

Vanessa's Law Activity

A serious adverse drug reaction is a noxious and unintended response to a drug regardless of the dose.

CASE #1: POSSIBLE SERIOUS ADVERSE DRUG REACTION

A patient was admitted with autoimmune hemolytic anemia thought to be due to sulfamethoxazole + trimethoprim. Patient was administered intravenous antibiotics (to meet anti-infective needs). Patient received intravenous (IV) methylprednisolone for five days, blood transfusions, and was treated with folic acid. IV steroids were transitioned to oral steroids, and patient was discharged eight days after admission on a high-dose taper-course of prednisone.

Has the ADR resulted in:

- death?
- a life-threatening condition?
- persistent or significant disability or incapacity?
- congenital malformation?
- in-patient hospitalization?
- an extended length of stay?
- significant medical intervention (in emergency or hospital) to prevent any outcome listed above?
- Does this case meet mandatory reporting criteria?

CASE #2: POSSIBLE SERIOUS ADVERSE DRUG REACTION

A patient presented to emergency department with anaphylactic reaction to ibuprofen (swelling to lips/face and dysphagia). While enroute to hospital, patient was administered intramuscular diphenhydramine (50 mg) by emergency medical services. In emergency department, patient was administered intramuscular epinephrine (0.3 mg) and intravenous famotidine (20 mg). Patient was discharged home three hours after registration.

Has the ADR resulted in:

- death?
- a life-threatening condition?
- persistent or significant disability or incapacity?
- congenital malformation?
- in-patient hospitalization?
- an extended length of stay?
- significant medical intervention (in emergency or hospital) to prevent any outcome listed above?
- Does this case meet mandatory reporting criteria?

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A medical device incident (MDI) is:

- the failure of a medical device, or
- deterioration in the effectiveness of a medical device, or
- any inadequacy in labelling or directions for use of a medical device.

CASE #3: POSSIBLE MEDICAL DEVICE INCIDENT

During a patient's laparoscopic radical nephrectomy, the seal and cut button of the single-use vessel cutter/sealing device would not activate. The device was replaced, and surgery was completed without further incident. (No injury to this patient.)

The instructions for use of the device state "to always prepare a secondary method for achieving hemostasis or dissection" when using the device (for example, prepare a spare instrument and a back-up of the transducer for use in the operative suite).

Has the MDI resulted in:

- death?
- a serious deterioration in the state of health of a patient, user, or other person? (definition below) OR
- (Near Miss) Failure or deterioration in the effectiveness of a medical device was identified BEFORE it was used; however, use of the device would have resulted in serious harm to a patient, user, or other person.

A serious deterioration in the state of health means:

- a life-threatening disease, disorder, or abnormal physical state;
 - the permanent impairment of body function or permanent damage to a body structure;
 - A condition that necessitates an unexpected medical or surgical intervention to prevent a disease, disorder, or abnormal physical state; or permanent impairment or damage.
- Does this case meet mandatory reporting criteria?

CASE #4: POSSIBLE MEDICAL DEVICE INCIDENT

While performing spinal anesthesia on a patient, a 5 cm to 6 cm section of the spinal needle broke off inside patient's back. Neurosurgeon was consulted and removed foreign body under local anesthesia. A second attempt at spinal anesthesia was successful, and the original procedure proceeded as scheduled.

Has the MDI resulted in:

- death?
- a serious deterioration in the state of health of a patient, user, or other person? (definition below) OR
- (Near Miss) Failure or deterioration in the effectiveness of a medical device was identified BEFORE it was used; however, use of the device would have resulted in serious harm to a patient, user, or other person.

A serious deterioration in the state of health means:

- a life-threatening disease, disorder, or abnormal physical state;
 - the permanent impairment of body function or permanent damage to a body structure;
 - A condition that necessitates an unexpected medical or surgical intervention to prevent a disease, disorder, or abnormal physical state; or permanent impairment or damage.
- Does this case meet mandatory reporting criteria?