



## Mandatory reporting

of serious adverse drug reactions and medical device incidents to Health Canada takes effect **December 16, 2019**.

National  
System  
for Incident  
Reporting

# NSIR



Canadian Institute  
for Health Information  
Institut canadien  
d'information sur la santé

## Collect. Analyze. Share. Learn.



Welcome to the quarterly National System for Incident Reporting (NSIR) electronic bulletin. This is where you can find information on medication and radiation treatment incident reporting and analysis for sharing and learning across Canada.

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# Highlights

## Vanessa's Law — *Protecting Canadians From Unsafe Drugs Act*

### Who was Vanessa?

Vanessa Young died suddenly of a heart attack on March 19, 2000, while taking Prepulsid. She was 15 years old. At that time, Prepulsid (cisapride) was the subject of clear warnings in the United States.<sup>1</sup>

### What is Vanessa's Law?

Terence Young, Vanessa's father and Member of Parliament for Oakville, Ontario, introduced Vanessa's Law in 2014; it was signed into Canadian law on November 5, 2014.<sup>2</sup>

The bill has empowered Health Canada to<sup>3</sup>

- Require strong surveillance, ***including mandatory adverse drug reaction reporting by health care institutions***;
- Recall unsafe therapeutic products;
- Impose tough new penalties for unsafe products, including jail time and new fines of up to \$5 million per day instead of the current \$5,000;
- Provide the courts with discretion to impose even stronger fines if violations were caused intentionally;
- Compel drug companies to revise labels to clearly reflect health risk information, including potential updates for health warnings for children; and
- Compel drug companies to do further testing on a product, including when issues are identified with certain at-risk populations such as children.

### Mandatory reporting of ADRs and MDIs

Starting in December 2019, hospitals will be required to report serious adverse drug reactions and medical device incidents to Health Canada.<sup>4</sup>

Health Canada defines the terms as follows:<sup>4</sup>

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.

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 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.

## Where and how do I report?

Serious adverse reactions to health products and MDIs are reported to Health Canada's [Canada Vigilance Program](#).

Health Canada can receive reports using various submission methods and formats, which allow hospitals to select the most efficient method.<sup>4 (s. 7.4)</sup>

### 1. Electronic reporting

Facilities can submit reports electronically (e.g., secure File Transfer Protocol [sFTP], system-to-system exchanges). For more information, email Health Canada's Vigilance Program at [hc.canada.vigilance.sc@canada.ca](mailto:hc.canada.vigilance.sc@canada.ca).

### 2. Online

Facilities can submit a report using the online reporting applications available at [MedEffect Canada](#).

### 3. Mail or fax

Hospitals can report ADRs and MDIs using the following forms and submit them via mail or fax:<sup>4 (s. 7.4)</sup>

[Serious Adverse Drug Reaction Reporting Form for Hospitals](#)

[Medical Device Problem Report Form for Health Care Professionals](#)

Mail: Canada Vigilance Program  
Health Products Surveillance and Epidemiology Bureau  
Marketed Health Products Directorate  
Health Products and Food Branch  
Health Canada  
Address Locator 1908C  
Ottawa, Ontario K1A 0K9

Fax: 1-866-678-6789

## Where can I learn more about ADR and MDI reporting?

Contact the Canada Vigilance Program via email at [hc.canada.vigilance.sc@canada.ca](mailto:hc.canada.vigilance.sc@canada.ca) or call 1-866-234-2345.

## Where can I find educational support/materials?

Educational materials to support the implementation of ADR reporting developed by Health Canada, the Institute for Safe Medication Practices (ISMP) Canada, the Canadian Patient Safety Institute and Health Standards Organization are available online.<sup>5</sup> These educational resources support and promote awareness of the mandatory reporting program for hospital staff, educators, professional associations/regulatory colleges and patients/consumers.<sup>6, 7</sup>

The materials include 4 PowerPoint modules:

**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

### **Can I report my ADRs through NSIR?**

Adverse drug reactions cannot be reported to NSIR. NSIR only collects information on medication and radiation treatment incidents from participating facilities.

In the vast majority of cases, ADRs are not medication incidents. Unlike a medication incident, an ADR generally doesn't involve a mistake and typically can't be prevented.<sup>7</sup>

### **Other resources**

[Mandatory reporting of serious adverse drug reactions and medical device incidents by hospitals](#)

(Health Canada Guidance document)

[Educational Support for Mandatory Reporting of Serious Adverse Drug Reactions and Medical Device Incidents](#) (ISMP Canada)

[Protecting Canadians From Unsafe Drugs Act \(Vanessa's Law\)](#)

[Death by Prescription](#) (by Terence Young)

## Sharing and learning

### **Sharing details of critical incidents**

The occurrence of a critical incident is unsettling to all involved. Careful reflection on the details of the event afterward can result in a constructive outcome and lasting change. Sharing the results of an incident investigation through NSIR can have a widespread impact. There are 6 data elements applicable for critical incidents that make up the Investigation and Findings Domain in NSIR-Rx.

- Patient/Resident Informed of Incident
- Likelihood of Recurrence
- Interventions Required
- Unplanned Admissions/Readmission
- Root Cause Analysis Status
- Future Strategies/Recommendations

Recommendations developed in the wake of a critical incident can be shared using the text field Future Strategies/Recommendations. Organizations such as ISMP Canada look carefully at this section to inform the work they do. All facilities that participate in NSIR can view this field to inform their own work on similar areas of safe practice. For example, if an organization had a recent incident involving an overdose of hydromorphone, it could look to NSIR for similar incidents to read the recommendations documented with other similar incidents. One such event reported to NSIR listed the following recommendations:

1. Implement concentration and hard limits for all high-risk medications based on gap analysis and inventory. Provide relevant education and training for all nursing staff.
2. Establish standard concentration for subcutaneous infusion versus intravenous infusions.
3. Ensure order sets for infusions match pharmacy standard concentrations and the drug library settings for smart pumps.
4. Establish criteria for when infusions must be maintained on a pump (e.g., all high-risk medications).
5. Make sure that transfer of accountability includes a clear process for independent double-check of high-risk medications.
6. Ensure that pharmacies review and implement reference charts at all sites where required and that they are accessible for areas that do not use electronic Medication Administration Record (eMAR) software.

ISMP Canada has published a number of articles on hydromorphone with recommendations for safe practice, some of which are similar to those offered in the example<sup>8,9</sup>

Another critical incident involving administration of paliperidone to the wrong patient provided the following recommendations:

1. Change in policy to require an independent double-check for paliperidone and all other antipsychotic medications that do not have a reversal agent/antidote.
2. Audits required to check for compliance of positive patient ID.
3. Patient Safety Culture Survey — Use recent results of survey to assist with unit-specific endeavours aimed at improving teamwork and psychological safety.

Recommendations, such as those above, are created in response to a single tragedy. However, the changes address systemic issues that target processes and policies in an attempt to improve the overall safe practices of an organization. They are often real-world, practical solutions that could be implemented in other facilities. We encourage you to share the learning and recommendations with your critical incidents submitted to NSIR.

## **ISMP Canada's recent safety bulletins and newsletters**

[Educational Support for Mandatory Reporting of Serious Adverse Drug Reactions and Medical Device Incidents](#)

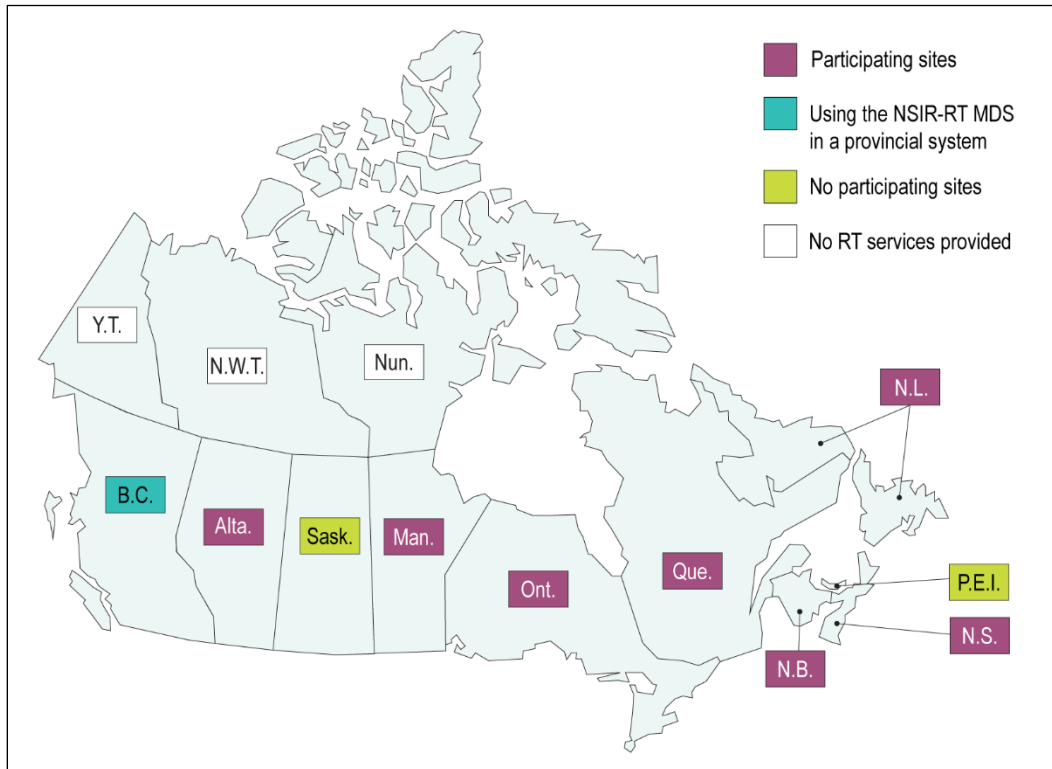
[Potentially Harmful Interaction Between Polyethylene Glycol Laxative and Starch-Based Thickeners](#)

[Mistaken Identity — A Recurring Problem](#)

[Protecting Canadians From Unsafe Drugs Act — What It Means for You](#)

# NSIR — Radiation Treatment (RT)

## NSIR-RT updates



NSIR-RT continues to add new participating centres across Canada.

- Participation in NSIR-RT is excellent, with 66% of RT centres signed on to provide data. Newfoundland and Labrador, Nova Scotia, New Brunswick, Quebec, Ontario, Manitoba and Alberta have some or all centres with signed agreements to participate. Translation of the NSIR-RT system, which is underway, will increase the appeal of NSIR-RT to sites in Quebec and New Brunswick.
- British Columbia is currently collecting data using the NSIR-RT data standard and plans to participate through a recently developed application program interface enabling the BC Patient Safety & Learning System to connect to NSIR-RT.
- Saskatchewan and Prince Edward Island currently do not have participating sites. Each has contacted CIHI about participation, and steps toward a signed service agreement have been initiated.
- No radiation treatment services are provided in Yukon, the Northwest Territories or Nunavut.

# Additional information

## Upcoming conferences and learning



### [Canadian Patient Safety Week](#)

October 28 to November 1, 2019

The Canadian Patient Safety Institute invites all Canadians — the public, providers and leaders — to become involved in making patient safety a priority.

### [ISMP Canada Med Safety Exchange webinar series](#)

November 20, 2019

Join your colleagues across Canada for ISMP Canada's complimentary bimonthly 50-minute webinars, where they share, learn about and discuss incident reports, as well as trends and emerging issues in medication safety.

To register and for more information on this series, please visit [ISMP Canada — Med Safety Exchange](#).

## Recent CIHI releases

### [New data available on home care and mental health and addictions](#)

May 30, 2019

This media release is about 3 new indicators that show how Canada's health systems are faring in home care and mental health and addictions services.

### [Falls and vehicle collisions top causes of injury hospitalizations for seniors](#)

July 11, 2019

Learn more about emergency department visits and hospitalizations for injuries among seniors in Canada in recent years, particularly during 2017–2018.

## Contact us



Thank you for taking the time to read the NSIR eBulletin. Unless otherwise stated, the reported NSIR findings are based on the voluntary reporting of incidents at participating health care facilities across Canada. If there is anything you would like to see featured in an upcoming edition, please contact us at [nsir@cihi.ca](mailto:nsir@cihi.ca).

The NSIR eBulletin is distributed on a quarterly basis. Previous editions can be found on the [NSIR web page](#).

[Twitter](#) | [Facebook](#) | [LinkedIn](#) | [Instagram](#) | [YouTube](#)

## References

1. CBC News. [Inquest continues into Oakville teenager's death](#). March 20, 2001.
2. National Post. [MP's 14-year mission to make prescription drug use safer nearly over with law named after his late daughter](#). October 7, 2014.
3. Health Canada. [Protecting Canadians From Unsafe Drugs Act \(Vanessa's Law\): Questions/answers](#). Accessed September 11, 2019.
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5. Institute for Safe Medication Practices Canada. [Educational support for mandatory reporting of serious adverse drug reactions and medical device incidents](#). *ISMP Canada Safety Bulletin*. July 31, 2019.
6. Canadian Patient Safety Institute. [Educational support for mandatory reporting of serious ADRs and MDIs by hospitals](#). Accessed September 11, 2019.
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9. Institute for Safe Medication Practices Canada. [Shared learning — Reported incidents involving hydromorphone](#). *ISMP Canada Safety Bulletin*. December 28, 2006.