Alberta Health Services

PROCEDURE

TITLE
MEDICAL DEVICE INCIDENT OR PROBLEM REPORTING

SCOPE
Provincial

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APPROVAL AUTHORITY
Clinical Operations Executive Committee

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Contracting, Procurement & Supply Management

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Medical Device Safety Policy (#PS-103)

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NOTE: The first appearance of terms in bold in the body of this document (except titles) are defined terms – please refer to the Definitions section.

If you have any questions or comments regarding the information in this document, please contact the Policy & Forms Department at policy@ahs.ca. The Policy & Forms website is the official source of current approved policies, procedures, directives, standards, protocols and guidelines.

OBJECTIVES

- To establish a consistent process for reporting **medical device incidents (MDI)** or **medical device problems (MDP)** to centralized Alberta Health Services' (AHS) **medical device safety (MDS) responsible departments**.
- To clarify the circumstances for mandatory reporting and **quarantine** of **medical devices** involved in MDI in order to meet requirements under the *Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)* (Canada) and *Medical Devices Regulations* (Canada).
- To set out the internal and external reporting requirements and related processes followed by AHS MDS responsible departments on behalf of **AHS representatives** using medical devices and applicable **medical device-related entities**, to fulfill regulatory requirements and promote **patient** safety and device improvement.

APPLICABILITY

Compliance with this document is required by all Alberta Health Services employees, members of the medical and midwifery staffs, Students, Volunteers, and other persons acting on behalf of Alberta Health Services (including contracted service providers as necessary).

ELEMENTS

1. Medical Device Incident and Problem Reporting

1.1 AHS representatives using medical devices shall promote patient safety, safe practice, and medical device improvements through established AHS mechanisms by reporting all MDIs and MDPs.

1.2 AHS and medical device-related entities are expected to carry out reporting in accordance with Section 1.1 above.

1.3 For the purposes of this Procedure, any medical device involved in an MDI or with an observed or suspected MDP shall be referred to as a **suspect medical device**.

2. Report Suspect Medical Devices to Alberta Health Services' Medical Device Safety Responsible Departments from the Point of Use

2.1 AHS representatives using medical devices shall report all suspect medical devices using the AHS *Medical Device Incident or Problem (MDIP) Report* Form. The AHS *MDIP Report* Form link is available on Insite and will be available on Epic Hyperspace for all Connect Care users.

2.2 AHS representatives using medical devices shall report every known MDI. Reporting known MDIs is mandatory to meet AHS obligations according to *Medical Devices Regulations* (Canada).

a) Every known MDI includes:

(i) all observed or witnessed MDIs; and

(ii) MDIs or other medical device-attributed **harm** which AHS is made aware of but may not have witnessed.

Examples include, but are not limited to:

- a MDI that occurred outside an AHS hospital, such as in Continuing Care or in the patient's home, but was reported to an AHS representative in a hospital;
- harm attributed to an implanted medical device, reported by a patient to an AHS representative; or
- serious medical device-related harm or potential for serious harm from a previous treatment/procedure discovered by an AHS representative during a subsequent treatment/procedure.

b) Every known MDI shall be reported through the AHS *MDIP Report* Form within one (1) business day of the MDI or awareness of the MDI, preferably the same business day.

c) Frontline teams involved with, or aware of, a MDI shall designate an individual to be responsible for reporting the MDI based upon knowledge of the MDI and availability to respond to MDS responsible departments.

2.3 AHS representatives using medical devices shall report MDPs (defect, failure, **close call**) through the AHS *MDIP Report* Form within three (3) business days of detecting the MDP.

2.4 MDI or Problem (MDIP) report information is automatically routed to the AHS MDS responsible department's central report repository when submitted and will also inform the Reporting & Learning System for Patient Safety (RLS).

a) The AHS MDS responsible department shall review and follow-up with the MDIP primary clinical contact regarding next steps in the reporting process.

b) MDIP report information shall be reviewed for patient safety quality improvement by the AHS MDS responsible department.

2.5 MDIPs that caused harm or pose a hazard to AHS representatives using medical devices shall also be reported in MySafetyNet. This report is in addition to reporting through the AHS *MDIP Report* Form.

2.6 Enquiries and requests for assistance related to reporting MDIs may be directed to the AHS Medical Device Safety Information Line: 1-877-390-2330.

3. Quarantine, Label, and Hold Suspect Medical Devices at the Site While Reporting

3.1 Suspect medical devices shall be retained for **investigation** wherever possible.

3.2 Suspect medical devices involved in a MDI shall be quarantined, labelled, and held according to the PLEASE Quarantine Process, and follow the AHS *Medical Device Safety – Preparing and Shipping for Investigation* Procedure while the reporting processes unfold; this quarantine is mandatory.

3.3 Medical devices with reported MDPs should be quarantined by the local clinical manager or designate, as appropriate, while reporting processes take place.

3.4 AHS MDS responsible departments shall review all suspect medical device reports received through the MDIP system (AHS MDS responsible department's central report repository), as well as any reports received by AHS MDS responsible departments central repository through other means and convert them to reports in the MDIP system.

3.5 AHS MDS responsible departments shall assess all MDIP reports for risk and priority, determine which reports appear to meet Health Canada's mandatory reporting requirements, and determine the most appropriate next steps.

3.6 AHS MDS responsible departments shall communicate with MDIP primary clinical contacts and/or those holding devices under quarantine about next steps in the reporting process, within one (1) business day, for MDI reports, and within three (3) days for MDP reports.

4. Medical Device Safety Team Actions, External Reporting, and Sharing Results

4.1 AHS MDS responsible departments shall determine and initiate the most appropriate actions for reviewed reports according to risk and priority:

a) AHS MDS responsible departments shall guide all areas where AHS representatives or patients use medical devices through the PLEASE Quarantine Process for each reported MDI.

b) AHS MDS responsible departments shall report internally and externally, initiate, and coordinate device investigations on behalf of frontline MDIP reporters as required:

(i) for MDIs, further reporting and device investigation is mandatory:

- AHS MDS responsible departments shall gather additional information as needed and report the MDI to the AHS or related entities Litigation team within two (2) business days of receipt of an MDI report.
- AHS MDS responsible departments shall submit proposed device investigation arrangements to Legal Services for approval, prior to investigation actions being taken.
- Legal Services shall fulfill internal processes and respond to AHS MDS responsible departments as soon as possible.
- AHS MDS responsible departments shall gather additional information, as required, for internal and external reporting and investigation arrangements.
- AHS MDS responsible departments shall initially report all MDIs to Health Canada within 30 calendar days of awareness of the MDI, as required by *Vanessa's Law* (Canada) and the *Medical Devices Regulations* (Canada).
- AHS MDS responsible departments may update Health Canada with additional information about the MDI thereafter.
- AHS MDS responsible departments shall make device investigation arrangements at an investigation facility (internal or external) deemed appropriate by AHS MDS responsible departments (e.g., Clinical Engineering shop or **vendor** facility).
- AHS MDS responsible departments shall further report MDIs to vendors and others as appropriate and approved by Legal Services.

(ii) For reported MDPs further reporting and device investigation is recommended:

- AHS MDS responsible departments shall report MDPs to vendors, Health Canada, and/or other stakeholders as appropriate.
- AHS MDS responsible departments shall arrange MDP investigations when possible (i.e., the suspect medical device was retained), and when appropriate (i.e., when an investigation will provide information and/or a correction to improve safety or medical devices).
- Some reported MDPs may be appropriately managed without a physical device investigation (e.g., through photographs and descriptions).
- AHS MDS responsible departments may occasionally refer MDP reports about a medical device exclusively used in a **designated specialty area** to designated specialty area representatives for further action as appropriate (e.g., Laboratory or Pharmacy exclusive items).

4.2 AHS MDS responsible departments shall share individual medical device investigation results and reports received from Health Canada, the vendor, and any other relevant information, with the MDIP primary clinical contact, manager, AHS Legal Services and others as appropriate.

4.3 AHS MDS responsible departments shall consider, recommend, or initiate additional actions in order to prevent harm, prevent waste, promote patient safety, and promote medical device improvement based on MDIP report circumstances, investigation results received, and other relevant information as appropriate.

4.4 AHS MDS responsible departments shall document and retain according to the AHS *Record Retention Schedule*:

a) MDIP reports;

b) investigations;

c) results;

d) additional actions taken; and

e) other relevant information as appropriate.

4.5 AHS MDS responsible departments shall monitor MDIP report data, analyze the data for trends and signals of larger-scale issues, and conduct root-cause analysis as prompted by the data.

4.6 MDS responsible departments shall report:

a) individual medical device and aggregate information about investigation findings;

b) medical device improvements; and

c) other relevant information to:

AHS representatives using medical devices, managers, leaders and others as appropriate for learning, medical device improvement, and organizational benefit in accordance with the AHS *Recognizing and Responding to Hazards, Close Calls and Clinical Adverse Events* Policy and procedures.

DEFINITIONS

AHS representative means Alberta Health Services employees, members of the medical and midwifery staffs, students, volunteers, and other persons acting on behalf of Alberta Health Services (including contracted service providers as necessary).

Close call means an event that has potential for harm and is intercepted or corrected prior to reaching the patient.

Designated specialty area means Laboratory Services, Pharmacy Services, Medical Physics, and other specialty areas with medical device use that is exclusive to only that department. In consultation with AHS MDS responsible departments, they may implement safety notification procedures for medical devices that are specific to that device and area.

Harm means an unexpected outcome for the patient, resulting from the care and/or services provided, that negatively affects the patient's health and/or quality of life.

Investigation means, for the purposes of the *Medical Device Safety* Policy Suite, all activities carried out from the time of first awareness of a problem involving safety or performance of a medical device to its closure. Reported problems include:

- problems involving the medical device itself, its packaging and labelling;
- compliance with regulatory requirements, among the medical device “performance characteristics”; and
- other complaints or medical device incidents reported by patients or users of the medical device.

Medical device means an item, whether used alone or in combination, including software, intended by the manufacturer for use on patients, for any of the following purposes:

- diagnosis, prevention, monitoring, treatment, or alleviation of, or compensation for a disease, an injury, or handicap;
- investigation, replacement, or modification of the anatomy or of a physiologic process; and/or
- control of conception.

At AHS, and related entities, “Medical Devices” are generally referred to as either “equipment” or “product” to correspond with the functional work streams (acquisition, maintenance, and risk

management processes) associated with equipment (maintained medical devices) or product (consumable medical devices and surgical instruments).

Medical device incident (MDI) means, according to Health Canada, a medical device problem that has led to the death or a serious deterioration in the state of health of a patient, medical device user, or other person, or could do so were it to recur; serious deterioration in health means a life-threatening disease, disorder or abnormal physical state, the permanent impairment of a body function or permanent damage to a body structure, or a condition that necessitates an unexpected medical or surgical intervention to prevent such a disease, disorder or abnormal physical state or permanent impairment or damage. MDIs include any that occur as a result of an off-label/abnormal use. This is the equivalent of a Serious Clinical Adverse Event (CAE) or Near-Miss Serious CAE, or a worker incident with serious harm, at AHS.

Medical device problem (MDP) means, according to Health Canada, an actual or potential deficiency that may affect product performance or safety, a defect, malfunction or fault, a failure of the medical device to perform in accordance with its intended purpose when used in accordance with the manufacturer's instructions for use (MIFU), or a deterioration in its effectiveness, or any inadequacy in its labelling or in its directions for use. This includes any medical device, labelling, or packaging quality issue or safety hazard, whether or not the medical device affected a patient or other person.

Medical device-related entities means any other entity to which AHS provides medical device supply chain and/or Product Quality & Safety services pursuant to standard CPSM processes and/or Clinical Engineering Safety services pursuant to standard Capital Management processes.

Medical device safety (MDS) responsible department means the department that has responsibility to ensure medical device risk management and post-market surveillance activities are completed, such as internal and external reporting and device problem and clinical adverse event investigation, or refers or delegates those activities to another area or department. At AHS, the Medical Device Safety responsible departments are Product Quality & Safety and Clinical Engineering Safety, who may refer or delegate certain MDS activities to another area or department.

Patient means an adult or child who receives or has requested health care or services from Alberta Health Services and its health care providers or individuals authorized to act on behalf of Alberta Health Services. This term is inclusive of residents, clients and outpatients.

Quarantine means, for the purposes of the *Medical Device Safety* Policy Suite, effective restriction of the availability of a device for use, until released by a designated authority.

Suspect medical device means a medical device that is suspected to have failed to perform in accordance with its intended purpose when used in accordance with the manufacturer's instructions for use (MIFU), or a deterioration in its effectiveness, or any inadequacy in its labelling or in its directions for use.

Vendor means an individual or company that supplies, or seeks to provide, goods and/or services to AHS, and includes manufacturers, importers, and distributors.

REFERENCES

- Alberta Health Services Governance Documents:
  - *Medical Device Recall* Procedure (#PS-103-02)
  - *Medical Device Safety* Policy (#PS-103)
  - *Medical Device Safety – Preparing and Shipping for Investigation* Procedure (#PS-103-01)
  - *Recognizing and Responding to Hazards, Close Calls and Clinical Adverse Events* Policy and procedures (#PS-95)
  - *Records Retention Schedule* (#1133-01)
- Alberta Health Services Forms:
  - *Medical Device Incident or Problem (MDIP) Report* Form
- Alberta Health Services Resources:
  - *MySafetyNet*
  - *Reporting & Learning System for Patient Safety*
- Non-Alberta Health Services Documents:
  - *Medical Devices Regulations* (Canada)
  - *Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)* (Canada)

VERSION HISTORY

Date	Action Taken
	Optional: Choose an item