Adverse reaction reporting tool

Contributed by Medsafe Clinical Risk Management Team

Key concepts

- An electronic adverse reaction reporting tool has been launched in New Zealand
- Reporting suspected adverse reactions enables the detection of medicine safety signals
- The reporting tool pre-populates patient details making reporting adverse reactions easier and allowing more data to be included
- The reporting tool will help with the identification of medicine safety issues and enable more timely advice to be provided to prescribers

Launch of an electronic adverse reaction reporting tool

Adverse reaction reporting is regarded as one of the most important sources of data for assessing the safety of a medicine. Adverse reaction reports enable the detection of medicine safety signals and medicine quality defects.

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

The tool is designed to facilitate the reporting of adverse reactions to the Centre for Adverse Reactions Monitoring (CARM), and it uses an online reporting form pre-populated with patient details from the GP practice software.

The reporting form can be easily accessed by clicking on an icon within the Patient Management Software (a link to the instructions for creating an icon for the reporting form on the MedTech32 pallet can be found in the *bestpractice* Decision Support news items on the menu page). Once opened the tool automatically pre-populates the patient's medical history, medicine history and gives the reporter the option of including laboratory test results.

As vaccines make up approximately 50% 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, one click of the mouse sends a confidential encrypted report electronically to CARM.

ADR reporting in New Zealand

CARM receives on average 4000 spontaneous adverse reaction reports a year. General Practice accounts for approximately 60% of these adverse reaction reports.

When CARM receives a report, it is processed, coded then assessed by expert clinicians. Every report receives a personal reply from CARM. including advice on the likely cause of the reaction, information specific to that reaction and how frequently the reaction is reported.

The World Health Organisation rates New Zealand as having the highest number of adverse reaction reports submitted per capita compared to other countries in their programme. In addition, reports from New Zealand are also regarded as being of the highest quality. This is because New Zealand has one of the best reporting systems in the world. It is also apparent that New Zealand's healthcare professionals, who are interested in the safety of medicines, are motivated to report and understand that adverse reaction reporting is part of their professional responsibility.

Although our adverse reaction reporting is rated highly, research indicates that at best only one in ten adverse reactions are being reported in New Zealand i.e. the rate of under-reporting is in excess of 90%. Moreover, recent research conducted in New Zealand examined the data stored in the Patient Management Systems of 30 General Practices. 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.

As many GPs will know there are a number of barriers to reporting adverse reactions. These barriers include the absence of a prompt to initiate reporting, realising that an adverse reaction has occurred, considering that the reaction is already well known and finally, the time required to manually fill in reaction forms.

What are the benefits of using this tool?

First and foremost, the adverse reaction tool has been developed to help decrease the time involved in reporting. Pre-populating the reporting form with patient data means manual entry of information is minimal. Electronic reporting means less paperwork for busy GPs and removes the need to post or fax reports to CARM.

The ability to extract data from Patient Management software makes it easier for reporters to include results from laboratory tests and other investigations. It is hoped that this will improve the ability of CARM's experts to review the data and to determine whether the medicine is causing the reaction.

Improving the analysis of adverse reaction reports is expected to provide direct benefits for all healthcare professionals. As well as improving the identification of medicine safety issues, it will enable more timely advice to be provided. In the future CARM will provide feedback to reporters electronically. This information can then be entered directly into the patient's records.

CARM is also able to add patient specific alerts through the medical warning module of the NZHIS system. Alerts are attached to the patient's unique NHI number so,

for example, when a patient is admitted to hospital the presence of the alert reduces the risk of that patient receiving medication they have already reacted to.

Reporters can be assured that the confidentiality of patient and reporter details is maintained in the electronic reporting tool. As with the paper-based form, the information provided in the report is only viewed and used by CARM.

This new reporting tool is one of the first in the world that allows direct electronic reporting of adverse reactions from GP practices. Regular use of the system will strengthen the close relationship that exists between prescribers and the medicines safety community, and cement New Zealand's position as a world leader in monitoring and managing medicines safety issues.