

RGH Pharmacy E-Bulletin

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A joint initiative of the Patient Services Section and the Drug and Therapeutics Information Service of the Pharmacy Department, Repatriation General Hospital, Daw Park, South Australia. The RGH Pharmacy E-Bulletin is distributed in electronic format on a weekly basis, and aims to present concise, factual information on issues of current interest in therapeutics, drug safety and cost-effective use of medications.

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Medical records and adverse drug reactions

Adverse drug reactions (ADRs) are an important cause of morbidity and mortality amongst hospital patients. Even relatively mild reactions may lead to significant patient distress, changes in therapy, symptomatic treatment, further investigations, and prolongation of hospital stay. Once a reaction is suspected, timely documentation of the ADR in the patient's medical record in a way which ensures easy future reference can help to prevent similar reactions occurring in the future. At the Repatriation General Hospital the alert sheet has been used for this purpose, but for a number of reasons drug alerts have been inconsistently documented in the past. These include lack of awareness of the alert sheet system, uncertainty about what type of reactions to document and the use of a less than ideal ADR classification system.

Proposed changes to the alert sheet system will address some of these issues. During admission alert sheets will be placed at the front of the patient's bedside folder. At admission clinical pharmacists will record details of past adverse drug reactions and hypersensitivities on the alert sheet if this has not already been done. Each reaction will be classified according to the following criteria, which have been adapted from those used by the World Health Organisation's pharmacovigilance program:

Causality assessment	Criteria
Definite (D)	<ul style="list-style-type: none">• Plausible time relationship to drug intake• Cannot be explained by disease or other drugs• Response to withdrawal clinically plausible• Confirmed by rechallenge or further investigations
Probable (P)	<ul style="list-style-type: none">• Plausible time relationship to drug intake• Unlikely to be attributed to disease or other drugs• Response to withdrawal clinically plausible• Rechallenge not required
Suspected (S)	<ul style="list-style-type: none">• Plausible time relationship to drug intake• Could also be explained by disease or other drugs• Information on withdrawal may be lacking or unclear
Unclassified (U)	<ul style="list-style-type: none">• Report suggesting an adverse reaction• Cannot be evaluated because information is lacking or contradictory• Information cannot be supplemented or verified

It is expected that most past and self-reported reactions, which may include serious reactions such as anaphylaxis, will be "Unclassified" due to lack of information. For example, many patients report penicillin allergy but are uncertain about the nature and time of the reaction. For this reason drugs in the unclassified category should generally be regarded as contraindicated.

Significant ADRs which are observed during admission or at an outpatient visit should be recorded on the alert sheet by medical staff or pharmacists as they occur. The first three categories reflect an assessment of the likelihood that a certain drug has caused a particular reaction. They do not assess reaction severity. Some judgement is required about which ADRs to document. In general ADRs should be documented if the reaction leads to cessation of drug therapy. Most clinicians would probably choose not to record common, anticipated reactions which do not usually require drug withdrawal e.g. constipation with opioids. As a final step any new drug alerts documented during admission or at an outpatient visit should be communicated in writing to both the patient and their GP.

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FOR FURTHER INFORMATION – CONTACT THE PHARMACY DEPARTMENT ON 82751763 or email: chris.alderman@rgh.sa.gov.au
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