SA Health

Policy

Preventing Adverse Drug Events

Version 2.0
Approval date: 08 May 2024
PDS Reference No: D0320

Government of South Australia
SA Health

1. Name of Policy

Preventing Adverse Drug Events

2. Policy statement

This policy provides the mandatory requirements in relation to documenting, monitoring and communicating adverse drug events (ADEs), including adverse drug reactions (ADRs) and allergies.

3. Applicability

This policy applies to all employees and contracted staff of SA Health; that is all employees and contracted staff of the Department for Health and Wellbeing (DHW), Local Health Networks (LHNs) including state-wide services aligned with those Networks and SA Ambulance Service (SAAS).

4. Policy principles

SA Health's approach to preventing adverse drug events is underpinned by the following principles:

- We support staff in the documentation, communication and handover of adverse drug events including adverse drug reactions and allergies.
- We will ensure that all new adverse drug events are reported appropriately.
- We are committed to ensuring that re-exposure to medicines, for which there is a previously documented adverse drug reaction or allergy, are prevented.
- We will ensure appropriate governance to minimise any patient-harm from the use of medicines.
- We act in the public interest.

5. Policy requirements

LHNs and health services must:

- Develop, implement and maintain local systems to ensure the documentation of the patient adverse drug events, including new, existing or nil known adverse drug reactions, within the patient's health record, in accordance with Appendix 1: Documentation of Adverse Drug Events Mandatory Instruction.
- Ensure appropriate clinical handover and transfer of information in regard to adverse drug events, including:
  - to any subsequent medical record.
  - to the patient and/or carer and all relevant health professionals at transitions of care.
- Ensure appropriate reporting of adverse drug events to the:
  - Safety Learning System in accordance with the Clinical Incident Management Policy,and
  - Therapeutics Goods Administration, where appropriate.
- Ensure all staff have access to information resources and local procedures about adverse drug reactions and allergies.
- Refer to the National Safety and Quality Health Services Standards (Standard 4- Medication Safety) when measuring, auditing or reviewing documentation and management of adverse drug events.

6. Mandatory related documents

The following documents must be complied with under this policy, to the extent that they are relevant:

- Clinical Incident Management Policy

7. Supporting information

- Continuity in Medication Management – a Handbook for South Australian Hospitals
- Guiding Principles to achieve continuity in medication management
- National Safety and Quality Health Service Standards – Standard 4 - medication safety standard
- National Inpatient Medication Chart User Guide
- Standards of practice for clinical pharmacy services

8. Definitions

- **Adverse drug event** means: any event due to a medicine. This includes harm from the medicine itself (see adverse drug reaction) and harm resulting from errors or system failures associated with the prescribing, dispensing, distribution or administration of the medicines.
- **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. A pharmacological classification divides most ADRs into one of two major subtypes (see 'Type A reactions' and 'Type B reactions' below).
- **Drug allergy** means: hypersensitivity reactions that involve an immune mechanism, see 'Type B reactions' below.
- **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. A medicine includes prescription and non-prescription medicines, including complementary and alternative medicines, irrespective of the route of administration.
- **Statewide services** means: Statewide Clinical Support Services, Prison Health, SA Dental Service, BreastScreen SA and any other state-wide services that fall under the governance of the Local Health Networks.
- **Type A reactions** means: pharmacological effects that are predictable and dose dependent. Most adverse drug reactions 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), and/or
    - drug interactions.
- **Type B reactions** means: hypersensitivity reactions that are unpredictable and not dose dependent (for example, anaphylaxis with penicillin). Type B reactions comprise approximately 10-15% of all adverse drug events.

9. Compliance

This policy is binding on those to whom it applies or relates. Implementation at a local level may be subject to audit/assessment. The Domain Custodian must work towards the establishment of systems which demonstrate compliance with this policy, in accordance with the requirements of the Risk Management, Integrated Compliance and Internal Audit Policy.

Any instance of non-compliance with this policy must be reported to the Domain Custodian for the Clinical Governance, Safety and Quality Policy Domain and the Domain Custodian for the Risk, Compliance and Audit Policy Domain.

10. Document ownership

Policy owner: Domain Custodian for the Clinical Governance, Safety and Quality Policy Domain.

Title: Preventing Adverse Drug Events Policy

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Contact for enquiries: Health.OfficeoftheChiefPharmacist@sa.gov.au

11. Document history

Version	Date approved	Approved by	Amendment notes
2.0	08/05/2024	Deputy Chief Executive, Clinical System Support & Improvement	Transfer to new Policy Framework template. Incorporation of mandatory instructions from Policy Guideline. Formally reviewed in line with 1-5 year scheduled timeline for review.
1.1	29/10/2018	A/Deputy Chief Executive	Formally reviewed in line with 1-5 year scheduled timeline for review
1.0	25/06/2013	Portfolio Executive	Original Portfolio Executive approved version.

12. Appendices

1. Documentation of Adverse Drug Events Mandatory Instruction

Appendix 1: Documentation of Adverse Drug Events Mandatory Instruction

The following Instruction must be complied with to meet the requirements of this policy.

1. Documentation of Adverse Drug Events

The following must be documented in a patient's health record regarding new, existing or historical (event which has occurred and resolved) adverse drug events:

- Generic name of the medication and brand name where relevant
- Type of reaction (if known)
- Date of reaction or approximate
- Signature or initials of person documenting
- Date of documentation

Where a patient reports nil known adverse drug reactions, this must be recorded in their health record. For existing or known adverse drug reactions, best practice is to seek verification by a second source.

2. Amendments or Updates to Documentation of Adverse Drug Events

Any updates or additional information in relation to a patient's adverse drug events must be documented on their health record, including modification of existing entries or inclusion of new entries.

SA Health employees, contractors and consultants must report breaches of this policy through institutional reporting structures, including the Safety Learning System in accordance with the Clinical Incident Management Policy.