RISK NOTE

Responding to Medical Device Issues

OVERVIEW OF ISSUE

Medical devices may be involved in events that cause or have the potential to cause patient harm. Medical device issues can arise for a variety of reasons such as device deficiency, system factors (e.g. inadequate training), and operator performance issues (e.g. inappropriate use). When there is an issue with a medical device, several steps need to be taken to ensure risk is mitigated and to promote patient safety.

KEY POINTS

When there is an issue with a medical device:

- Sequester the device.
- Document what happened.
- Disclose the issue in accordance with the organization's disclosure policy and critical incident legislation.
- Report the incident to appropriate parties.
- Learn from what happened to prevent recurrence.

THINGS TO CONSIDER

Sequestering the Device Following Patient/Client Event

- In consultation with the healthcare organization's Biomedical Engineering resource, without changing any control settings/levers/dials, remove the device from use as soon as it is safe to do so. Ensure the device is sequestered (i.e. locked up) to avoid any tampering; the device needs to be in the state it was discovered in for any internal or external review. For large immovable devices, consider electronically disabling the device to prevent re-use until completion of the investigation.
- Consider error codes stored in the device before turning the device off, unplugging it or removing the battery. Audit records may need to be obtained before device is turned off.
- Retain all accessories related to the device (including disposables) as well as any packaging materials that may contain manufacturing lot numbers.
- Take photos of the device in its 'as is' state.
- For sequestered equipment, establish a chain-of-custody protocol to monitor the device's integrity; the protocol should outline proper collection and handling.
- Have Biomedical Engineering approve the return to use of any device once the investigation is complete.

Documentation

- Retain training logs in accordance with the organization's retention policy; questions may arise later regarding who received training on the device.
- Retain the contract(s) of sale or lease, warranties, purchase order(s), any promotional and descriptive material, invoice(s), operating manual(s) and any instructions related to the device.

Notification and Disclosure

- Complete an incident report in accordance with the organization's incident reporting policy. The incident report should include the manufacturer and model number, lot and/or serial number, and date used on or removed from patient care.
- Disclose the event to the patient/substitute decision maker as appropriate. If multiple patients are affected:
  - Where in place, follow the organization's protocol for the management of look-back/ multi-patient events, including

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immediately consulting with the organization's risk management, communications and clinical leadership.

- Report the issue to HIROC in line with HIROC's claims reporting guidelines.
- If breaches in infection control are involved, offer follow-up testing to patient(s) and facilitate the return of test results.
- Consider reporting the issue to the manufacturer. Confer with HIROC before releasing the device to the manufacturer. If the manufacturer offers to examine the device, ensure that internal analysis including documentation has occurred first (it may be necessary for an independent assessor to examine the device before it is examined by the hospital or manufacturer). Ensure that all communication with the manufacturer is documented including requesting the manufacturer to acknowledge that they have received the device.
- Report the issue to Health Canada as required and consider reporting to ECRI.

Analysis of the Issue

- If a patient was directly involved in the cause of the issue (e.g. home hemodialysis equipment), ascertain whether:
  - The function of the device was thoroughly explained to the patient before the procedure started;
  - The healthcare team was confident that the patient understood the instructions and would comply with them;
  - The patient was specifically aware of what they must and must not do;
  - The patient was adequately monitored during the procedure.
- Assemble an interdisciplinary review team. Ideally the team should have either direct knowledge of the issue or be responsible for changes that might stem from the review.
- Consider utilizing prospective analysis (e.g. failure mode and effects analysis) to identify potential failures when using the device including the potential for operator error.
- Implement identified process changes that come about as a result of the review.
- Report results of analysis back to those who were involved in the incident; disseminate learnings within the organization.

Alerts and Recalls

- Adopt a standardized process to manage alerts and recalls.
- Upon receiving an alert or recall, ensure that the organization's device inventory is checked against information listed in the vendor's alert/recall documentation.
- If requested, remove the device from circulation and report back to the vendor; the vendor may want the device returned or will notify the organization of corrective actions that are going to be taken at no cost to the organization.
- Document and centralize actions taken in response to alerts and recalls.

REFERENCES

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