE OF PAEDIATRIC ADVERSE DRUG REACTIONS

D. Stewart,<sup>1</sup> D. Mccaig,<sup>1</sup> C. Bond,<sup>2</sup> P. J. Helms<sup>3</sup> & J. S. Mclay. <sup>1</sup>The School of Pharmacy, The Robert Gordon University, and Departments of Medicine and Therapeutics, <sup>2</sup>General Practice, and <sup>3</sup>Child Health. University of Aberdeen, Aberdeen.

Spontaneous suspected adverse drug reaction (ADR) reporting to the Committee on Safety of Medicines by healthcare professionals is the main source of information used for regulatory pharmacovigilance in the UK. However relatively little is known of the frequency and severity of ADRs in the paediatric population, although the limited information available suggests that ADRs account for 1.53–2.09% of paediatric hospital admissions, that 2.64–9.3% of paediatric inpatients, and 1.5–11.1% of children in the community suffer from ADRs. There is a clear need for a comprehensive and accessible means of monitoring ADRs in paediatrics. The aim of this study was to pilot a community based method of ADR monitoring and reporting, suitable for both prescribed and over the counter medicines.

Data were collected for 4 weeks in seven community pharmacies in Grampian on children under 12 years old collecting prescriptions for amoxicillin, salbutamol, paracetamol or ibuprofen suspension or purchasing paracetamol or ibuprofen suspension. After obtaining informed consent, the parent was interviewed to determine: age of child, post code, details of study medicines and any other medication being taken. The parent was asked to complete and return a 5 day questionnaire for each of the study medicines, recording dose, frequency of dosing, and possible side effects both in the form of an ADR tick list and in freehand. Ethics approval was obtained from the Grampian Research Ethics Committee. During the study period a total of 360 prescriptions or purchases of the study medication were recorded, of which 312 were suitable for study inclusion and 267 (85.5%) parents agreed to participate in the study. Two-hundred and forty-one (90.3%) children were prescribed one study medicine, 23 (8.6%) children two, and 3 (1.1%) children three study medicines. One hundred and six parents (40%) returned a total of 122 completed questionnaires, (95 for 1, 9 for 2, and 3 for 3 medicines). There were no significant differences in the distributions of child age and Depcat scores between the responders and non responders. A comprehensive tick list of possible side effects occurring since starting the study medication was completed by each parent/guardian. Using the symptom tick list 49.5% of ADRs were reported for amoxicillin, 35.8% for paracetamol, 9.2% for ibuprofen, and 5.5% for salbutamol. The most commonly reported ADRs for amoxicillin were diarrhoea (28.9%) and tiredness (31.6%). Using freehand reporting 15 (12.3%) completed questionnaires reported specific ADRs. Diarrhoea was reported by 10.5% of children prescribed amoxicillin, and 5.5% prescribed paracetamol. Only one off label prescription was identified and this was for salbutamol syrup prescribed to a 2 year old child. No off label prescribing due to age, formulation, or dose was noted.

This study demonstrates that a paediatric ADR monitoring system, with wide public access, could be operated via community pharmacies with parental monitoring and reporting of ADRs.