RÉSEAU DE SANTÉ vitalité HEALTH NETWORK

CASE EXAMPLE TO REPORT  AND NOT TO REPORT  TO HEALTH CANADA

Examples of Adverse Drug Reaction (ADR)		
Case	**Report?**	**Rationale**
A patient had been taking warfarin, among other medications, and presented to the emergency department with a life-threatening gastrointestinal bleed. The patient required hospitalization in order to be stabilized.		Life-threatening condition  Resulted in in-patient hospitalization
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 condition  Resulted in in-patient hospitalization
A 25-year-old patient with seizure disorders was admitted to hospital after experiencing fever, chills and lymphadenopathy for one week. In addition, a non-itchy, erythematous maculopapular rash affecting the trunk and extremities was observed for two weeks. He also began to show yellowish discoloration of the eyes seven days after the onset of fever. Laboratory data demonstrated a marked increase in eosinophils, serum creatinine and liver enzymes. The patient was taking phenytoin. Suspected hypersensitivity syndrome caused by phenytoin is suspected.		Resulted in in-patient hospitalization
A patient has been recently started on the oral anticoagulant warfarin and is having international normalized ratio (INR) monitored at an out-patient anticoagulation clinic at a hospital. 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.		While the patient may be at increased risk for another bleed (with an elevated INR and recent nosebleed), the ADR does not meet the criteria for “serious”.
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.		While the patient may be at increased risk for potentially fatal infections, the ADR is not immediately life-threatening. Note: This ADR would need to be reported if the patient developed febrile neutropenia and required in-patient hospitalization for treatment (e.g., antimicrobials to prevent infectious complications from febrile neutropenia).

A patient experienced dizziness and sweating after a dose of insulin. The patient required glucose tablets to recover. It was discovered that a short-acting insulin had been provided instead of the patient's usual long-acting insulin.		A medication incident, also referred to as a medication error, is a mistake with medication or a problem that could cause a mistake with medication. Medication incidents are generally preventable and include errors such as receiving the wrong medication or dose or using the wrong route of administration. NB : An Incident Report must be completed.
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.

Examples of Medical Device Incident (MDI)		
Case	**Report?**	**Rationale**
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).		Serious deterioration in the state of health of a patient
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.		Potential for death or serious deterioration in the state of health of this patient due to extended surgical time and this possible defect being missed prior to surgical close on other patients leading to emergency failure
A batch of out-of-specification blood glucose test strips is released by a manufacturer. The patient uses strips according to instructions, but readings provide incorrect values leading to incorrect insulin dosage, resulting in hypoglycemic shock and hospitalization.		Serious deterioration in the state of health of a patient
A user performed an inflation test prior to inserting the balloon catheter into the patient, as required in the instructions for use accompanying the device. A malfunction on inflation was detected and another balloon was used.		This device deficiency would always be found by the user prior to patient use and is an expected potential deficiency noted in the product's instructions for use. If the user performed the testing prior to use, as per the instructions, no harm would come to a patient.
A patient died after dialysis treatment. The patient had end-stage renal disease and died of renal failure.		When the hospital has information that the cause of the incident was definitely due to a patient's condition, the incident does not need to be reported. The patient's condition could be pre-existing or occurring during device use. An incident due to a patient's condition does not meet the requirements of an MDI.

An infusion pump stopped, due to a malfunction, but failed to give an alarm. The patient received an under-infusion of antibiotics, causing septic shock and a required stay in the hospital's intensive care unit to correct.		Serious deterioration in the state of health of a patient
The loss of sensing after a pacemaker has reached "end of life". The elective replacement indicator did not show up in due time, although it should have according to device specifications. This has a potential for serious harm.		Serious deterioration in the state of health of a patient likely to occur.
During patient examination, the C-arm on an X-ray vascular system had uncontrolled motion. The patient was hit by the image intensifier and was permanently and severely injured. The system was installed, maintained, and used according to manufacturer's instructions.		Serious deterioration in the state of health of a patient
A monitor suspension system, that was installed, maintained and used according to the manufacturer's instructions, fell from the ceiling when the bolts holding the swivel joint broke off. No one was injured in the surgical theatre at that time. However, if there had been a surgical team and a patient with an open surgical site on the table below there could have been serious harm to one or more people.		This is an example of a near incident/near miss
Sterile, single-use implantable device packaging was labelled with the caution, "Do not use if package is opened or damaged". By incorrect design, the label is placed on the inner packaging. The device was subsequently stored only in the inner packaging, which did not offer a sufficient sterile barrier. The outer package was removed, but the device was not used during the procedure. There is a potential for serious harm because of potential sepsis.		Serious deterioration in the state of health of a patient likely to occur.
The premature revision of an orthopaedic implant due to loosening. No cause yet determined. The patient has the potential of having serious permanent harm caused by this loosening.		Serious deterioration in the state of health of a patient likely to occur.
During the use of an external defibrillator on a patient, the defibrillator failed to deliver the programmed level of energy due to a malfunction. The patient was not revived. Note: If the patient was revived, this would be considered a near incident and would also be reportable.		Death of a patient.
A user reported that there were insufficient details in the instructions for use regarding cleaning methods for reusable surgical instruments used in brain surgery, despite the risk of variant Creutzfeldt-Jakob Disease (vCJD) transmission.		Serious deterioration in the state of health of a patient likely to occur.
After a malfunction of an infusion pump that was not related to a manufacturing defect, the pump gives an appropriate alarm and stops. There was no harm to the patient.		Malfunction protection operated correctly