Policy

Policy Guideline
Preventing Adverse Drug Events Policy Guideline

Policy developed by: Public Health and Clinical Systems
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Summary
The purpose of the Preventing Adverse Drug Events Guideline is to provide guidance across the public health sector to ensure a uniform approach to documenting, monitoring and communicating adverse drug reactions and allergies. The Policy Guideline outlines the responsibilities and procedures for health professionals to report both known and new adverse drug reactions and allergies.

Keywords
Adverse drug reaction, ADR, allergy, allergies, adverse drug event, ADE, reporting ADR, known ADR, new ADR, preventing adverse drug event, Preventing Adverse Drug Events Policy Guideline

Policy history
Is this a new policy? N
Does this policy amend or update an existing policy? Y
Does this policy replace an existing policy? N

Applies to
All Health Networks
CALHN, SALHN, NALHN, CHSALHN, WCHN, SAAS
SA Pharmacy

Staff impact
All Staff, Management, Admin, Students, Volunteers

PDS reference
G0129

Version control and change history

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Preventing Adverse Drug Events

Documenting, monitoring and communicating adverse drug reactions and allergies

Guideline
The Preventing Adverse Drug Events – documenting, monitoring and communicating adverse drug reactions and allergies policy is based on the Australian Pharmaceutical Advisory Council Guiding principles to achieve continuity in medication management, and the Society of Hospital Pharmacists of Australia standards of practice for clinical pharmacy.

1. Background

Medicines are a key component of disease management and prevention. Their use is not without risk, however, and medication-related errors are among the most frequent medical errors and the most common threat to patient safety.

In Australia, estimates suggest that each year:

- in excess of 190,000 hospital admissions are associated with medication-related problems
- medication related incidents account for 10-20% of the incidents that occur in hospitals, and up to 50% of these incidents are preventable
- medication errors in the hospital system cost $660 million per annum
- medication incidents remain the second most common type of incident reported in hospitals.

Australian studies have demonstrated that failure to document previously known adverse drug reactions (ADRs) occurs in up to three quarters of cases.

More recent local data shows that ADR documentation in SA hospitals has improved following implementation of the National Inpatient Medication Chart (NIMC) and increased clinical pharmacy services (in some areas). However, incidents continue to be reported, highlighting the need to ensure ADR documentation is complete and referred to at the point of care.

Incomplete or absent documentation of a known prior ADR on medication charts and in the medical record predisposes patients to potentially fatal outcomes. Preventing these types of errors is dependent on the correct information being available and referred to at the time of prescribing, dispensing and administration.

Documentation and use of ADR information is addressed under the National Safety and Quality Health Service Standard 4.7:

- The clinical workforce documenting the patient’s previously known adverse drug reactions on initial presentation and updating this if an adverse reaction to a medicine occurs during the episode of care.
- 4.7.1 Known medication allergies and adverse drug reactions are documented in the patient clinical record
- 4.7.2 Action is taken to reduce the risk of adverse drug reactions
- 4.7.3 Adverse drug reactions are reported within the organisation and to the Therapeutic Goods Administration.

Compliance with the SA Health ‘Preventing Adverse Drug Events – documenting, monitoring and communicating adverse drug reactions and allergies Directive’ should ensure hospitals meet this standard.
2. Core principles

The following core principles are acknowledged:

- Many ADRs are avoidable when documentation is complete, available and referred to at the point of care
- Documentation and communication of ADRs needs to be considered at each step of the medication management cycle; for example, prior to prescribing, dispensing and administering medicines
- Systems should support the documentation and communication of ADR information at all stages of the medication management cycle, including transfer of information to new episodes of care and between care settings.

![Medication Management Cycle Diagram]

**Steps in the medication management cycle:**

a. decision to prescribe medicine
b. record of medicine order/prescription
c. review of medicine order/prescription
d. issue of medicine
e. provision of medicine information
f. distribution and storage
g. administration of medicine
h. monitor for response
i. transfer of verified information

**Figure 1: Medication Management Cycle**

3. Procedure

Health services should have systems in place to ensure documentation, monitoring and communication of ADR details as well as referring to the information prior to prescribing, dispensing and administering a medicine.

3.1. Documentation of known (previous) ADR/allergies

- Documentation of the type and nature of any known ADRs or allergies or, where relevant, the absence of any ADR history should occur at the time of documenting the medication history. The ADR should be verified by a second source where possible; for example the patient’s general practitioner, carer or past medical notes.
- **Documentation should include, as a minimum:**
  - generic name of the medication and brand name where relevant; for example with combination products. Medicines include all complementary and alternative medicines and those available over-the-counter without a doctor’s prescription.
  - type of reaction
> date of reaction or approximate timeframe (eg 2 years ago)
> signature of person documenting (or initials if on NIMC)
> date of documentation.

Ideally the following would also be documented:
> how the reaction was managed
> how long after exposure to the medicine the reaction developed
> source of the information and whether it was confirmed by a health professional
> class effect ADR (see below).

3.1.1. **Class Effect ADR**

> Adverse drug reactions may occur with most or all of the drugs in a class; for example, cough from angiotensin converting enzyme inhibitors.
> Consider the type of reaction and seek advice prior to prescribing another medicine from the same or different class from:
  > medicines information centre
  > clinical pharmacist or pharmacologist.

3.1.2. **No known ADR**

> Where there is no known ADR or allergy, this must be documented on the medication chart, and the medication history form and medication management plan, where available. For example – ‘Nil known’ or ‘No known allergy’.

3.1.3. **Unknown ADR or allergy history**

> Where it is not known if the patient has any previous ADRs, ‘Unknown’ should be documented.

3.1.4. **Where to document ADRs and allergies**

> Details of ADR/allergies should be documented in patient medical records and related documentation specifically on all medication charts, the hospital alert sheet, the medication history form and medication management plan (where in use), and any other relevant forms in use. This includes electronic patient records.
> ADR details must be included on any new medication chart commenced during the episode of care.
> Where an ADR/allergy has been documented, an “ADR sticker” should be placed on both sides of all medication charts and an alert sticker applied to the front cover of the patient’s medical record.
> ADR/allergy details must be transferred to any subsequent volumes of the patient’s medical record.
  > hospital alert forms should be copied and placed in the front of the new volume
  > an alert sticker should be placed on the front cover of the new volume
> Electronic systems such as EPAS, HASS ED and the pharmacy management system (iPharmacy) support documentation of
patient ADR/allergies and this functionality should be used to enhance decision support and transfer of information.

3.1.5. **Responsibility for documenting and referring to ADR/allergy information**

- All clinicians involved in patient care are responsible for ensuring ADR/allergy documentation is completed. For example:
  - In most cases, medical officers are responsible for documenting a medical history and writing up medication orders. In this setting they are responsible for documenting ADR/allergy information.
  - Pharmacists document medication histories on medication management forms and reconcile this information against the medication charts. This also involves documenting and checking ADR/allergy information.
  - Nurses may become aware of ADR/allergy information which is not documented. In this case the nurse should document the information and inform the treating medical officer and pharmacist.
  - If any information is determined after the initial interviews, the person adding the information must document their initials in the designated area.
  - All clinicians are responsible for referring to ADR information prior to prescribing, dispensing and administering a medicine.

3.1.6. **Clinical handover and transfer of information**

- ADR/allergy details must be transferred to any subsequent volumes of the patient’s medical record (as outlined previously in section 3.1.4).
- ADR details should be communicated to the patient and/or carer and all relevant health professionals at transitions of care. This includes on separation summaries and letters to community-based health professionals (for example, general practitioners and community pharmacists).
- ADR/allergy details available in EPAS are to be included in correspondence to all relevant health professionals at transitions of care, both within and outside SA Health services. This includes discharge summaries and letters to general practitioners and medical specialists following day treatments or outpatient appointments.
- Information about ADRs should be incorporated into clinical handover and time out prior to a procedure e.g. prior to administering a medicine.
3.1.7. Examples of documentation

3.2. Documenting and reporting new ADRs/allergies

> Document the details of the reaction as for previously known reactions (section 3.1) as well as any other information relevant to the ADR/allergy in the progress notes section of the medical record, include:

> reaction progress
> efficacy of treatment
> rechallenge
> desensitisation etc.

> The treating clinician is responsible for determining whether an ADR is clinically important.

> The nature and response of the ADR should be accurately communicated to the patient and/or carer and other health care professionals, including the patient’s general practitioner and community pharmacist, at discharge.

> In addition:

3.2.1. Local reporting of new ADRs

Health services should have systems in place for reporting and review of new adverse drug reactions. This should include reporting to the Therapeutic Goods Administration.
3.2.2. **Reporting to the Therapeutic Goods Administration (TGA)**

- Information about reporting new ADRs can be found on the Therapeutics Goods Administration (TGA) website.
- Reports of adverse reactions should be submitted using the [Blue Card](adr.reports@tga.gov.au) available from the TGA website, or [online](adr.reports@tga.gov.au).
- Reports using this form can be emailed (adr.reports@tga.gov.au), posted or faxed to the Office of Product Review. Please see the back of the Blue Card for details.

3.2.3. **Reporting ADR incidents**

Incidents related to ADRs should be reported to the Safety Learning System in accordance with the SA Health Incident Management Policy.

3.3. **Access to information on ADRs and allergies**

Health services should have systems in place to ensure information about ADRs is available to clinicians when:

- prescribing a medicine
- dispensing medicine
- administering medicine
- writing a new medication chart
- transferring or discharging patients

3.4. **Communicating ADRs and allergies**

- ADR details should be communicated to the patient and/or carer and all relevant health professionals at transitions of care; for example, included in separation summaries and discharge letters to community-based health professionals such as general practitioners, specialists and community pharmacists.
- ADR/allergy details stored in EPAS should be transferred in correspondence to all relevant health professionals at transitions of care. This includes discharge summaries and letters generated following day treatments and outpatient appointments.

4. **Relevant resources**

- Continuity in Medication Management – a Handbook for South Australian Hospitals
- Guiding Principles to achieve continuity in medication management
- NIMC User Guide
- SA Health Incident Management Policy (ref no. D0162)
- SHPA standards of practice for clinical pharmacy
References


Patient presents to health service
Document medication history and ADR/allergy details

Has the patient had an adverse drug reaction or allergy?

YES
Document the details of the reaction in the patient administration system (eg EPAS), on the NIMC, other medication charts in use, medication history form, medication management plan and pharmacy management system, where available.
> Generic/brand name of medication responsible
> Type of reaction
> Date of reaction (or timeframe)
> Signature or initials of person documenting
> Date of documentation

Verify the reaction with a second source, where possible

Ensure there is an alert sticker on the front cover of the medical record

Ensure an alert sheet has been completed and placed in the medical record.
> Generic/brand name of medication responsible
> Type of reaction
> Date of reaction (or timeframe)
> How the reaction was managed
> How long after exposure to the medication did the reaction occur?
> Was the reaction confirmed by another health professional?
> Signature of person documenting
> Date of documentation

NO
Indicate Nil Known on NIMC and/or other relevant charts/forms
Sign and date

UNKNOWN
Indicate Unknown on NIMC and/or other relevant charts/forms
Sign and date
Documenting a new adverse drug reaction (ADR) or allergy

Patient experiences a suspected adverse drug reaction or allergy

Is the ADR/allergy clinically important? (Determined by treating clinician)

Document the details of the reaction in the patient administration system (eg EPAS), on the NIMC, on other medication charts in use, on an alert sheet in the medical record, in the progress notes of the medical record, on the medication history form, medication management plan and the pharmacy management system, where available.

- Generic/brand name of medication responsible
- Type of reaction
- Date of reaction (or timeframe)
- How the reaction was managed
- How long after exposure to the medication did the reaction occur?
- Signature or initials of person documenting
- Date of documentation

Communicate details of the ADR/allergy to:
- Patient and/or carer
- Other health professionals at transitions of care
- Patient’s general practitioner and community pharmacist

Report the ADR to the Therapeutic Goods Administration

Report the ADR incident to the Safety Learning System