VANESSA'S LAW: ADVANCING MANDATORY REPORTING

Reporting serious adverse drug reactions (ADRs) and medical device incidents (MDIs) in BC Patient Safety & Learning System (PSLS)

British Columbia Patient Safety Learning System

OVERVIEW

1. Vanessa’s Law
2. Why report?
3. Who should report
4. What to report
5. Where to report

VANESSA'S LAW

Vanessa's story

Vanessa's Law

What can Health Canada do?

VANESSA'S STORY

start

- Vanessa Young

- US FDA

- Health Canada

- Prepulsid

- Terence Young

- Vanessa's Law

end

VANESSA'S STORY

start

Vanessa Young

In 2000, Vanessa Young died of cardiac arrhythmia at the age of fifteen after being prescribed Prepulsid (cisapride) for a stomach disorder.

Vanessa's Law

end

Terence Young

VANESSA'S STORY

start

US FDA

At that time, the US Food & Drug Administration (FDA) had advised against prescribing the medication to patients that had conditions similar to Vanessa's.

Vanessa's Law

end

Terence Young

VANESSA'S STORY

start

Health Canada

When Vanessa died, Health Canada was in the process of reviewing the drug but had few adverse reaction reports compared with the US FDA.

Vanessa's Law

end

Terence Young

VANESSA'S STORY

start

Prepulsid

Prepulsid was removed from the Canadian and many other international markets later in 2000.

Vanessa's Law

end

Terence Young

VANESSA'S STORY

start

Vanessa's Law

end

Terence Young

Terence Young

Terence Young

After Vanessa died, her father Terence Young embarked on a campaign to increase regulation of therapeutic products in Canada.

Terence served as an MPP in Ontario from 1995-1999 and an MP from 2008-2015.

VANESSA'S STORY

start

Vanessa's Law

Terence Young's campaign resulted in Vanessa's Law, paving the way to giving Health Canada greater power to request data from hospitals and industry about medications and medical devices in the marketplace.

Vanessa's Law

end

Terence Young

WHAT IS VANESSA'S LAW?

Act

Vanessa's Law is the *Protecting Canadians from Unsafe Drugs Act,* which received royal assent in 2014

Amendments

Vanessa's Law introduces amendments to the *Food and Drugs Act* that gives Health Canada more power to protect Canadians from unsafe products

Regulations

Regulations requiring mandatory reporting will advance Vanessa's Law, effective December 16, 2019

WHAT CAN HEALTH CANADA DO?

- Require information, tests, or studies
- Recall unsafe therapeutic products
- Require label changes and package modifications
- Require mandatory reporting by hospitals of serious adverse drug reactions (ADRs) and medical device incidents (MDIs)

WHY REPORT?

Why mandatory reporting?

Why should I report?

Safety information

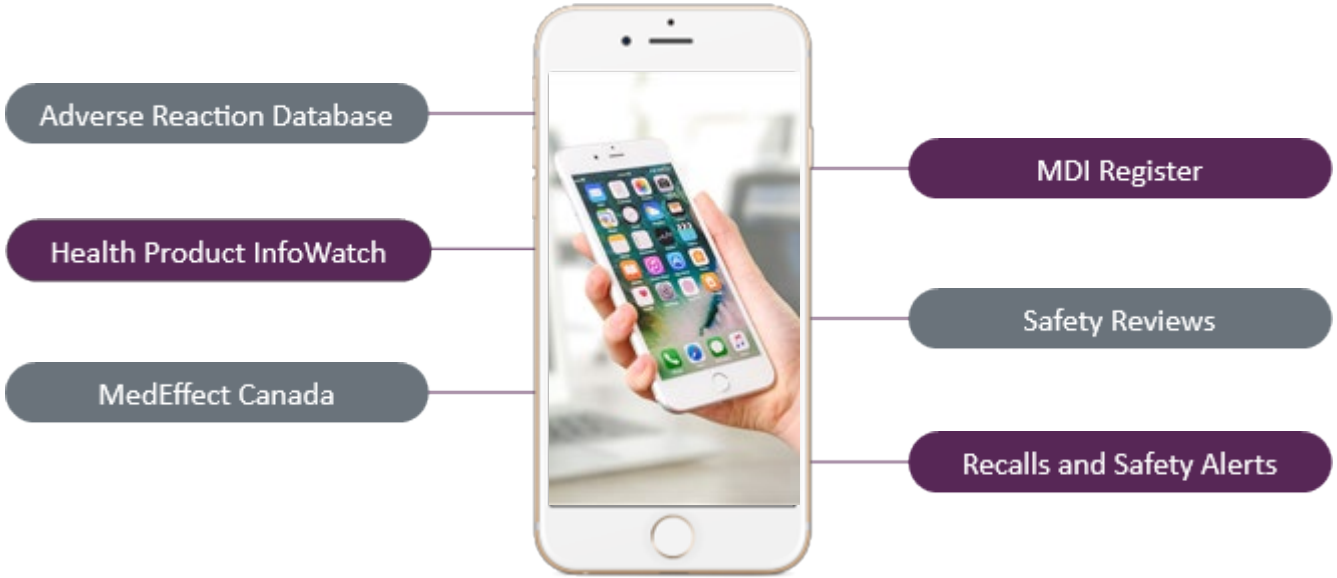
WHY MANDATORY REPORTING?

1. To improve the **quality** and increase the **quantity** of serious ADRs and MDIs reported to Health Canada in order to optimize detection of health product safety issues
2. Many ADRs and MDIs are ONLY detected after market approval
3. ADRs and MDIs are underreported in Canada (and all over the world)

WHY SHOULD I REPORT?

- It helps protect patients, and at some point or another, we are all patients
- Safe, effective products and up-to-date information help me and my patients make informed treatment decisions
- I want to receive feedback and information from Health Canada about the safety of therapeutic products I prescribe or administer
- Reporting is a shared responsibility
- When I report a serious ADR or MDI, PSLS Central Office may forward me any relevant information they've received about the drug or device
- The more reports Health Canada receives, the more information it will have to identify issues and act more quickly to protect Canadians from unsafe products

SAFETY INFORMATION



WHAT TO REPORT

Required reporting
Serious adverse drug reactions
Adverse drug reactions vs. medication incider
Medical device incidents
Responding to MDIs
When in doubt

REQUIRED REPORTING

Mandatory reporting requires that:

Hospitals report serious adverse drug reactions (ADRs) and medical device incidents (MDIs) to Health Canada within 30 days of the event being documented within the hospital (i.e. recorded electronically or on paper in a medical record, pathology report, product complaint form, etc.)

SERIOUS ADVERSE DRUG REACTIONS

What is a serious ADR?

The following information focuses on **serious** ADRs as per Vanessa's Law regulations; however, all ADR reports are helpful and welcome in PSLS

1. **Definition**
2. **Medications**
3. **Examples**
4. **Exceptions**

ADVERSE DRUG REACTIONS

Definition

A “serious ADR” is defined as a noxious, unintended response to a drug at any dose that:

- Required inpatient hospitalization or prolongation of existing hospitalization
- Caused congenital malformation
- Resulted in persistent or significant disability or incapacity
- Was life-threatening, or resulted in death
- Led to other important medical event (use professional judgement)

1 **Definition**

2 Medications

3 Examples

4 Exceptions

ADVERSE DRUG REACTIONS

Medications

- Pharmaceuticals (prescribed, over-the-counter, and contrast media)
- Radiopharmaceuticals (e.g. Technetium-99m)
- Disinfectants (hard surface, topical antiseptic, with drug identification number – DIN)
- Biologic drugs
- Natural health products

1 Definition

2 **Medications**

3 Examples

4 Exceptions

ADVERSE DRUG REACTIONS

Examples of Serious ADRs

- 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

1 Definition

2 Medications

3 **Examples**

4 Exceptions

ADVERSE DRUG REACTIONS

Exceptions

- Only report **known and anticipated reactions** to drugs (e.g. chemotherapy), if the reaction was serious, or the mitigation strategy ineffective, or if a previously unknown serious reaction is mitigated when symptoms first appear
- Only report serious **drug interactions** between drugs that are not contraindicated; if contraindicated, these should be reported as medication incidents
- Adverse events following immunization (AEFI) should be reported via usual processes (e.g. to BCCDC), not in PSLS
- Adverse reactions related to transfusion should be reported via usual processes (e.g. TTISS), not in PSLS.

1 Definition

2 Medications

3 Examples

4 **Exceptions**

ADVERSE DRUG REACTIONS VS. MEDICATION INCIDENTS

1. Adverse drug reactions are not errors in care! They occur even if processes and procedures are followed correctly

2. Medication safety incidents (or events) are often preventable and should be reported via the medication incident report form in PSLS

3. Examples of medication incidents are: incorrect medication, incorrect dose, incorrect patient, incorrect preparation

MEDICAL DEVICE INCIDENTS

What is an MDI?

The following information focuses on medical device **incidents** as per Vanessa's Law regulations; however, all medical device problems are helpful and welcome in PSLS

1. **Definition**
2. **Devices**
3. **Examples**
4. **Exceptions**

MEDICAL DEVICE INCIDENTS

Definition

An MDI is defined as an incident related to the failure of a medical device, deterioration in its effectiveness, or inadequacy in its labeling or directions that:

- led to the death or serious deterioration in health of a patient, user, or other person

OR

- could do so were it to recur

1 **Definition**

2 Devices

3 Examples

4 Exceptions

MEDICAL DEVICE INCIDENTS

Applicable medical devices

“Medical device” covers a wide range of health and/or medical instruments used to treat, mitigate, diagnose, or prevent disease or abnormal physical conditions

All classes of medical devices are included in mandatory reporting by hospitals:

- Class I (e.g. hospital beds, wheelchairs)
- Class II (e.g. infusion sets, urethral catheters)
- Class III (e.g. infusion pumps, intrauterine devices)
- Class IV (e.g. pacemakers, defibrillators, bone grafts)

1 Definition

2 **Devices**

3 Examples

4 Exceptions

MEDICAL DEVICE INCIDENTS

Examples of MDIs

- An infusion pump stopped due to a malfunction but failed to give an alarm; the patient received an under-infusion of antibiotics, resulting in septic shock that prolonged the patient's stay in hospital
- An external defibrillator failed to deliver the programmed level of energy to a patient due to a malfunction; the patient was revived but there was a potential to cause serious harm were this to recur

1 Definition

2 Devices

3 **Examples**

4 Exceptions

MEDICAL DEVICE INCIDENTS

Exceptions

Do not report:

- Deficiencies that would always be detected prior to use (e.g. balloon catheter fails inflation test)
- Incidents caused by a patient's condition (e.g. a patient with end-stage renal disease dies of renal failure after dialysis treatment)
- Malfunctions where built-in protections operate correctly (e.g. infusion pump malfunctions, gives alarm, and stops before an harm to patient occurs)

1 Definition

2 Devices

3 Examples

4 **Exceptions**

RESPONDING TO MDIs

- Leave accessories and disposables (e.g. IV sets, bags wires, pads) “as is” on the device
- Keep packaging materials if available
- If possible, leave device turned ON and plugged into a power supply
- Label the device as “PSLS” so staff are aware it was involved in an incident
- Do not clean the device unless directed by Biomed. Label as “DIRTY” if used on a patient
- All supporting photos and videos of the equipment are helpful

SHOULD AN MDI ARISE

Lower Mainland Biomedical Engineering recommends five steps to take when MDIs involving biomedical equipment ARISE:

- **A** Assess and protect patient
- **R** Report to a supervisor
- **I** Isolate the device (as per previous slide)
- **S** Speak to Biomedical Engineering
- **E** Enter BCPSLS report

WHEN IN DOUBT

Report and ADR or MDI even if:

- its association with the drug and/or medical devices is only suspected
- causality is not confirmed
- all the details are not known
- it may or may not be serious

If you’re not sure, report!

WHO SHOULD REPORT

Who should report

If you discover it, report it

Engage patients in identifying ADRs and MDIs

All health care providers are encouraged to report

WHO SHOULD REPORT

Vanessa's Law regulations mandate **hospitals** to report

Targeting hospitals is anticipated to capture serious ADRs and MDIs that occur in **other settings**, such as long term care facilities, resulting in patient transfers to hospital and emergency room visits

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Hospitals rely on health care professionals to report, including **physicians and other prescribers, nurses, technicians,** and **pharmacists**

IF YOU DISCOVER IT, REPORT IT

1. If you are the first person to discover an ADR or MDI, you are the one who should report it in PSLS

2. The person who discovers the ADR or MDI is best positioned to give the most accurate account of what happened

3. As the reporter, you may be contacted by PSLS Central Office for more information or to receive feedback about the drug or device involved

ENGAGE PATIENTS IN IDENTIFYING ADRs AND MDIs

Seek emergency care if you have a serious reaction or device malfuntion

Contact us if you think your implanted device may be malfunctioning

Anyone can have an adverse reaction to any drug at any time

Contact us if you have a reaction that isn't a common side effect

Tell your doctor that you might be reacting to a drug

While its only mandatory for hospitals to
report *serious* ADRs and MDIs,
all health care providers in all settings
are encouraged to report
all ADRs and medical device problems in PSLS

WHERE TO REPORT

PSLS Process

Reporting in PSLS

Tips for reporting

PSLS PROCESS

ADR reporting to Health Canada via PSLS has been in place since 2014

ADR and MDI reporting in PSLS is designed to meet Health Canada's requirements

When you report a serious ADR or MDI in PSLS, the Central Office team will ensure that your report is reviewed, de-identified, and submitted to Health Canada within the 30-day deadline

You (or a designate in your health authority) may be contacted by PSLS Central Office if your report needs clarifying or we have feedback about the product you reported about

REPORT IN PSLS

Access PSLS

Report an ADR

Report an MDI

REPORT IN PSLS

Access PSLS

Report an ADR

Report an MDI

Report by phone

Each health authority has its own way of accessing PSLS – here are some common ways:

- Desktop shortcut
- Search “PSLS” on health authority intranet
- Use link to “report an event” on health authority intranet PSLS page

REPORT IN PSLS

Access PSLS

Report an ADR

Report an MDI

Report by phone

Once you've access PSLS, look for the ADR report form with this icon:

REPORT IN PSLS

Access PSLS

Report an ADR

Report an MDI

Report by phone

Once you've accessed PSLS, select the MDI report form

OR

Select the report form that best reflects what happened to the patient (e.g. Fall, Medication) and choose "Yes" for the question "Was a device involved?"

TIPS FOR REPORTING

Drug and device ID

Be sure to make note of:

- Device type and any identifying numbers
- Drug's DIN, brand name, or common name and manufacturer

Thanks for sharing

Tell us as much information as you can when you report an ADR or MDI in PSLS

Patient-centered

Report what happened to the patient, if you can e.g. how did they report to intervention?

Update, please

Don't forget to update the patient's record where appropriate

Required information

Health Canada requires specific information – these fields are in **purple** on the ADR form in PSLS

FOR MORE INFORMATION

Visit:

- www.bcpslscentral.ca/vanessas-law
- www.canada.ca and search “Vanessa’s Law”

Contact:

- Your health authority PSLS coordinator
- BCPSLS Central Office at bcpslscentral@phsa.ca or 1 877 789 (PSLS) 7757
- Health Canada’s BC coordinator Dr. Thanh Vu at thanh.vu@canada.ca

Complete:

- Vanessa’s Law eLearning module on LearningHub and iLearn
- PowerPoint modules on Health Canada website