Institute for Safe Medication Practices Canada
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A KEY PARTNER IN
CMIRPS Canadian Medication Incident Reporting and Prevention System
SCDPIM Système canadien de déclaration et de prévention des incidents médicamenteux

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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

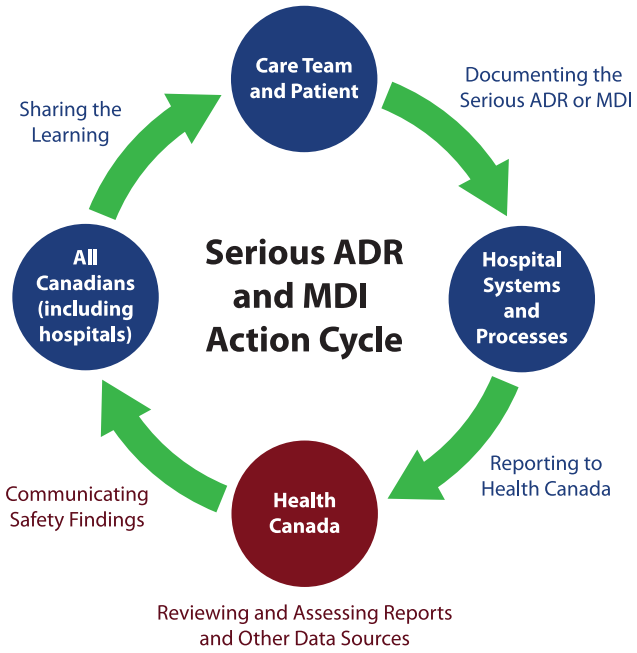
- requires in-patient hospitalization or prolongation of existing hospitalization,
- causes congenital malformation,
- results in persistent or significant disability or incapacity,
- is life-threatening, or
- results in death.[3,4,5]

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]

These materials provide information about the new regulatory requirements for mandatory reporting, describe reporting processes, offer strategies to promote and support reporting, and describe Health Canada's review and communication of safety findings (Figure 1).

Figure 1. Conceptual model of serious ADR and MDI reporting by hospitals.[7]



There are 4 PowerPoint modules that contain core content intended for use by hospitals, health care professionals, educators, and patients and their families, to explain, describe, or promote the reporting of serious ADRs and MDIs. These 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.

The modules were developed following a needs assessment and creation of an implementation plan. A pilot test was conducted over 3 weeks in March and April 2019 and garnered feedback from 255 of the pilot participants, who represented individual and organizational stakeholders from across Canada. The largest numbers of respondents were "pharmacists" and "hospitals". Most respondents (83.1%) had reviewed all modules.

The following are key results from the pilot test:

- 89% of respondents reported that they had a good or strong understanding of the mandatory reporting requirements after reviewing the educational modules
- 94% indicated that using some or all of the slides would be a helpful approach to communicate information about Vanessa's Law and reporting requirements
- 91% of respondents indicated that they planned to use the slides to communicate about the mandatory reporting requirements
- Many respondents provided helpful suggestions for additional information to be included in the final version of the PowerPoint modules.
- Respondents also provided suggestions for additional educational formats that could be considered for knowledge dissemination/ translation in the future.

The educational modules were refined on the basis of the pilot feedback and Health Canada review. Updated modules are available from: https://www.patientsafetyinstitute.ca/en/toolsResources/Vanessas-Law/Pages/default.aspx

Module 1: Overview of Vanessa's Law and Reporting Requirements
Module 2: Reporting Processes to Health Canada
Module 3: Strategies to Promote and Support Mandatory Reporting
Module 4: Health Canada's Review and Communication of Safety Findings

The modules are intended to inform both health care providers and patients, to raise awareness of Vanessa's Law, and to support reporting and learning. It is expected that individuals and organizations will be able to use these materials in various ways:

- *Hospitals* can include some or all of the content in information-sharing activities (e.g., "Lunch and Learn" sessions, presentations, orientation programs for staff).
- *Educators* in the health care sector can use the content in presentations or as part of a curriculum.

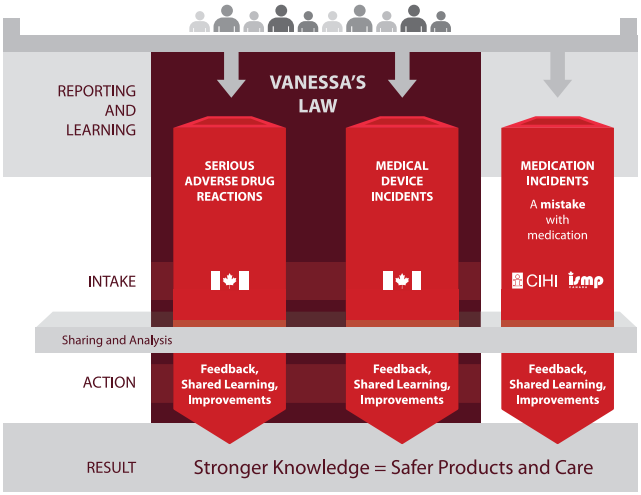
- *Professional associations, societies, and regulatory colleges, as well as other training institutions for health care workers*, may incorporate the content of the modules into accredited courses or continuing education certification programs.
- *Patient and consumer organizations* can help disseminate some or all of the information in the modules to increase awareness and knowledge among their members.

REPORTING AND LEARNING CONTRIBUTE TO THE SAFETY OF HEALTH PRODUCTS AND HEALTH CARE (Figure 2)

- Under Vanessa's Law, the reporting of serious ADRs and MDIs to Health Canada is mandatory for hospitals.[8]
  Note: Voluntary reporting of adverse reactions and medical device problems continues to be encouraged in all health care settings.
- Medication incident-related reporting and learning occurs through a separate and complementary program, the Canadian Medication Incident Reporting and Prevention System (CMIRPS).[9,10]

Analysis and shared learning from all of these reports contribute to continuous improvement in the safety of health products and health care.

Figure 2. Reporting and learning contribute to the safety of health products and health care.



References

1. Protecting Canadians from Unsafe Drugs Act (Vanessa's Law): questions/answers. Ottawa (ON): Government of Canada; 2014 Oct 31 [cited 2019 Apr 15]. Available from: https://www.canada.ca/en/health-canada/services/drugs-health-products/legislation-guidelines/questions-answers-regarding-law-protecting-canadians-unsafe-drugs-act-vanessa-law.html
2. Regulations amending certain regulations made under the Food and Drugs Act (post-market surveillance of medical devices). Can Gazette Part I. 2019 Jun 15 [cited 2019 Jul 14]; 153(24). Available from: http://www.gazette.gc.ca/rp-pr/p1/2019/2019-06-15/html/reg7-eng.html
3. Mandatory reporting of serious adverse drug reactions and medical device incidents by hospitals. Guidance document. Ottawa (ON): Health Canada; 2018 Jul [cited 2019 July]. Available from: https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-hospital-reporting/drugs-devices/guidance.html
4. Regulations amending the Food and Drugs Regulations (serious adverse drug reaction reporting – hospitals). Can Gazette Part I. 2018 Jun 16 [cited 2019 Apr 22];152(24): 2225-2264. Available from: http://www.gazette.gc.ca/rp-pr/p1/2018/2018-06-16/html/reg5-eng.html
5. Food and Drug Regulations, C.R.C., c. 870. Ottawa (ON): Government of Canada; 2019 Jun 26 [cited 2019 Jun 23]. Available from: https://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._870/page-92.html#s-C.01.001
6. Medical Device Regulations, SOR/98-282. Ottawa (ON): Government of Canada; 2019 Jun 26 [cited 2019 Jul 14]. Available from: https://laws-lois.justice.gc.ca/eng/regulations/SOR-98-282/page-7.html#h-1021831
7. Educational support for mandatory reporting: Module 1 – Overview of Vanessa's Law and Reporting Requirements. Health Canada; 2019. Available from: https://www.patientsafetyinstitute.ca/en/toolsResources/Vanessas-Law/Pages/default.aspx
8. Overview of Vanessa's Law. Ottawa (ON): Government of Canada; 2014 Nov 6 [cited 2019 May 9]. Available from: https://www.canada.ca/en/health-canada/services/drugs-health-products/legislation-guidelines/overview-vannessa-law-protecting- canadians-unsafe-drugs-act-vanessa-law-amendments-food-drugs-act.html
9. Health Canada's role in the management and prevention of harmful medication incidents. Ottawa (ON): Government of Canada; 2011 Jun 20 [cited 2019 May 8]. Available from: https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/medeffect-canada-role-management-prevention-harmful-medication-incidents.html
10. CMIRPS: The Canadian Medication Incident Reporting and Prevention System [website]. CMIRPS Collaborating Parties; © 2011-18 [cited 2019 May 9]. Available from: https://www.cmirps-scdpim.ca/?lang=en

NEW!

Focus on Never Events
Medication Safety Self-Assessment

ISMP Canada and the Canadian Patient Safety Institute (CPSI) would like to thank all those who took part in our pilot of the Medication Safety Self-Assessment: Focus on Never Events (MSSA – Never Events) in December 2018 and January 2019. We have incorporated comments received during the pilot and are pleased to announce the launch of this assessment program. In addition, in response to feedback from pilot participants, we have developed a separate version of the assessment program for the long-term care setting. This is ISMP Canada's 11th MSSA program; unique to this iteration of the MSSA is its focus on key pharmaceutical "never events",[1] as well as safety strategies targeted to high-alert medications.

"Never events" are patient safety incidents that result in serious harm or death, and that can be prevented by using organizational checks and balances.

This program will help Canadian health care practitioners to identify vulnerabilities in their own settings with the goal of preventing similar incidents. This assessment is aligned with the World Health Organization Global Patient Safety Challenge: Medication Without Harm.[2]

The MSSA – Never Events is an online self-administered questionnaire about policies and practices at the participating site. After submitting data into the online survey, participants will be able to view and graph their own results and compare their responses with those in the aggregate database. Data submitted by participants are anonymized and will be used by ISMP Canada and CPSI to identify future opportunities for improvement.

Highlights from the Pilot

A total of 33 sites (21 hospitals, 3 ambulatory care centres, and 9 long-term care homes) completed the pilot version of the assessment. Although the majority of respondents were from Ontario, most of the provinces and territories were represented.

The selected pharmaceutical "never events" were most relevant to hospitals and participating sites scored well (i.e., > 75% of maximum) on these items. Analysis of responses to other sections of the assessment revealed a possible opportunity for hospitals relating to strategies to reduce the risk of confusion between lipid-based medications and their conventional formulations, for which scores at all sites were only 50% of the maximum.

In long-term care, most of the participating homes indicated that they did not use standardized protocols to direct reversal of anticoagulation, which presents a potential improvement opportunity in this setting.

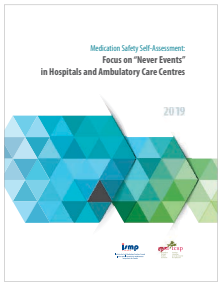
Half of the sites that participated in the pilot assessment also completed a post-assessment evaluation of their experience. Most teams reported finishing the assessment in 2 hours or less (i.e., during a single team meeting). More than 80% of respondents felt that the learning gained from this program was valuable or highly valuable, and all respondents indicated that they would recommend this MSSA to a colleague in another facility.

Accessing the MSSA – Never Events

The MSSA – Never Events is available free of charge to all Canadian health care organizations.

Documents related to the MSSA – Never Events are available in both English and French. However, at this time, the MSSA – Never Events online program (for submission of data and completion of the assessment) is available in English only; a French version of the online program will be released later in 2019.

For more information visit ISMP Canada's MSSA page. (https://www.ismp-canada.org/mssa.htm)



References

1. Never events for hospital care in Canada. Health Quality Ontario and Canadian Patient Safety Institute; 2015 [cited 2019 July 9]. Available from: https://www.patientsafetyinstitute.ca/en/toolsResources/NeverEvents/Documents/Never%20Events%20for%20Hospital%20Care%20in%20Canada.pdf
2. WHO's Third Global Patient Safety Challenge: Medication Without Harm. World Health Organization; [cited 2019 July 9]. Available from: https://www.who.int/patientsafety/medication-safety/en/

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Wednesday, September 18, 2019

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CMIRPS SCDPIM
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The Canadian Medication Incident Reporting and Prevention System (CMIRPS) is a collaborative pan-Canadian program of Health Canada, the Canadian Institute for Health Information (CIHI), the Institute for Safe Medication Practices Canada (ISMP Canada) and the Canadian Patient Safety Institute (CPSI). The goal of CMIRPS is to reduce and prevent harmful medication incidents in Canada.

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ismp CANADA

The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent national not-for-profit organization committed to the advancement of medication safety in all healthcare settings. ISMP Canada's mandate includes analyzing medication incidents, making recommendations for the prevention of harmful medication incidents, and facilitating quality improvement initiatives.

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