Classifying Medication Incidents

Safety Learning System Topic Guide

Medications (medicines, drugs) are the most common treatment used in health care. Although appropriate use of medications contributes to significant improvements in health, medications can be associated with patient/consumer harm. Because they are so commonly used, medications are associated with a higher rate of patient incidents (adverse events) than any other healthcare intervention.

This guide will assist notifiers to quickly and accurately classify medication incidents.

Reporting incidents enables investigation and better understanding of contributing factors, and guides the actions to take to improve care to reduce the risk of harm.

Classification of medication incidents within the Safety Learning System (SLS)

The classification of medication incidents is structured around the stages in the medication management cycle. (Reference - Medication Management Cycle). The diagram on the following page describes the classification tree for medication incidents.

	Stage in the medication cycle	Example types of patient incidents that occur at each stage
Level 2 Classifications	Prescribing of medication	Inaccurate, invalid or incomplete record or documentation of the medication order or prescription. Inappropriate prescribing
	Supply of medication	Inaccurate, delayed or incomplete supply of medication
	Storage and accountability of medication	Unsecure storage of medication, or storage of medications in non-optimal conditions that could affect their safety or effectiveness
	Administration of medication	Inaccurate or delayed administration to patient
	Monitoring of response to medication	Inadequate monitoring or follow-up of the patient's response to the medication that was administered, or unintended continuation of use or delayed / failed cessation of the medication
	Adverse drug reaction	Unexpected or adverse reaction by patient to medication or vaccine
	Consumer advice and information - medication	Inaccurate, incomplete or delayed provision of information to the patient and / or carer

When notifying and reviewing incident reports, consider:

- When – at which stage of the medication cycle did the incident occur?
- Where – at which location did the incident occur?
- Who – which staff were involved, and which manager needs to review the incident?
- What – were the contributing factors for this patient incident?

Systems that underpin excellence in medication safety

- Procurement of medication and associated devices, materials management
- Data collection through reporting and audit
- Review of quality and safety (patient incidents), and system improvement
- Effective communication of accurate, complete and comprehensive information within and between teams
- Effective communication with patients, families and carers to ensure they are informed about medications and understand their individual medication needs and risks.

Level 1 - Medication						
Level 2						
Prescribing of medication	**Supply of medication**	**Storage and accountability of medication**	**Administration of medication**	**Monitoring of response to medication** *(Previously 'Monitoring or follow-up of medicine use')*	**Adverse drug reaction** *(Previously 'Patients reaction to medication')*	**Consumer advice and information - medication** *(Previously 'Advice and information transfer')*
Level 3						
Illegible prescription order	Delayed or not dispensed	Incorrect storage of medication	Delayed dose	Delay or failure to act on results	Adverse reaction to vaccine (NEW)	Delay or failure to transfer information
Invalid or incomplete order	Expired medication supplied	S8 / RS4(DDA) Count incorrect	Diverted / attempted to divert medication	Delay or failure to monitor	Inadequate documentation of a known adverse drug reaction (NEW)	Medicine profile error (NEW)
Medication not prescribed or charted	Expiry date omitted	S8 / RS4(DDA) Count omitted	Documentation of administration absent or incorrect (NEW)	Failure to discontinue treatment	Medication administered to patient with known allergy or adverse reaction	Patient Info leaflet wrong or omitted
Medication prescribed to patient with known allergy or adverse reaction	Failure to order / maintain stock of medication	Storage of patient's own medication (NEW)	Duplicate medication administered	Failure to follow up	New / unanticipated adverse drug reaction	Transcription error
Medication prescribed when contraindicated due to medication interaction (NEW)	Manufacturer / supplier shortage - no alternative available (NEW)		Expired medication or vaccine administered	Other medication monitoring incident		Verbal direction to patient wrong or omitted
Medication prescribed when contraindicated for health condition (NEW)	Medication supplied to patient with known allergy or adverse reaction		Incorrect self-administration by patient			Wrong dose
Telephone order error	Medication supplied when contraindicated due to medication interaction (NEW)		Medication administered despite known allergy or previous reaction			Wrong patient identification (NEW)
Transcription error	Medication supplied when contraindicated for health condition (NEW)		Medication administered without an order (NEW)			Other medication advice incident
Unapproved abbreviation (NEW)	Omitted medication or ingredient		Omitted medication			
Wrong dose	Unauthorised supply of medication (NEW)		Wrong device / device setting			
Wrong formulation	Wrong / omitted medication label		Wrong dose			
Wrong frequency / rate	Wrong device / device setting		Wrong formulation			
Wrong medication	Wrong dose		Wrong frequency / rate			
Wrong patient identification	Wrong formulation		Wrong medication			
Wrong quantity	Wrong frequency / rate		Wrong method of preparation			
Wrong route	Wrong medication		Wrong patient identification			
Wrong strength	Wrong method of supply		Wrong route			
Other medication prescribing incident	Wrong patient identification		Wrong strength			
	Wrong quantity		Wrong / omitted user applied labelling (NEW)			
	Wrong route		Other medication administration incident			
	Wrong strength					
	Other medication supply incident					

Example incidents and how to classify at Level 2 and Level 3

Level 2 - Prescribing of medication

What happened?

- Medication ordered but no dose documented
- Medication chart does not include all medications
- Non-standard abbreviation used e.g. 'U' instead of units
- Patient prescribed medication for one condition that has adverse effect on another condition
- Doctor entered new medication on the wrong patient's National Inpatient Medication Chart (NIMC)

Level 3 Classification

- Invalid or incomplete order
- Medication not prescribed or charted
- Unapproved abbreviation
- Medication prescribed when contraindicated for health condition
- Wrong patient identification

Examples:

Patient's BSA was calculated using weight of 70kg however patient now weighs 61kg so their dose of cyclophosphamide is too high

Level 3 Classification: Wrong dose
Contributing Factor(s): Staff – Procedure / guideline / protocols not followed, not available

Intranasal Fentanyl 140 microgram prescribed PRN for procedural burns dressing. Patient weight is 14 kg and protocol is 1.5 microgram/kg therefore meant to be charted as 21 microg.

Level 3 Classification: Wrong dose
Contributing Factor(s): Staff – Procedure / guideline / protocols not followed, not available

Level 2 - Supply of medication

What happened?

- No stock for patient / ward available
- Wrong formulation in patient's cupboard
- Unable to replace patient patch, no stock
- Medication had another patient's details
- Medication past use by date
- Medication supplied without completed authorisation / prescription
- National shortage of a medication

Level 3 Classification

- Delayed or not dispensed
- Wrong formulation
- Delayed or not dispensed
- Wrong / omitted medication label
- Expired medication supplied
- Unauthorised supply of medication
- Manufacturer / supplier shortage - no alternative available

Examples:

Five vials of cefazolin were sent to the ward from pharmacy instead of ceftriaxone.

Level 3 Classification: Wrong medication
Contributing Factor(s): Staff – knowledge / skills / competency
Work – physical environment

Wrong patient label attached to back of medication chart. Order faxed to pharmacy and the medication was dispensed in the wrong patient name.

Level 3 Classification: Wrong patient identification
Contributing Factor(s): Documentation – quality of information
Paper-based Medication Management System

Level 2 - Storage and accountability of medication

What happened?	Level 3 Classification
> Oxycodone tablet count incorrect	> S8 / RS4(DDA) Count incorrect
> Temazepam count not completed	> S8 / RS4(DDA) Count omitted
> Medication / vaccine left out of fridge, delay to find replacement	> Incorrect storage of medication
> Patient's own insulin not refrigerated	> Storage of patient's own medication

Examples:

Found during controlled drug balance check at change of shift that the oxycodone count should be 11 tablets but there are only 10 tablets in the DD cupboard.

Level 3 Classification: S8 / RS4 (DDA) Count incorrect
Contributing Factor(s): Staff – Procedure / guideline / protocols not followed, not available

Medications not stored in fridge upon delivery to ward over weekend
note: no refrigerate label on bag

Level 3 Classification: Incorrect storage of medication
Contributing Factor(s): Documentation – quality of information
Staff – Procedure / guideline / protocols not followed, not available

Level 2 - Administration of medication

What happened?	Level 3 Classification
> Medication missed – given two hours late	> Delayed dose
> Tablet found in pill cup / webster pack / bed / floor	> Omitted medication
> IV antibiotics not given at correct flow rate	> Wrong frequency / rate
> Patient's patch was two days overdue to be changed	> Omitted medication
> Medication injected IM instead of IV	> Wrong route
> Given 25mg tablet instead of 5mg	> Wrong dose
> IV medication given over 1 hour rather than 3 hours	> Wrong strength
> Used mask instead of inhaler to deliver medication	> Wrong device / device setting
> IV pump flow rate incorrect	> Wrong frequency / rate
> Patient taking own home medication as well as those provided by hospital	> Incorrect self-administration by patient

Examples:

Patient prescribed metoprolol 25mg bd. At start of afternoon shift, noticed that tonight's 2000 dose was accidentally signed last night

Level 3 Classification: Documentation of administration absent or incorrect
Contributing Factor(s): Communication – inadequate team communication
Communication – inadequate handover/discharge/transfer

Nocte dose of Targin 10/5mg (oxycodone/naloxone) modified release tablet was crushed and given to the patient

Level 3 Classification: Wrong method of preparation
Contributing Factor(s): Staff – Procedure / guideline / protocols not followed, not available

Patient was administered paracetamol 520mg liquid PI at 2005 before it was noticed that paracetamol 520mg liquid was previously given at 1750 as noted on the STAT chart.

Level 3 Classification: Wrong frequency / rate
Contributing Factor(s): Communication – inadequate handover / discharge / transfer
Paper-based Medication Management System

Level 2 - Monitoring of (the patient's) response to medication

What happened?

- Unwanted drop in blood pressure not noted for several hours after medication administered
- Antiemetic continued after patient recovered

Level 3 Classification

- Delay or failure to monitor
- Failure to discontinue treatment

Examples:

Patient was administered their 0800 antihypertensives despite blood pressure of 90/50mmHg.

Level 3 Classification:	Delay or failure to act on results
Contributing Factor(s):	Staff – procedure / guideline / protocols not followed, not available Staff - knowledge / skills / competency Work – physical environment

Level 2 - Adverse drug reaction

Note: If Level 3 'New/Unanticipated adverse drug reaction' or 'Adverse reaction to vaccine' is selected, there will be an additional question asking for the TGA report number to be entered. (Refer to Appendix 1 for further information.)

What happened?

- Patient developed rash after two doses of medication
- No documentation in medical record alerts section that patient experienced an adverse drug reaction
- Patient given penicillin despite documented allergy

Level 3 Classification

- New / unanticipated adverse drug reaction
- Inadequate documentation of a known adverse drug reaction
- Medication administered to patient with known allergy or adverse reaction

Examples:

Patient was given amoxycillin/clavulanic acid but they have a known history of penicillin allergy. Previous reaction was 'facial swelling'.

Level 3 Classification:	Medication administered to patient with known allergy or adverse reaction
Contributing Factor(s):	Communication – inadequate team communication Documentation – availability of information

Patient started on oral flucoxacilin for cellulitis then developed maculopapular rash two days into the course.

Level 3 Classification:	New / unanticipated adverse drug reaction
Contributing Factor(s):	Communication – inadequate team communication

Level 2 - Consumer advice and information – medication

What happened?

- Patient left without important medication information
- Patient information had incorrect dose written
- Medicine profile not correct

Level 3 Classification

- Delay or failure to transfer information
- Transcription error
- Medicine profile error

Examples:

Patient prescribed levonorgestrel for emergency contraception. Patient was told not to breastfeed her baby for three days and to discard any expressed milk; however, levonorgestrel is safe to use in breastfeeding.

Level 3 Classification:	Verbal direction to patient wrong or omitted
Contributing Factor(s):	Staff – knowledge / skills / competency Communication – inadequate patient communication

New medication questions

If more than one medication is involved in the one patient incident (for example, missed all medications due at 1400), notifiers will be asked to select the primary medication involved, and then select the other medication(s) from a multi-pick box. In both fields, select medications by entering the first four letters then choose the correct option(s). The primary medication has potentially the most effect on the outcome for the patient.

There is also a new question 'Did the incident involve a standing drug order? Yes / No'

Contributing factors

In the future SLS will provide a list of contributing factors for notifiers to select the most relevant for the incident. For now, this information can now be recorded in the 'What happened' field. Knowing the pattern of contributing factors helps to plan the actions to take to reduce the risk of recurrence.

Examples of contributing factors for medication incidents:

- Electronic Medication Management System
- Paper-based Medication Management system
- Communication – inadequate team communication
- Communication – inadequate handover/discharge/transfer
- Communication – inadequate patient communication
- Documentation – quality of information
- Documentation – availability of information
- Equipment failure

- Equipment not available
- Patient – non-compliance / refusal / or challenging behaviour
- Staff – procedure / guideline / protocols not followed, not available
- Staff – knowledge / skills / competency
- Staffing – allocation / scheduling / availability
- Work – physical environment

References

Terminology

- The terms 'consumer' and 'patient' are used interchangeably in this document.
- Controlled drugs. Two Level 3 Classification refer to 'S8 / RS4(DDA)' medications – in some services these are referred to as 'Controlled drugs'.
- Some incidents will meet the definitions of Hospital Acquired Complications of Care, and Sentinel events (see below).

Medication Hospital Acquired Complications of Care and Sentinel Events

These are considered to be patient incidents. The SLS provides a place to record the open disclosure with the patient, and also the investigation done (to uncover ways to reduce risk of their recurrence).

Three of the current list of **Hospital acquired complications of care** relate to medication:

- Drug related respiratory complications / depression
- Haemorrhagic disorder due to circulating anticoagulants
- Hypoglycaemia

Sentinel event –National Sentinel Events list (ACSQHC). These are always rated ISR 1 incidents.

- Medication error resulting in serious harm or death
    - As a result of the incident the patient requires life-saving surgical / medical intervention, or has shortened life expectancy, or has experienced permanent or long term physical harm or loss of function.

What are the patient incidents? (SA Health Patient Incident and Open Disclosure Policy Directive)

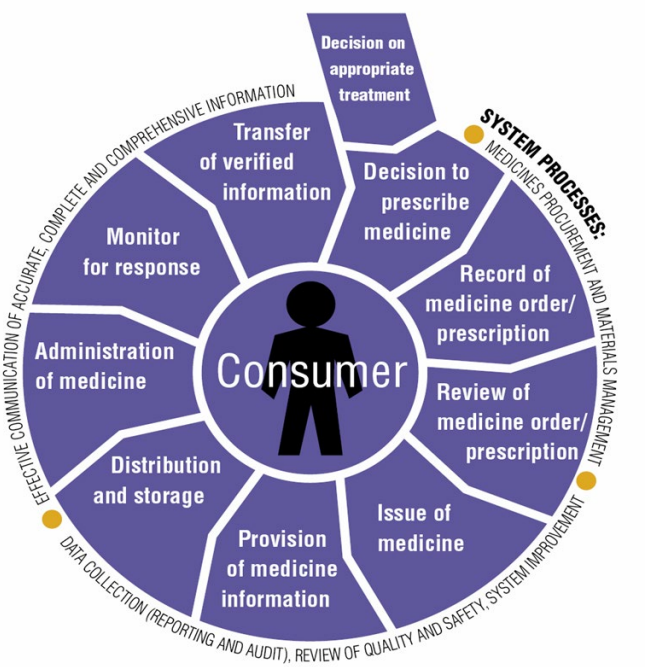
- An incident is any event or circumstance which could have (near miss) or did lead to unintended and/or unnecessary psychological or physical harm to a patient or consumer or that occurs during an episode of health care.
- A harmful incident means any event or circumstance which resulted in unintended and/or unnecessary psychological or physical harm to a patient or consumer during an episode of health care. For example, the patient received incorrect medication and became very ill.
- No harm means the incident occurred and the patient or consumer was exposed, but no harm resulted, for example the patient received a double dose, but there were no harmful effects.
- A near miss is a patient incident that did not cause harm, but had the potential to do so, for example the nurse was about to administer the medication, but on checking realised that this medication was contraindicated for a patient with this condition, and so the incident was averted.

The nine rights of medication administration

Right patient	Right time	Right action
Right drug	Right dose	Right form
Right route	Right documentation	Right response

The nine rights of medication administration; an overview, Malcolm Elliott, Yisi Liu, British Journal of Nursing, 2010, Vol 19, No 5

Medication Management Cycle



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

Appendix 1 – Adverse drug reactions

Adverse drug reactions (called ‘adverse events’ by the TGA) are unintended and sometimes harmful occurrences associated with the use of a medicine, vaccine or medical device (collectively known as therapeutic goods). Adverse drug reactions include side effects to medicines and vaccines.

Examples of adverse drug reactions are any unfavourable and unintended sign, symptom or disease associated with the use of a therapeutic good. An abnormal laboratory finding could be one example of an unfavourable and intended sign.

SA Health documentation

SA Health requires that any adverse drug reaction is recorded:

- in the medical record
- on the medication chart
- in Sunrise EMR (EPAS)
- in the discharge summary.

In addition, the occurrence of an adverse drug reaction is considered critical information and must be included in the handover.

TGA reporting criteria

Reports by consumers and health professionals provide important information for the TGA's safety monitoring program. SA Health encourages reporting of:

- all suspected adverse events to new therapeutic goods.
- all suspected medicine and/or vaccine interactions
- unexpected adverse events (that is, adverse events that do not appear in the Product Information, Consumer Medicine Information and/or product labelling)
- serious adverse events, such as those suspected of causing:
    - death
    - danger to life
    - admission to hospital
    - prolongation of hospitalisation
    - absence from productive activity
    - increased investigational or treatment costs
    - birth defects.

https://www.tga.gov.au/reporting-adverse-events

Example information required by TGA

Contact details for the reporter

Patient identifier (*such as initials, date of birth or age, but not their full name*)

- Weight ……..…
- Gender ……
- DoB ……..……
- Patient's diagnosis ……

Description of ADR (*including lab results, drug serum levels, etc as appropriate*)

Suspected drug ……..……

- Dose, frequency, route
- Date started
- Time of reaction after last dose
- Date ceased

Action taken when ADR identified (e.g. when drug ceased, dose reduced, other treatment prescribed)

Outcome

- Recovered data recovered
- Not yet recovered
- Fatal date of death
- Unknown
- Sequelae No Yes (describe ……)
- Did reaction contribute to hospital admission Yes No
- Did reaction prolong hospital admission Yes No
- Other drugs being taken when reaction occurred ……..

Vaccine reaction reporting: Adverse event following immunisation

SA Health webpage provides information on reporting vaccine adverse events.
To submit a report to SA Health, complete the online Vaccine Reaction Report Form.

For more information

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