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NEW Reporting Requirement

Serious Adverse Drug Reactions and

Medical Device Incidents

Health Canada Santé Canada

ismp CANADA

HSO

cpsi icsp

Acknowledgment: Educational Support for Mandatory Reporting. Health Canada; 2019.

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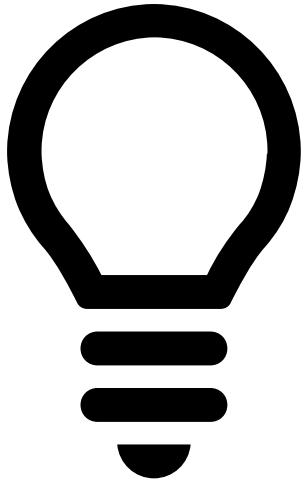
Learning Goals

1. Be able to define Serious Adverse Drug Reactions (Serious ADR) and Medical Device Incidents (MDI).
2. Know why Health Canada requires all hospitals to report Serious ADRs and MDIs.
3. Describe the reporting process, including who to notify and where to report.
4. Review case examples.
5. Successfully complete Classmarker Quiz.



Learning Goal 1:

DEFINE

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What is a Serious Adverse Drug Reaction (Serious ADR)?

A **serious adverse drug reaction (serious ADR)** is an unintended response to a drug that occurs at any dose and that:

- requires in-patient hospitalization or prolongation of existing hospitalization
- causes congenital malformation
- results in persistent or significant disability or incapacity
- is life-threatening (ie: patient was at risk of death. This does not refer to a reaction which hypothetically might have caused death if it were more severe.)
- results in death
- requires medical intervention to avoid any of the above outcomes.

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What is a Medical Device Incident (MDI)

A **medical device incident (MDI)** is a death or serious deterioration in the state of health* of a patient, user, or other person caused by:

- A failure of a medical device
- A deterioration in its effectiveness
- Any inadequacy in its labelling or in its directions

Note: Near Misses involving devices are also reportable MDIs.

*life-threatening disease, disorder or abnormal physical state, 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.

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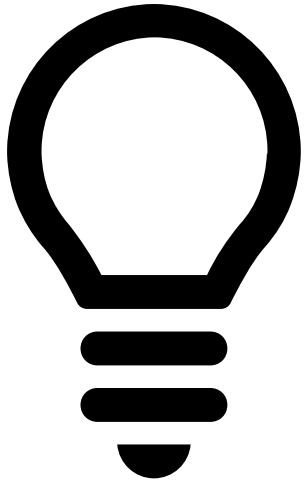
Therapeutic Products to Report

The mandatory reporting requirements for hospitals apply to:

- **Pharmaceuticals**
  - Prescription and non-prescription drugs
- **Biologic drugs**
  - Biotechnology products, fractionated blood products, plasma proteins, and vaccines, etc.
- **Radiopharmaceutical drugs**
- **Disinfectants**
  - chlorhexidine, surgical scrubs, labelled with a DIN
- **Medical devices**
  - ie: hospital beds, infusion pumps, ICDs, external pacemakers, etc.
- **Consumables**
  - IV's, tubing, dressing trays, bandages, bioglues, etc.



Learning Goal 2:

KNOW WHY TO REPORT

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Vanessa's Law (*Protecting Canadians from Unsafe Drugs Act*)

- Vanessa Young died in 2000, at the age of 15, of a cardiac arrhythmia after taking cisapride (Prepulsid®) as prescribed.
- A campaign for increased regulation of therapeutic products, headed by Vanessa's father, subsequently led to greater powers for Health Canada to request safety data from hospitals and industry about drugs and medical devices.
- **Vanessa's Law** was enacted in 2014 and the mandatory reporting requirements come into effect on December 16th, 2019.

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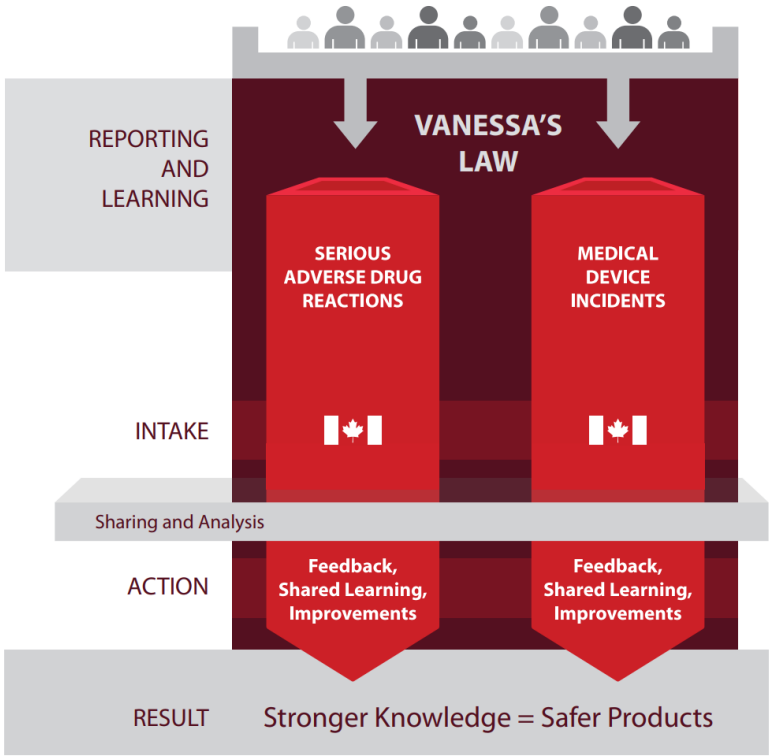
Why is Reporting Important?

- Health Canada is always looking for ways to strengthen its knowledge base on product safety in the interest of improving patient outcomes and public health.
- Serious ADR and MDI reports are important sources of information for identifying emerging safety issues.
- Serious ADR and MDI reports help us learn from incidents and make improvements to safety such as labelling changes, product information updates, or recalls.



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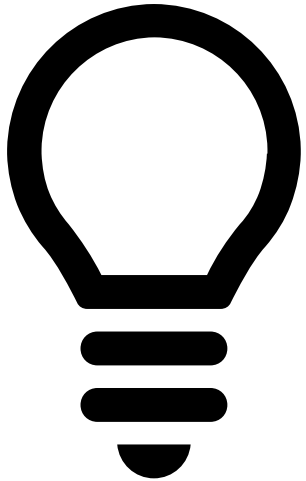
Legal Obligation to Report

- **All** hospitals must report Serious ADRs and MDIs to Health Canada.
- Reports must be made **within 30 calendar days** of first documentation of the Serious ADR or MDI within the hospital.
- All hospitals must report to Health Canada even if the incident happened at home or at another hospital.



Learning Goal 3:

REPORTING

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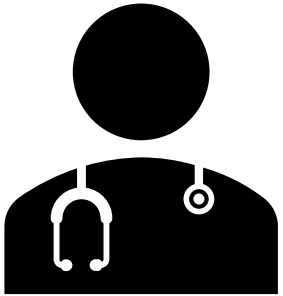
When in doubt, Report!

- **Report any suspicions, even if:**
  - You aren't 100% sure of the root cause.
  - You don't have all of the details yet.
  - The incident was a Near Miss, but could have caused death or serious harm (for MDIs only).

Quick Tips: Identifying a Serious ADR or MDI

- Serious harm from a drug or from a medical device can be mistaken for a symptom of a disease.
- A high level of suspicion, clinical awareness, and patient dialogue are key components in identifying a serious ADR or MDI.
- A serious ADR or MDI can occur shortly after beginning treatment or much later.

Quick Tips: Making an Assessment



An incident may be a Serious ADR or MDI if there is:

- An unexpected change in the patient's health condition
- A new health problem
- A need for new urgent therapies, procedures or surgeries
- Sudden need for a rescue drug, such as naloxone, epinephrine or glucagon
- A medical order for an acute change to therapy

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Reporting Process – Serious ADR

- ✓ **Notify**
  - Your Clinical Manager or the Nursing Coordinator
- ✓ **Report in SLS**

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Reporting Process – MDI

- ✓ **Notify**
  - Your Clinical Manager or the Nursing Coordinator
  - Biomed (Business hrs x17447; Off-hrs call the Bunker and ask them to page Biomed on-call)
- ✓ **Report in SLS**
- ✓ **Take the equipment out of service:**
  1. Place smaller item(s) in unit's drop-box for pick up and attach a "request for service" tag, found with the drop-box.
     - Ref# is the SLS Report #
  2. Call a porter to take the equipment to Biomed.

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RESEARCHERS

- ✓ **Notify**
  - Research Ethics Board if the Serious ADR is also unexpected (as per REB SOPs)
  - For MDIs: Biomed (Business hrs x17447; Off hrs call the Bunker and ask them to page Biomed on-call)
- ✓ **Report in SLS**
  - Reporting SADRs and MDI remains unchanged for those that occur in clinical trial participants under a Health Canada approval (CTA with NOL/NOA, ITA), and are the responsibility of the study team to report.
  - Reporting SADRs for Phase IV drug trials remains the responsibility of the study team, but will be through this new process of disclosing to the Institution for their reporting to Health Canada.
- ✓ **For MDIs: Take the equipment out of service**
  1. Place item(s) in unit's drop-box for pick up and attach a "request for service" tag, found with the drop-box.
  2. Call a porter to take the equipment to Biomed.

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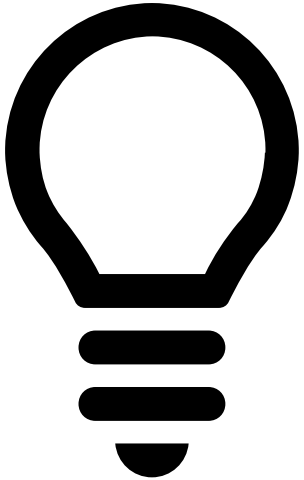
Report Form

1. The person who discovers the serious ADR or MDI is responsible for reporting it in the Safety Learning System (SLS).
2. SLS will be updated to include new data fields for Serious ADR and MDI. Please be sure to complete these fields.
3. Once in SLS, the report is sent to Quality & Patient Safety to complete the final submission to Health Canada on behalf of UOHI.



Learning Goal 4:

CASE EXAMPLES

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Case Example 1

A patient had been taking warfarin, among other medications, and presented to the emergency department with a life-threatening gastrointestinal bleed. The patient required hospitalization in order to be stabilized.

Report

Life-threatening condition

Hospitalization

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Case Example 2

A patient experienced dizziness and sweating after a dose of insulin. The patient required glucose tablets to recover. It was discovered that a short-acting insulin had been provided instead of the patient's usual long-acting insulin.

NOT a Serious ADR

This is a medication error (patient given wrong drug) and should be reported in SLS as such, rather than as a Serious ADR. Med errors such as this are preventable.

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Case Example 3

A health care professional reported that the sewing cuff was discovered to be defective during a heart valve implant. The defective valve was abandoned, a new valve was implanted, and pumping time during surgery was extended. This defect had the potential to cause serious harm.

Report

Potential for death or serious deterioration due to extended surgical time.

Possibility that defect could have been missed prior to close on other patients, leading to emergency failure.

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Case Example 4

A patient is admitted to hospital in hypoglycemic shock. The patient thinks that he was using his glucose strips properly. The nurse realizes that the patient had been using a batch of out-of-specification blood glucose test strips released by the manufacturer. The readings provide incorrect values leading to incorrect insulin dosages.

✓ Report

Serious deterioration in the state of health of a patient.

Report even though patient was not hospitalized when the strips were used.

Even though it's possible that the patient was either non-compliant or not using the test strips correctly, since the testing strips are out of specification, it is reasonable to suspect that this caused the hypoglycemic shock and to report it. Staff are not required to get to the root cause before reporting.

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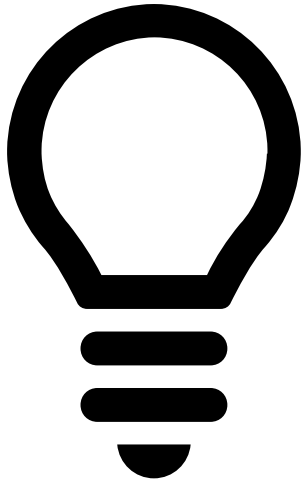
Case Example 5

A user performed an inflation test prior to inserting the balloon catheter into the patient, as required in the instructions for use accompanying the device. A malfunction on inflation was detected and another balloon was used.

Inflation test is part of the standard procedure prior to patient use to look for deficiencies and avoid patient harm.



Learning Goal 5:

QUIZ

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Take your designated quiz

If you have a Classmarker account:

- Log in to Classmarker. Your Clinical Nurse Educator has assigned this quiz to you and it will appear in your list.

All other staff:

- Please click here to take the quiz.
- Save a copy of your completion certificate and send it to your Manager.