

ADRIC: Adverse Drug Reactions In Children – a programme of research using mixed methods

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Declared competing interests of authors: Rosalind L Smyth has been a member of the Commission on Human Medicines and Chairperson of the Paediatric Medicines Advisory Group of the Medicines and Healthcare products Regulatory Agency (MHRA) until December 2013. Munir Pirmohamed is currently Chairperson of the Pharmacovigilance Expert Advisory Group for the MHRA and is a Commissioner on Human Medicines.

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Plain English summary

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Plain English summary

Many common medicines have not been tested on children either properly or at all. We wanted to improve the safety of medicines used in children by investigating their side effects [adverse drug reactions (ADRs)].

We showed that three out of every 100 children admitted to hospital experienced an ADR due to a medicine taken at home. One out of five times this might have been avoidable. Nearly half of all ADRs were due to anticancer medicines.

We found that one in six children experienced an ADR while in hospital. More than half were due to medicines used in general anaesthesia and to treat pain after an operation. We used the results of these studies to develop tools to assess the likelihood of symptoms resulting from an ADR (causality) and whether an ADR was avoidable (avoidability).

We reviewed the literature on previous studies of ADRs in children and found that most studies had flaws in design and reporting, and lacked essential information, such as the name of the drugs causing ADRs and whether they were avoidable.

We interviewed children, parents and clinicians about ADRs. Many children and parents thought that communication about medicines could be improved, whereas parents of children with cancer were generally happy about the way clinicians communicated. Clinicians often made decisions about when and what to tell families but this did not always match what parents needed or expected. To address this, we developed information leaflets for parents and children to support communication between clinicians and families about ADRs.

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