

New Zealand Paediatric Surveillance Unit

SERIOUS PAEDIATRIC ADVERSE DRUG REACTIONS (ADRs) PROTOCOL

Study 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).

CASE DEFINITION AND REPORTING INSTRUCTIONS

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.*

Please report any patients who you have seen in the last month and that you have not previously reported to NZPSU. Report through our monthly reporting surveys or via email to nzpsu@otago.ac.nz. Please also submit the case as a CARM report using the webform: <https://pophealth.my.site.com/carmreportnz/s/>

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 to NZPSU:

In addition to reporting to NZPSU, please also submit the case as a CARM report using the webform: <https://pophealth.my.site.com/carmreportnz/s/> Include as much information as you can but do not worry if you do not complete every field.

Investigators:

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If you have any questions, contact the pharmacovigilance team using the email

CARMreport@health.govt.nz.

THANK YOU FOR YOUR HELP AND SUPPORT

***THE RESULTS OF THIS SURVEILLANCE WILL BE INCLUDED IN THE ANNUAL REPORT
OF THE NZPSU WHICH WILL BE AVAILABLE ON THE NZPSU WEBSITE AND CAN BE
REQUESTED DIRECTLY FROM NZPSU***