Canterbury District Health Board
Te Poari Hauora ō Waitaha

Clinical Pharmacology Bulletin

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Reporting Adverse Drug Reactions (ADR) – why is it important?

Pharmacovigilance is the process of identifying, reporting and responding to medicine safety issues such as ADRs. The goal of this process is the safer use of medicines. This bulletin aims to describe pharmacovigilance.

What is an ADR?

The World Health Organisation defines an ADR as:

"Any response to a drug that is noxious and unintended, and that occurs at doses normally used in man."

While some evidence of safety is available on new drugs from pre-marketing clinical trials, the numbers of patients studied and time of these trials (approximately three months) are insufficient to define ADRs accurately. ADRs may not be detected in pre-marketing clinical trials because; the reaction is rare, the reaction is from prolonged therapy, the drug is used in a specific population, or the drug is used for a specific indication. Post-marketing surveillance helps detect ADRs. See below for some examples.

Drug withdrawals due to pharmacovigilance

1971 *diethylstilboestrol*
vaginal carcinoma in daughters of women who took this in pregnancy

1985 *growth hormone (natural)*
transmission of Creutzfeldt-Jakob disease

2000 *cisapride*
fatal ventricular arrhythmias

Drug cautions due to pharmacovigilance

1970 *oestrogen contraceptives (high-dose)*
associated with thromboembolic disease

1980s *clozapine*
withdrawn due to agranulocytosis, but reintroduced in the late 80s with a blood monitoring system to ensure safety

1990s *losartan*
identification of new ADRs, which included vasculitis, allergic purpura, anaphylactic shock and anaphylactoid reactions

Pharmacovigilance in New Zealand

Medicine safety issues are managed by the Centre for Adverse Reactions Monitoring (CARM) in Dunedin. CARM collects and evaluates spontaneous reports of adverse reactions to medicines, vaccines, herbals and dietary supplements from health professionals. This information is entered into a national database.

CARM also co-ordinates the Intensive Medicines Monitoring Programme (IMMP) that uses a method called prescription event monitoring to note any effects related to the use of specific new drugs, regardless of likely causality. Funding for CARM and IMMP has been under threat despite international acclaim for their work.

The role of health professionals

Pharmacovigilance only happens if health professionals detect and report possible ADRs. Nurses, pharmacists and doctors are all responsible for ADR documentation.
Pharmacovigilance can:

- minimise harm and improve patient safety
- prevent situations where therapy for an individual is withheld unnecessarily
- contribute to global drug safety

What to do if you suspect an ADR?

- Document the suspected ADR clearly in the medical record and on the drug chart.
- Complete an ADR triplicate report form (QMR0128), which is available on all wards (ask the ward clerk or pharmacist) and record that one has been completed in the patient's medical record.
- Leave the form for the clinical pharmacist to collect or send it to the Pharmacy if your ward has no clinical pharmacist cover.
- Alternatively, the form can be completed on the intranet, which will be sent directly to the ADR pharmacist (via the Clinical Pharmacology Intranet site).

What happens next?

- The ADR pharmacist (Caroline Innes) will ensure the forms are forwarded to Clinical Records (to be filed in the front of the medical record) and CARM.
- CARM assesses the probability of causality from the information provided on the ADR form and will enter an appropriate alert on the Patient Management System (PMS). The alert will be seen if the patient is re-admitted. However, if the reaction is severe the ADR pharmacist will add the alert to the PMS when they receive the ADR form. This ensures the PMS update is timely when patients are considered to be at serious risk if re-administered a particular drug.

Medication safety pharmacist

The medication safety pharmacist position has been created to promote patient safety throughout the CDHB. Mary Young (maryy1@cdhb.govt.nz) has taken up this role, and in addition to other tasks, will be involved with:

- promotion of ADR reporting
- provision of education and training regarding ADRs and other medication safety issues.

You don't need to be certain of an ADR.
If you are suspicious, report it!