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

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Introduction

- Under the Protecting Canadians from Unsafe Drugs Act (“Vanessa’s Law”) the reporting of serious adverse drug reactions (serious ADRs) and medical device incidents (MDIs) became mandatory for Canadian hospitals effective December 2019.
- Educational materials were developed to support the implementation of mandatory reporting.

Objectives

Assess the type of outreach, education and feedback needed to support serious ADR and MDI reporting

Develop and pilot test an educational approach and content

Undertake an early evaluation of the implementation of the educational approach

Methods

Advisory Panel & Project Logic Model

- created to guide the educational approach, including aims and outcomes

Needs Assessment

- included a literature review and stakeholder interviews, and provided consensus on the key considerations for development of outreach, education and feedback to facilitate serious ADR and MDI reporting in Canada

Implementation Plan

- Included principles e.g., Design for easy integration into educational programs/platforms

Educational Modules

- 4 PowerPoint modules created to explain, describe, or promote the reporting of serious ADRs and MDIs

Pilot Test & Early Evaluation

- pilot test of the educational approach and content was conducted in early 2019
- early evaluation of the implementation was conducted in mid-2019

Pilot Test (early 2019)

- Educational Approach
  - Provide core content about serious ADR and MDI reporting that can be used by hospitals, health care leadership, health care providers, patients and families, and educators
  - The content can be used as entire modules or individual slides or selected content

- Feedback was received from **255 Pilot Test participants**
  - represented individual and organizational stakeholders from across Canada
  - most respondents (83.1%) had reviewed all 4 modules
- Feedback received was incorporated into the final educational modules

Pilot Test – Key Results

89% reported that they had a good or strong understanding of the mandatory reporting requirements after reviewing the educational modules

94% indicated using some or all of the slides would be a helpful approach to communicate information about Vanessa's Law and reporting requirements

91% stated that they planned to use the slides to communicate about the mandatory reporting requirements

Early Evaluation (mid-2019)

- Goals were to track processes and impacts related to:
  - implementation of the education materials;
  - module dissemination approaches used;
  - uptake of the education materials, and
  - effectiveness of education materials.

- Evaluation data were collected via:
  - web-based analytics of education module access;
  - post-webinar questionnaire (134 responses); and
  - online questionnaire (30 responses).

Early Evaluation – Key Results

Evaluation area	Evaluation questions	Key findings
Implementation	Were the modules implemented as intended?	• Modules launched July 31, 2019
Dissemination	Are the education materials reaching the intended target audience?	• 4376 sessions between July 31 and October 16, 2019 • Stakeholders across all provinces and territories
Uptake	Are the modules being taken up? Are they accessible?	• 3763 modules downloaded (more often in PowerPoint than PDF format) • Ease of module access rated highly (mean of 4.8 out of 5)

Early Evaluation – Key Results

Evaluation area	Evaluation questions	Key findings
Effectiveness	Are the education materials helpful to the target audience?	• Module helpfulness rated highly (mean of 4.5 out of 5) • 93% indicated module content would contribute to improved serious ADR and MDI reporting
	Are the education materials useable and adaptable by the target audience?	• 57% intend to use module 1; 40% intend to use all modules • 73% reported that having content that is adaptable (i.e., adapting PowerPoint slides) is important
	Do stakeholders perceive that the learning objectives of the materials were achieved?	• Understanding of reporting requirements following modules rated highly (mean 4.5 out of 5) • Understanding of strategies to support mandatory reporting rated positively (mean 4.0 out of 5)
	Do they intend to implement and use the material within their organization/practice?	• Modules intended to be used in a variety of ways (e.g., self-learning, education of others) • 97% indicated that they would recommend the modules to colleagues • 82% and 100% (from each post-webinar questionnaire) intended to use modules

Conclusion

- The educational materials (as entire modules or as individual slides or selected content) can be used for individual learning or incorporated into presentations, orientation, continuing education, and other information-sharing activities.
- Web-based analytics demonstrate continued use of the modules:
  - 3763 modules downloaded between July 31 and October 16, 2019
  - 5718 module downloads from January 2020 to June 2021.
- Longer-term monitoring is needed to ascertain whether there is integration into organizational practices, and if so, whether these changes are contributing to improved quality and quantity of reporting.

Example slides: Module 1
Overview of Vanessa's Law and Reporting Requirements

Who was Vanessa?

- 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 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 December 16th, 2019.

Key Points to Remember

- The ***Protecting Canadians from Unsafe Drugs Act*** (Vanessa's Law) introduces amendments to the *Food and Drugs Act*, including mandatory reporting of serious adverse drug reactions (**serious ADRs**) and medical device incidents (**MDIs**) by health care institutions.
- The Act aims to improve the quality and quantity of serious ADR and MDI reports to **strengthen the safety oversight** of therapeutic products.
- The reporting of serious ADRs and MDIs contributes to **identification** of emerging safety issues, **assessment** of harm vs. benefit, **sharing** of learning, and **improvement** of product safety.
- The mandatory reporting regulations require **hospitals to report in writing** serious ADRs and MDIs to Health Canada **within 30 calendar days of first documentation** of the reaction or incident within the hospital.
- These regulations apply to **therapeutic products**, defined as: pharmaceuticals (prescription and non-prescription), biologic drugs, radiopharmaceutical drugs, disinfectants and medical devices.
- There are **required data elements** for mandatory reporting of serious ADRs and MDIs.

Example slides: Module 2
Reporting Processes to Health Canada

Submitting Serious ADR and MDI Reports to Health Canada

- Health Canada remains flexible and is able to receive reports in various formats via multiple secure submission methods, recognizing that hospital systems vary.
  - If interested in submitting reports electronically to Health Canada, please email the Canada Vigilance Program at hc.canada.vigilance.sc@canada.ca.
  - Health Canada supports report submissions using a secure File Transfer Protocol (sFTP) and continues to explore system-to-system options.
- The reporting forms for serious ADRs and MDIs, together with instructions, are available on the Health Canada website:
  - Serious ADR reporting form: https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-reporting-hospital-drug-eng.pdf
  - MDI reporting form: https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-reporting-hospital-device-eng.pdf

Key Points to Remember

- **Hospital systems, processes, policies, procedures, and forms** may need to be updated to reflect requirements for mandatory reporting of serious ADRs and MDIs to Health Canada.
- Health care professionals have an **important role** in serious ADR and MDI reporting.
- Health Canada is open to accepting **different formats for reports** of serious ADRs and MDIs, recognizing that hospital systems vary.
- It is important to understand **the differences** between serious ADRs, MDIs, medication incidents, ARs, and MDPs, and how to report them.
- The **Guidance Document** offers information to help hospitals comply with the regulatory requirements for serious ADR and MDI reporting to Health Canada.
- Health Canada values **voluntary reporting** and has programs to support it.

Example slides: Module 3
Strategies to Promote and Support Mandatory Reporting

Self-Assessment Questions for Hospitals

The following self-assessment questions may be helpful to identify opportunities to prepare for the implementation of mandatory reporting within your hospital:

- In what way is serious ADR and MDI documentation and reporting promoted?
- Are our hospital policies and procedures aligned with the mandatory reporting requirements?
- Can our hospital systems be leveraged to facilitate documentation and reporting?
- How can awareness and knowledge of serious ADR and MDI documentation and reporting be improved?
- Has our hospital leadership created an environment that supports serious ADR and MDI documentation and reporting?
- Are patients and families empowered to ask questions and be engaged in monitoring their treatments?
- Is serious ADR and MDI documentation and reporting included in orientation or education programs?
- Is the learning or feedback derived from serious ADR and MDI reports shared with health care providers?

Tips for Recognizing 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. The following can help:
  - Ask about the patient's medical history
  - Consider a serious ADR or MDI if there is:
    - an unexpected change in the patient's clinical condition
    - a new health problem for the patient
    - a need for urgent additional therapies, procedures or surgeries
    - a sudden need for a rescue drug (e.g., naloxone, epinephrine, glucagon)
    - a medical order for an acute change to therapy (e.g., abrupt discontinuation)
- A serious ADR or MDI can occur shortly after beginning treatment or much later

Example slides: Module 4
Health Canada's Review and Communication of Safety Findings

Adverse Reaction Online Database

Canada Vigilance Adverse Reaction Online Database

- Searchable database that contains information from post-market AR reports since 1965
- Contains suspected adverse reactions to health products
- Files can be exported and saved in various formats

AR reports can be searched by:

- report date, seriousness and source
- patient information (gender, age and outcomes)
- suspect health product by brand name and active ingredient
- adverse reaction term or by system organ class

Source: https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-database.html

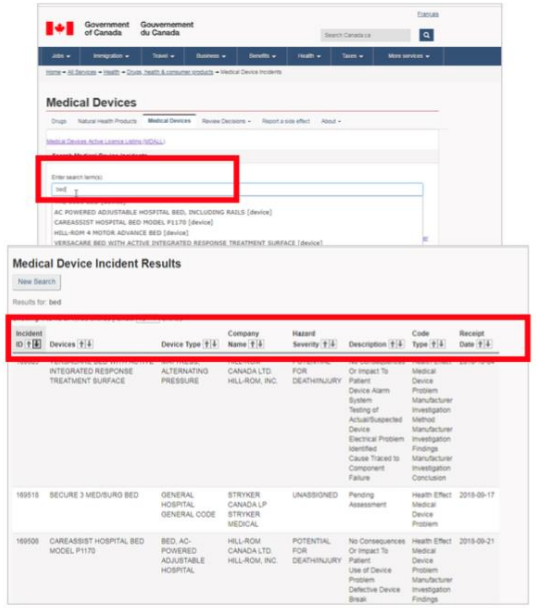
Medical Devices Online Database

Medical Device Incident Database

- Searchable database that contains information from post-market MDP reports since 1980
- Includes devices approved for the Canadian market
- Downloadable full extract available

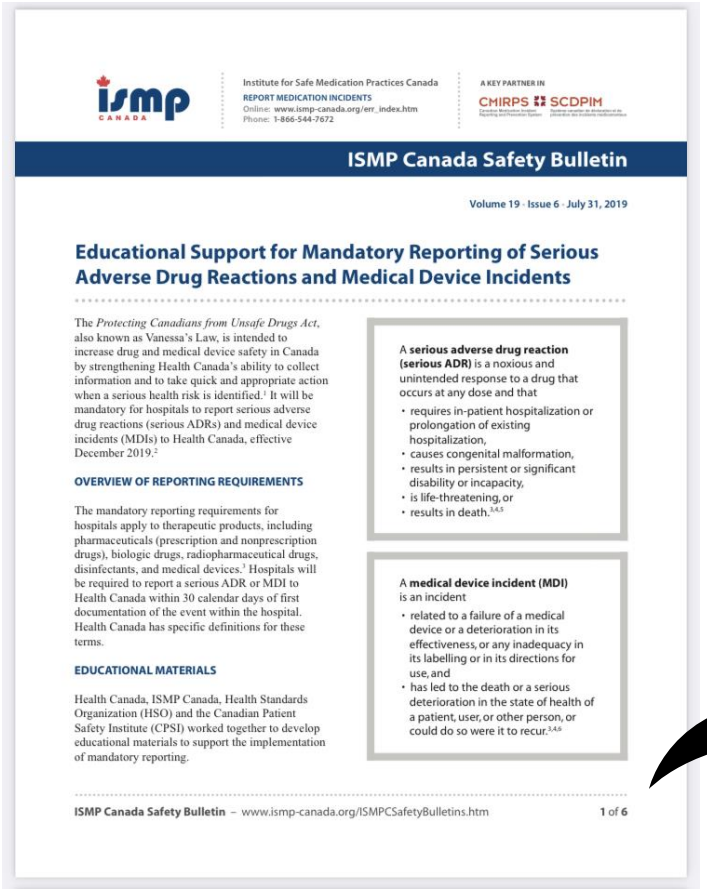
MDP reports are searched by free text and the following data is returned:

- incident ID
- receipt date
- device name
- device type
- company name
- hazard severity
- description
- code types assigned



Source: https://hpr-rps.hres.ca/mdi_landing.php

Knowledge Dissemination: Safety Bulletin Describes how ADR, MDI and Medication Error Reporting and Learning Systems Contribute to Safety in Canada



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Educational Support for Mandatory Reporting of Serious Adverse Drug Reactions and Medical Device Incidents

The *Protecting Canadians from Unsafe Drugs Act*, also known as Vanessa's Law, is intended to increase drug and medical device safety in Canada by strengthening Health Canada's ability to collect information and to take quick and appropriate action when a serious health risk is identified.[1] It will be mandatory for hospitals to report serious adverse drug reactions (serious ADRs) and medical device incidents (MDIs) to Health Canada, effective December 2019.[2]

OVERVIEW OF REPORTING REQUIREMENTS

The mandatory reporting requirements for hospitals apply to therapeutic products, including pharmaceuticals (prescription and nonprescription drugs), biologic drugs, radiopharmaceutical drugs, disinfectants, and medical devices.[3] Hospitals will be required to report a serious ADR or MDI to Health Canada within 30 calendar days of first documentation of the event within the hospital. Health Canada has specific definitions for these terms.

EDUCATIONAL MATERIALS

Health Canada, ISMP Canada, Health Standards Organization (HSO) and the Canadian Patient Safety Institute (CPSI) worked together to develop educational materials to support the implementation of mandatory reporting.

A **serious adverse drug reaction (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,
- is life-threatening, or
- results in death.[3,4,5]

A **medical device incident (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, and
- 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.[3,4,6]

Educational Modules Available from: Health Canada, ISMP Canada and CPSI websites

Acknowledgments

- All materials were developed by the collaborating parties: Health Canada, Institute for Safe Medication Practices Canada (ISMP Canada), Health Standards Organization (HSO), and the Canadian Patient Safety Institute (CPSI).

- Any stakeholder interested in using the materials should acknowledge Health Canada as the owner and source:
  Educational Support for Mandatory Reporting. Health Canada; 2019.

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Thank You

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