Mandatory Reporting of Serious Adverse Drug Reactions and Medical Device Incidents by Hospitals

Educational Support for Vanessa’s Law

Module 1: Overview of Vanessa’s Law and Reporting Requirements
Goals of the Education Approach

• Support the implementation of Vanessa's Law by providing hospitals with information on Health Canada's new regulatory requirements for serious adverse drug reaction (serious ADR) and medical device incident (MDI) reporting

• Provide strategies for healthcare leadership and healthcare providers to promote and support reporting of serious ADR and MDI documented within hospitals

• Describe Health Canada’s assessment and feedback mechanisms
Components of the Education Approach

• The Education Approach provides core content about ADR and MDI reporting that can be used by healthcare leadership, healthcare providers, patients and families, and educators.

• These educational materials are designed to be building blocks (either as an individual slide or an entire module) for you to integrate into your own learning or to incorporate into orientation, continuing education and other education activities.

• There are 5 PowerPoint modules:
  Module 1 – Overview of Vanessa’s Law and Reporting Requirements
  Module 2 – Culture of Safety
  Module 3 – ADR and MDI Reporting Processes
  Module 4 – System Supports for Reporting and Learning
  Module 5 – Health Canada’s Review and Communication of Safety Findings
Module 1

Overview of Vanessa’s Law and Reporting Requirements
Learning Outcomes

Completion of Module 1 will enable you to:

- Explain the need for improved ADR and MDI reporting
- Understand the purpose and impact of Vanessa’s Law
- Describe the proposed regulations for mandatory reporting
- Recognize the required data elements for mandatory reporting of a serious ADR
- Recognize the required data elements for mandatory reporting of an MDI
- Describe tips on recognizing an ADR or MDI
Module 1 Outline – Overview of Vanessa’s Law and Reporting Requirements

1. Importance of Mandatory ADR and MDI Reporting
2. Purpose and Impact of Vanessa’s Law
3. Regulations for Mandatory Reporting
   - Who is required to report?
   - What types of reactions and incidents are reportable?
   - What therapeutic products are included in mandatory reporting?
4. Required Data Elements
   - Serious ADR report
   - MDI report
5. Timeline Requirements for Mandatory Reporting
6. Tips for Recognizing an ADR and MDI
7. Visual overview of Serious ADR and MDI Reporting and Learning
8. Key Points to Remember
9. Abbreviations
Importance of Mandatory ADR and MDI Reporting
Why Is Mandatory ADR and MDI Reporting Important?

• Health Canada is continuously looking for ways to strengthen its knowledge base on product safety in the interest of improving patient outcomes and public health.

• Under-reporting and poor quality of reports is an issue in all countries. It is estimated that only 6% of ADRs are reported.¹

Who is Vanessa?

“A rare and brilliant light, loving, caring, forgiving; home with the angels and forever in our hearts”.

- Vanessa Young died in 2000 of a cardiac arrhythmia after being prescribed cisapride (Prepulsid®).

- Her father, Terence Young, embarked on a campaign for increased regulation of therapeutic products which has resulted in greater powers for Health Canada to request safety data from hospitals and industry about drugs and medical devices.

- Vanessa’s Law received Royal Assent on November 6th, 2014.

Purpose and Impact of Vanessa’s Law
Vanessa’s Law
Protecting Canadians from Unsafe Drugs Act

• The Protecting Canadians from Unsafe Drugs Act (Vanessa's Law) introduces amendments to the Food and Drugs Act to improve Health Canada's ability to:
  o collect post-market safety information;
  o take appropriate action when a serious risk to health is identified; and
  o promote greater confidence in the oversight of therapeutic products by increasing transparency.

Vanessa’s Law
Protecting Canadians from Unsafe Drugs Act

• Amendments to the *Food and Drugs Act* include:
  1. Power to require information, tests or studies
  2. Power to require a label change/package modification
  3. Power to recall unsafe therapeutic products
  4. Ability to disclose information in certain circumstances
  5. Tougher measures for those that do not comply
  6. **Mandatory reporting of serious adverse drug reactions and medical device incidents by healthcare institutions**

Impact of Vanessa’s Law

• Improve the quality and increase the quantity of ADR and MDI reports to ensure sufficient data to detect safety problems

• Strengthen safety oversight of therapeutic products throughout their life cycle

• Promote greater confidence in the oversight of therapeutic products by increasing transparency

Regulations for Mandatory Reporting
Regulations for Mandatory Reporting – Who?

The proposed regulations apply to all hospitals regulated through provincial or territorial legislation, as well as to those operated by the federal government and that provide health services to persons who are in-patients.

• The proposed regulations define a hospital as a facility that:
  ○ is licensed, approved or designated as a hospital by a province or territory, in accordance with the laws of the province or territory, to provide care or treatment to persons suffering from any form of disease or illness; or
  ○ is operated by the Government of Canada and provides health services to in-patients.
Regulations for Mandatory Reporting – What?

**Required Information**

- The proposed regulations require hospitals to report a serious ADR or MDI to Health Canada within 30 calendar days of first documentation of the reaction within the hospital.
  - Serious ADR or MDI documentation within the hospital includes:
    - a serious ADR or MDI that is identified in a patient’s clinical/medical record;
    - a serious ADR or MDI that is identified in a separate report form (electronic or hard copy) that has been completed by a healthcare professional; and
    - a serious ADR or MDI that has been documented in an ADR form or a product complaint form (MDI) as per internal hospital policy, a pathology report, an incident/patient safety learning database, or a computerized prescription recording system.
Regulations for Mandatory Reporting – What?
Types of Reportable Reactions and Incidents

The proposed regulations require hospitals to report all documented serious ADRs as well as all documented MDIs, including MDIs with the potential to cause harm if they reoccur, where the required information is within the control of the hospital.

• A **serious ADR** is a noxious and 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, or
  - is life-threatening or results in death.

• An **MDI** is an incident related to a failure of a medical device or a deterioration in its effectiveness, or any inadequacy in its labelling or in its directions for use that has led to the death or a serious deterioration in the state of health of a patient, user, or other person, or could do so were it to recur.

When in doubt, Health Canada encourages hospitals to report.
Regulations for Mandatory Reporting – What?  
*Within the Control of the Hospital*

• Information that is **within the control** of the hospital is information that would be reasonably accessible within the hospital.

• While it is encouraged for those who document the serious ADR or MDI to take all reasonable steps to retrieve the required information to complete as thorough a report as possible, there is no requirement to do further investigation in order to obtain the pieces of information.
Regulations for Mandatory Reporting – What?

*Therapeutic Products*

- Vanessa’s Law defines a “therapeutic product” as “a drug or device or any combination of drugs and devices, but does not include natural health products within the meaning of the *Natural Health Products Regulations*.

- The proposed mandatory reporting requirements for hospitals apply to therapeutic products, including:
  - Pharmaceuticals (prescription and non-prescription)
  - Biologic drugs
  - Radiopharmaceutical drugs
  - Disinfectants
  - Medical devices
Medical Devices Described

• A **medical device** is an instrument, apparatus, contrivance or other similar article, or an in vitro reagent, including a component, part or accessory of any of them, that is manufactured, sold or represented for use in:
  
  (a) diagnosing, treating, mitigating or preventing a disease, disorder or abnormal physical state, or any of their symptoms, in human beings or animals;
  
  (b) restoring, modifying or correcting the body structure of human beings or animals of the functioning of any part of the bodies of human beings or animals;
  
  (c) diagnosing pregnancy in human beings or animals;
  
  (d) caring for human beings or animals, during pregnancy or at or after the birth of the offspring, including caring for the offspring; or
  
  (e) preventing conception in human beings or animals.

Source: [https://lois-laws.justice.gc.ca/eng/acts/F-27/page-1.html#h-1](https://lois-laws.justice.gc.ca/eng/acts/F-27/page-1.html#h-1)
Types of Medical Devices Included in Mandatory Reporting

• The term **medical device** covers a wide range of health and/or medical instruments used in the treatment, mitigation, diagnosis or prevention of a disease or abnormal physical condition.

• Medical devices are classified into **Class I** (lowest risk) to **Class IV** (highest risk)

• Examples of medical devices, by class:
  
  Class I – hospital beds
  Class II – infusion sets
  Class III – infusion pumps
  Class IV – certain pacemakers/defibrillators

• **All classes of medical devices are included in mandatory reporting by hospitals.**
Required Data Elements
Required Data Elements when Hospitals Report a Serious ADR

1. Name of the hospital and contact information of the representative of that hospital
2. Drug’s brand name, proper name or common name
3. In the case of a drug imported under Division 10 of the Regulations (Access to Drugs in Exceptional Circumstances), the identifying number or code of the drug
4. Patient’s age and sex
5. Description of the serious adverse drug reaction
6. Drug identification number assigned for the drug, if applicable
7. Date on which the patient first used the drug and, if applicable, the date on which the patient stopped using the drug
8. Date on which the serious adverse drug reaction first occurred and, if applicable, the date on which the patient’s health was restored to its state prior to the adverse drug reaction
9. Any medical condition of the patient that directly relates to the serious adverse drug reaction
10. Any concomitant therapeutic products used by the patient
11. Result of the serious adverse drug reaction on the patient’s health
Required Data Elements when Hospitals Report an MDI

1. Name of the hospital and contact information of the representative of that hospital
2. Name of the device and its identifier
3. Name of the manufacturer of the device
4. Description of the medical device incident
5. Lot number of the device or its serial number
6. Any contributing factors to the medical device incident, including any medical condition(s) of the patient that directly relates to it
7. Result of the medical device incident on the patient’s health
Methods for Submitting Serious ADR and MDI Reports to Health Canada

From a Hospital System Database
If you are interested in submitting reports electronically to Health Canada using hospital databases, please email the Canada Vigilance Program at hc.canada.vigilance.sc@canada.ca.

Directly Online
The new reporting forms for serious ADR and MDI, together with instructions, will be available on the Health Canada website in June 2019.

Fax or Mail
Download, print, and complete the applicable form and send by fax or by mail to the Canada Vigilance Office.

Fax to: 613-957-0335  
Mail to:  
Canada Vigilance Program  
Marketed Health Products Directorate  
Health Products and Food Branch  
Health Canada  
Address Locator 1908C  
Ottawa, Ontario K1A 0K9

Note: Do not send by email, as secure transfer of personal information is not ensured.
Timeline Requirements for Mandatory Reporting
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• The proposed regulations require hospitals to report serious ADRs and MDIs to Health Canada in writing **within 30 calendar days** of first documentation of the reaction or incident within the hospital.

• If the report is completed earlier than 30 days, Health Canada encourages hospitals to report sooner.

• The requirements for mandatory reporting will come into force in December 2019.
Tips for Recognizing an ADR or MDI
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• An adverse drug reaction, or harm 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 an ADR or MDI. The following can help:
  ◦ Ask about the patient’s medical history
  ◦ Consider an ADR or MDI if there is an unexpected change in the clinical condition of a patient
  ◦ Consider an ADR or MDI if a patient develops a new health problem
  ◦ Consider an ADR or MDI if there is a sudden need for a rescue drug (e.g., naloxone, epinephrine, glucagon)
  ◦ Consider that an ADR or MDI can occur shortly after beginning treatment or can occur much later
Visual overview of Serious ADR and MDI Reporting and Learning
Overview of Serious ADR and MDI Reporting and Learning
Multi-pronged Approach to Increase the Reporting of Serious ADR and MDI
Key Points to Remember

• ADR and MDI are **under-reported** in Canada and across the world.
• Vanessa’s Law aims to improve the quality and quantity of serious ADR and MDI reports to **strengthen the safety oversight** of therapeutic products.
• Vanessa’s Law mandates hospitals to report serious ADR and MDI to Health Canada within **30 calendar days** of first documentation of the reaction or incident within the hospital.
• Vanessa’s Law applies to: pharmaceuticals (prescription and non-prescription), biologic drugs, radiopharmaceutical drugs, disinfectants, and medical devices.
• There are **required data elements** for mandatory reporting of serious ADR or MDI.
• A high level of suspicion, clinical awareness, and patient dialogue are key components in identifying an ADR or MDI.
Abbreviations

• **ADR**: Adverse Drug Reaction
• **MDI**: Medical Device Incident
Use of PowerPoint Slides and Education Modules

The educational materials (either as individual slides or entire modules) can be used to explain, describe or promote ADR and MDI reporting.

The educational approach was developed by the Institute for Safe Medication Practices Canada (ISMP Canada), in a Joint Venture with Health Standards Organization (HSO) and the Canadian Patient Safety Institute (CPSI), to assist Health Canada with outreach, education and feedback regarding the Protecting Canadians from Unsafe Drugs Act (Vanessa’s Law).

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Your Thoughts are Welcome

As we continue to provide this education content we welcome your feedback:

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HSO: https://healthstandards.org/contact/

CPSI: info@cpsi-icsp.ca