Vanessa's Law
Protecting Canadians from Unsafe Drugs Act

Serious Adverse Drug Reaction and Medical Device Incident Reporting

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

Outline

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- Mandatory Reporting
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  - 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
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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).

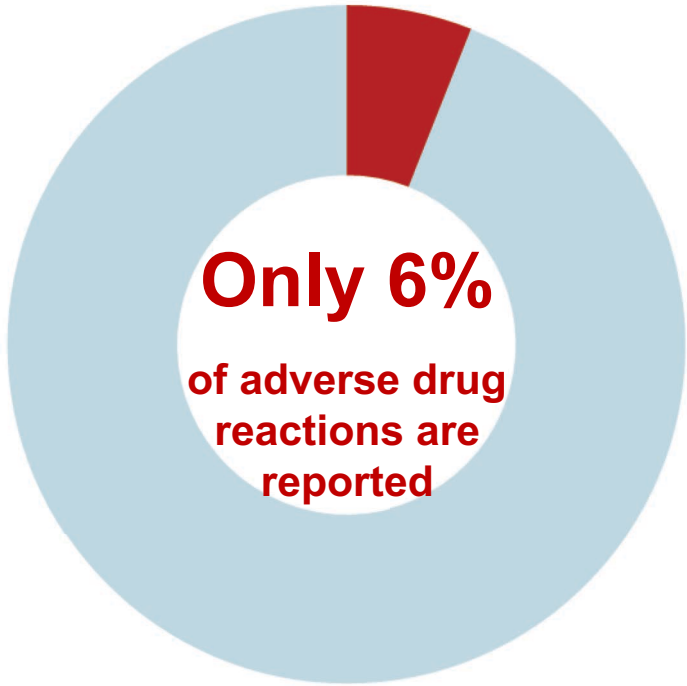
Source: https://www.canada.ca/en/health-canada/services/drugs-health-products/legislation-guidelines/protecting-canadians-unsafe-drugs-act-vanessa-law-amendments-food-drugs-act.html

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.

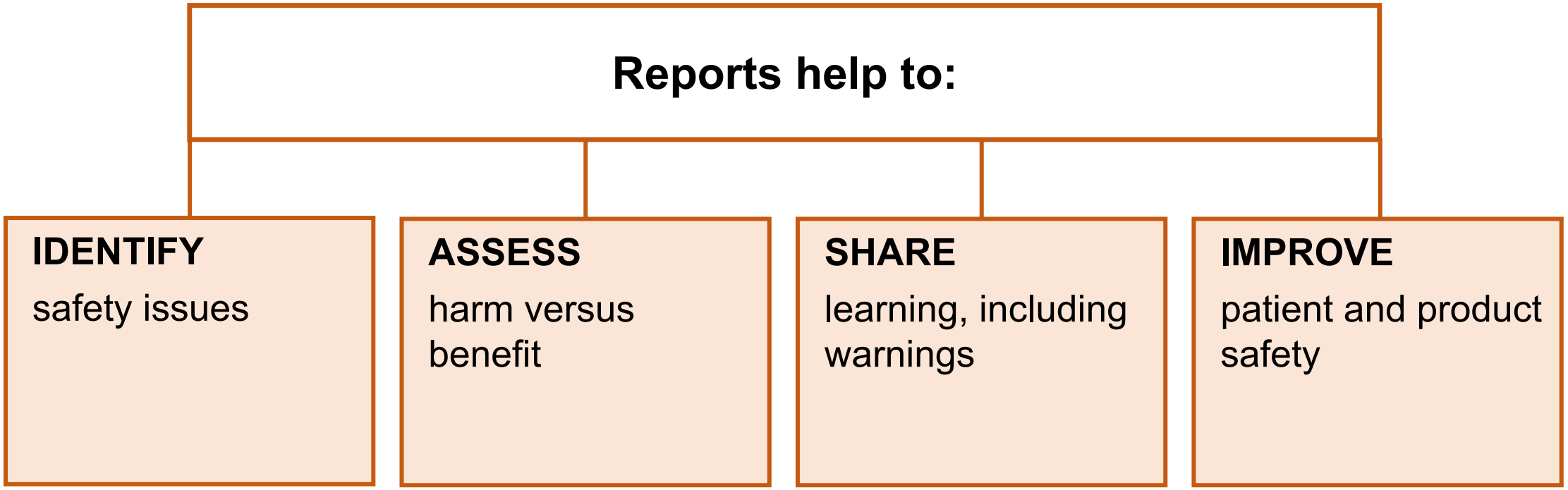
Why Is Mandatory Reporting Important?

- 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.

Source: https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-hospital-reporting/drugs-devices/guidance.html

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

Adapted from: https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-hospital-reporting/drugs-devices/guidance.html

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.

Adapted from: https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-hospital-reporting/drugs-devices/guidance.html

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

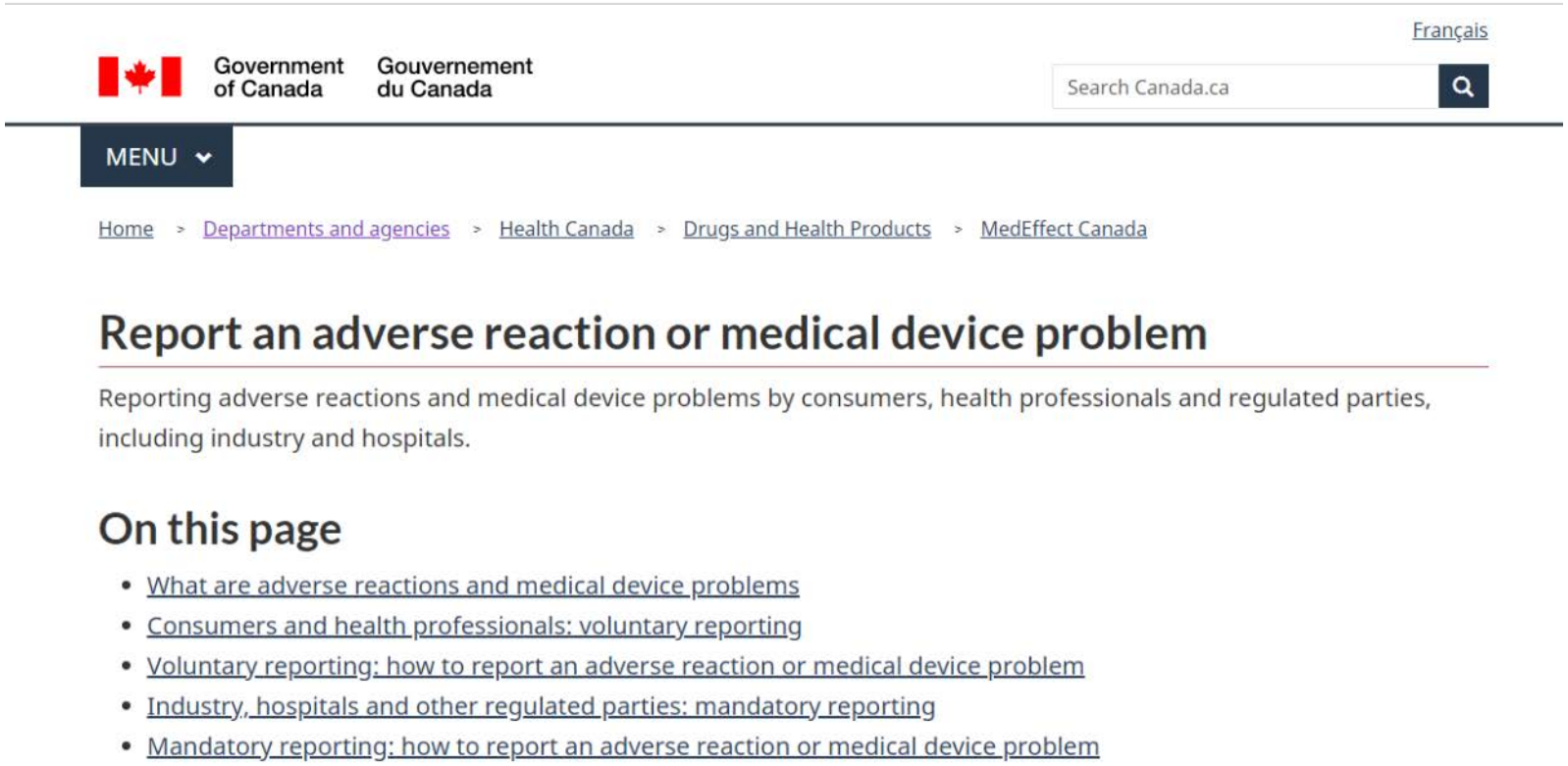
- Patients and families ask questions and monitor their treatments.
  - The *5 Questions to Ask about your Medications* is a helpful resource.

- 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 web page provides access to more information and forms.



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)
- Medical Device Incidents Database (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)
- Health Canada Safety Reviews (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/safety-reviews.html)
- Health Canada Recalls and Safety Alerts (http://www.healthycanadians.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)
- Drug and Health Product Register (DHPR) (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

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

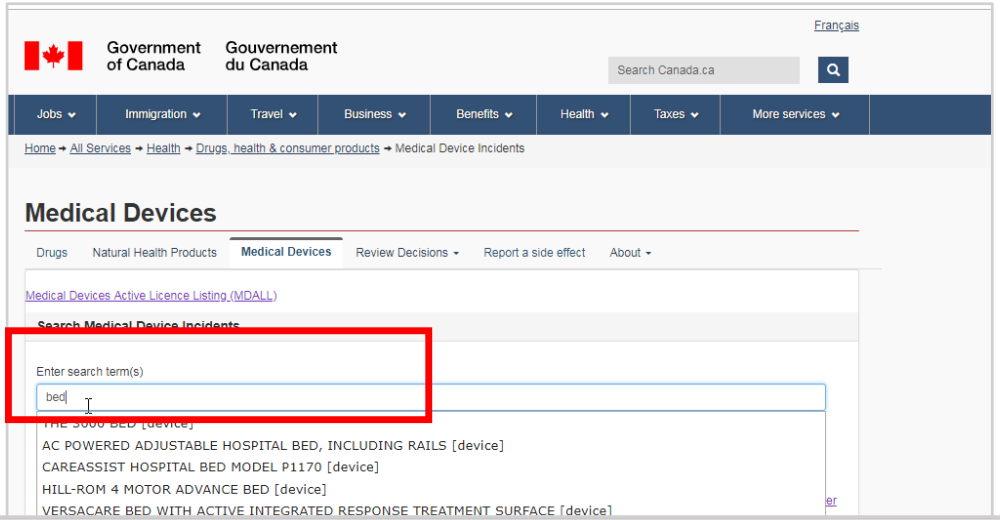
Medical Devices Online Database

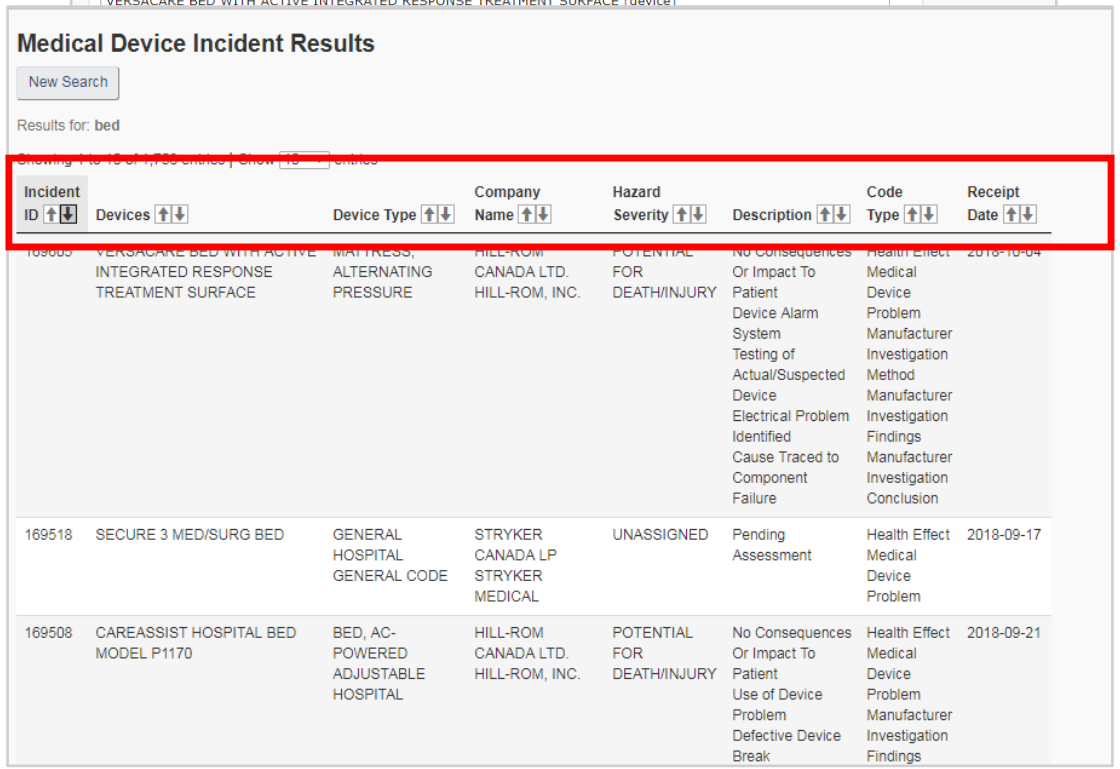
Medical Device Incident Database

- 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

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

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