Government of **Western Australia**
Department of **Health**

Policy Frameworks
Related Document
MP 0053/17
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Patient Alert Procedure for Adverse Drug Reactions

This procedure supports the application of MP 0053/17 *Patient Alert Policy*.

Clinicians that prescribe medication are responsible for determining if an existing or newly identified Adverse Drug Reaction (ADR) is a serious life-threatening reaction as this information will impact future prescribing decisions.

1. Interview and review

During every episode of care with the patient (i.e., admission to hospital or outpatient clinic presentation) the patient and/or carer must be interviewed, and records checked to determine if the patient has experienced any previous ADRs or allergic responses when taking medications in the past. Examples of records include the:

- Patient medical record
- Patient's My Health Record
- Patient Administration System (e.g., webPAS)
- Previous discharge summary(ies).

Clinicians must also review existing patient alert documentation before prescribing, dispensing or administering new medications to a patient.

Patients with a known allergy or suspected clinically important ADR or other known reaction risk must be issued a RED patient identification band during their hospital admission. No other coloured patient identification band is to be used.

2. Identification of a new ADR

In the case of new ADRs involving allergic reactions or clinically important side effects, the following actions are required:

- Complete the patient alert notification form (e.g., MR ALERT 2 Form) or electronic equivalent to initiate a patient alert.
- Document ADR information in existing data capture systems, as specified in section 3 PAS inclusion criteria for ADRs.
- If a new ADR is identified during admission, the standard WHITE patient identification band must be replaced with a RED patient identification band.
- Provide patient/carer with the Adverse Drug Reaction Information Brochure for Consumers.

- Information detailing a new ADR must be communicated to the general practitioner, the receiving hospital, if transferring care, and in the discharge summary.
- Report the ADR to the Therapeutic Good Administration if appropriate, as specified in section 4 Information to be reported.

3. PAS inclusion criteria for ADRs

Only serious life-threatening reactions and potential patient risks are to be documented on the PAS. The treating clinician or pharmacist is responsible for determining whether a reaction requires a medication-related patient alert to be documented on the PAS.

A serious adverse drug reaction is defined as an absolute or relative contraindication to repeat administration of a medication. Medications of concern are those likely to be given without verbal consultation with the patient (i.e., when the patient is too unwell). Examples include antibiotics, anaesthetics, and analgesics.

The table below outlines the types of drug reactions for which a patient alert is required and not required.

Life-threatening reactions deemed patient alerts ☑	**Adverse reactions NOT deemed patient alerts** ☒
Medication and non-medication allergies for example, penicillin, latex, intravenous contrasts, chlorhexidine: • Rash: serious/severe or accompanied by swelling of the whole body (i.e., not localised). • Anaphylaxis or anaphylactoid reactions. • Serum sickness. • Angioedema: swelling of face, throat, neck, tongue. • Bronchospasm, asthma, other breathing difficulties. **Other non-allergic, serious or life-threatening reactions** For example: • Agranulocytosis from clozapine. • Extrapyramidal side effects (severe dystonia / laryngospasm) to antipsychotics. • Stevens Johnson Syndrome. • Toxic epidermal necrolysis. • Anaesthetic reactions including malignant hyperthermia[1] (Refer also to anaesthetic alerts). • Scoline apnoea or cholinesterase problem. • Neuroleptic Malignant Syndrome. • Hepatitis or nephritis. • Other: must be deemed serious and life-threatening and/or cause significant harm.	**Non-dose related reactions** Unpredictable and uncommon side-effects not related to pharmacological action, with a low mortality rate. For example: • Timolol causing depression. • Lithium induced neutrophilia. **Time-related reactions** Uncommon reactions which are usually dose-related and occur after administration of the medication. For example: • Tardive dyskinesia secondary to antipsychotic medications. **Dose related reactions** Predictable side-effects related to pharmacological action of medications. For example: • Moderate extrapyramidal side-effects to antipsychotics. • Excessive nausea and vomiting from opioids. • Vancomycin causing red man syndrome.

[1] Refer to the Australia and New Zealand Anaesthetic Allergy Group (ANZAAG) for resources including patient letters, standardised referral forms and details of all state and territory testing centres.

Mild to moderate side-effects or unknown reactions must not be recorded as a patient alert but documented in the patient's medical record. Examples include:

- Mild diarrhoea, nausea and vomiting, itch, hay fever / blocked nose, local swelling, or pain.
- Non-serious adverse reactions to non-medication allergens (e.g., bee stings, grasses).

Medication-related patient alerts may also be raised as a result of significant monitoring requirements and risks with either sudden cessation of therapy (e.g., withdrawal-associated psychosis with clozapine) or accumulation of therapy (e.g. lung injury with bleomycin).

4. Information to be documented

For each ADR identified, the clinician must document the following information in the relevant data capture systems:

Information	Data Capture Systems
• The generic name of the suspected medication • The reaction which occurred • Date of the reaction (if known) • The person documenting the ADR must sign and date each record	• Patient medical record • Patient Administration System (e.g., webPAS) • All WA Hospital Medication Charts (WA HMCs) • Other relevant medication charts • Patient medication history and management plan (WA MHMP) • Patient discharge summary • Electronic allergy platform (if access available)

To indicate a known ADR, the clinician must:

- Place an "ALERT" sticker next to the text on the front cover of the medical record (or on the front page of the digital medical record, if applicable.
- affix an ADVERSE DRUG REACTION" sticker on the red "Attach ADR Sticker" box and on the back page of the WA Hospital Medication Chart (WA HMC).

- ADR details must be transferred to all new medication charts that are commenced.

5. Reporting

Reports of suspected ADRs can be made:

- Online at 'Report a Problem' (Home - Adverse event reporting (tga.gov.au))
- Using a 'Blue Card' available from the TGA's Office of Product Review (call 1800 044 114, complete the Blue card adverse reaction reporting form | Therapeutic Goods Administration (TGA)) or download the 'Blue Card' adverse reaction reporting form from the TGA website.

In event of an ADR where the agent is not clearly identified, clarification from Immunology (where available) and documentation of all medications the patient is prescribed must be reported to the TGA - Advisory Committee of the Safety of Medicines (ACSOM).

6. Rechallenge of medication

If a medication has been prescribed and there is documentation identifying a previous ADR has occurred (e.g., WA HMC, medical record, triage records), the clinician intending to administer the medication (e.g., nurse/midwife/anaesthetic technician) must check with the prescriber that the medication is safe to administer.

If a previous ADR has been identified and documented appropriately, and there is a clinical need to rechallenge the patient due to no other therapeutic option being available and/or lack of clarification of the reaction, the ADR must be acknowledged by the prescriber and reasons for the rechallenge must be documented in the medical record.

Where it is confirmed that an ADR is no longer relevant or serious e.g., previous nausea or diarrhoea, the prescriber undertaking the rechallenge or review, must update all relevant records with this new information.

If the reaction is a serious ADR (e.g., anaphylaxis, angioedema, bronchospasm, rash etc.) the team consultant must review the order and document in the medical record if the drug is required to be administered.

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