GUIDE TO ADVERSE REACTION REPORTING
Your adverse reaction reports contribute to the world data pool

The goal of adverse reaction reporting is to improve the safety of medicine use. The Centre for Adverse Reactions Monitoring (CARM) in Dunedin is contracted by Medsafe to collect voluntary reports of adverse reactions to medicines, vaccines, herbal products, dietary supplements and blood products. The CARM database holds over 48,000 reports from around New Zealand, providing a local pattern of adverse reactions to medicines. These reports also contribute to international knowledge of pharmacovigilance. They are anonymised and pooled with other countries’ reports in the World Health Organisation’s International Monitoring Centre database in Uppsala, Sweden. Participating monitoring centres can use this database to complement their own reports.

Reports can help identify NZ patterns and potential safety issues

A medical assessor evaluates each report received by CARM to determine whether there is an association between the adverse reaction and a medicine, and the strength of any association. CARM monitors its database for patterns, clusters and unusual events that could have significance for medicine safety and prescribing practices in New Zealand. The database is also used to support enquiries from health professionals regarding the possibility of adverse reactions as the cause of a diagnostic dilemma.

Ultimately patients benefit from improved safety

When a serious adverse reaction is reported, CARM enters a danger (where re-administration of the medicine is likely to be life threatening) or warning (where re-administration of the medicine is likely to cause a clinically significant reaction) against the patient’s name in the National Health Index (NHI) database. Most hospitals access this database when patients seek health care.

The Medicines Adverse Reactions Committee (MARC) meets four times a year to review published material, all fatal reports and selected reports of significant, unusual or serious reactions reported to CARM. The MARC may recommend that Medsafe alert prescribers to an adverse reaction through an article in Prescriber Update or a ‘Dear Doctor’ letter. The MARC may also recommend that the pharmaceutical company update the data sheet with advice to improve the safe use of a medicine.

Anyone can report adverse reactions to CARM

Reports from health professionals are preferred, in particular from doctors and other prescribers, pharmacists and nurses. Interestingly, 65% of the reports CARM receives are from community doctors (mostly general practitioners) while hospital doctors contribute 17% of the reports. Pharmacists (community and hospital) submit 2.3% of the reports lodged with CARM. Pharmaceutical companies are another source of reports but unlike other countries where the majority of reports originate from industry, in New Zealand they contribute only a small proportion of the total reports CARM receives.

CARM accepts reports from consumers but where possible an attempt is made to involve the patient’s practitioner who often may be unaware of the reaction.

CARM sends replies to reporters of adverse reactions. These written responses may include information about causality, similar reactions and prescribing advice to assist with risk:benefit assessment of future

If in doubt, report!

Please do not hesitate to report any suspected reaction of clinical concern, even if you are unable to supply all the details outlined above. A copy of the patient’s discharge letter from the hospital or specialist is always helpful. It is particularly important to report reactions that are serious, unexpected or of clinical concern, or involve new medicines or interactions.
New yellow reporting form, same information needed

In June 2001, the CARM adverse reaction reporting form changed back to a pale yellow colour to make it easier to find. Forms are included in Prescriber Update and New Ethicals Catalogue. Please also note that forms can be downloaded from the CARM web site (www.otago.ac.nz/carm/reporting.html) or obtained by phoning CARM on (03) 479 7185 or e-mailing to carmnz@stonebow.otago.ac.nz.

Reporting is as easy as 1, 2, 3

Please follow these steps for recording details of adverse events on the reporting form, and then forward it to CARM by post (Freepost 112002, CARM, PO Box 913, Dunedin) or fax (03) 479 7150.

1. Step 1: The patient
   Patient details (name, address, date of birth, sex and ethnicity) are needed in case a danger or warning needs to be entered in the NHI database, as explained above. The patient details are held at CARM and remain totally confidential. They also help to identify duplicates if a report has already been received from another source. Please provide the NHI number, if known.

2. Step 2: The medicine(s) including OTC and alternative health products
   The name of the medicine (and brand name if available) suspected of causing the reaction and dose is necessary. Ideally list all medicines including OTC and herbal or alternative remedies, and asterisk the suspected medicine if known. Also provide dates of starting and stopping the medicines as this information is particularly helpful when assessing causality.

3. Step 3: The event
   It is important to provide the date of onset of the adverse reaction as this is crucial for causality assessment. The more details, the better; list symptoms, signs, laboratory results, past medical history. Also describe what happened later: did the person fully recover after withdrawal of the medicine (dechallenge), did they have a similar reaction if the medicine was used again (rechallenge), and was the event severe or fatal? Give any alternative diagnoses that have been excluded. More evidence will provide the CARM medical assessor with more certainty when deciding whether the medicine caused the adverse reaction.

Correspondence to:
Medical Assessor
Centre for Adverse Reactions Monitoring (CARM)
PO Box 913
Dunedin

Phone: (03) 479 7247
Fax: (03) 479-7150
e-mail: carmnz@stonebow.otago.ac.nz