Policy No.: D0320

Preventing Adverse Drug Events Policy Directive

Version No.: 1.1
Approval date: 29/10/2018

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Government of South Australia
SA Health

Contents

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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]

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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 policy.

2.2 Local Health Network Chief Executive Officers will:

- delegate the day-to-day responsibility for complying with this policy 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 for appropriate recording, monitoring and communication of adverse drug reactions and allergies. This includes embedding the documenting of ADRs and referring to it 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 policy by:

- ensuring they document, monitor and communicate adverse drug reactions in accordance with the procedures set out within the SA Health Preventing Adverse Drug Events 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 Directive.

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.

Incidents involving administration of medicines to patients who have a known previous ADR to that medicine continue to be reported to the SA Health incident monitoring system. This has included a number of incidents with severe or fatal consequences.

Australian studies have demonstrated that failure to document previously known ADRs occurs in up to three-quarters of cases.[3,4] More recent local data shows that ADR documentation in SA hospitals has improved following implementation of the national

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inpatient medication chart and increased clinical pharmacy services. 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 medical records predisposes patients to potentially fatal outcomes. These incidents are highly preventable when the correct information is available and referred to at the time of prescribing, dispensing and administration.[5]

3.2 Scope

All SA Health employees and persons who provide services on behalf of SA Health, involved in medication management, must adhere to this policy. 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 medicine. The steps in the medication management cycle are:

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

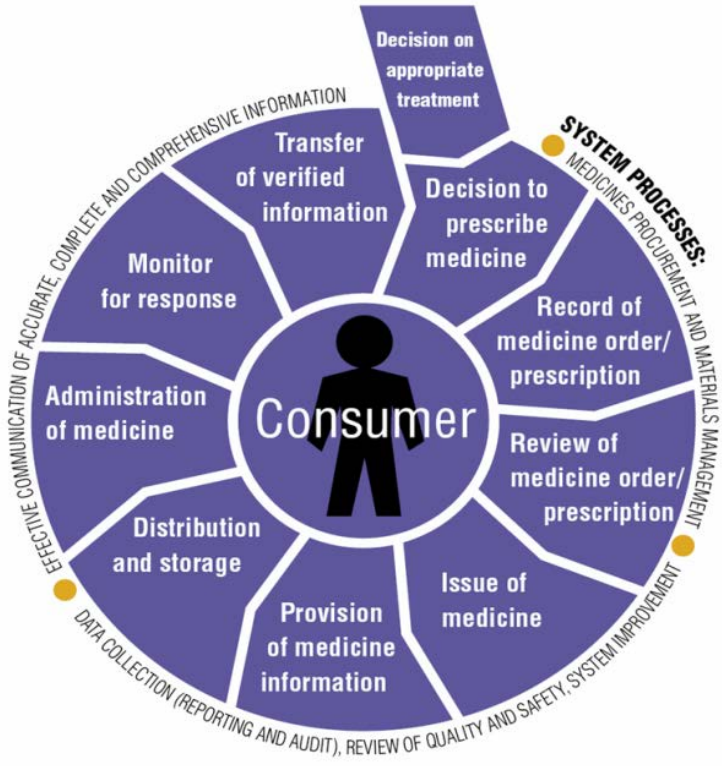

Figure 1: Medication Management Cycle[6]

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3.3 Policy Rationale

The purpose of this policy is to:

- establish an approach to preventing avoidable ADRs in South Australian health services
- establish a process for documenting previously known and new ADRs, including in electronic prescribing systems (for example, EPAS), and pharmacy management systems
- provide governance which outlines individual and health service responsibilities in relation to documenting, monitoring and communicating ADRs.

3.4 Principles

The SA Health Preventing Adverse Drug Events – documenting, monitoring and communicating adverse drug reactions and allergies policy is based on the 2005 Guiding principles to achieve continuity in medication management[6], and the Society of Hospital Pharmacists of Australia standards of practice for clinical pharmacy services.[9]

The following core principles are acknowledged:

- Many ADRs are unavoidable; however re-exposure to medicines for which there is a previously documented ADR is highly preventable.
- Documentation and communication of ADRs needs to be considered at each step of the medication management cycle, in accordance with the National Safety and Quality Health Service Standards.

4. Implementation & 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 Monitoring 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
☐	☐	☐	☒	☐	☒	☐	☐	☐	☐

Please note these National Standards above apply until 31 December 2018.

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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
☐	☐	☐	☒	☐	☒	☐	☐

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'.[7]

A pharmacological classification[8] 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.

A 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.[6] 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 and Resources

- Preventing Adverse Drug Events Policy Guideline.
- Patient Incident Management and Open disclosure Policy Directive.
- Continuity in Medication Management – a Handbook for South Australian Hospitals.
- Guiding Principles to achieve continuity in medication management.

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- National Inpatient Medication Chart User Guide.
- Standards of practice for clinical pharmacy services 2013.[9]
- 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. *Accessed 20/07/2018* https://journals.lww.com/ijebh/Pages/ArticleViewer.aspx?year=2016&issue=09000&article=00003&type=Fulltext

3 Coombes ID, Pillans PI, Storie WJ, Radford JM. Quality of medication ordering at a large teaching hospital. *Aust J Hosp Pharm* 2001;31:102-106

4 Shenfield GM, Robb T, Duguid M. Recording previous adverse drug reactions – a gap in the system. *Br J Clin Pharmacol* 2001;51:623-626

5 Building a Safer NHS for Patients: Improving Medication Safety: A report by the Chief Pharmaceutical Officer: National Health Service, 2004:173.

6 Australian Pharmaceutical Advisory Council. Guiding principles to achieve continuity in medication management. Commonwealth Department of Health and Ageing, Canberra. 2005

7 Edwards IR, Aronson JK. Adverse drug reactions; definitions, diagnosis and management. *The Lancet* 2000; 356:1255-9.

8 Rawlins MD, Thompson JW. Pathogenesis of adverse drug reactions. In: Davies DM, editor. Textbook of adverse drug reactions. Oxford: Oxford University Press, 1977: 10

9 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

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25/06/2013	V1.0	Portfolio Executive	Original Portfolio Executive approved version.

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