Serious Paediatric Adverse Drug Reactions (ADRs)

(including reactions to complementary medicines)

Objectives:

1. To study the incidence and nature of serious paediatric ADRs in children below the age of 16 years.
2. To determine the level to which the NZPSU active surveillance method captures information about serious paediatric ADRs not currently captured by an existing passive spontaneous reporting system (CARM) operated by the New Zealand Pharmacovigilance Centre (NZPhvC).

Reporting Case Definition

Any child below the age of 16 years with a suspected adverse drug reaction (ADR) with a serious outcome – an ADR which results in patient hospitalisation, prolonged hospitalisation, congenital abnormality, persistent or significant disability, or death. (May also include emergency department visits, such as for an anaphylactic-type event). ADRs include suspected reactions associated with the use of prescription, non-prescription and complementary medicines (including herbal and alternative medicines).

Report even if you are not certain if the product caused the adverse reaction or you do not have all the reporting details.

Exclusions: Do not report reactions due to vaccines, blood products, medical devices, poisonings or self-administered overdoses.

Background

The CARM spontaneous reporting programme, established in 1965, continues to be a valuable national resource allowing early identification of new adverse reactions, rare reactions and assessments of local patterns of reactions. However, it is perceived that CARM may not capture the more serious ADRs occurring in children.

It is particularly important to report and detect potential drug safety issues in children. This prospective study, through use of the NZPSU active surveillance methodology directed to paediatricians in NZ, the number of reported serious ADRs is expected to increase. This will provide a greater understanding of the scope of the problem and opportunities to address medication safety issues for the betterment of child health. The feasibility of an ongoing active surveillance system will also be investigated.

Follow up of notified cases

A preformatted ADR reporting form will be forwarded to those clinicians who notify a case to the NZPSU. Once completed, this form may be sent either by Freepost or Fax, to the Principal Investigator.

Importantly, cases should still be reported direct to the NZPhvC using the CARM ADR reporting card.

Thank you for your assistance.
The results of this surveillance will be included in the NZPSU Annual Report.

Investigators

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