

Preventing Adverse Drug Events Policy Guideline

Version No.: 2.0
Approval date: 29/10/18

INFORMAL COPY WHEN PRINTED



Contents

1.	Policy Statement	3
2.	Roles and Responsibilities	3
3.	Policy Requirements	4
4.	Implementation and Monitoring	10
5.	National Safety and Quality Health Service Standards	10
6.	Definitions	11
7.	Associated Policy Directives / Policy Guidelines & Resources	11
8.	References.....	12
9.	Document Ownership & History	12

INFORMAL COPY WHEN PRINTED

Preventing Adverse Drug Events Policy Guideline

1. Policy Statement

SA Health acknowledges and recognises that:

- > safe use of medicines is an essential component of patient safety
- > accurate documentation, monitoring and communication of known and new adverse drug reactions (ADRs) and allergies is required in order to reduce potential for patient harm from the use of medicines
- > patients may experience unpredictable adverse responses to prescribed medicines.

This policy:

- > is aimed at minimising patient harm by improvement in documenting, monitoring, and reporting of ADRs
- > is aimed at preventing adverse drug events by improvement in checking ADR information prior to prescribing, dispensing and administering a medicine
- > aligns with the National Safety and Quality Health Service Standards, second edition, endorsed by Australian Health Ministers.

Standard Four:

- '4.7 The health service organisation has processes for documenting a patient's history of medicine allergies and adverse drug reactions in the healthcare record on presentation
- 4.8 The health service organisation has processes for documenting adverse drug reactions experienced by patients during an episode of care in the healthcare record and in the organisation-wide incident reporting system
- 4.9 The health service organisation has processes for reporting adverse drug reactions experienced by patients to the Therapeutic Goods Administration, in accordance with its requirements.'¹

2. Roles and Responsibilities

2.1 Chief Executive, SA Health, is responsible for:

- > ensuring SA public hospitals and health services are aware of and comply with the principles of this guideline.

2.2 Local Health Network Chief Executive Officers will:

- > delegate the day-to-day responsibility for complying with this guideline to the relevant senior managers
- > ensure the health services under their administration have systems in place to ensure appropriate recording, monitoring and communication of adverse drug reactions and allergies
- > ensure the health services under their administration have systems in place to ensure ADR information is available and referred to at the time of prescribing, dispensing and administration of a medicine

- > ensure the health services under their administration have systems in place which facilitate effective management and notification of adverse drug reaction incidents (in accordance with the Patient Incident Management and Open Disclosure Policy Directive).

2.3 Executive Directors, Directors, Heads of Service/Departments and other Senior Managers will:

- > promote awareness of the importance of documenting ADR information and referring to it at the time of prescribing, dispensing and administration of a medicine.
- > ensure local policies and procedures are implemented in accordance with this guideline for appropriate recording, monitoring and communication of adverse drug reactions and allergies. This includes embedding the documenting of ADRs and referring to them prior to prescribing, dispensing and administration of a medicine into practice.
- > ensure local policies and procedures are implemented for reporting and assessment of new ADRs including reporting to the Therapeutic Goods Administration (TGA)
- > create an environment where any incident relating to an ADR is notified and investigated, including implementation of strategies to reduce the likelihood of a similar incident occurring.

2.4 All SA Health employees will:

Adhere to the principles and aims of this guideline by:

- > ensuring they document, monitor and communicate adverse drug reactions in accordance with the procedures set out within this guideline
- > ensuring they check and consider ADR information prior to prescribing, dispensing and administering a medicine
- > reporting new ADRs according to hospital policy
- > reporting ADR incidents to the Safety Learning System in accordance with the Patient Incident Management and Open Disclosure Policy.

3. Policy Requirements

3.1 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:²

- > in excess of 230,000 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 \$1.2 billion per annum
- > medication incidents remain the second most common type of incident reported in hospitals.

3.2 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.

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

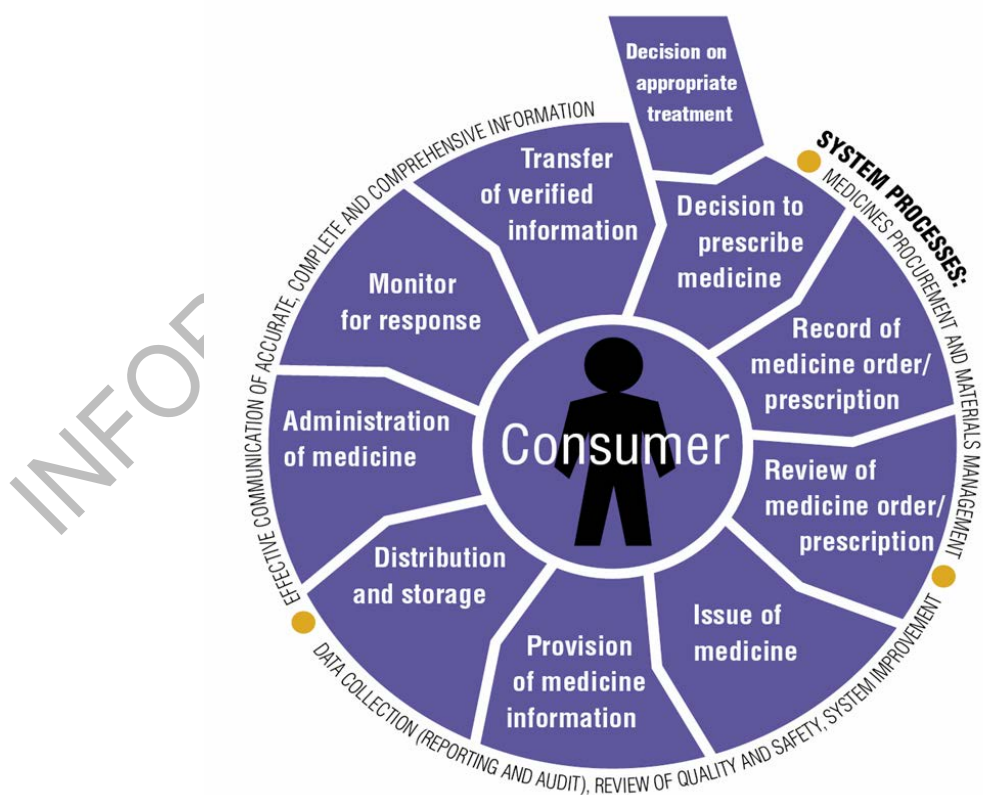


Figure 1: Medication Management Cycle³

3.3 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.

3.3.1 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).

3.3.1.1 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.

3.3.1.2 No known ADR

Where there is no known ADR or allergy, this must be documented in electronic systems, on the medication chart, the medication history form and the medication management plan, where available.

For example: **'Nil known'** or **'No known allergy'**.

3.3.1.3 Unknown ADR or allergy history

Where it is not known if the patient has any previous ADRs, **'Unknown'** should be documented.

3.3.1.4 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.

3.3.1.5 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.
- > Prescribers are responsible for checking and ensuring ADR and allergy documentation is accurate at every interaction in electronic systems.
- > 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.

3.3.1.6 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 3.3.1.4).

- > 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; for example prior to administering a medicine.

3.3.1.7 Examples of documentation

Example ADR sticker and documentation:

Adverse Drug Reaction

Attach ADR sticker

Allergies and adverse drug reactions (ADR)		
<input type="checkbox"/> Nil known <input type="checkbox"/> Unknown (tick appropriate box or complete details below)		
Medicine (or other)	Reaction / type / date	Initials
<i>Penicillin</i>	<i>Shortness of breath & rash 1990</i>	<i>AD</i>
<i>Ace Inhibitors</i>	<i>Angioedema 1998</i>	<i>AD</i>
<i>Latex</i>	<i>Hives</i>	<i>AD</i>

Sign *A Doctor* Print A DOCTOR Date 1/7/18

Attach ADR sticker

Allergies and adverse drug reactions (ADR)		
<input type="checkbox"/> Nil known <input checked="" type="checkbox"/> Unknown (tick appropriate box or complete details below)		
Medicine (or other)	Reaction / type / date	Initials

Sign *A Doctor* Print A DOCTOR Date 1/7/18

3.3.2 Documenting and reporting new ADRs/allergies

Document the details of the reaction as for previously known reactions (section 3.3.1) as well as any other information relevant to the ADR/allergy in the progress notes section of the medical record, including:

- > 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.

Consider contacting an immunologist where anaphylaxis has occurred.

In addition:

3.3.2.1 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.

3.3.2.2 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](#) available from the TGA website, or [online](#).

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.

3.3.2.3 Reporting ADR incidents

Incidents related to ADRs should be reported to the Safety Learning System in accordance with the Patient Incident Management and Open Disclosure Policy.

3.3.3 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

3.3.4 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. Implementation and Monitoring

SA Health employees, contractors and consultants are required to report breaches of this policy through institutional reporting structures, including the Safety Learning System in accordance with the Patient Incident Management and Open Disclosure Policy Directive.

Compliance with this policy will also be measured in the National Standard 4 – Medication Safety and the National Standard Medication Chart audits

5. National Safety and Quality Health Service Standards

National Standard 1 Governance for Safety and Quality in Health Care	National Standard 2 Partnering with Consumers	National Standard 3 Preventing & Controlling Healthcare associated infections	National Standard 4 Medication Safety	National Standard 5 Patient Identification & Procedure Matching	National Standard 6 Clinical Handover	National Standard 7 Blood and Blood Products	National Standard 8 Preventing & Managing Pressure Injuries	National Standard 9 Recognising & Responding to Clinical Deterioration	National Standard 10 Preventing Falls & Harm from Falls
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please note the National Standard/s above apply until 31 December 2018 and are to be used until then.

The National Standards below will be implemented from 1 January 2019.

National Standard 1 Clinical Governance	National Standard 2 Partnering with Consumers	National Standard 3 Preventing & Controlling Healthcare-Associated Infection	National Standard 4 Medication Safety	National Standard 5 Comprehensive Care	National Standard 6 Communicating for Safety	National Standard 7 Blood Management	National Standard 8 Recognising & Responding to Acute Deterioration
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. Definitions

In the context of this document:

Adverse drug reaction means 'an appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or specific treatment, or alteration of the dosage regimen, or withdrawal of the product'.⁴

A pharmacological classification⁵ divides most ADRs into one of two major subtypes:

- > **Type A reactions:** pharmacological effects that are predictable and dose-dependent. Most ADRs are type A reactions and include:
 - > toxic effects (for example, digoxin toxicity, and serotonin syndrome)
 - > side effects (for example, nausea with opioids)
 - > secondary effects (for example, antibiotic-associated diarrhoea)
 - > drug interactions.
- > **Type B reactions:** hypersensitivity reactions that are unpredictable and not dose-dependent (for example, anaphylaxis with penicillin). Type B reactions comprise approximately 10-15% of all ADRs.

Class effect means reactions which occur with most or all of the drugs in a class; for example, cough from angiotensin converting enzyme inhibitors.

Drug allergy means hypersensitivity reactions that involve an immune mechanism.

Medicine means a chemical substance given with the intention of preventing, diagnosing, curing, controlling or alleviating disease or otherwise enhancing the physical or mental welfare of people.³ A medicine includes prescription and non-prescription medicines, including complementary and alternative medicines, irrespective of the route of administration.

7. Associated Policy Directives / Policy Guidelines & Resources

- > [Preventing Adverse Drug Events Policy Directive](#)
- > [Continuity in Medication Management – a Handbook for South Australian Hospitals](#)
- > [Guiding Principles to achieve continuity in medication management](#)
- > [National Inpatient Medication Chart User Guide](#)
- > [Patient Incident Management and Open Disclosure Policy Directive](#)
- > [Standards of practice for clinical pharmacy services 2013.](#)⁶
- > [National Safety and Quality Health Service Standards – Standard 4 - Medication Safety Standard.](#)¹

8. References

- 1 Australian Commission on Safety and Quality in Health Care. National Safety and Quality Health Service Standards. 2nd ed. Sydney: ACSQHC; 2017
- 2 Roughead EE, Semple SJ, Rosenfeld E. The extent of medication errors and adverse drug reactions throughout the patient journey in acute care in Australia. *Int J Evid Based Healthcare* Sept 2016 – Vol 14 – Issue 3 – 113-122.
- 3 Australian Pharmaceutical Advisory Council. Guiding principles to achieve continuity in medication management. Commonwealth Department of Health and Ageing, Canberra. 2005
- 4 Edwards IR, Aronson JK. Adverse drug reactions; definitions, diagnosis and management. *The Lancet* 2000; 356:1255-9.
- 5 Rawlins MD, Thompson JW. Pathogenesis of adverse drug reactions. In: Davies DM, editor. Textbook of adverse drug reactions. Oxford: Oxford University Press, 1977: 10
- 6 SHPA Committee of Specialty practice in Clinical Pharmacy. Standards of practice for clinical pharmacy services. *J Pharm Pract Res* 2013: Volume 43, No 2 supplement

9. Document Ownership & History

Document developed by: Medicines and Technology Programs
File / Objective No.: 2018-10480 | A962366
Next review due: 01 July 2023
Policy history: Is this a new policy (V1)? **N**
Does this policy amend or update an existing policy version
Y
If so, which version? V1.0
Does this policy replace another policy with a different title? **N**
If so, which policy (title)?

ISBN No.: 978-1-76083-038-0

Approval Date	Version	Who approved New/Revised Version	Reason for Change
29/10/18	V2.0	A/Deputy Chief Executive	Formally reviewed in line with 1-5 year scheduled timeline for review. Minor amendments.
03/11/14	V1.1	Executive Director	Updated to reflect EPAS capabilities
25/06/2013	V1.0	Portfolio Executive	Original Portfolio Executive approved version.