Reporting Medical Devices or Equipment

Safety Learning System

Topic Guide

Why and when to report patient incidents involving medical devices or equipment

The purpose of patient incident reporting is to improve the safety and quality of care.

Data will help services to monitor patterns of incidents and plan quality improvements.

It is a requirement of SA Health Patient incident management and open disclosure Policy Directive to report incidents and near misses within 24 hours.

Definitions

- The term medical devices/equipment includes all products (except medicines/drugs) used in healthcare for the diagnosis, prevention, monitoring or treatment or disability (Therapeutics Goods Administration)
- Medical devices have therapeutic benefits, and generally have a physical or mechanical effect on the body or are used to measure or monitor functions of the body.

The range of products is very wide. It includes syringes, intravenous pumps to products such as pacemakers that are implanted within the body. And all of the accessories and consumables used with those medical devices. (See Appendix – List of product types).

Typical problems with medical devices include:

- deficiencies in labelling, instructions or packaging
- defective components
- performance failures / malfunction
- poor construction or design
- incorrect calibration / measurement
- omissions or errors in Instructions for use (IFU).

How to report incidents involving medical devices or equipment into SLS

Pop up alerts assist SA Health staff to know what actions are required for affected medical devices or equipment after an incident occurs.

1. Date / time

2. Location of incident

The location/place where the Medical Device/Equipment incident occurred must be entered into SLS.

3. Subject of incident

Select 'Incident affecting patient'

4. Person Affected.

Use this section to record any actual injury to the consumer/patient affected

- Under 'Type', select patient / consumer/client and complete details.
- For the question 'Was this person harmed in the incident?' if the answer is yes the 'Harm/Injury details' section will appear. From the drop down lists select:
    - the harm/injury
    - the body part affected
    - the treatment required for the injury.

Then click 'Add another injury' to record details of other injury(s).

If the device failure, malfunction or error has affected more than five patients, consult your local Safety and Quality Manager or SLS Administrator.

5. Description of the Incident / Event.

Write a brief factual description of the incident and outcome. It is preferable to use staff designations, rather than names.

6. Open disclosure

For the question 'Has this incident been disclosed to patient/family?' indicate yes if you, or a team member, have discussed the incident with the patient and/or carer or family.

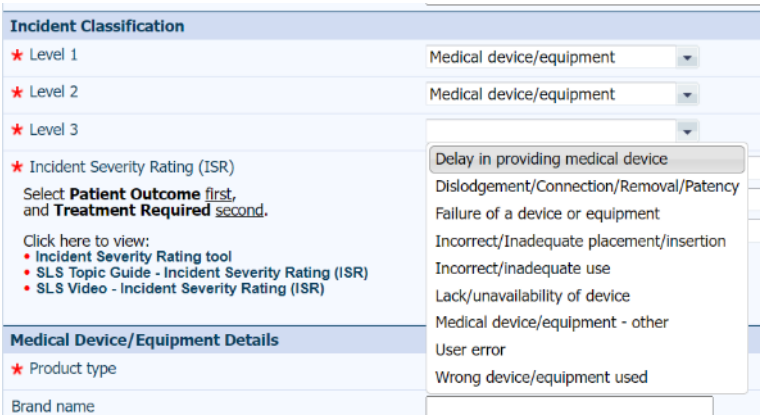
- This discussion should include expressing regret that this has occurred, providing information about what will happen next, and answering any questions they may have.
- If there is any comment about how this discussion went, eg family angry or upset you should inform your line manager and include this information in the section above 'What was the outcome of the incident'

7. Notifier details

Enter your professional group, and additional details.

8. Incident classification

Level 3 classifications were revised in 2016.

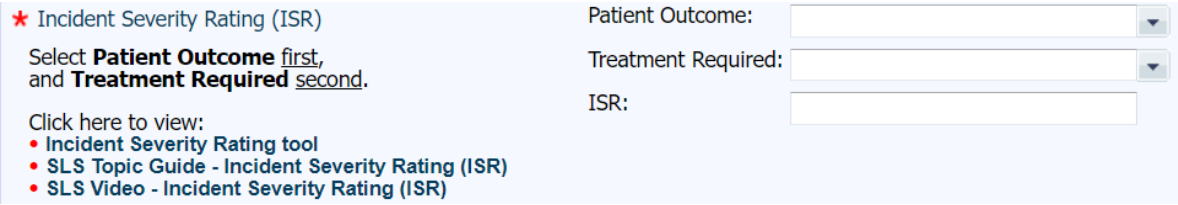


9. Incident Severity Rating (ISR)

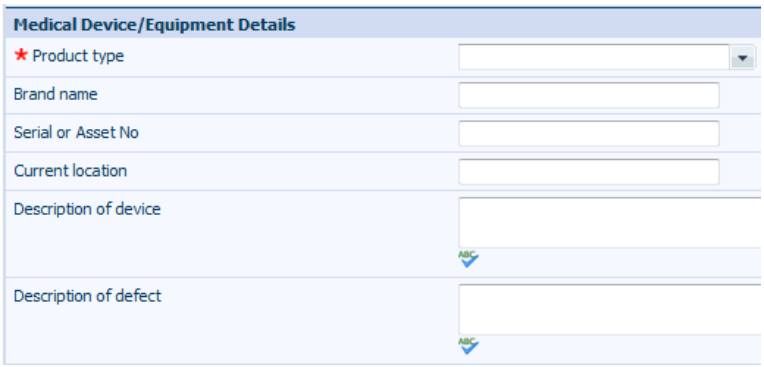
The Incident Severity Rating (ISR) Is a numerical score applied to patient incidents that considers the direct outcome and follow up treatment required following and incident. The Notifier ISR guides the level of escalation and investigation required for all patient incidents reported into the Safety Learning System (SLS).

All patient incidents reported into the SLS require allocation of a Notifier ISR at the time of reporting. When completing the ISR fields within the SLS, the notifier should consider what both the direct patient outcome was and the subsequent treatment required at the time of reporting.

The ISR is automatically calculated upon selection of the relevant ‘Patient Outcome’ and ‘Treatment Required’ for that patient incident at both the notifier and manager levels. Refer to the link on the SLS form which will take you to the ISR tool.



Additional questions appear that request information about the product. Select product type from the list.



10. Final steps

Once the form is complete, click **submit**.

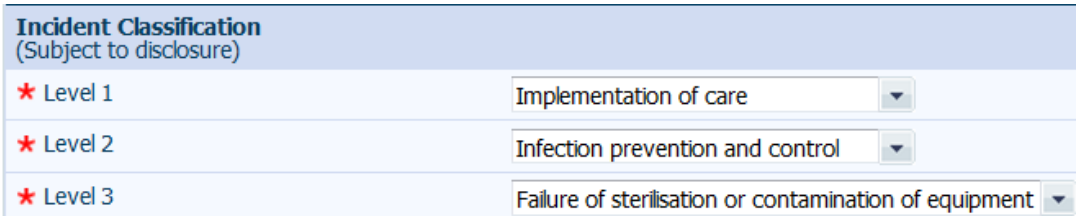
A message stating the incident number will appear. You will need to note this information if you would like to follow up with the relevant manager regarding its progress.

Note that if incident is classified as a medical device/equipment type incident, BME will receive notification from SLS automatically.

What incidents do not belong in this classification

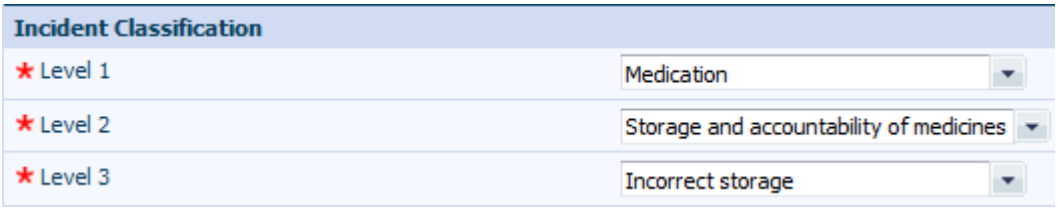
Incidents relating to

- Sterilisation, reprocessing or contamination of equipment. These are classified as follows:

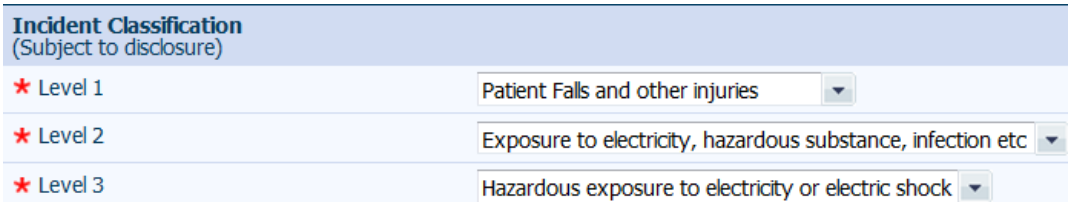


- Power or Refrigeration failure resulting in disposal of medications or vaccines. These are not patient incidents. Report equipment failure or power supply failure to facilities manager.
- Patient incidents resulting from breach in cold chain. Examples include:
    - If a patient was given medication that had been stored incorrectly
    - If a patient experiences a delay in receiving medication or vaccine because of break in cold chain.

  These are classified as follows:



- Electric shock or electrocution of a patient from the main power supply (rather than a fault in the medical device). These are classified as follows:



If unsure, contact SA Biomedical Engineering

The role of the Patient Incident Manager

- The patient incident manager is to review the incident within 2 working days of it being reported and to verify the incident ISR
- Ensure that the faulty device/equipment is isolated until it can be investigated.
- If Open disclosure has not yet occurred the incident manager arranges this.
- Refer to the SLS Tool 3 – How to manage a patient incident (insert hyperlink)

Biomedical Engineer Review

SA Health incident managers are encouraged to **add SA BME staff as reviewers** to any incident where a medical device or equipment is involved, to facilitate a comprehensive investigation and management of the incident.

Some incidents may not be classified primarily as a Medical Device / Equipment incident, for example the incident may be best classified as Treatment / Procedure. However, if a device or equipment involved in the procedure was damaged or malfunctioned, **review by BME is recommended**.

The SLS includes fields to record BME work order numbers.

For more information

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