Welcome

Our webinar will begin shortly

Happy Canadian Patient Safety Week 2019

Canadian Patient Safety Week Webinar: Mandatory Reporting of Serious Adverse Drug Reactions And Medical Device Incidents

November 1, 2019

ConquerSilence.ca

Today's Moderator and Sponsors

Mr. Christopher Thrall

Canadian Patient Safety Institute
Communications Officer

A huge thank you to GOJO Industries, Inc. and HealthPRO for sponsoring CPSW this year!

Today's Speakers

Mr. Marc Mes

MHPD Director General,

Health Canada

Ms. Maryann Murray

Patient Advocate,

Patients for Patients Safety Canada

Ms. Maryanne D'Arpino

CPSI Senior Director,

Patient Safety Improvement and Capability Building

Today's Speakers (continued)

Ambika Sharma

Medication Safety Specialist,

ISMP Canada

Sylvia Hyland

VP Operations and Privacy Officer,

ISMP Canada

Nancy Louis

Manager, Medication Quality & Safety

Alberta Health Services

Holly Myer

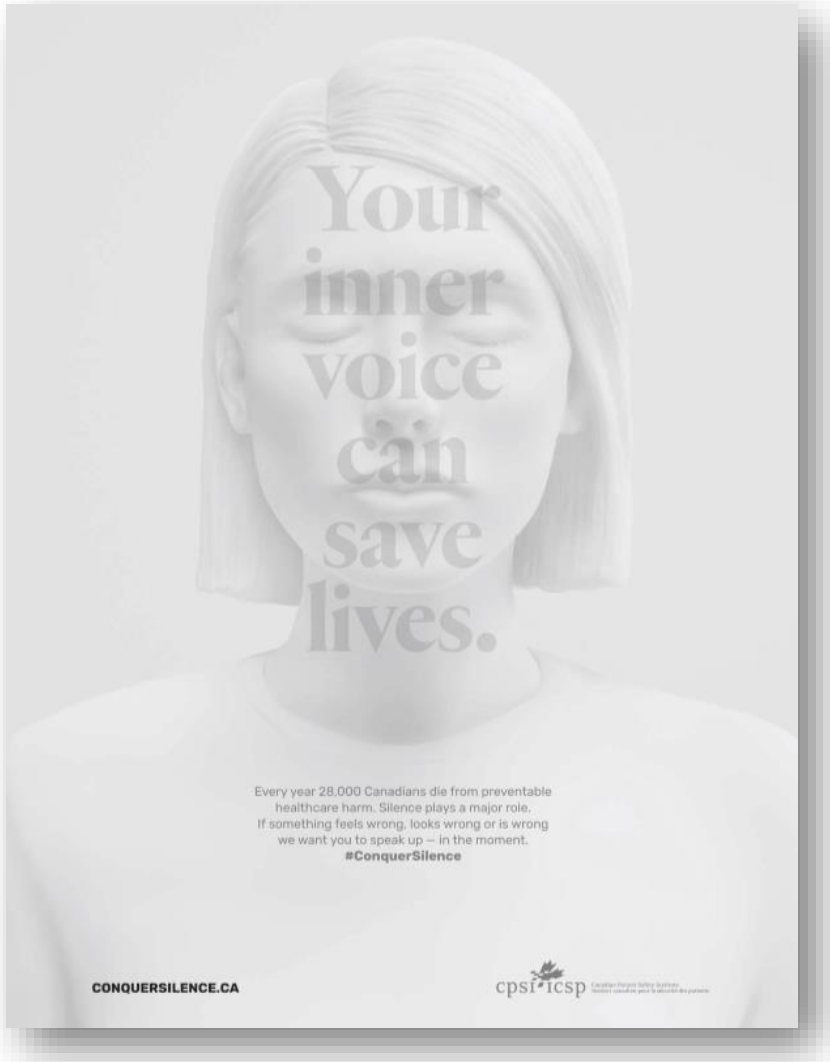
Provincial Director, AHS Product Quality & Safety

Alberta Health Services

Today's Moderator

Patient Safety RightNow

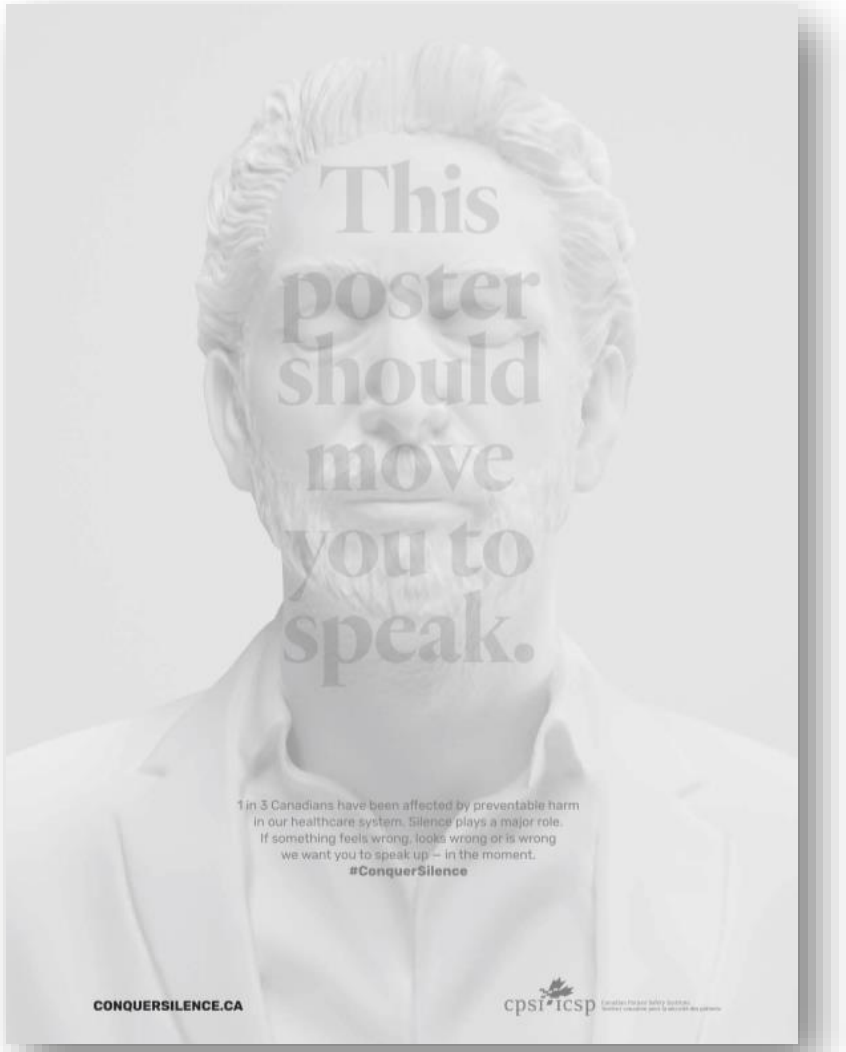
Patient safety incidents are the third leading cause of death in Canada, behind cancer and heart disease.



Today's Moderator

Patient Safety RightNow

Today in Canada every 17 minutes someone dies in a hospital from an adverse event.

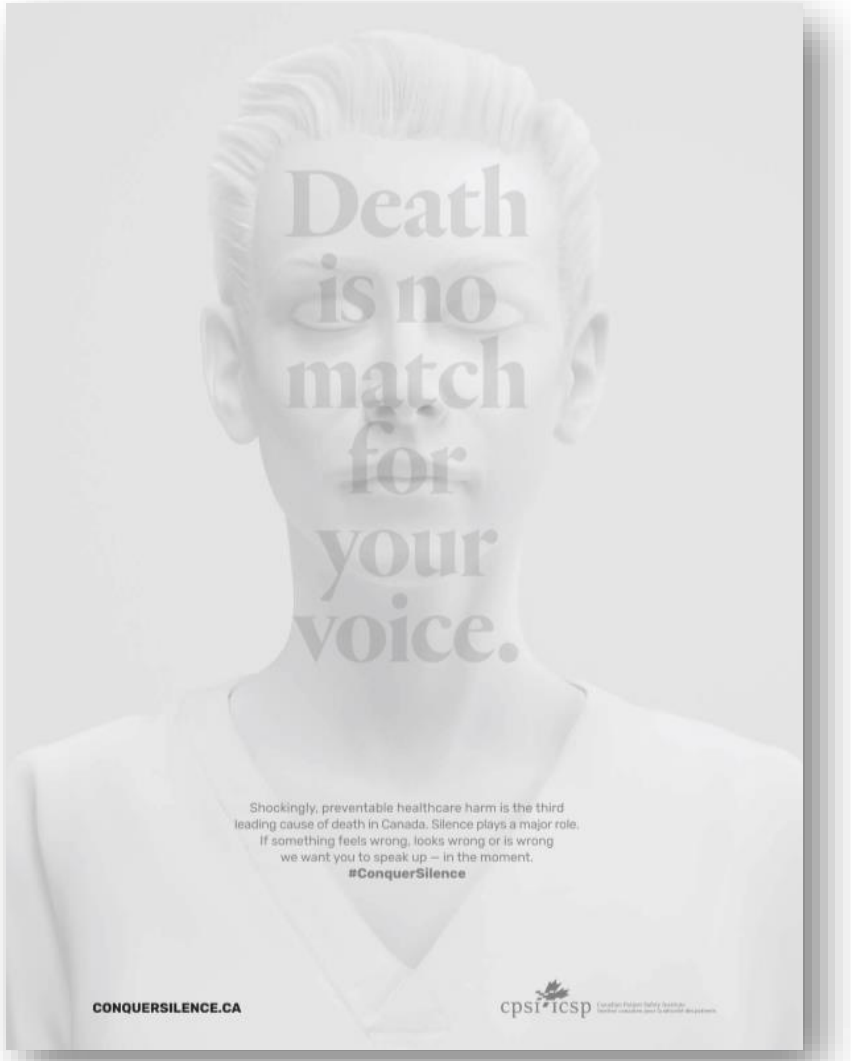


Today's Moderator

Patient Safety RightNow

Let's #ConquerSilence in healthcare together.
It's time to speak up.

- **Your inner voice can save lives.**
- **This campaign should move you to speak.**
- **Death is no match for your voice.**



Learning Outcomes

Patient Safety RightNow

Participation in this presentation will enable you to:

1. Understand mandatory reporting of serious ADRs and MDIs in the context of patient safety
2. Describe the regulatory requirements for mandatory reporting of serious ADRs and MDIs by hospitals
3. Identify strategies and systems to support mandatory reporting of serious ADRs and MDIs

Mr. Marc Mes

MHPD Director General
Health Canada

Maryann Murray

Patients for Patient Safety Canada

Purpose of Vanessa's Law

The *Protecting Canadians from Unsafe Drugs Act* (Vanessa's Law) introduces amendments to the *Food and Drugs Act* to improve Health Canada's ability to:

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?

Patient Safety RightNow

Vanessa's Law was enacted in 2014 and the mandatory reporting requirements come into effect **December 16th, 2019**.

Patients for Patient Safety Canada: Importance of Public Awareness

- **Patients for Patient Safety Canada** members are world leaders in patient safety improvement initiatives

- An active member of PFPSC, Maryann Murray, lost her daughter, Martha Murray, to an adverse drug reaction when Martha was 22 years old

We All Have a Role in Safety

Maryanne D'Arpino

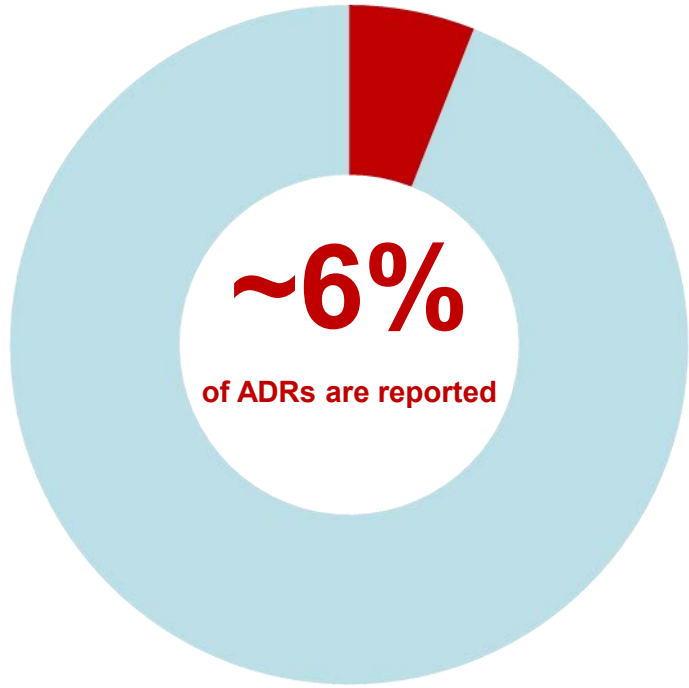
Senior Director,

Canadian Patient Safety Institute (CPSI)

Why Is Mandatory Reporting of Serious ADRs and MDIs Important?

Patient Safety RightNow

Health Canada is continuously looking for ways to strengthen its knowledge base on product safety in the interest of improving patient outcomes and public health.



[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 Serious ADR and MDI Reporting?

Patient Safety RightNow

Serious ADR and MDI Reporting Contributes to:

IDENTIFICATION

of emerging safety issues related to drugs and medical devices

ASSESSMENT

of harm vs. benefit of drugs and medical devices

SHARING

of learning, including warnings and advisories for health care providers, patients, and stakeholders

IMPROVEMENT

of safety of products through risk mitigation such as a labelling change, a product information update, or a recall

Ambika Sharma
Medication Safety Specialist

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www.ismp-canada.org
info@ismp-canada.org

Educational Support for Mandatory Reporting

The educational materials provide core content about serious adverse drug reaction (serious ADR) and medical device incident (MDI) reporting

There are 4 PowerPoint modules:

Module 1 – Overview of Vanessa's Law and Reporting Requirements

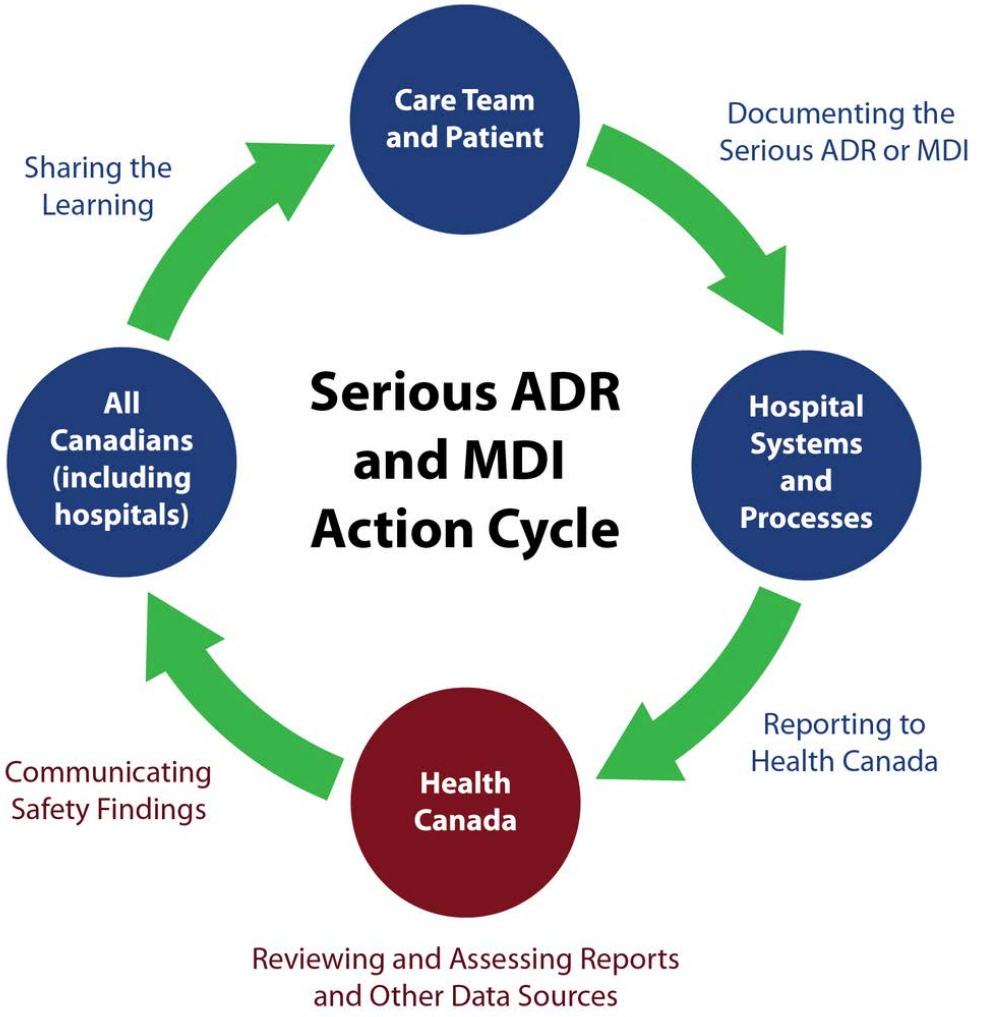
Module 2 – Reporting Processes to Health Canada

Module 3 – Strategies to Promote and Support Mandatory Reporting

Module 4 – Health Canada's Review and Communication of Safety Findings

More information is available from:
https://www.patientsafetyinstitute.ca/en/toolsResources/Vanessas-Law/Pages/default.aspx

Conceptual Model of Serious ADR and MDI Reporting by Hospitals



Source: Serious ADR and MDI Action Cycle. ISMP Canada, HSO, CPSI; 2019.

Regulations for Mandatory Reporting

Who Is Required to Report?

The regulations apply to **all hospitals.**

The regulations define a **hospital** as a facility that:

- is licensed, approved or designated as a hospital by a province or territory, in accordance with the laws of the province or territory, to provide care or treatment to persons suffering from any form of disease or illness; or
- is operated by the Government of Canada and provides health services to in-patients.

Notes:

- Outpatient clinics are subject to the regulations if they are legally part of the hospital, even if they are physically separate from the hospital. On the other hand, clinics that may be physically located within a hospital, but that are not legally part of the hospital, will not be subject to the regulations.
- Health care institutions that are outside the scope of the definition of 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 are the Definitions of a Serious ADR and MDI?

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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.

Note: Hospitals are not required to establish causality; the information to be submitted by the hospital to Health Canada only needs to represent the suspicions of a health care professional that a serious ADR or MDI has been observed.

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 Products Are In Scope of these Regulations?

The mandatory reporting requirements for hospitals apply to therapeutic products, including:

- Pharmaceuticals (prescription and non-prescription drugs)
- Biologic drugs (biotechnology products, fractionated blood products, plasma proteins, and vaccines [excluding vaccines administered under a routine immunization program of a province or territory])
- Radiopharmaceutical drugs
- Disinfectants
- Medical devices
- Drugs for an urgent public health need

When in doubt, Health Canada encourages hospitals to report.

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

Types of Medical Devices Included

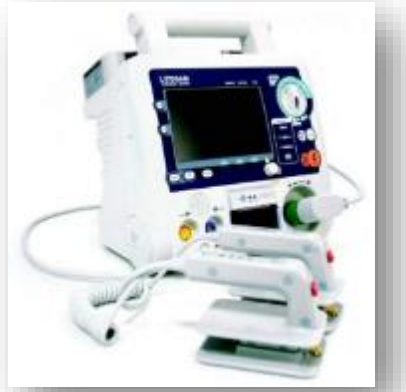
The term **medical device** covers a wide range of health and/or medical instruments used in the treatment, mitigation, diagnosis or prevention of a disease or abnormal physical condition.

Medical devices are classified into **Class I** (lowest risk) to **Class IV** (highest risk). Examples are:

- Class I – hospital beds, wheelchairs, leg prostheses
- Class II – infusion sets, syringes, tracheostomy tubes, urethral catheters
- Class III – infusion pumps, anesthesia gas machines, intrauterine devices
- Class IV – pacemakers, defibrillators, breast implants, bone grafts

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

Class I (Hospital bed)



Class IV (Defibrillator)

Source: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/guidance-document-guidance-risk-based-classification-system-non-vitro-diagnostic.html

When Must Hospitals Report?

The regulations require hospitals to report serious ADRs or MDIs in writing to Health Canada **within 30 calendar days of first documentation** of the serious ADR or MDI within the hospital.

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

Information "Within the Control of the Hospital"

The regulations require hospitals to report all documented serious ADRs and all documented MDIs, where the required information is **within the control of the hospital**.

- Information that is within the control of the hospital is information that would be reasonably accessible within the hospital.
- While it is encouraged for hospitals to take all reasonable steps to retrieve the required information to complete as thorough a report as possible, there is no requirement to do further investigation in order to obtain the pieces of information.

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

Examples of Documentation Within the Hospital

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Examples of serious ADR or MDI documentation within the hospital include:

- a serious ADR or MDI that is identified in a patient's clinical/medical record;
- a serious ADR or MDI that is identified in a separate report form (electronic or hard copy) that has been completed by a health care professional; and
- a serious ADR or MDI that has been documented in an ADR form or a product complaint form (e.g., an MDI form) as per internal hospital policy, a pathology report, an incident/patient safety learning database, or a computerized prescription recording system.

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

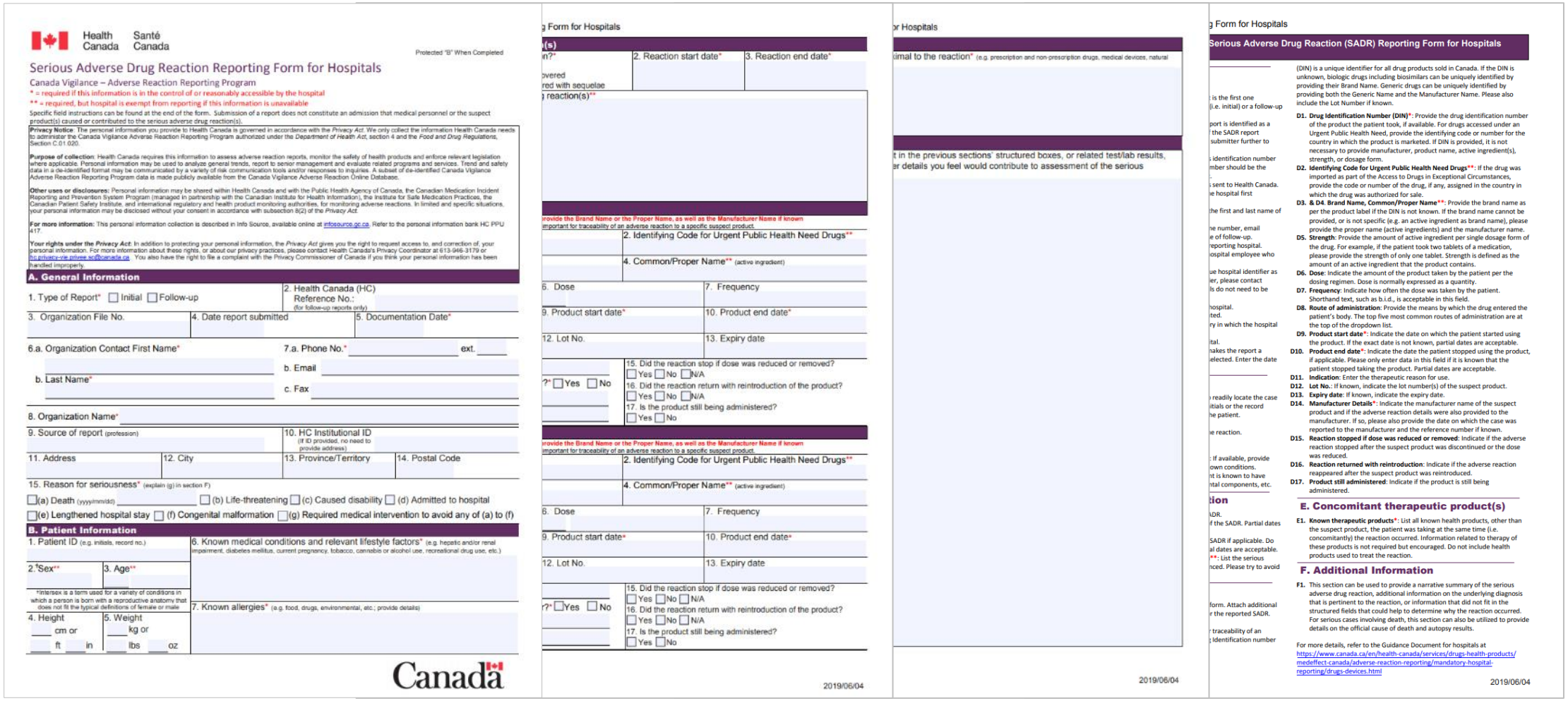
Serious ADR and MDI Reports to Health Canada

Patient Safety RightNow

- Health Canada remains flexible and is able to receive reports in various formats via multiple secure submission methods, recognizing that hospital systems vary.
  - If interested in submitting reports electronically to Health Canada, please email the Canada Vigilance Program at hc.canada.vigilance.sc@canada.ca.
  - Health Canada supports report submissions using a secure File Transfer Protocol (sFTP) and continues to explore system-to-system options.
- The reporting forms for serious ADRs and MDIs, together with instructions, are available on the Health Canada website:
  - Serious ADR reporting form: https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-reporting-hospital-drug-eng.pdf
  - MDI reporting form: https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-reporting-hospital-device-eng.pdf

New Form for Mandatory Reporting of Serious ADRs

Patient Safety RightNow



Health Canada / Santé Canada

Protected "B" When Completed

Serious Adverse Drug Reaction Reporting Form for Hospitals

Canada Vigilance – Adverse Reaction Reporting Program

* = required if this information is in the control of or reasonably accessible by the hospital

** = required, but hospital is exempt from reporting if this information is unavailable

Specific field instructions can be found at the end of the form. Submission of a report does not constitute an admission that medical personnel or the suspect product(s) caused or contributed to the serious adverse drug reaction(s).

Privacy Notice: The personal information you provide to Health Canada is governed in accordance with the *Privacy Act*. We only collect the information Health Canada needs to administer the Canada Vigilance Adverse Reaction Reporting Program authorized under the *Department of Health Act*, section 4 and the *Food and Drug Regulations*, Section C.01.020.

Purpose of collection: Health Canada requires this information to assess adverse reaction reports, monitor the safety of health products and enforce relevant legislation where applicable. Personal information may be used to analyze general trends, report to senior management and evaluate related programs and services. Trend and safety data in a de-identified format may be communicated by a variety of risk communication tools and/or responses to inquiries. A subset of de-identified Canada Vigilance Adverse Reaction Reporting Program data is made publicly available from the Canada Vigilance Adverse Reaction Online Database.

Other uses or disclosures: Personal information may be shared within Health Canada and with the Public Health Agency of Canada, the Canadian Medication Incident Reporting and Prevention System Program (managed in partnership with the Canadian Institute for Health Information), the Institute for Safe Medication Practices, the Canadian Patient Safety Institute, and international regulatory and health product monitoring authorities, for monitoring adverse reactions. In limited and specific situations, your personal information may be disclosed without your consent in accordance with subsection 8(2) of the *Privacy Act*.

For more information: This personal information collection is described in Info Source, available online at infosource.gc.ca. Refer to the personal information bank HC PPU 417.

Your rights under the *Privacy Act*: In addition to protecting your personal information, the *Privacy Act* gives you the right to request access to, and correction of, your personal information. For more information about these rights, or about our privacy practices, please contact Health Canada's Privacy Coordinator at 613-946-3179 or hc.privacy-vie.privee.sc@canada.ca. You also have the right to file a complaint with the Privacy Commissioner of Canada if you think your personal information has been handled improperly.

A. General Information

1. Type of Report* ☐ Initial ☐ Follow-up
2. Health Canada (HC) Reference No.: (for follow-up reports only)
3. Organization File No.
4. Date report submitted
5. Documentation Date*
6.a. Organization Contact First Name*
7.a. Phone No.* ext.
b. Last Name*
b. Email
c. Fax
8. Organization Name*
9. Source of report (profession)
10. HC Institutional ID (if ID provided, no need to provide address)
11. Address
12. City
13. Province/Territory
14. Postal Code
15. Reason for seriousness* (explain (g) in section F)

☐(a) Death (yyyy/mm/dd) ☐(b) Life-threatening ☐(c) Caused disability ☐(d) Admitted to hospital

☐(e) Lengthened hospital stay ☐(f) Congenital malformation ☐(g) Required medical intervention to avoid any of (a) to (f)

B. Patient Information

1. Patient ID (e.g. initials, record no.)
2. *Sex**
3. Age**

*Intersex is a term used for a variety of conditions in which a person is born with a reproductive anatomy that does not fit the typical definitions of female or male

4. Height ___ cm or ___ ft ___ in
5. Weight ___ kg or ___ lbs ___ oz
6. Known medical conditions and relevant lifestyle factors* (e.g. hepatic and/or renal impairment, diabetes mellitus, current pregnancy, tobacco, cannabis or alcohol use, recreational drug use, etc.)
7. Known allergies* (e.g. food, drugs, environmental, etc.; provide details)

Canada

g Form for Hospitals

(s)

n?*

2. Reaction start date*
3. Reaction end date*

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red with sequelae
reaction(s)**

rovide the Brand Name or the Proper Name, as well as the Manufacturer Name if known
important for traceability of an adverse reaction to a specific suspect product.

2. Identifying Code for Urgent Public Health Need Drugs**
4. Common/Proper Name** (active ingredient)
6. Dose
7. Frequency
9. Product start date*
10. Product end date*
12. Lot No.
13. Expiry date

?* ☐Yes ☐No

15. Did the reaction stop if dose was reduced or removed? ☐Yes ☐No ☐N/A
16. Did the reaction return with reintroduction of the product? ☐Yes ☐No ☐N/A
17. Is the product still being administered? ☐Yes ☐No

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10. Product end date*
12. Lot No.
13. Expiry date

?* ☐Yes ☐No

15. Did the reaction stop if dose was reduced or removed? ☐Yes ☐No ☐N/A
16. Did the reaction return with reintroduction of the product? ☐Yes ☐No ☐N/A
17. Is the product still being administered? ☐Yes ☐No

2019/06/04

or Hospitals

imal to the reaction* (e.g. prescription and non-prescription drugs, medical devices, natural

t in the previous sections' structured boxes, or related test/lab results,
er details you feel would contribute to assessment of the serious

2019/06/04

g Form for Hospitals

Serious Adverse Drug Reaction (SADR) Reporting Form for Hospitals

is the first one
(i.e. initial) or a follow-up

port is identified as a
the SADR report
submitter further to

identification number
mber should be the

sent to Health Canada.
e hospital first

the first and last name of

ne number, email
e of follow-up.
reporting hospital.
ospital employee who

ue hospital identifier as
er, please contact
ls do not need to be

hospital.
ted.
ry in which the hospital

ital.
nakes the report a
elected. Enter the date

readily locate the case
itials or the record
he patient.

e reaction.

: If available, provide
own conditions.
nt is known to have
ntal components, etc.

tion

ADR.
f the SADR. Partial dates

SADR if applicable. Do
al dates are acceptable.
**: List the serious
nced. Please try to avoid

form. Attach additional
r the reported SADR.

traceability of an
Identification number

(DIN) is a unique identifier for all drug products sold in Canada. If the DIN is unknown, biologic drugs including biosimilars can be uniquely identified by providing their Brand Name. Generic drugs can be uniquely identified by providing both the Generic Name and the Manufacturer Name. Please also include the Lot Number if known.

D1. Drug Identification Number (DIN)*: Provide the drug identification number of the product the patient took, if available. For drugs accessed under an Urgent Public Health Need, provide the identifying code or number for the country in which the product is marketed. If DIN is provided, it is not necessary to provide manufacturer, product name, active ingredient(s), strength, or dosage form.

D2. Identifying Code for Urgent Public Health Need Drugs**: If the drug was imported as part of the Access to Drugs in Exceptional Circumstances, provide the code or number of the drug, if any, assigned in the country in which the drug was authorized for sale.

D3. & D4. Brand Name, Common/Proper Name**: Provide the brand name as per the product label if the DIN is not known. If the brand name cannot be provided, or is not specific (e.g. an active ingredient as brand name), please provide the proper name (active ingredients) and the manufacturer name.

D5. Strength: Provide the amount of active ingredient per single dosage form of the drug. For example, if the patient took two tablets of a medication, please provide the strength of only one tablet. Strength is defined as the amount of an active ingredient that the product contains.

D6. Dose: Indicate the amount of the product taken by the patient per the dosing regimen. Dose is normally expressed as a quantity.

D7. Frequency: Indicate how often the dose was taken by the patient. Shorthand text, such as b.i.d., is acceptable in this field.

D8. Route of administration: Provide the means by which the drug entered the patient's body. The top five most common routes of administration are at the top of the dropdown list.

D9. Product start date*: Indicate the date on which the patient started using the product. If the exact date is not known, partial dates are acceptable.

D10. Product end date*: Indicate the date the patient stopped using the product, if applicable. Please only enter data in this field if it is known that the patient stopped taking the product. Partial dates are acceptable.

D11. Indication: Enter the therapeutic reason for use.

D12. Lot No.: If known, indicate the lot number(s) of the suspect product.

D13. Expiry date: If known, indicate the expiry date.

D14. Manufacturer Details*: Indicate the manufacturer name of the suspect product and if the adverse reaction details were also provided to the manufacturer. If so, please also provide the date on which the case was reported to the manufacturer and the reference number if known.

D15. Reaction stopped if dose was reduced or removed: Indicate if the adverse reaction stopped after the suspect product was discontinued or the dose was reduced.

D16. Reaction returned with reintroduction: Indicate if the adverse reaction reappeared after the suspect product was reintroduced.

D17. Product still administered: Indicate if the product is still being administered.

E. Concomitant therapeutic product(s)

E1. Known therapeutic products*: List all known health products, other than the suspect product, the patient was taking at the same time (i.e. concomitantly) the reaction occurred. Information related to therapy of these products is not required but encouraged. Do not include health products used to treat the reaction.

F. Additional Information

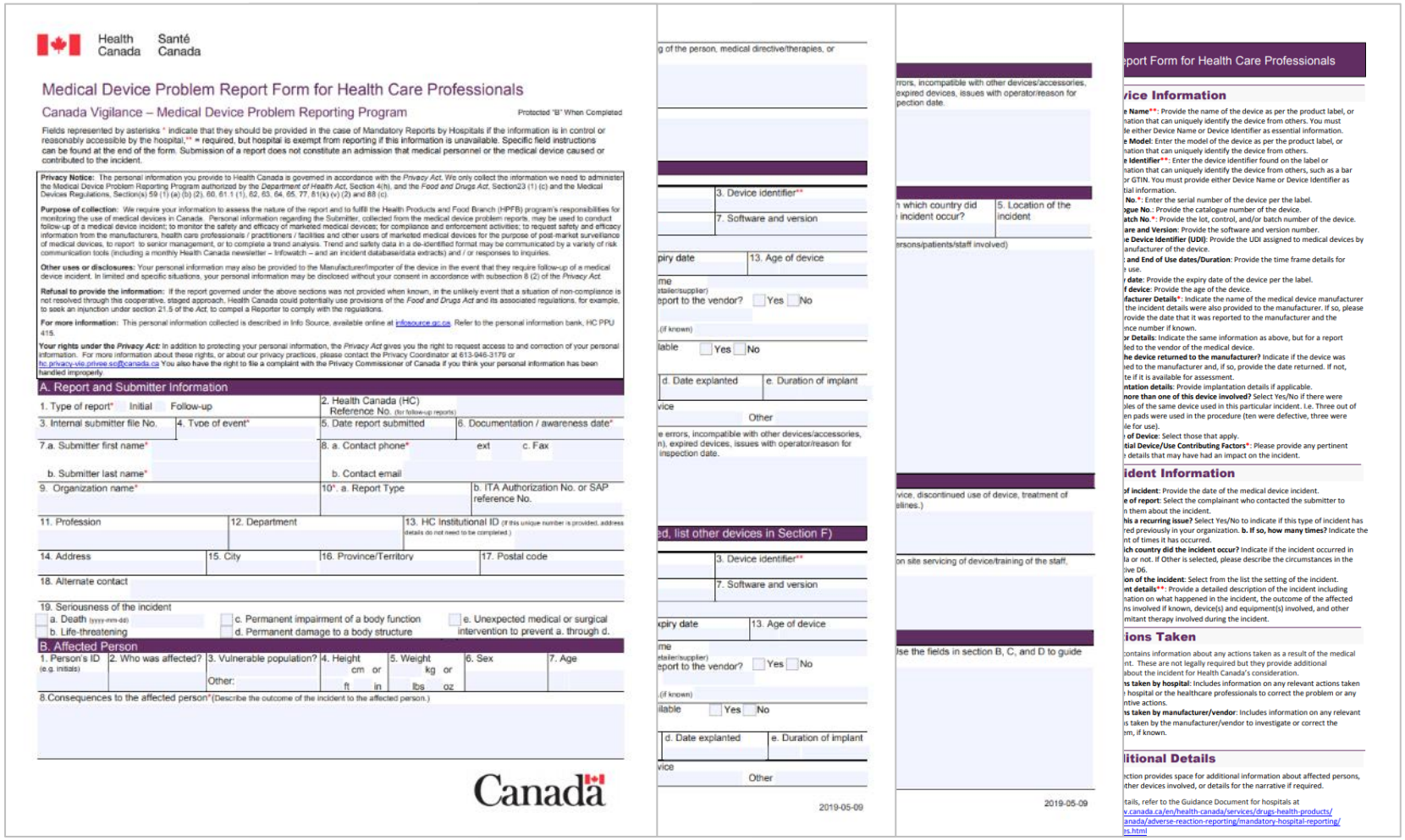
F1. This section can be used to provide a narrative summary of the serious adverse drug reaction, additional information on the underlying diagnosis that is pertinent to the reaction, or information that did not fit in the structured fields that could help to determine why the reaction occurred. For serious cases involving death, this section can also be utilized to provide details on the official cause of death and autopsy results.

For more details, refer to the Guidance Document for hospitals at https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-hospital-reporting/drugs-devices.html

2019/06/04

https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-reporting-hospital-drug-eng.pdf

New Form for Mandatory Reporting of MDIs



Health Canada / Santé Canada

Medical Device Problem Report Form for Health Care Professionals

Canada Vigilance – Medical Device Problem Reporting Program

Protected "B" When Completed

Fields represented by asterisks * indicate that they should be provided in the case of Mandatory Reports by Hospitals if the information is in control or reasonably accessible by the hospital."* = required, but hospital is exempt from reporting if this information is unavailable. Specific field instructions can be found at the end of the form. Submission of a report does not constitute an admission that medical personnel or the medical device caused or contributed to the incident.

Privacy Notice: The personal information you provide to Health Canada is governed in accordance with the *Privacy Act*. We only collect the information we need to administer the Medical Device Problem Reporting Program authorized by the *Department of Health Act*, Section 4(h), and the *Food and Drugs Act*, Section23 (1) (c) and the Medical Devices Regulations, Section(s) 59 (1) (a) (b) (2), 60, 61.1 (1), 62, 63, 64, 65, 77, 81(k) (v) (2) and 88 (c).

Purpose of collection: We require your information to assess the nature of the report and to fulfill the Health Products and Food Branch (HPFB) program's responsibilities for monitoring the use of medical devices in Canada. Personal information regarding the Submitter, collected from the medical device problem reports, may be used to conduct follow-up of a medical device incident; to monitor the safety and efficacy of marketed medical devices; for compliance and enforcement activities; to request safety and efficacy information from the manufacturers, health care professionals / practitioners / facilities and other users of marketed medical devices for the purpose of post-market surveillance of medical devices, to report to senior management, or to complete a trend analysis. Trend and safety data in a de-identified format may be communicated by a variety of risk communication tools (including a monthly Health Canada newsletter – Infowatch – and an incident database/data extracts) and / or responses to inquiries.

Other uses or disclosures: Your personal information may also be provided to the Manufacturer/Importer of the device in the event that they require follow-up of a medical device incident. In limited and specific situations, your personal information may be disclosed without your consent in accordance with subsection 8 (2) of the *Privacy Act*.

Refusal to provide the information: If the report governed under the above sections was not provided when known, in the unlikely event that a situation of non-compliance is not resolved through this cooperative, staged approach, Health Canada could potentially use provisions of the *Food and Drugs Act* and its associated regulations, for example, to seek an injunction under section 21.5 of the *Act*, to compel a Reporter to comply with the regulations.

For more information: This personal information collected is described in Info Source, available online at infosource.gc.ca. Refer to the personal information bank, HC PPU 415.

Your rights under the *Privacy Act*: In addition to protecting your personal information, the *Privacy Act* gives you the right to request access to and correction of your personal information. For more information about these rights, or about our privacy practices, please contact the Privacy Coordinator at 613-946-3179 or hc.privacy-vie.prives.sc@canada.ca. You also have the right to file a complaint with the Privacy Commissioner of Canada if you think your personal information has been handled improperly.

A. Report and Submitter Information

1. Type of report* Initial Follow-up
2. Health Canada (HC) Reference No. (for follow-up reports)
3. Internal submitter file No.
4. Type of event*
5. Date report submitted
6. Documentation / awareness date*
7.a. Submitter first name*
b. Submitter last name*
8. a. Contact phone* ext c. Fax
b. Contact email
9. Organization name*
10*. a. Report Type
b. ITA Authorization No. or SAP reference No.
11. Profession
12. Department
13. HC Institutional ID (if this unique number is provided, address details do not need to be completed.)
14. Address
15. City
16. Province/Territory
17. Postal code
18. Alternate contact
19. Seriousness of the incident
a. Death (yyyy-mm-dd)
b. Life-threatening
c. Permanent impairment of a body function
d. Permanent damage to a body structure
e. Unexpected medical or surgical intervention to prevent a. through d.

B. Affected Person

1. Person's ID (e.g. initials)
2. Who was affected?
3. Vulnerable population? Other:
4. Height cm or ft in
5. Weight kg or lbs oz
6. Sex
7. Age
8.Consequences to the affected person* (Describe the outcome of the incident to the affected person.)

Canada

g of the person, medical directive/therapies, or

3. Device identifier**
7. Software and version
piry date
13. Age of device
eport to the vendor? Yes No
(if known)
liable Yes No
d. Date explanted
e. Duration of implant
vice
Other
e errors, incompatible with other devices/accessories, n), expired devices, issues with operator/reason for inspection date.
ed, list other devices in Section F)
3. Device identifier**
7. Software and version
xpiry date
13. Age of device
eport to the vendor? Yes No
(if known)
iliable Yes No
d. Date explanted
e. Duration of implant
vice
Other

2019-05-09

rrors, incompatible with other devices/accessories, expired devices, issues with operator/reason for pection date.
h which country did incident occur?
5. Location of the incident
ersons/patients/staff involved)
vice, discontinued use of device, treatment of alines.)
on site servicing of device/training of the staff.
lse the fields in section B, C, and D to guide

2019-05-09

eport Form for Health Care Professionals

vice Information

e Name**: Provide the name of the device as per the product label, or nation that can uniquely identify the device from others. You must e either Device Name or Device Identifier as essential information.
e Model: Enter the model of the device as per the product label, or nation that can uniquely identify the device from others.
e Identifier**: Enter the device identifier found on the label or nation that can uniquely identify the device from others, such as a bar or GTIN. You must provide either Device Name or Device Identifier as tial information.
No.*: Enter the serial number of the device per the label.
gue No.: Provide the catalogue number of the device.
atch No.*: Provide the lot, control, and/or batch number of the device.
are and Version: Provide the software and version number.
e Device Identifier (UDI): Provide the UDI assigned to medical devices by anufacturer of the device.
and End of Use dates/Duration: Provide the time frame details for use.
date: Provide the expiry date of the device per the label.
f device: Provide the age of the device.
facturer Details*: Indicate the name of the medical device manufacturer the incident details were also provided to the manufacturer. If so, please rovide the date that it was reported to the manufacturer and the nce number if known.
r Details: Indicate the same information as above, but for a report led to the vendor of the medical device.
he device returned to the manufacturer? Indicate if the device was ed to the manufacturer and, if so, provide the date returned. If not, te if it is available for assessment.
ntation details: Provide implantation details if applicable.
nore than one of this device involved? Select Yes/No if there were les of the same device used in this particular incident. I.e. Three out of en pads were used in the procedure (ten were defective, three were le for use).
of Device: Select those that apply.
tial Device/Use Contributing Factors*: Please provide any pertinent details that may have had an impact on the incident.

ident Information

of incident: Provide the date of the medical device incident.
e of report: Select the complainant who contacted the submitter to n them about the incident.
his a recurring issue? Select Yes/No to indicate if this type of incident has ed previously in your organization. **b. If so, how many times?** Indicate the nt of times it has occurred.
ich country did the incident occur? Indicate if the incident occurred in la or not. If Other is selected, please describe the circumstances in the ive D6.
on of the incident: Select from the list the setting of the incident.
nt details**: Provide a detailed description of the incident including nation on what happened in the incident, the outcome of the affected ns involved if known, device(s) and equipment(s) involved, and other mitant therapy involved during the incident.

ions Taken

contains information about any actions taken as a result of the medical nt. These are not legally required but they provide additional about the incident for Health Canada's consideration.
s taken by hospital: Includes information on any relevant actions taken hospital or the healthcare professionals to correct the problem or any ntive actions.
s taken by manufacturer/vendor: Includes information on any relevant s taken by the manufacturer/vendor to investigate or correct the em, if known.

litional Details

ction provides space for additional information about affected persons, ther devices involved, or details for the narrative if required.

tails, refer to the Guidance Document for hospitals at v.canada.ca/en/health-canada/services/drugs-health-products/anada/adverse-reaction-reporting/mandatory-hospital-reporting/es.html

The reporting form for medical device problems was created for multiple reporting uses:

- Mandatory reporting for
  - hospitals,
  - Special Access Program (SAP),
  - Investigational Testing Authorization (ITA)
- Voluntary reporting to Canadian Medical Devices Sentinel Network (CMDSNet) by participating institutions

https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-reporting-hospital-device-eng.pdf

Sylvia Hyland

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Strategies to Support Mandatory Reporting

Note: Health Canada does not endorse any particular strategy
The following examples, in alphabetical order, are provided for information sharing only.

Self-Assessment Questions for Hospitals

Patient Safety RightNow

The following self-assessment questions may be helpful to identify opportunities to prepare for the implementation of mandatory reporting within your hospital:

- In what way is serious ADR and MDI documentation and reporting promoted?
- Are our hospital policies and procedures aligned with the mandatory reporting requirements?
- Can our hospital systems be leveraged to facilitate documentation and reporting? \
- How can awareness and knowledge of serious ADR and MDI documentation and reporting be improved?
- Has our hospital leadership created an environment that supports serious ADR and MDI documentation and reporting?
- Are patients and families empowered to ask questions and be engaged in monitoring their treatments?
- Is serious ADR and MDI documentation and reporting included in orientation or education programs?
- Is the learning or feedback derived from serious ADR and MDI reports shared with health care providers?

Strategic and Operational Considerations for Teams

Patient Safety RightNow

- **Create a multidisciplinary team (e.g., 'Safety Team')** to support serious ADR and MDI documentation and reporting, and assist with:
  - identifying serious ADRs and MDIs through proactive monitoring;
  - completing and submitting serious ADR and MDI reports;
  - disseminating learning from serious ADR and MDI reporting;
  - providing coaching and education;
  - enabling continuous quality improvement for serious ADR and MDI reporting processes; and
  - providing regular updates to senior leadership.
- **Identify individual 'Champions'** to help lead serious ADR and MDI reporting efforts and/or provide support for identifying and submitting serious ADR or MDI reports to Health Canada.
- **Identify networking opportunities** to support collaboration and shared commitment to serious ADR and MDI documentation and reporting.

EXAMPLE: Alberta Health Services

Patient Safety RightNow

- A **centralized provincial approach** has been developed for serious ADR reporting and for improved MDI reporting.
  - Provincial Task Force is in place to coordinate the initiative
  - Includes centralized process to receive, review and further report
- Alberta is implementing a province-wide clinical information system
  - All sites will use a single **electronic health record**
  - There is a phased roll out across the province over five years
  - Serious ADR reporting will be integrated into the electronic health record
  - MDI reporting will be linked from the electronic health record, as well as from the Alberta Health Services intranet

Source: Alberta Health Services; 2019.

EXAMPLE: British Columbia

- The BC Patient Safety & Learning System (BCPSLS) has **partnered** with the BC Ministry of Health, health authorities, and Health Canada to create a provincial strategy for implementing the mandatory reporting requirements.
- The **provincial strategy** includes:
  - the use of an established, province-wide incident reporting system (BCPSLS) to report ADRs and MDIs;
  - a steering committee and working groups to guide and implement the approach; and
  - a communication and education campaign to promote reporting.
- Members of the steering committee and working groups include representatives from BCPSLS, BC Ministry of Health, Health Canada, pharmacy, biomedical engineering, supply chain, and quality, safety and risk.

Source: British Columbia Patient Safety and Learning System Central Office; 2019.

EXAMPLE: Newfoundland and Labrador

- In Newfoundland and Labrador, the Department of Health and Community Services has partnered with the four regional health authorities in a steering committee to create a provincial strategy for implementing the mandatory reporting requirements.
- The **Provincial Steering Committee's** mandate includes:
  - establishing the most effective and efficient method for mandatory reporting,
  - promoting interdisciplinary collaboration in mandatory reporting, and
  - implementing an educational approach.
- Team members of the steering committee include representatives from quality, patient safety and risk management, pharmacy services, nursing, physicians, biomedical services, and information technology.

Source: Department of Health and Community Services, Newfoundland and Labrador; 2019.

EXAMPLE: Quebec (CHU Sainte-Justine)

Patient Safety RightNow

- Goal: Collaboration between the pharmacist and medical archivist to lead implementation of mandatory serious ADR reporting.
- A **pharmacovigilance coordinator (pharmacist)**
  - manages the reporting of serious ADRs to Health Canada, and
  - reviews and disseminates risk communications from Health Canada.
- A **medical archivist** (i.e., medical records staff) codes serious ADRs from notes in the patient's medical record and sends the information to the Pharmacovigilance Coordinator.

Notes:

- A serious ADR may be missed if it is not well documented in the medical record. Providing training to health care providers about documenting ADRs is useful.
- A process to document a serious ADR identified by the medical archivist after discharge is also helpful.

Source: CHU Sainte-Justine, Quebec; 2019.

Strategic and Operational Considerations for Technology

- **Integrate the reporting process into workflow and technology systems** to make reporting as effective and efficient as possible.
  - Explore opportunities to incorporate serious ADR and MDI reporting in **electronic health record** (or electronic medical record) systems
  - Explore opportunities to incorporate serious ADR and/or MDI reporting in **electronic incident reporting** systems
  - Explore opportunities to use the **pharmacy information system** to record serious ADRs and facilitate reporting to Health Canada

Strategic and Operational Considerations for Technology

Patient Safety RightNow

- To facilitate serious ADR and MDI **traceability to a specific product**, technology systems and documentation practices may need to accommodate product-specific identifiers:
  - Drug identification number (DIN) for drugs, disinfectants and biologics / biosimilars
  - Device identifier, catalogue number or model name for medical devices
  - Brand name for all health products
  - Manufacturer's name for all health products
- Explore the feasibility of support from a designated team (e.g., health record team, patient safety team, or risk management team) to **track serious ADRs and MDIs** from the hospital's documentation/coding system(s).

EXAMPLE: Coding Support for Serious ADR and MDI Tracking

- Facilities across Canada capture administrative, clinical, and demographic information on all hospital stays for reporting to the Canadian Institute for Health Information's (CIHI) Discharge Abstract Database (DAD).
- Upon a patient's discharge, the health record is reviewed and coded, according to national standards, using ICD-10-CA .
  - ICD-10-CA is the enhanced Canadian version of the 10th revision of the *International Statistical Classification of Diseases and Related Health Problems*.
  - ICD-10-CA contains codes for diseases, signs and symptoms, abnormal findings, complaints, social circumstances, and external causes of injury or diseases.
  - ICD-10-CA coding can be leveraged to support serious ADR and MDI tracking.

Source: Canadian Institute for Health Information; 2019.

EXAMPLE: Coding Support for Serious ADR and MDI Tracking

- Adverse effect categories in ICD-10-CA:

Y40-Y59	Adverse effects during therapeutic use of a drug, medicament or biological substance	These external cause codes are assigned when the drug/substance is used as prescribed or intended in therapeutic use.
Y70-Y82	Adverse events with medical devices	These external cause codes are assigned exclusively for unexpected malfunctioning or breakage of a device.

- There are some gaps in what is captured to meet DAD reporting requirements and what is needed to comply with mandatory reporting requirements:
  - CIHI's DAD ICD-10-CA coding does not capture specific drug/device names, therefore this information would need to be obtained from the patient's health record for mandatory reporting.
  - CIHI's DAD ICD-10-CA coding is based on physician*-documented adverse effects that cause harm.
  - CIHI's DAD ICD-10-CA coding is based on actual events and would not identify potential for serious harm in the case of medical device incidents.

*Mandatory reporting regulations do not require physician confirmation of a serious ADR or MDI.

Source: Canadian Institute for Health Information; 2019.

Strategic and Operational Considerations for Education

Patient Safety RightNow

- **Refer to Health Canada's resources**:
  - Modules – Educational support for mandatory reporting
  - Posters to promote reporting
- **Include education about serious ADR and MDI reporting in:**
  - orientation programs,
  - student teaching programs and curricula, and
  - continuing education programs.
- **Empower patients and families** to ask questions and be engaged in monitoring their treatments
- **Share tips for recognizing a serious ADR or MDI** with health care providers
  - Consider if symptoms experienced by the patient might be due to a serious ADR or MDI
- **Develop a process** to regularly share within the hospital (e.g., newsletters, intranet) Health Canada's safety findings related to serious ADRs and MDIs

Tips for Recognizing a Serious ADR or MDI

- Serious harm from a drug or from a medical device can be mistaken for a symptom of a disease.
- A high level of suspicion, clinical awareness, and patient dialogue are key components in identifying a serious ADR or MDI. The following can help:
  - Ask about the patient's medical history
  - Consider a serious ADR or MDI if there is:
    - an unexpected change in the patient's clinical condition
    - a new health problem for the patient
    - a need for urgent additional therapies, procedures or surgeries
    - a sudden need for a rescue drug (e.g., naloxone, epinephrine, glucagon)
    - a medical order for an acute change to therapy (e.g., abrupt discontinuation)
- A serious ADR or MDI can occur shortly after beginning treatment or much later

Examples of Safety Information Sharing

Patient Safety RightNow

Health Canada disseminates findings to health care providers and the public to **alert** and **educate** them about identified health risks related to health products.

Multiple sources of safety information are available to provide up-to-date information:

- 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/)

Alberta Health Services (AHS)

Nancy Louis

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Provincial Director, AHS Product Quality & Safety
Alberta Health Services

Vanessa's Law
The Alberta Approach

Alberta Health Services: Get to Know Us

Alberta Health Services

HISTORY

08

Founded
May 2008

Brought together

9 regional health authorities

and

3 agencies

Largest, fully-integrated health system in Canada.

BY THE NUMBERS – OUR PEOPLE

108,000
Employees

Serving
4.2 million
Albertans

650
Facilities across the province

8,968
Acute and sub-acute care beds/spaces

Connect Care
Who will we reach?

POPULATION
86,900 AHS
8,800 Covenant
8,000 Physicians
10,000 Students
2,100 Carewest / Capital Care / CLS

BEDS
8,940 Total Hospital Acute and Sub-Acute Care
25,323 Total Continuing Care
2,659 Total Addiction and Mental Health

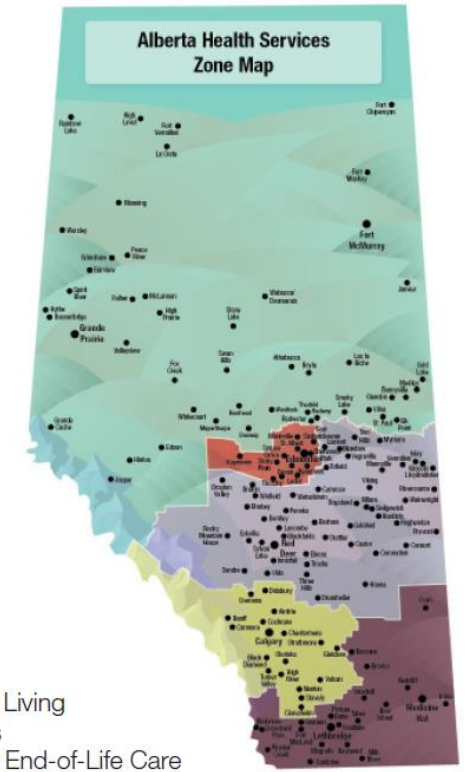
FACILITIES
Community Ambulatory Care
6 Urgent Care Centres
7 Ambulatory Care Centres
3 Family Care Clinics
139 Public Health Centres

Addiction and Mental Health
39 Addiction
26 Community Mental Health
5 Standalone Psychiatric

Acute Care
106 Total Designated Hospitals

Cancer Care
17 Cancer Centres

Community-Based Care
331 Long-Term Care and Supportive Living
108 Additional Contracted Care Sites
20 Community Hospice, Palliative & End-of-Life Care



Alberta Approach

- Centralized provincial approach
  - In development for Serious Adverse Drug Reaction (SADR) reporting
  - Existing process is under improvement for Medical Device Incident or Problem (MDIP) reporting
- AHS Vanessa's Law Task Force
  - Multidisciplinary committee responsible for coordinating the initiative
- Will include a centralized process to receive, review, collate, and submit reports

Alberta Approach

- Communication plan in development
  - Goals: generate awareness, promote understanding of the importance of the legislation, convey the importance of reporting, engage audiences to make the necessary practice changes
  - AHS specific educational resources (e.g. memos, posters, videos, learning module)
  - Landing page on AHS intranet
  - Central email account for questions and follow up

Alberta Approach

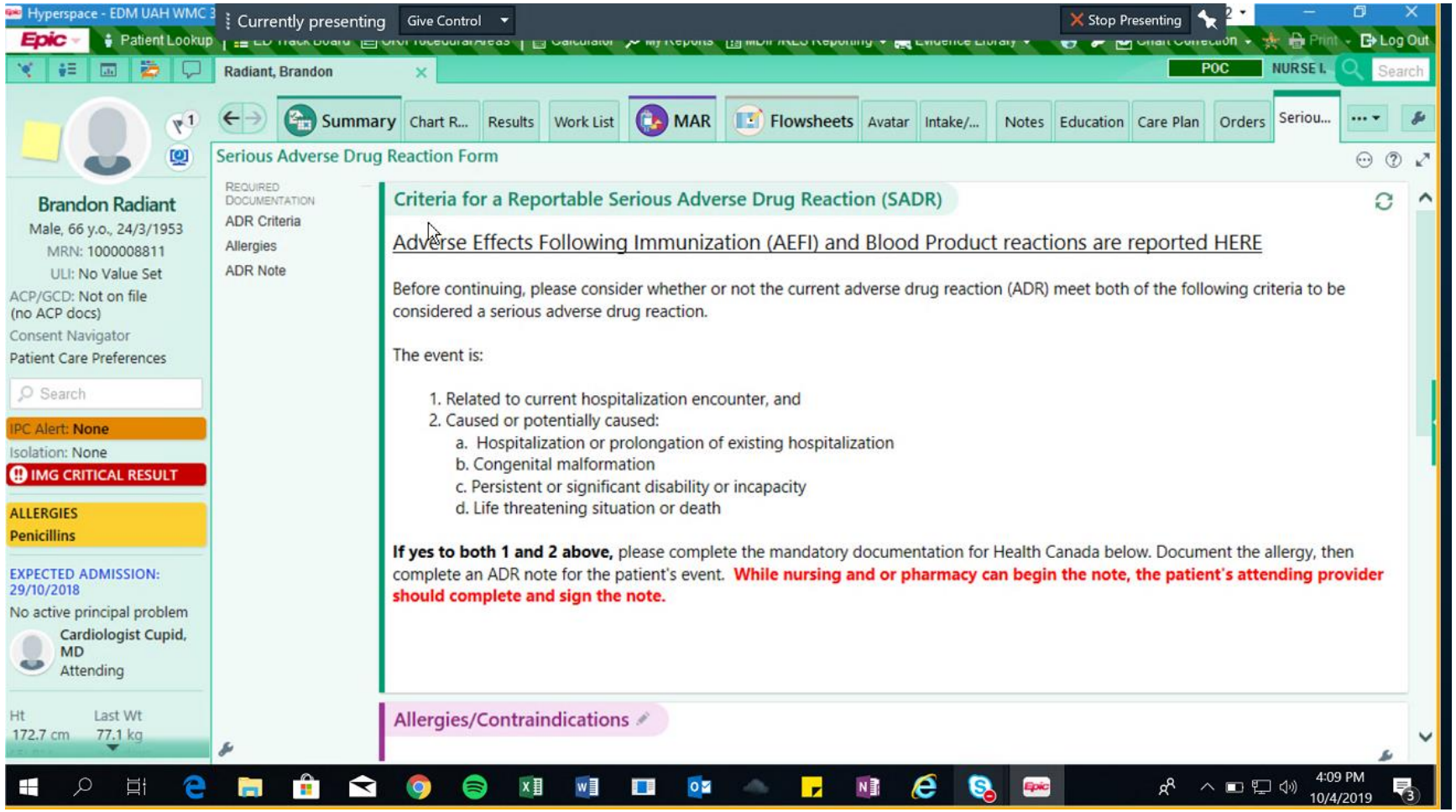
- Alberta is implementing a province wide electronic medical record
  - All sites will use a single electronic health record after a staggered roll out across the province

    Epic
  - Timeline for Epic – first site goes live in November 2019
  - SADR reporting will be integrated into Epic
  - MDI reporting will be linked from within Epic, as well as from the AHS intranet

SADR reporting process in AHS

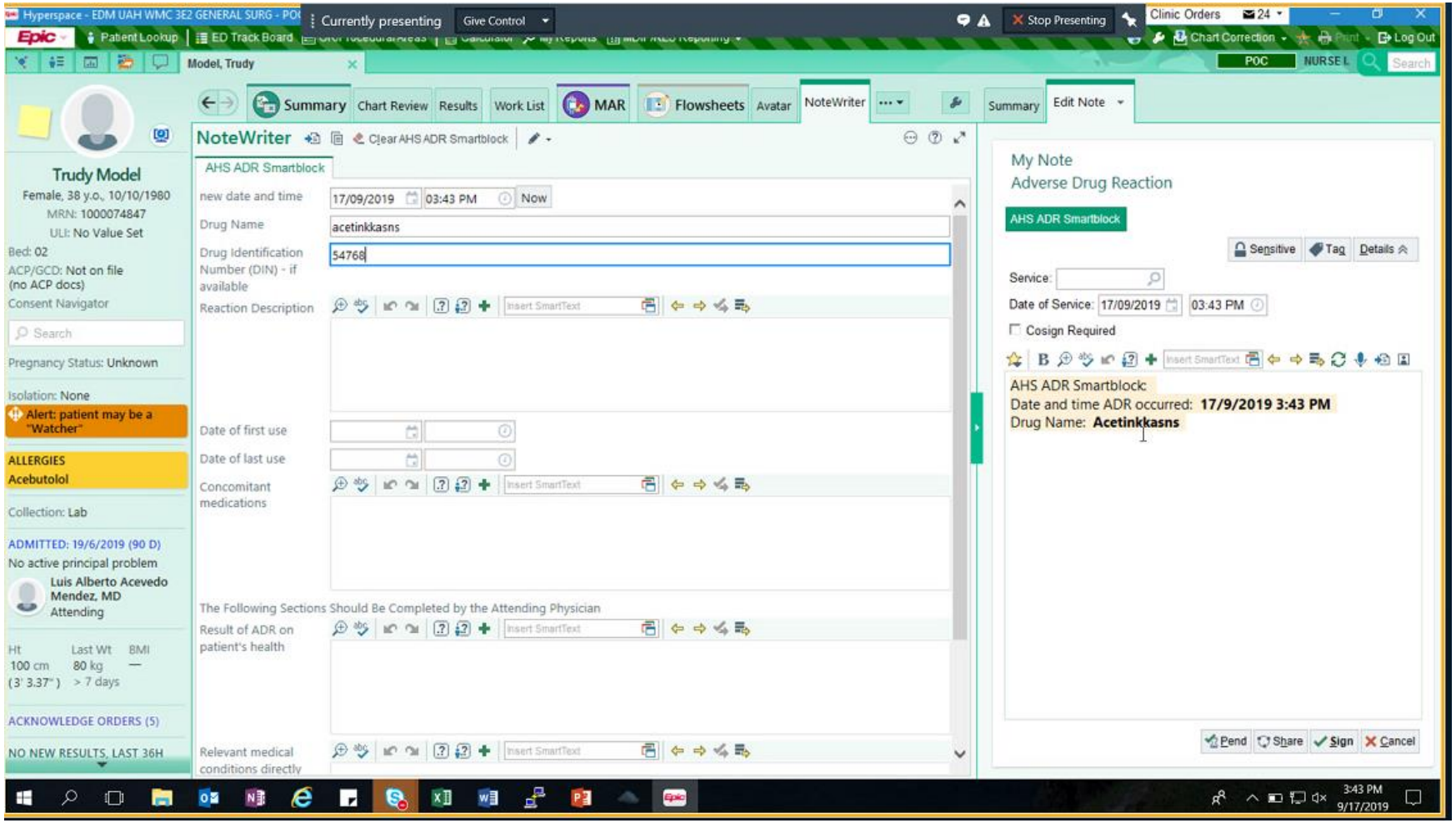
Sites that have implemented Epic	Sites that have not yet implemented Epic
SADR reporting functionality will be fully integrated into the electronic health record	Existing online reporting system (AHS Reporting and Learning System – RLS) will be used

SADR reporting process in Epic



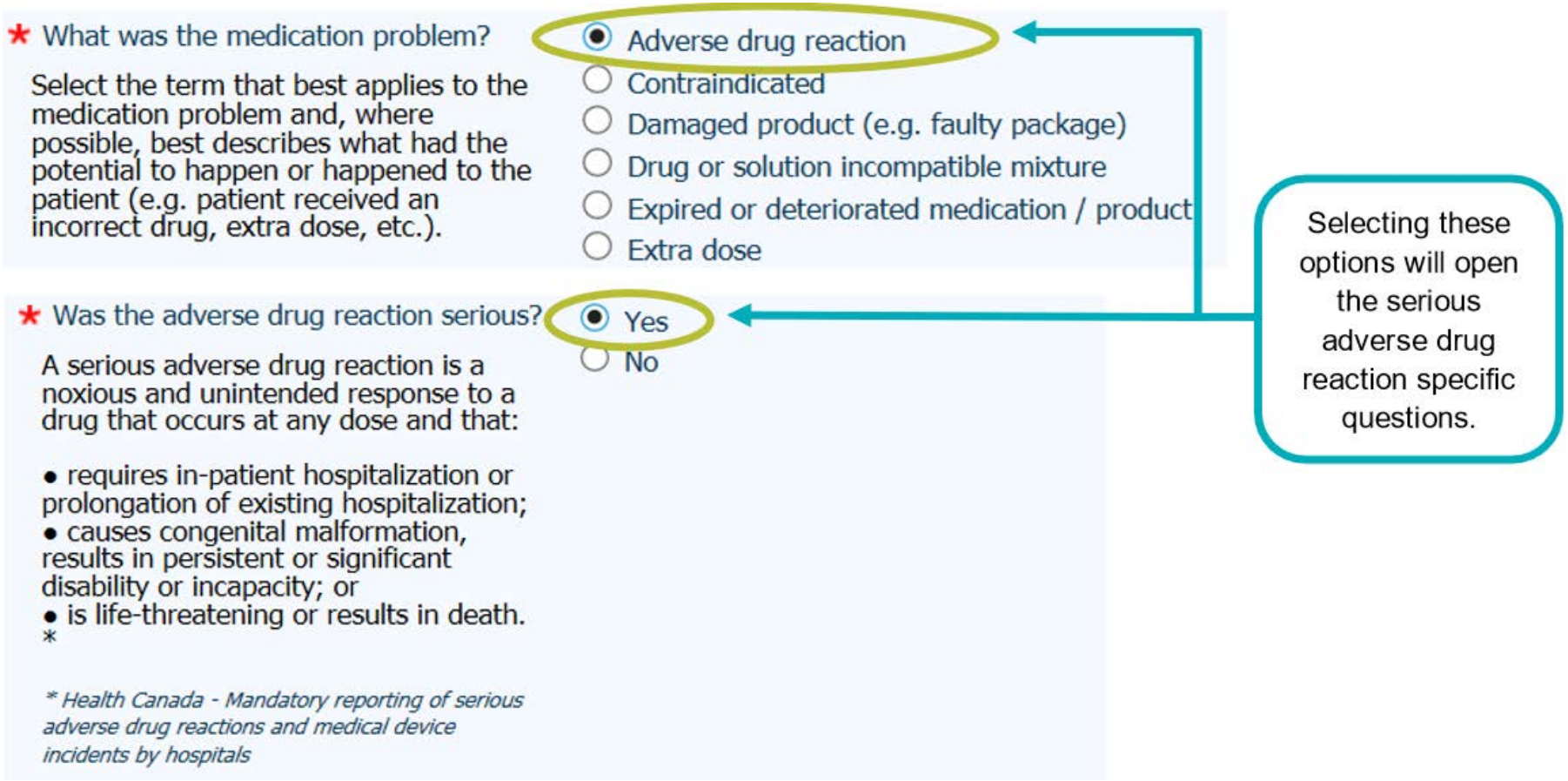
SADR reporting process in Epic

Patient Safety RightNow



SADR reporting process in RLS

SADR reporting process in RLS



MDIP reporting process - Legacy

Patient Safety RightNow

Two Teams – Two Streams
3+ forms, 2 teams, 1 Medical Device Hotline (1-888)

"Equipment"
Maintained devices

- *Incidents (harm)* typically reported through **RLS**
- *Problems* typically reported by Clinical Engineering via **Equipment Feedback form**

"Product"
Consumable devices

- ~23% reported through **RLS**
- *Incidents and Problems* typically reported through **Product Feedback form**

Updated MDIP process

Patient Safety RightNow

New, Single MDIP Reporting Form (& MDIP Hotline)	
• InfoPath Form (eventually stand-alone Datix form) • Feed into MDS Teams' Sharepoint site • MDS Teams validate, facilitate, investigate, report	
Epic Locations	**Non-Epic Locations**
Link on every Epic user's 'hyperspace' to MDIP form	Link on intranet to same MDIP form, feeds same SP site

New MDIP form – four views

Patient Safety RightNow

Additional proposed supports to MDIP reporting

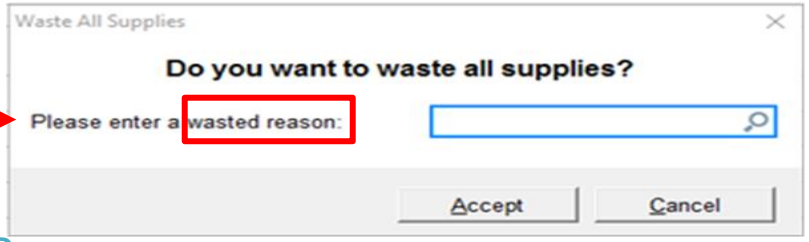
Patient Safety RightNow

Barcode scanning + UDIs

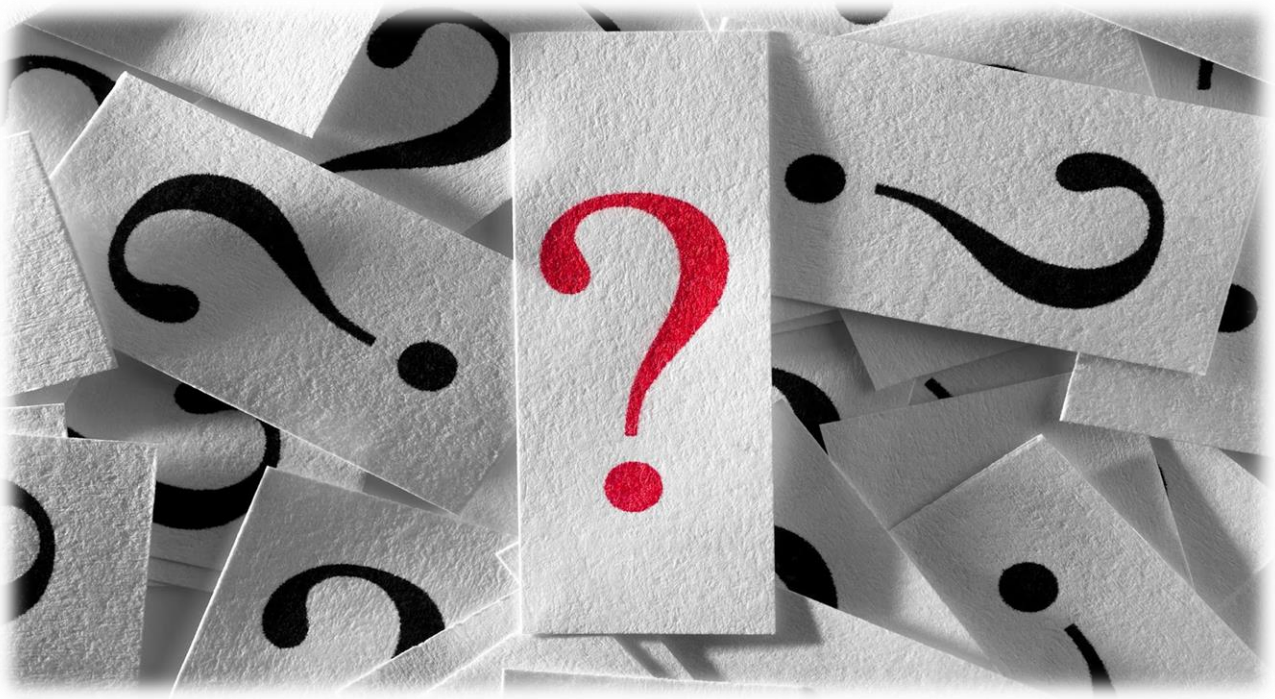
- Barcode scanning for implants, *to start*
- UDI eventually required all devices (USFDA & HC we hope)

Supply MDIP "Wasted Reason"

- Device problem before or during use
- Cue/double-check that we have not missed MDIP



Thank you!
Questions?



Thanks to our sponsors

Patient Safety RightNow

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#ConquerSilence Campaign is here to stay

Acknowledgments

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More information is available from:

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