Vanessa's Law

Questions and Answers

What types of medical devices do the mandatory reporting requirements apply to?

Reporting requirements apply to a wide range of health and medical instruments used in the treatment, mitigation, diagnosis or prevention of a disease or abnormal physical condition. Specifically, all types of medical devices under Health Canada's Risk-based Classification System are included, meaning classes I to IV. For example, bandages are Class I medical devices, tubing is Class II, infusion pumps are Class III and implantable medical devices are Class IV. The full range is included, not just capital equipment but the disposable types as well.

Are new allergies considered serious adverse drug reactions?

Once again, one should refer to the definition of a serious adverse drug reaction. If the reaction meets these requirements, it is reportable.

Could you please define disinfectants? Would disinfectants include environmental cleaning products? Would all disinfectants be included in the reporting obligation, or just the ones used to treat patients?

Disinfectants refer to **hard surface disinfectants and not topical antiseptic agents**. Disinfectants are either classified as natural health products (have a Natural Product Number, or NPN), drugs (have a Drug Identification Number, or DIN) or medical devices. Disinfectants are only subject to mandatory reporting if they are a drug or a medical device. **Only disinfectants with a DIN are subject to mandatory reporting for hospitals.**

The definition of serious adverse drug reaction defines it as noxious and unintended instead of unexpected. Why is that?

The consideration around expectedness is not included in the definition of a serious adverse drug reaction, since a reaction could be noxious and unintended but expected (labelled reaction in the product monograph) or noxious and unintended but unexpected (not labelled in the product monograph). Both types of reactions are important sources of information about the safety of a health product. Under the regulations, hospitals would be required to report all documented serious expected and unexpected ADRs (including off-label use), as well as all documented MDIs, including MDIs with the potential to cause harm if they reoccur.

If a known ADR is seen, for example an intracranial hemorrhage in a patient who is on anticoagulant therapy, do we report this even though the reason that we think the patient has this reaction was that they fell and hit their head?

Hospitals are not required to establish causality between a therapeutic product and a serious ADR or MDI to send a report to Health Canada. The information to be submitted by the hospital to Health Canada only needs to represent the suspicions of the documenting health care professional that a serious ADR or MDI has been observed and relatedness to the drug or device.

In the example provided, if the health care professional attributes the intracranial hemorrhage to the anticoagulant the patient was taking, even if the serious adverse drug reaction is an expected one, the hospital should report it to Health Canada.

Are allergies considered to be an adverse drug reaction?

The decision whether an allergy is an adverse drug reaction depends on the opinion/suspicion of the health care professional as to whether the allergy is related to the drug. Hospitals are not required to establish causality between a therapeutic product and a serious ADR or MDI to send a report to Health Canada. It is also important to note that only serious adverse drug reactions are required to be reported. Consequently, if a patient has an allergy due to a medication, but the reaction they experienced was a minor non-serious reaction (for example a minor skin rash), this reaction would not be mandatory to be reported.

There is a difference between unintended and unexpected such as increased propensity of bleeding risk associated with anticoagulant. In this case, we expect the outcome (bleeding) but the magnitude of risk is unintended if it occurs. Does that make it mandatory to be reported if the patient requires prolonged hospitalization or needs to be hospitalized?

All serious adverse drug reactions are required to be reported as per the new regulations, regardless of the expectedness of the event. If the reaction is in line with the definition, which is noxious and unintended without consideration for the expectedness, it should be reported to Health Canada.

Provide clarification on serious adverse reactions with respect to hospitalization. So what if the patient was admitted to the emergency department and kept in the emergency department for 6 hours versus 12 hours versus 24 hours or 48 hours?

Even if the patient was not admitted as an in-patient after being treated in the emergency department, as long as the serious ADR or MDI was documented at the hospital, the hospital is responsible for reporting the event to Health Canada. It should also be noted that, regardless of the specific service area in the hospital where the serious ADR or MDI report was documented, the hospital is responsible for sending all documented serious ADR or MDI reports to Health Canada.

If a drug causes a fall which results in one of the “serious” outcomes, is this considered a serious ADR?

The definition of a serious adverse drug reaction implies that the causal relationship between the drug and the occurrence of the adverse reaction is suspected, and for the reaction to be considered serious, a minimum of one or any combination of the outcomes should be fulfilled. The serious outcome for the adverse drug reaction would be attributed to the fall, directly linked to the drug, and for this reason, would be grounds for reporting to Health Canada. Medical judgment is required to make this determination.

Would every overdose have to be reported even if it was an intentional overdose?

No. An intentional drug overdose is outside of the scope of these new regulations, and therefore not required to be reported to Health Canada. An intentional overdose does not meet the definition of a serious adverse drug reaction (ADR), because it is not considered as being an unintended response to a drug. It is also important to note that overdoses and other serious ADRs that are the result of illegal drugs (e.g. heroin, methamphetamine, etc.) are not subject to mandatory reporting.

If a patient becomes addicted to a prescribed drug and requires hospitalization for this issue, is this to be a mandatory report assuming the addiction is an unintended response?

A serious adverse drug reaction 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. Going back to the example, the addiction is both noxious and unintended, and led to (in-patient) hospitalization. Therefore, this should be reported as part of the mandatory reporting regulations.

Would we have to report every use of an antidote (e.g. sugammadex, vitamin K, naloxone)?

An antidote is the treatment administered to reverse/limit the effects of an adverse drug reaction. As per the regulations, the treatment (antidote) of a reaction is not required to be reported. However, if the reaction having necessitated the use of an antidote meets the definition of a serious adverse drug reaction, then the reaction should be reported to meet the regulatory requirements.

Do serious ADRs caused by human error have to be reported?

No. Serious ADRs that occur because of a medication error are not subject to these regulations, because they are due to human factors and not the drug itself. Examples of medication errors include incorrect prescribing, dispensing or administration of a medication. The regulation of health care professionals is a provincial and territorial jurisdiction. How will I differentiate serious ADR or MDI from a symptom of a disease? Serious harm from a drug or from a medical

device can be mistaken for a symptom of a disease. A high level of suspicion and clinical awareness is key. 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.

What are examples of medical devices that fall under *Vanessa's Law*?

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):

• 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.

Examples of serious adverse drug reactions (ADRs)

To determine whether the ADR meets the threshold of "serious", the following questions should be considered. Has the ADR resulted in:

- Treatment in the emergency department, hospitalization, prolongation of existing hospitalization?
- Congenital malformation?
- Persistent or significant disability or incapacity?

Is the ADR life-threatening or has it resulted in death? The term "life-threatening" in the definition of "serious" refers to a reaction in which the patient was at risk of death at the time of the reaction; it does not refer to a reaction which hypothetically might have caused death if it were more severe.

Anticoagulant-induced nosebleed

A patient has been recently started on the oral anticoagulant warfarin and is having international normalized ratio (INR) monitored at a hospital's out-patient anticoagulation clinic.

The patient reported a nosebleed that occurred in the time between clinic appointments. Based on the patient's INR level, the patient's warfarin dose was adjusted. The patient will continue to have INR monitored at the hospital.

Although this is an ADR, it does not meet the criteria of “serious”.

Medication-induced GI bleed

A patient had been taking warfarin, among other medications, and presented to the emergency department with a life-threatening GI bleed and was required to be hospitalized in order to be stabilized.

- ✔ Life-threatening
- ✔ Admitted to hospital

This ADR meets the criteria of “serious” because it is a life-threatening event that has resulted in the hospitalization of the patient.

Alopecia from chemotherapy drugs

A patient who has recently started chemotherapy but is being managed as an out-patient notes to her physician that one of the ADRs she has noticed is alopecia (hair loss).

This adverse drug reaction, although considered serious from the patient's perspective, does not meet the criteria of “serious” in relation to a reportable ADR.

Bleomycin-induced pulmonary fibrosis

A patient diagnosed with Hodgkin's lymphoma was being treated with doxorubicin, bleomycin, vincristine and dacarbazine. Following cycle 3, the patient was admitted as an in-patient with complaints of dry cough and shortness of breath on exertion. Bleomycin-induced pulmonary fibrosis was suspected.

- ✔ Life-threatening
- ✔ Caused disability
- ✔ Admitted to hospital

This ADR **meets** the criteria of “serious” because it is a life-threatening event that has resulted in the patient being hospitalized. It also meets the criteria of “serious” because bleomycin-induced pulmonary fibrosis may be considered a persistent and significant disability as it can impact the patient's quality of life given that it can take a long time for an improvement in pulmonary function.

Patient develops neutropenia from chemotherapy drugs

A patient was being treated with doxorubicin and cyclophosphamide and developed neutropenia. After assessing the severity of the neutropenia, a decision was made to continue with chemotherapy at a reduced dose with growth factor support.

This ADR would not meet the criteria of "serious". While the patient may be at increased risk for potentially fatal infections, the ADR is not immediately life-threatening. **However, if the patient develops febrile neutropenia and requires in-patient hospitalization and treatment with antimicrobials to prevent infectious complications, then the ADR would meet the criteria of "serious".**

Examples of Medical Device Incident

Device labelling

Patients undergoing endometrial ablation of the uterus suffered burns to adjacent organs; these burns were due to thin uterine walls and were an unanticipated side effect of ablation. The manufacturer failed to change the ablation device label to warn users of this side effect (which may be produced when the device is working within specification).

Defective device discovered during procedure

A health care professional reported that the sewing cuff was discovered to be defective during a heart valve implant. The defective valve was abandoned, a new valve was implanted, and pumping time during surgery was extended. This defect had the potential to cause serious harm.

Manufacturer releases out-of-specification devices

A batch of out-of-specification blood glucose test strips is released by a manufacturer. The patient uses the strips according to instructions, but readings provide incorrect values leading to incorrect insulin dosage, resulting in hypoglycemic shock and hospitalization.

Any serious ADR or MDI documented in a hospital is subject to mandatory reporting.

When in doubt, report!

Questions?

To learn more about serious adverse drug reaction (ADR) or medical device incident (MDI) reporting, contact your please contact the Regional Coordinator of Alerts/Recalls and Mandatory Reporting at rim.iim-adr.mdi@vitalitenb.ca or visit Mandatory Reporting - Vanessa's Law Page on Boulevard (for employees) or Mandatory Reporting (Vanessa's Law) | Vitalité (vitalitenb.ca) (for physicians)