



Update on the **Adverse Drug Reaction reporting tool**

Reporting suspected adverse drug reactions enables the collection of information on the safety and quality of medicines and vaccines after they have been approved. An electronic adverse reaction reporting tool was launched in New Zealand in 2009. The reporting tool was designed to make the process of reporting events easier by pre-populating patient details, allowing more data to be included and enabling more timely advice to be provided to prescribers. In the five years since its launch, electronic notifications using the ADR tool have doubled.

Adverse drug reactions reporting in New Zealand

Adverse drug reaction reporting is one of the most important sources of data for assessing the safety and quality of a medicine. Prior to marketing, all of the information on a medicine's safety and efficacy is based on clinical trial data. While vital, clinical trials rarely reflect the actual use of a medicine or the typical population for whom a medicine is prescribed.

Adverse drug reaction reporting forms the core of post-marketing surveillance, and the identification of unusual patterns of adverse effects has led to the withdrawal or restriction of many medicines since the World Health Organisation began the international drug monitoring programme in 1971.

Adverse reactions reporting in New Zealand is managed by Medsafe and the Centre for Adverse Reactions (CARM). CARM receives, on average, 4000 spontaneous adverse reaction reports each year. Approximately half of these adverse reaction reports are submitted from general practice.

When CARM receives a report, it is processed, coded and then assessed by relevant specialist clinicians. The person submitting a report will then receive a reply from CARM that includes information on the likely cause of the reaction and how frequently the reaction is reported.

Although New Zealand's adverse reactions reporting system is highly regarded internationally, it is thought that, at most, one-in-ten adverse reactions are reported. For example, analysis of the data stored in the Patient Management Systems of 30 general practices found that of the 725 entries in the medical warnings files that recorded an adverse reaction or allergy to at least one medicine, only 21 were reported to CARM.

There are a number of reasons why an adverse reaction might not be reported. These include the absence of a prompt to initiate reporting, failing to realise that an adverse reaction has occurred, assuming that a reaction is already well known and the time required to manually fill in reaction forms.

The launch of an electronic adverse reaction reporting tool

On 1 April, 2009, the Minister of Health launched a new electronic adverse drug reaction (eADR) reporting tool in New Zealand.

The tool was designed to make the reporting of adverse reactions to CARM easier. To do this, it uses an online reporting form pre-populated with patient details from the Practice Management software.

Simpler reporting should mean more reporting

The adverse reaction tool was developed to help decrease the time involved in reporting. Pre-populating the reporting form with patient data reduces manual entry of information. Electronic reporting means less paperwork and removes the need to post or fax reports to CARM.

The ability to extract data from Patient Management software makes it easier to include results from laboratory tests and other investigations. This has improved the ability of CARM's advisory clinicians to review the data and to determine whether the medicine is responsible for the reaction.

As well as making the process simpler, electronic reporting reduces the time it takes for advice to be provided. In addition, CARM now adds patient-specific alerts through the medical warning module of the NZHIS system. Alerts are attached to the patient's NHI number so, for example, when a patient is admitted to hospital, the patient does not receive a medicine they have already reacted to.

Electronic reporting is gaining traction

As of February, 2014, 594 general practices have transmitted information to CARM via the eADR tool which launched in 2009.

In 2009 there were 378 individual reports submitted through the eADR tool. In 2013 this had doubled to 616 reports. As a percentage of total reports to CARM, this represents an increase from 8% in 2009 to 15% in 2013.

While the total number of adverse reactions reported to CARM via any method has remained stable from 2009 to 2013, the percentage of reports received from general practice has increased from 46% in 2009 to 55% in 2013. This suggests that the eADR tool may be encouraging reporting from the general practice sector especially among nurses; 20% of reporters in 2009 were nurses compared to 33% in 2013.

How do I use the eADR?

To access the eADR, look for "Adverse Drug Reactions Reporting" on the modules list on your BPAC Dashboard.

Once opened the tool automatically pre-populates the patient's medical history, medicine use and gives the option of including laboratory test results.

As vaccines make up approximately one-third of the adverse reaction reports received every year, the tool has been designed with a specific vaccine tab. If the suspected medicine is a vaccine, the tool pre-populates the batch number, the date of administration and how the vaccine was given.

Once a description of the reaction and other pertinent information is entered, a report can be electronically sent to CARM. The details of the patient and reporter are encrypted in the electronic reporting tool, and as with the paper-based form, the information provided in the report is only viewed and used by CARM.

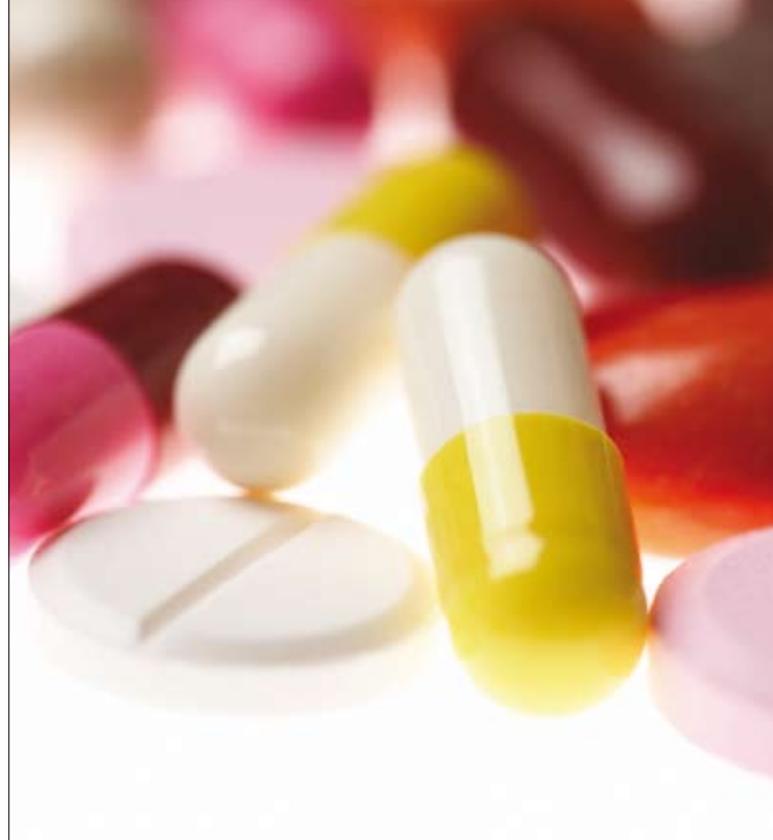


In general, it appears that the reports generated by the eADR tool reflect a standard set of subsidised medicines being prescribed, e.g. smoking cessation medicines, antibiotics, antihypertensives, antidepressants and NSAIDs were all among the most commonly reported medicines. The reports generated through the electronic form are similar to the overall make-up of the reports, e.g. vaccines make up 39% of e-reports compared to 35% of reports overall.

Health professionals are encouraged to make use of the eADR tool and ensure that all potential adverse drug reactions are reported to CARM.

 **A request from CARM:** ensure that the dates of prescriptions for each of the medicines are included in the report to enable clear identification of the concomitant medicines at the time of the adverse reaction occurring.

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Adverse Drug Reaction

Adverse Drug Reaction Reporting Tool

GPs in all regions of New Zealand have access to an online tool to report Adverse Drug Reactions directly to the Centre for Adverse Reactions Monitoring (CARM).

The reporting form pre-populates with patient demographic and relevant clinical data from the GP practice software. This facilitates completion of a detailed report while encrypted electronic submission ensures confidentiality of information. Every report submitted receives a personal reply from CARM.

Look for 'Adverse Drug Reaction Reporting' on the Module list of your BPAC Dashboard.



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