Reporting Medication Incidents PHC Remote Guideline

<table>
<thead>
<tr>
<th>Target Audience</th>
<th>All Clinical Employees</th>
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<tr>
<td>Jurisdiction</td>
<td>Primary Health Care Remote CAHS; Primary Health Care Remote TEHS</td>
</tr>
<tr>
<td>Jurisdiction Exclusions</td>
<td>N/A</td>
</tr>
</tbody>
</table>
| Document Owner  | Nicola Morris  
Senior Pharmacist Primary Health Care TEHS |
| Approval Authority | Chair  
Primary Health Care Remote Executive |
| Author          | PHC Safety and Quality Team |

The attributes in the above table will be auto-filled from the PGC System. Do not update in this document.

Purpose

To provide a Primary Health Care Remote clinician with a guideline on reporting medication incidents including all errors and mishaps involving medicines, breakdowns in systems, and adverse drug events.

Guideline

1. General Information

Primary Health Care Remote mandates the reporting of medication incidents including all errors and mishaps involving medicines, breakdowns in systems, and adverse drug events.

Reporting medication incidents is not intended to identify or punish those involved in the incident, but to provide the opportunity for information to be collated about circumstances leading to these incidents which can then be used to inform risk minimisation strategies.

In any clinical environment the causes of medication incidents are multifactorial and involve working environment factors as well as team, individual, client, task and system factors. In remote health centres / communities the risk of medication incidents is compounded by a number of practical matters such as:

- the large number of clients on multiple chronic disease medications (the number of medication related problems that people experience increases with the number of medications taken)\(^1\)
- communication issues related to culture, language and literacy, including differing cultural views on disease causation and treatment
- extreme climatic conditions which can affect drugs in transit, in the health centre and in the client's home
- insecure medication storage facilities in client homes
- transport and supply issues related to isolation.

This document must be read in conjunction with:

2. Definitions

**Adverse Drug Event:** an event which occurs when a medicine is administered to a person in order to improve their health but instead causes harm or exposes the person to potential harm. There are two types of Adverse Drug Events:

- **Adverse Drug Reaction:** something which occurs when a drug has been correctly administered to a person, but the person experiences a harmful effect due to the properties of the drug. The reporting mechanism varies according to the type of incident.
- **Medication Error:** a mistake made in the administration of a medicine which causes an adverse reaction to the medicine or an unpleasant experience.

**Health Profession Manager:** for the purpose of this document refers to the Director of Aboriginal and Torres Strait Islander Health Practitioners (ATSIHPs), Director of Nursing and Midwifery and Director of Medical Services.

**Incident Severity Rating (ISR):** is a system used to prioritise all reports, and is utilised by the RiskMan system which takes into account both the consequences (outcome of the incident or near miss) and the likelihood of recurrence and applies a numerical rating. This rating guides the level of investigation undertaken and the need for additional notification. ISRs are graded from 1 (high) to 5 (low).

**Medication Incident:** an event or circumstance that resulted, or could have resulted in unintended and/or unnecessary harm where medication is likely to have been an important contributing factor.

**Near miss:** A medication incident that has the potential to cause harm but no actual harm is experienced.

3. Responsibilities

3.1 Clinical Staff

- Ensure adverse drug events are managed to minimise client harm as the first priority, including consultation with the Duty Rural Medical Practitioner (RMP)
- After responding appropriately to the incident/event, generate an incident report via RiskMan for each medication incident. Also see Incident Reporting PHC Remote CAHS Guideline.
- Verbally report sentinel events, ISR 1 incidents and ISR 2 incidents to the Primary Health Care Manager / Line Manager / Manager on-call immediately
- Be aware of and contribute to notification requirements to other regulatory bodies, e.g. Therapeutic Drugs Administration (TGA), Centre for Disease Control (CDC).

3.2 Primary Health Care Manager (PHCM)

As for clinical staff, plus:

- Foster an environment to encourage medication incident reporting
- When present in the community at the time of a medication incident, be actively involved with the immediate follow up required
- Be involved in subsequent follow up relating to any incident

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3.3 Medical Practitioner / Duty Rural Medical Practitioner

- Provide on-site or on-call telephone consultation service if a medication incident affects or potentially affects a client adversely
- Provide clinical leadership to support health centre clinical staff in managing a client affected by a medication incident
- Notify the relevant PHC Director of Medical Services (CA/TE) following a significant medication incident or adverse drug reaction as appropriate.
- Notify relevant regulatory bodies of medication incidents as appropriate, e.g. TGA, CDC

3.4 District Manager

- Foster an environment to encourage medication incident reporting
- Ensure medication incidents are reported and managed according to the guidelines in this document and Incident Reporting PHC Remote CAHS Guideline
- Be actively involved with the immediate follow up when required
- Be involved in subsequent follow up relating to any incident
- Notify and liaise with the Primary Health Care General Manager as required
- In consultation with Management Teams and PHC Remote Pharmacist as appropriate, review trend data and implement appropriate responses / interventions as required

3.5 Primary Health Care Remote Pharmacist

- Review reported medication incidents
- Ensure medication incidents are referred to the relevant bodies as required, eg Remote Health Pharmacy Group, DoH Poisons Control, TGA, CDC
- Review trend data and implement appropriate responses / interventions as required in consultation with the District Manager / Management Team

3.6 Other Pharmacists (S100 Pharmacy / Hospital Pharmacy)

- Advise on appropriate responses / interventions as required

4. Procedure

Medication incidents or adverse drug events include not only medication errors but all adverse drug reactions and near misses. Medication incidents must be reported within 24-hours, using RiskMan. See 4.1 for reporting details.

As soon as a medication incident is identified, the first priority is prompt assessment and appropriate clinical care. When a medication incident with clinical consequences (actual or potential) occurs the Duty RMP must be notified and consulted.

It is important to record any medication incident in the client's medical record. Incident reports must not be filed or attached to the client's medical record.

According to the Incident Severity Rating (ISR) of the incident, the District Manager or Manager on-Call must be notified. Also see Incident Reporting PHC Remote CAHS Guideline, Critical Incident Follow-up PHC Remote CAHS Guideline and DoH Open Disclosure intranet site for further information.
4.1 Reporting Medication Incidents

4.1.1 Medication Errors

Factors most commonly linked to medication errors include not having systems in place to check medications and client identities, failure to read medical records / rural prescriptions properly and poor labelling. Issuing & Administering Medications provides information on managing these and other issues.

There are many types of medication errors that must be reported when they are identified. These include, but are not limited to errors:

- resulting from incomplete client information (not knowing the client's allergies or previous diagnoses, not having current laboratory results or a complete record of current medications)
- resulting from poor communication. e.g. at the time of discharge from hospital (delays in receiving discharge summaries, transcription errors, poor handwriting) or not advising/inbox messaging the RMP to update a client Rural Prescription
- in prescribing (inappropriate medicine is prescribed or prescriptions are transcribed incorrectly)
- in labelling (incorrect name or HRN or other identification detail)
- in issuing or administering medicines (giving the wrong medication or vaccine to a client, giving medication to the incorrect client, giving a client a Dose Administration Aid containing the wrong medications).

Complete an incident report using RiskMan as soon as possible after a medication incident is identified, and definitely within 24 hours.

4.1.2 Near Misses

A near miss or a 'close call' does not result in harm to the client but is a clear warning sign that staff may not be adhering to existing systems or that systems may not be robust or fail safe. All near misses are to be reported using RiskMan to enable review and amendment of medication safety systems as appropriate.

4.1.3 Adverse Drug Reaction

An adverse drug reaction is considered to be serious when it is suspected of causing admission to hospital, prolongation of hospitalisation, absence from productive activity, increased investigational or treatment costs, birth defects, death or danger to life.

Not all adverse drug reactions, such as some minor side-effects which are documented in product information require an incident report, but all events must be documented in the client's health record.

If a client experiences an adverse drug reaction, staff must consult the Duty RMP immediately or as soon as possible, for clinical guidance. Where appropriate the Medical Practitioner must report the event to the relevant regulatory body, e.g. TGA, CDC. The Online Australian Adverse Drug Reaction Reporting System can be used for reporting.

Note: Adverse Events Following Immunisation must be reported to CDC and not via the Online Australian Adverse Drug Reaction Reporting System. See Section 4.1.4 for details.

4.1.4 Adverse Events Following Immunisation

Not all Adverse Events Following Immunisation (AEFI) are notifiable. The Post Vaccination section of The Australian Immunisation Handbook 10th Ed. details the management of common adverse events and staff may contact CDC at any time if they would like further information on these.

In the case of an AEFI:

- provide appropriate clinical care in consultation with the RMP
- document in the client's EHR
- notify local area CDC of AEFI by phone
fax the completed AEFI Form to CDC Darwin (template also available via the EHR)
- scan and save the completed AEFI Form into the Client’s EHR. See EHR – Overview Section 4.6 for details.

CDC will submit data on AEFI’s to the TGA as appropriate.

4.1.5 CDC Contact Details

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<tr>
<th>Location</th>
<th>Telephone</th>
<th>Fax</th>
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<tr>
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<td>08 8951 9505</td>
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<tr>
<td>Darwin</td>
<td>08 8922 8564</td>
<td>08 8922 8310</td>
</tr>
<tr>
<td>Katherine</td>
<td>08 8973 9049</td>
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<tr>
<td>Nhulunbuy</td>
<td>08 8987 0282</td>
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</tr>
<tr>
<td>Tennant Creek</td>
<td>08 8962 4259</td>
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4.1.6 Dangerous Drugs of Addiction Incidents - Not Client Related

Health centre staff must report any incident involving Schedule 8 (S8) Medicines or Restricted Schedule 4 (RS4) Medicines including instances of broken or missing medicines or discrepancies in the S8 & RS4 Drug Register. S8 and RS4 medicine incidents must be reported to the PHCM for investigation immediately and an incident report via the RiskMan system completed as soon as practical.

The PHCM must report the discrepancy to the District Manager immediately and ensure incident reporting processes have been followed. Depending on the circumstances surrounding the incident, the discrepancy may be reported to the PHC Remote Pharmacist and relevant Health Profession Manager for further investigation.

The PHC Remote Pharmacist or relevant Health Profession Manager must notify Medicines and Poisons Branch when the S8 or RS4 medicines count cannot be reconciled and the discrepancy explained. The Drug Loss or Discrepancy Report Form should be used for reporting any loss or discrepancy of S8 or RS4 medicines.

Any incident involving delivery of S8 or RS4 Medicines from a Pharmacy should be reported to the sending Pharmacy immediately, in addition to the above incident reporting procedures.

Suspicions of misuse of S8 or RS4 medicines by a staff member must be reported to an appropriate manager in confidence. Management will initiate relevant follow-up action and request an incident report only where appropriate. Absolute confidentiality must be maintained throughout.

4.1.7 Medication Incidents - Environmental Conditions or Equipment Failure

Medications can be adversely affected by climate related temperature extremes or by power or equipment failure for extended periods. Contact pharmacy for issues related to medicines and/or CDC for vaccines for advice on how to manage damaged or potentially damaged stock. See Cold Chain for information on managing vaccines that have been outside the recommended temperature range. Report all medication incidents related to environmental and equipment failure using RiskMan.
# Implementation, Review & Evaluation Responsibilities

| Implementation | Document will be accessible via the Policy Guidelines Centre and Remote Health Atlas | Health Policy Guidelines Program
| | | Atlas Development Officer, Primary Health Care CAHS
| Review | Document is to be reviewed within 3 years, or as changes in practice occur | Atlas Development Officer, Primary Health Care CAHS
| Evaluation | Evaluation will be ongoing and informal, based on feedback. | Atlas Development Officer, Primary Health Care CAHS

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## Key Associated Documents

### Forms
- RiskMan intranet site (provides access to RiskMan ‘LIVE’ site and ‘Training’ site)
- RiskMan down time form (only to be used in the event of outages)
  - [Adverse Events after Immunisation Form](#)
  - [Online Australian Adverse Drug Reaction Reporting System](#)
  - [Drug Loss or Discrepancy Report Form](#)

### Key Legislation, By-Laws, Standards, Delegations, Aligned & Supporting Documents
- [Cold Chain](#)
- [Critical Incident Follow-up](#)
- [Duty RMP Telephone Consultations](#)
- [Incident Reporting PHC Remote CAHS Guideline](#)
- [Issuing & Administering Medicines](#)
- [Management on-Call PHC Remote CAHS Guideline](#)
- [Pharmacy Ordering](#)
- [Prescriptions](#)
- [Restricted Schedule 4 Medicines](#)
- [Schedule 8 Medicines](#)
- [Vaccines](#)
- [Advisory Committee on the Safety of Medicines](#)
- [The Australian Immunisation Handbook 10th Ed](#)
- [Definitions of Adverse Events following Immunisation](#)
- [Adverse Drug Reactions - FAQ](#)
- RiskMan (intranet)
- DoH [Open Disclosure](#) (intranet)
- [Health Incident Management Policy](#) (intranet)
- [Health Incident Management Guideline](#) (intranet)

### References
- As above
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<th>Reference</th>
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<th>Summary of recommendation from this reference</th>
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