Allergy and Adverse Drug Reaction Management Policy

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Approval

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Revision History

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<th>Version</th>
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Purpose

- The objective of this policy is to ensure that there is a consistent approach to the identification, recording, reporting and analysis of adverse drug reactions (ADRs) throughout the Department of Health and Human Services (DHHS) and Tasmanian Health Organisations (THOs).

Key Definitions

- **Department of Health and Human Services** (DHHS) refers to:
  - Departmental Groups that are responsible for the provision of support for policy, planning, funding performance monitoring and improvements across the service groups; interface with government. The DHHS Departmental Groups comprise Strategic Control, Workforce and Regulation and System Purchasing and Performance.
  - Service Groups deliver services to the public. The DHHS Service Groups include Ambulance Tasmania, Children and Youth Services, Disability, Housing and Community Services and Population Health.

- **Tasmanian Health Organisations** (THO) are responsible for delivering high quality, efficient and integrated healthcare services in their area, through the public hospital system and primary and community health services.

- **National Safety and Quality Health Service Standards (NSQHS):** The NSQHS Standards have been developed by the Australian Commission on Safety and Quality in Health Care (ACSQHC) to drive the implementation of safety and quality systems and improve the quality in health care in Australia. Standard 4 relates to Medication Safety, with Standard 4.7 relating specifically to the management of adverse drug reaction documentation and reporting.

- **Adverse drug reaction (ADR):** A drug response that is harmful and unintended, and which occurs at doses normally used or tested in humans for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function. This includes, but is not limited to, a medicine allergy.

- **Allergy:** A medicine allergy is a type of ADR. An allergy occurs when the body inappropriately over-produces IgE in response to allergen exposure (e.g. a medicine). This can result in relatively mild reactions (e.g. a rash), to severe and life-threatening reactions (e.g. anaphylaxis).

- **Medication incident:** An event (or near miss) due to error or failure of the systems associated with the preparation, prescribing, dispensing, distribution or administration of medicines. A near miss is an incident that did not cause harm but had the potential to do so.

- **Adverse Medicines Event:** An adverse event due to a medicine. This includes allergies, other ADRs, and medicine incidents (see definitions above).

- **Prescriber:** includes medical practitioners and other authorised non-medical prescribers.

- **ACSM:** Advisory Committee on the Safety of Medicines (previously known as ADRAC), and advisory committee to the Therapeutic Goods Administration.
Mandatory requirements

All adverse medicines events (see definition above) should be considered for reporting via the agency's approved incident reporting system (Safety Reporting and Learning System (SRLS)), in accordance with SRLS guidelines, and relevant policies. However, the primary scope of this policy is the requirements for the management of allergies and ADRs only.

Documentation

• Clinical staff must confirm and document the patient’s previously known allergies and ADRs on initial presentation to a THO health service, and update this information if an ADR occurs during the episode of care.

• Allergies and ADRs must be recorded in the following places as part of patient care:
  o In the patient’s clinical record
  o In the Patient Administration System
  o In the dedicated ‘allergy/ADR’ field of all current inpatient medication charts, treatment orders and prescriptions
  o In any other medication history systems (such as the ‘Medication Reconciliation’ form, HCS Clinical Suite Software (Pharmcare™/Electronic Discharge Summary software), ‘Preadmission’ forms)
  o On the Discharge Summary

• Allergies and ADRs must be recorded at the time of identification according to this policy and local protocol.

• A clear process must exist for the regular update of patient allergy and ADR history within the Patient Administration System (PAS).

• Allergies and ADRs must be recorded by generic name (where appropriate) and should include a description of the reaction. If known, the date of the reaction, or approximate timeframe (e.g. 20 years ago) should also be included.

• If a patient has no known allergies or ADRs, the dedicated ‘allergy/ADR’ field of all current medication charts, discharge and outpatient prescriptions, or other treatment orders should be marked appropriately with ‘nil known’, ‘NKA’ or ‘NKDA’. This record should be signed by the person recording the information.

• If the patient’s allergy and ADR history cannot be established, the dedicated ‘allergy/ADR’ field of all current medication charts, discharge and outpatient prescriptions, or other treatment orders should be marked appropriately with “unknown”. This should be regularly revisited and reviewed throughout the admission.

• For further information about the appropriate use of the ‘allergy/ADR’ field of an inpatient medication chart, refer to SPP-MSR: The use of the National Inpatient Medication Chart Policy).

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Review

The patient’s allergy and ADR history must be referred to by clinical staff whenever medications are prescribed, dispensed or administered.

Reporting

- Significant and suspected allergy and ADRs should be reported via SRLS.
- All new allergies and ADRs must be communicated with the patient. Patients must be advised of the importance of informing other prescribers and members of their health care team of identified or suspected allergies or ADRs.
- All new allergies and ADRs must be reported to the patient’s community health provider (e.g. general practitioner, aged care facility) by THO health service staff, in accordance with local procedures.
- Allergies and ADRs should be assessed against the following criteria, and reported to the Therapeutic Goods Administration (TGA), via ACSOM, within 15 days of the ADR occurrence:
  - all suspected adverse reactions to medicines that have been newly listed within Australia;
  - unanticipated drug interactions, or drug interactions involving newly list medicines, that result in an ADR;
  - unexpected reactions, i.e. not consistent with product information
  - serious reactions which are suspected of significantly affecting a patient's management, including reactions suspected of causing:
    - death;
    - danger to life;
    - admission to hospital;
    - prolongation of hospitalisation;
    - absence from productive activity;
    - increased investigational or treatment costs; or
    - birth defects.
- Areas with clinical pharmacy services may contact pharmacy for advice and assistance in reporting to ACSOM.

This is a statewide policy and must not be re-interpreted so that subordinate policies exist. Should discreet operational differences exist, these should be expressed in the form of an operating procedure or protocol.

Failure to comply with this policy, without providing a good reason for doing so, may lead to disciplinary action.

Roles and Responsibilities/Delegations

- All staff involved in medication management are responsible for ensuring the patient details recorded on a medication order are accurate and complete.

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- It is the responsibility of the initiating prescriber to ensure the ‘Allergy/ADR’ field of the medication order (inpatient medication chart, or other prescription) is completed.
- It is the responsibility of clinical staff to confirm any allergy/ADR information in PAS with each new admission, and follow appropriate procedures to update PAS with any new allergy/ADR information.
- It is the responsibility of the clinician completing a patient medication history to cross-check allergy/ADR information in PAS, and to comply with local procedure to ensure PAS is updated if new allergy/ADR information is identified on patient interview or during admission.
- Executive managers are responsible for facilitating implementation and oversight of the policy through governance arrangements.
- Service managers have operational responsibility to ensure that staff are aware of and able to appropriately and competently undertake their role and responsibility in relation to allergy and ADR.
- THO health service staff have individual responsibility for adhering to local protocols regarding allergy and ADR management.

**Risk Implications**

- The administration of medicines to a patient with a known allergy or previous ADR is highly preventable.
- Correct documentation of allergies and ADRs prevents re-exposure of patients to offending drugs.
- Local and national reporting of allergies and ADRs will also contribute to post marketing surveillance of medicines and may be beneficial for the future management and safety of patients.
- The outcome of this policy is a reduced risk of adverse medication events related to exposure of agents to patients where there is a known history of allergy or ADR. This is achieved by ensuring ADR information is consistently and accurately recorded and maintained.
- Allergies and ADRs routinely reported via SRLS for review and ACSOM contribute to national data on ADRs.

**Training**

- All staff involved in medication management must be made aware of this policy.

**Audit**

- This policy will audited within healthcare facilities using ACHS Medication Safety clinical indicators:
  - Clinical Indicator 1.1 Reporting of adverse drug reactions to Therapeutic Goods Administration.
  - Clinical Indicator 3.1 Documentation of known Adverse Drug Reactions.
  - National Inpatient Medication Chart audit.

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•  All medication incidents related to the administration of medicines to a patient with a known allergy or previous history of adverse drug reaction should be reported to the local Medication Safety and Improvement Committee (or equivalent) for analysis and review.

Attachments

Related documents/Useful Resources


2  DHHS Incident Reporting and Management Policy


6  Tasmanian Continuity in Medication Management Manual (in development).