

Vanessa's Law
Protecting Canadians from Unsafe Drugs Act

**Serious Adverse Drug Reaction
and Medical Device Incident
Reporting**



PATIENTS FOR PATIENTS POUR LA
PATIENT SAFETY SÉCURITÉ DES PATIENTS
CANADA DU CANADA

Outline

- *Protecting Canadians from Unsafe Drugs Act* (also known as Vanessa's Law)
- Mandatory Reporting
 - Who is required to report?
 - What is a serious adverse drug reaction?
 - What is a medical device incident?
- Patients as Partners in Safety
- How Patients Can Submit Reports to Health Canada
- How Health Canada Shares Information with the Public
- Key Points to Remember

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

The *Protecting Canadians from Unsafe Drugs Act* (Vanessa's Law) introduces the requirement for **mandatory reporting of serious adverse drug reactions and medical device incidents** by hospitals.

The Law improves Health Canada's ability to:

- collect safety information;
- take appropriate action (such as a label change or a product recall) when a serious health risk is identified; and
- increase transparency (by sharing more information).

Source: <https://www.canada.ca/en/health-canada/services/drugs-health-products/legislation-guidelines/protecting-canadians-unsafe-drugs-act-vanessa-law-amendments-food-drugs-act.html>

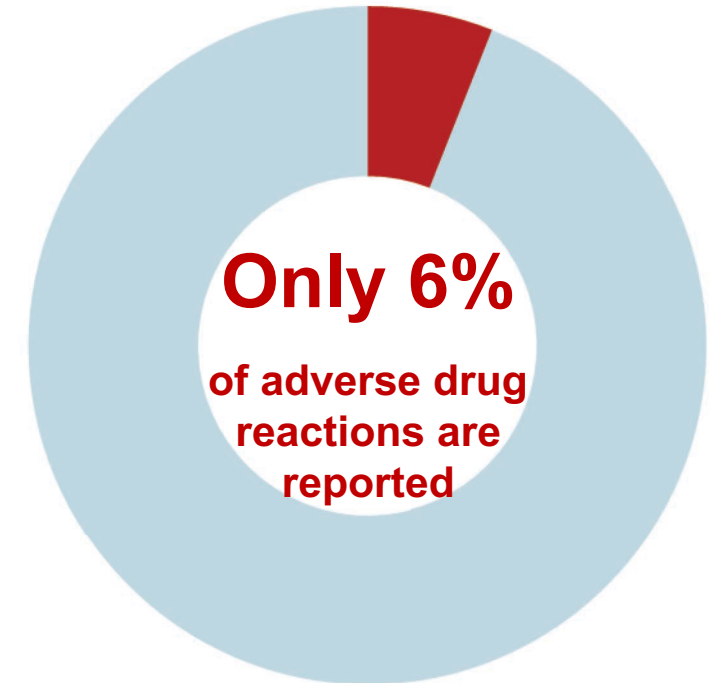
Who was Vanessa?

- Vanessa Young died at the age of 15, in 2000. She experienced a cardiac problem after taking cisapride (Prepulsid®) as prescribed.
- A campaign for increased regulation of drugs and devices was created.
- **Vanessa's Law** was enacted in 2014 and the mandatory reporting requirements come into effect December 16th, 2019.



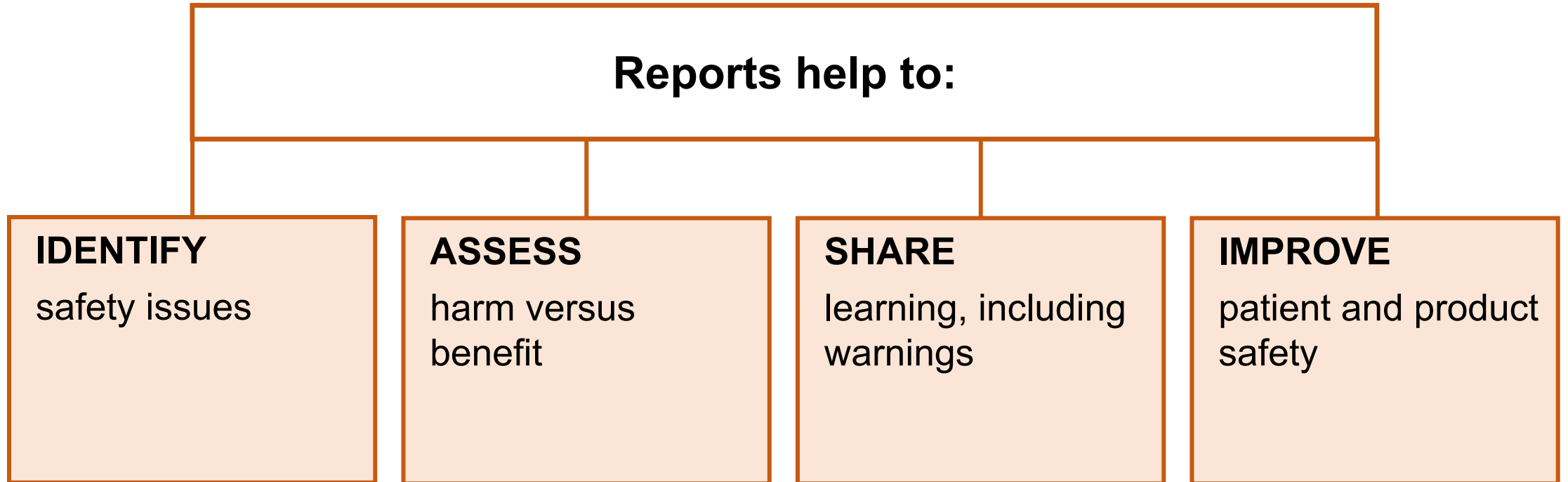
Why Is Mandatory Reporting Important?

- Health Canada looks at serious adverse drug reaction and medical device incident reports as an important source of information for identifying safety issues.
- Under-reporting and poor quality of reports is an issue in all countries. An international review estimated that only 6% of adverse drug reactions are reported.¹



¹ Hazell L, Shakir SAW. Under-reporting of adverse drug reactions: a systematic review. Drug Saf. 2006;29(5):385-396.

What Are the Benefits of Reporting?



Who Is Required to Report?

The requirement for mandatory reporting applies to **all hospitals**.

- The requirement applies to outpatient clinics if they are legally part of the hospital.
- Health care institutions that are not defined as hospitals, such as private clinics or long-term care facilities (e.g., nursing homes), continue to be encouraged to report on a voluntary basis.

What is a Serious Adverse Drug Reaction?

Serious adverse drug reactions are harms from a drug that are severe enough to result in hospital admission, birth defects, long-lasting disability or incapacity, a life-threatening medical situation, or death.



Examples of Serious Adverse Drug Reactions

- Kidney damage from a diuretic (water pill) that requires dialysis
- Lung damage from a chemotherapy drug that requires long-term oxygen therapy
- Allergic reaction to an antibiotic that is life-threatening

What is a Medical Device Incident?

Medical device incidents are problems with any type of medical product or equipment that led to or could have led to a serious health concern.



Examples of Medical Device Incidents

- An infusion pump stopped working and did not give an alarm. The patient needed a longer stay in hospital.
- A defibrillator used to treat a cardiac arrest did not work properly. The patient was not revived.
- A prosthetic knee replacement failed due to damaged material.
- A breast implant was suspected of causing a rare cancer.

Tips for Recognizing Harm from a Drug or Device

- Harm from a drug or from a medical device can be mistaken for a symptom of a disease.
- Awareness and conversation with health care providers are key components in identifying a serious adverse drug reaction or medical device incident.
- Consider a serious adverse drug reaction or medical device incident if there is:
 - a new health problem or unexpected change in health
 - a sudden need for treatments, procedures or surgeries
 - a sudden need for a rescue drug or antidote (e.g., naloxone, epinephrine, glucagon)
 - a sudden need to change treatment (e.g., stop a drug or device)
- A serious adverse drug reaction or medical device incident can occur shortly after beginning treatment or much later

We All Have a Role in Safety



Patients as Partners in Safety

- Patients and families ask questions and monitor their treatments.
 - The *5 Questions to Ask about your Medications* is a helpful resource.
- Patients and families can also report.
 - If you suspect that harm has been caused by a drug or device, you may talk to your health care provider about submitting a report.
 - You may also submit reports directly to Health Canada



Source: <https://www.ismp-canada.org/medrec/5questions.htm>

How Patients Can Submit Reports to Health Canada

The [Report an Adverse Reaction or Medical Device Problem](https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) web page provides access to more information and forms.



The screenshot shows the top navigation bar of the Health Canada website. It includes the Canadian flag, the text 'Government of Canada' and 'Gouvernement du Canada', a search bar with the text 'Search Canada.ca', and a 'Français' link. Below the navigation bar is a 'MENU' button. The breadcrumb trail reads: 'Home > Departments and agencies > Health Canada > Drugs and Health Products > MedEffect Canada'. The main heading is 'Report an adverse reaction or medical device problem'. Below this is a subheading: 'Reporting adverse reactions and medical device problems by consumers, health professionals and regulated parties, including industry and hospitals.' The section 'On this page' contains a list of five links: 'What are adverse reactions and medical device problems', 'Consumers and health professionals: voluntary reporting', 'Voluntary reporting: how to report an adverse reaction or medical device problem', 'Industry, hospitals and other regulated parties: mandatory reporting', and 'Mandatory reporting: how to report an adverse reaction or medical device problem'.

 Government of Canada / Gouvernement du Canada

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MENU

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Report an adverse reaction or medical device problem

Reporting adverse reactions and medical device problems by consumers, health professionals and regulated parties, including industry and hospitals.

On this page

- [What are adverse reactions and medical device problems](#)
- [Consumers and health professionals: voluntary reporting](#)
- [Voluntary reporting: how to report an adverse reaction or medical device problem](#)
- [Industry, hospitals and other regulated parties: mandatory reporting](#)
- [Mandatory reporting: how to report an adverse reaction or medical device problem](#)

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

Patients Can Contact Health Canada

The [Canada Vigilance Program](#) collects and assesses reports of harm involving health products marketed in Canada.

Voluntary Reporting for Health Products

- Online form: <https://hpr-rps.hres.ca/static/content/form-formule.php>
- Telephone: 1-866-234-2345 (toll-free)
- Fax or Mail: Download, print and complete the [Side Effect Reporting Form](#) (please read the instructions before completing the form)
 - Fax: 1-866-678-6789 (toll-free)
 - Mail: Canada Vigilance Office (using the postage paid label)

How Health Canada Shares Information with the Public

Health Canada shares findings with the public to **alert** and **educate** about risks related to health products.

Multiple sources of safety information are available:

- [Adverse Reaction Online Database](https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-database.html) (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-database.html)
- [Medical Device Incidents Database](https://hpr-rps.hres.ca/mdi_landing.php) (https://hpr-rps.hres.ca/mdi_landing.php)
- [Annual AR/MDP Trends Report](https://www.canada.ca/en/health-canada/services/publications/drugs-health-products/annual-trends-adverse-reaction-case-reports-health-products-medical-device-problem-incidents.html) (https://www.canada.ca/en/health-canada/services/publications/drugs-health-products/annual-trends-adverse-reaction-case-reports-health-products-medical-device-problem-incidents.html)
- [Health Canada Safety Reviews](https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/safety-reviews.html) (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/safety-reviews.html)
- [Health Canada Recalls and Safety Alerts](http://www.healthy Canadians.gc.ca/recall-alert-rappel-avis/index-eng.php?cat=3) (http://www.healthy Canadians.gc.ca/recall-alert-rappel-avis/index-eng.php?cat=3)
- [Health Product InfoWatch](https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/health-product-infowatch.html) (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/health-product-infowatch.html)
- [Drug and Health Product Register \(DHPR\)](https://hpr-rps.hres.ca/) (https://hpr-rps.hres.ca/)



Adverse Reaction Online Database

Canada Vigilance Adverse Reaction Online Database

- Searchable database with information from reports since 1965

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

The screenshot shows the official website for the Canada Vigilance Adverse Reaction Online Database. At the top, there is a header with the Government of Canada logo and a search bar. Below the header, a breadcrumb trail reads: Home > Drugs & Health Products > MedEffect Canada > Canada Vigilance Adverse Reaction Online Database. The main heading is "Search the Canada Vigilance Adverse Reaction Online Database". Below this, it says "From Health Canada". A grey box contains a note: "Select the help icon throughout this page for definitions of particular terms. Unless specified, all search criteria are optional and set to default values." The section "1. Report Search Criteria" is highlighted in blue. It states: "This database includes data from 1965-01-01 to 2019-03-31 only." Below this, there are radio buttons for "Initial Received Date" (selected) and "Latest Received Date". There are also input fields for "From (yyyy-mm-dd)" with the value "1965-01-01" and "To (yyyy-mm-dd)" with the value "2019-03-31". A link "Help with Report Search Criteria Section" is visible in the top right of the search criteria section.

Franglais

Government of Canada / Gouvernement du Canada

Search Canada.ca

MENU

Home > Drugs & Health Products > MedEffect Canada > Canada Vigilance Adverse Reaction Online Database

Search the Canada Vigilance Adverse Reaction Online Database

From [Health Canada](#)

Select the help icon throughout this page for definitions of particular terms. Unless specified, all search criteria are optional and set to default values.

1. Report Search Criteria

[Help with Report Search Criteria Section](#)

This database includes data from 1965-01-01 to 2019-03-31 only.

☒ Initial Received Date ☐ OR ☐ Latest Received Date

From (yyyy-mm-dd) 1965-01-01

To (yyyy-mm-dd) 2019-03-31

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

Medical Devices Online Database

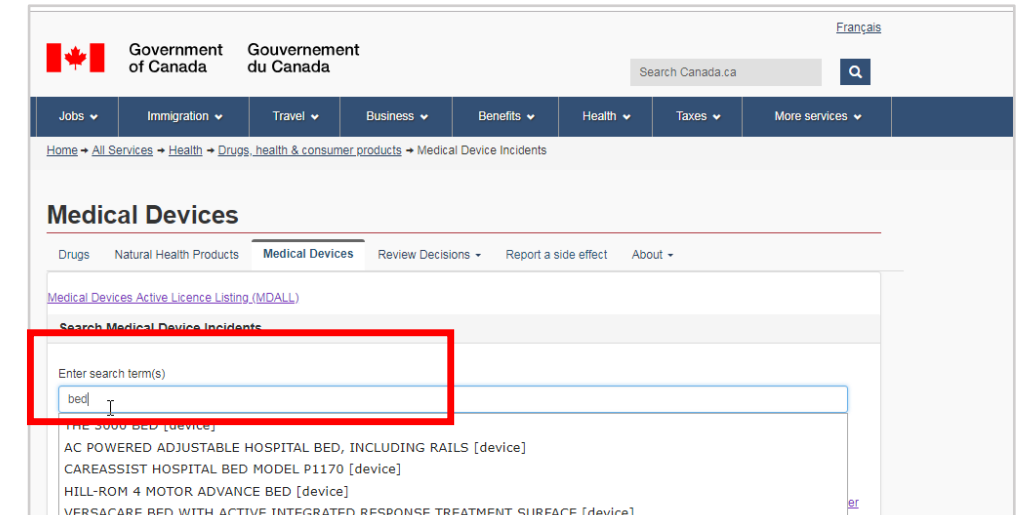
Medical Device Incident Database

- Searchable database with information from reports since 1980

Reports can be searched 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



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Medical Devices

Drugs Natural Health Products Medical Devices Review Decisions Report a side effect About

Medical Devices Active Licence Listing (MDALL)

Search Medical Device Incidents

Enter search term(s)

bed

THE 3000 BED [device]
AC POWERED ADJUSTABLE HOSPITAL BED, INCLUDING RAILS [device]
CAREASSIST HOSPITAL BED MODEL P1170 [device]
HILL-ROM 4 MOTOR ADVANCE BED [device]
VERSACARE BED WITH ACTIVE INTEGRATED RESPONSE TREATMENT SURFACE [device]

Medical Device Incident Results							
New Search							
Results for: bed							
Showing 1 to 10 of 1,700 entries Show 10 entries							
Incident ID	Devices	Device Type	Company Name	Hazard Severity	Description	Code Type	Receipt Date
169500	VERSACARE BED WITH ACTIVE INTEGRATED RESPONSE TREATMENT SURFACE	MATRESS, ALTERNATING PRESSURE	HILL-ROM CANADA LTD. HILL-ROM, INC.	POTENTIAL FOR DEATH/INJURY	No Consequences Or Impact To Patient Device Alarm System Testing of Actual/Suspected Device Electrical Problem Identified Cause Traced to Component Failure	Health Effect Medical Device Problem Manufacturer Investigation Method Manufacturer Investigation Findings Manufacturer Investigation Conclusion	2018-10-04
169518	SECURE 3 MED/SURG BED	GENERAL HOSPITAL GENERAL CODE	STRYKER CANADA LP STRYKER MEDICAL	UNASSIGNED	Pending Assessment	Health Effect Medical Device Problem	2018-09-17
169508	CAREASSIST HOSPITAL BED MODEL P1170	BED, AC-POWERED ADJUSTABLE HOSPITAL	HILL-ROM CANADA LTD. HILL-ROM, INC.	POTENTIAL FOR DEATH/INJURY	No Consequences Or Impact To Patient Use of Device Problem Defective Device Break	Health Effect Medical Device Problem Manufacturer Investigation Findings	2018-09-21

Key Points to Remember



- The ***Protecting Canadians from Unsafe Drugs Act*** (Vanessa's Law) introduces mandatory reporting of serious adverse drug reactions and medical device incidents **by hospitals**.
- Reporting helps to **identify** safety issues, **assess** harm versus benefit, **share** learning, and **improve** patient and product safety.
- A **shared commitment to safety** includes patients and families as key partners.
- **Patients and families** ask questions and monitor their treatments, and may also submit reports.
- **Patients can submit reports** directly to Health Canada.
- **Health Canada shares findings with the public** to alert and educate about risks related to health products.

Reporting Helps Prevent Harm from Happening Again



Maryann Murray's daughter Martha died of an adverse drug reaction at age 22.



Source: <https://www.patientsafetyinstitute.ca/en/toolsResources/Member-Videos-and-Stories/Pages/Patient-Safety-Stories---Martha%27s-Story.aspx>

Acknowledgments

Adapted from: **Educational Support for Mandatory Reporting. Health Canada; 2019.**

Prepared by: Patients for Patient Safety Canada, in collaboration with the Institute for Safe Medication Practices Canada (ISMP Canada) and the Canadian Patient Safety Institute (CPSI)

More information is available from:

<https://www.patientsafetyinstitute.ca/en/toolsResources/Vanessas-Law/Pages/default.aspx>

Contact: patients@cpsi-icsp.ca

