**Adverse Event and Patient Safety Use Cases for HL7 FHIR Adverse Event Resource**

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\**Have use case(s)*

1. Adverse Event:
   1. Drug\*
      1. Combination products – epi pen with drug, drug coated stents
   2. Biologic
   3. Device\*
   4. Vaccine
   5. Medical Food\*
   6. Dietary Supplement\*
   7. Herbals
   8. Food
   9. Cosmetics
   10. Reporter variations
       1. Healthcare Reported (3500)
       2. Patient Reported (more narrative-based)(3500b)(quantity vs. dose)(med hx)
       3. Manufacturer Reported (3500a)
       4. Veterinary Reported
2. Medication Reconciliation\*
3. Product Problem (device or product)
   1. Can be independent of a patient – could fail before therapy, e.g. breaking, heating up before it reach the patient
   2. Prep device to use – human factors cause issue
   3. Wear out prematurely
   4. Transport changes
   5. Sensor changes with wrong output
   6. Processing, manufacturing, QA
4. Product Quality (office of pharmaceutical quality) Mitra
5. Product Use Error (Suranjen)
   1. Wrong dose\*
   2. Package insert error\*
   3. Wrong technique\*
   4. Wrong route of administration\*
   5. Wrong rate\*
   6. Wrong duration\*
   7. Wrong time\*
   8. Expired drug\*
6. Problem with use of Medication from Different Manufacturers
7. Protocol Adverse Event with IND
   1. Serious Adverse Event
   2. Unanticipated Problem\* (Consider international terminology)
8. Patient Safety Incident\*
9. Patient Safety Near Miss\*
10. Patient Safety Unsafe Condition\*
11. **Adverse Events:**
    1. **Drug Adverse Event**

**Overview:** Confusion between two drugs results in death

**Story:** A 66 year old female died after receiving methotrexate instead of the intended metolazone.  A hospital nurse called in 8 discharge medications to a pharmacy.  One of the prescriptions was transcribed incorrectly at the pharmacy as methotrexate 2.5 mg daily instead of metolazone 2.5 mg.  During the trial, is was discussed that methotrexate is a high-alert medication that should be segregated of the drug away from the other stock in the pharmacy, and hard stop in dispensing software to prevent “one tablet daily” instructions on the label.

* 1. **Biologic Adverse Event**
  2. **Device Adverse Event**

An initial report received from a peritoneal dialysis nurse stated that her patient noticed a cassette leak and shortly thereafter developed peritonitis. The patient had experienced pain, nausea and vomiting and was evaluated in the ER and was subsequently treated for peritonitis. The report noted that the infection was difficult to clear resulting in treatment for over three weeks. The patient was unable to relate the exact period of time between the cassette leak and the development of peritonitis. No sample is available for analysis.

<http://icbo.buffalo.edu/2011/workshop/adverse-events/docs/talks/session3/GoldfainUseCaseAEICBO2011.pdf>

**Device Adverse Event**

On December 12, 2005, J. Doe, a 54 year old female was admitted to the Outpatient Surgery Center for the placement of a Medical Corporation X, Model LS 4700, implantable pain pump. In surgery, the pain pump was implanted without difficulty and was determined to be functional. After the procedure the patient was transferred to the recovery area for stabilization. In the recovery room, the anesthesiologist, Dr. Zoe, initiated the programming of Ms. Doe’s implanted pump. During this set-up procedure the pump stopped functioning and the pump’s visual display went blank. The anesthesiologist was unable to troubleshoot the cause of the device failure, nor restore its function. The patient was informed of the device failure and opted to return to the O.R. the next day for the removal of the defective device and placement of a new pain pump. The patient was scheduled to return to the O. R. for the repeated procedure. The second Model LS 4700 implantable pain pump was implanted and completed its programming process without difficulty.

HL7 Individual Case Safety Report Release 1:

Implementation Guide for FDA Medical Device Report

**Device Adverse Event**

A sterile device comes into the OR and the OR nurse fails to detect small debris and even a human hair in the packaging.  The nurse reports this to MedSun and MedSun trends these poor sterile practices over time.

* 1. **Vaccine Adverse Event**
  2. **Medical Food Adverse Event**

Amalia A. a newborn, was born on March 2 after an uneventful pregnancy. In the first few days after her birth, Amalia required treatment for pneumonia, associated with hypoxia and wheezing. She also was susceptible to aspiration of her formula and a diagnosis of gastroesophageal reflux disease (GERD) was made when she was about 2 weeks old.

XYZ Pharmaceutical’s thickening agent was started for the GERD on April 13. The dosage was a 4-ounce packet with every feeding. Amalia continued on the product at the same dosage until it was discontinued on May 4. Amalia’s mother noticed she had bloody diarrhea on May 9 and took her to the emergency room. Amalia required hospitalization and a gastrointestinal (GI) workup which confirmed the diagnosis of necrotizing enterocolitis. Amalia underwent a small bowel resection and the GI symptoms resolved completely over the next 10-14 days. Amalia was discharged and she remains in good health.

<http://www.accessdata.fda.gov/scripts/MedWatchLearn/adverse_effects/case-study-03.htm>

* 1. **Dietary Supplement Adverse Event**

Jack J. is a 26-year-old single white man and is a self-described body-builder. He went to the emergency room at his local hospital on April 2, 2015 because he felt tired and weak, and also had a cough and shortness of breath, which had become worse over the last two weeks.

Jack takes daily doses of two body-building supplements made by XYZ Nutritionals. He takes three to four pills each of Supplement A and Supplement B per day and has been doing so for the past 2-3 years. The ingredients listed on the labels for each of the supplements include:

Dietary Supplement A for Body Builders containing Ma Huang (ephedrine), guarana (caffeine), chromium picolinate and L-carnitine.

Dietary Supplement B for Body Builders containing HCA (garcinia cambogia extract), Ma Huang, guarana, willow bark extract (salicylates) and chromium picolinate).

The emergency room nurse took Jack’s blood pressure when he arrived and it was very high. The emergency room doctor examined Jack, noted the high blood pressure, and decided to perform an echocardiogram, a test that shows the heart’s size, structure, and function. The test showed Jack’s heart was enlarged and had a reduced pumping capacity. The doctor explained these are symptoms of congestive heart failure, a serious condition. The doctor told Jack it was likely the body-building supplements had caused his heart problems. He recommended that Jack stop using them. Jack was given a prescription for a blood pressure medication and told to have it filled at his local pharmacy. The doctor also recommended that Jack follow up with his primary care provider.

<http://www.accessdata.fda.gov/scripts/MedWatchLearn/adverse_effects/case-study-04.htm>

* 1. **Herbal Adverse Event**
  2. **Food Adverse Event**
  3. **Cosmetic Adverse Event**
  4. **Reporter Variations**
     1. Healthcare Reported
     2. Patient Reported
     3. Manufacturer Reported
     4. Veterinary Reported

1. **Medication Reconciliation**

Medication Reconciliation - Wrong Strength

Overview: Illegible handwriting leads to 10-fold wrong strength error.

Story: The family brought in a handwritten list of medications for a hospitalized patient. The attending physician prescribed the wrong strength of Belbuca (buprenorphine) because the handwritten list of medications used a trailing zero for the strength. The patient had been on 75 mcg, but it was written as 75.0 mcg, and the physician misread it as 750 mcg. Belbuca is available in multiple strengths, including 75 mcg and 750 mcg strengths. The patient received 5 doses of the wrong strength, and experienced dizziness and vomiting. FDA should avoid 10-fold strengths, and consider using strengths like 75 mcg and 749 mcg so they don’t get mixed up

1. **Product Problem (device)**

A sterile device comes into the OR and the OR nurse detects small debris and even a human hair in the packaging and subsequently reports this to MedSun.  While there is no impact to the patient, provision of this information to MedSun helps to trend sterile practices over time.

1. **Product Quality** 
   1. **Device Quality**

HeartWare Inc. is recalling the HVAD controller due to a loose power connector which may cause the rear portion of the pump's driveline connector to become separated from the front portion of the driveline connector. A loose connector may allow moisture to enter the controller causing corrosion, electrical issues, reduced speaker volume and connection failures. If the speaker volume is decreased, the patient may not hear the alarm. If there is a loss of connection, the pump may stop which could cause serious adverse health consequences, including death.

**BACKGROUND**: The HVAD helps deliver blood from the heart to the rest of the body. It is used in patients who are at risk of death from end-stage left ventricular heart failure and who are waiting for a heart transplant. The system includes a pump implanted in the space around the heart (pericardium) and a controller that controls the speed and function of the pump. The HVAD is designed for use both in and out of hospital settings, including during patient transport.

1. **Product Use Error** 
   1. **Wrong Dose (underdose, overdose, extradose)**

Overview: Nurse gave the wrong dose because the Potassium Chloride unit dose cup doesn’t state the total amount per total volume.

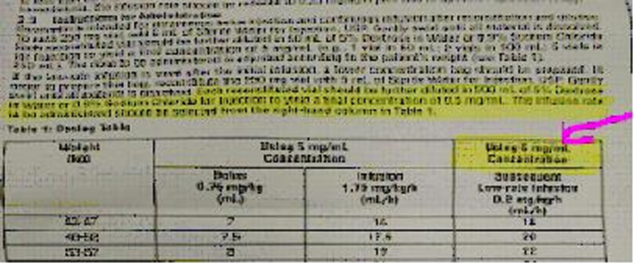
Story: I am a nurse working in a long term care facility. One of our patients has been getting the wrong daily dose of potassium for several weeks now and we only just now realized this error. The label is confusing - we thought the potassium cup contained 15 mL, but it actually contains 30 mL. The resident got twice the amount that the doctor prescribed, and she was transferred to the hospital with hyperkalemia (increased blood potassium levels). A picture of the potassium cup is below. We think the manufacturer should redo the label so everyone realizes the cup contains 30 mL, not 15 mL.



* 1. **Incorrect prescribing information**

Overview: Error in the Prescribing Information can result in a wrong dose error.

Story: Chart dosing error in package insert: Bivalirudin Sandoz Table 1: Dosing Table far right column reads Using 5 mg/ml Concentration. Should read using 0.5 mg/ml Concentration. This could lead to 10 times recommended dose of an anticoagulant.



* 1. **Wrong Technique**

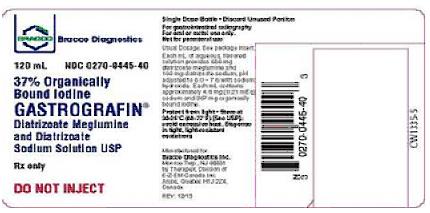
**Overview:** A patient doesn’t use his Trulicity pen correctly.

**Story:** A  32-year-old man with type 2 diabetes mellitus is prescribed a Trulicity pen, and refuses nurse and pharmacy counseling on how to use the pen, stating that he can “figure it out from the instructions in the box”  One month later is hospitalized with low glucose levels.  While hospitalized, he admits he didn’t understand the instructions because the pictures were confusing.  As a result, he sometimes removed the needle from the skin before the dose was administered or he pressed the dose button before he had the pen placed on the skin for injection.  If he wasn’t sure if he got the full dose, he would reuse the pen and give himself another dose.  It would be helpful if the instructions were more clear.

* 1. **Wrong Route of Administration**

**Overview:** An imaging agent intended only for oral or rectal administration was accidentally injected.

**Story:** Our facility has had several instances where MD-Gastroview was drawn up as an intravenous solution and injected (Gastroview is only supposed to be given via the oral or rectal routes).  One patient complained of heaviness and tightness in chest with the sensation that his throat was closing.  We eventually were able to stabilize him, and his symptoms reversed.  I think this happens because our providers misread the statement “Do Not Inject’ as ‘Inject.’  We recommend making the route of administration (For oral or rectal use only”)  more prominent and the ‘Do Not Inject’ less prominent on the container label.



* 1. **Wrong Rate (too fast or too slow)**

**Overview:** A patient was given a drug IV push rather than slow infusion.

**Story**:  An emergency room nurse gave a patient 25 mg of Phenergan (promethazine) IV push.  As the nurse started the injection, the patient cried out due to a stabbing burning pain in the surrounding arm area and elbow.  The nurse paused the injection then injected the rest of the syringe resulting in the patient once again crying out from a burning stabbing pain from the elbow to the wrist.  The patient was discharged later that day but the following day awoke with a numb feeling in the arm along with a red mottled burned appearance to the skin from the wrist to the elbow.  The patient subsequently required skin grafting and rehabilitation.  If promethazine is given intravenously, it should be diluted, and administered at a rate no faster than 25 mg/minute.

* 1. **Wrong Duration**

**Overview:**  Patient uses Afrin nasal decongestant spray longer than recommended.

**Story**:  I am a pharmacist and we have a patient who is on medication for high blood pressure, and always purchases an OTC nasal decongestant spray every month when he refills his blood pressure medicine.  I told him that it would be best to avoid taking the spray decongestant due to his high blood pressure, but the patient always says that he only uses it "now and then."  I told him that the medicine is likely contributing to his high blood pressure and that patient should only use the sprays for a maximum of 3 to 5 days or else the patient might experience severe rebound congestion.  The patient then admitted that he has been using the nasal decongestant spray at least 3-4 times per day for at least 5 years and that each time he has tried to stop using it, the congestion returns much worse than before.  I told him to contact his primary care provider for help weaning off it.  I wonder if FDA should issue a communication about the dangers of overusing nasal decongestant sprays?

* 1. **Wrong Time**

**Overview**: A woman takes her medicine at night instead of in the morning as recommended.

**Story:** A 65 year-old woman with osteoporosis started Fosamax 70 mg once weekly at bedtime.  The pharmacy and provider didn’t give her instructions on how to take Fosamax so she wasn’t aware that she should take it in the morning with a full glass of water and remain upright for 30 minutes.  Three months later, she presents at the clinic with severe sharp chest pain that radiated to her stomach and difficulty swallowing.  She undergoes an endoscopy that esophagitis and a few ulcers in her esophagus.  She was given a prescription for Prilosec, and advised to follow up with a gastroenterologist.

* 1. **Expired Drug**

**Overview:**  Parents administer an expired drug to their child.

**Story**: A 10-year old boy develops a sore throat with a high fever, a rash on his trunk, but no cough or nasal congestion.  His parents recognize the symptoms from the boy’s previous bouts of strep throat.  The mother remembers that they have a leftover partially full bottle of amoxicillin suspension in the medicine cabinet from a few years ago and start giving the amoxicillin to the boy.  After 3 days of treatment, the boy is still symptomatic so the family takes him to his pediatrician.  The physician admonishes them not only about delaying effective treatment but also about administering expired drugs, and exposing their son to low levels of amoxicillin that could potentially breed out a more resistant organism.  The pediatrician then prescribes a 10-day course of amoxicillin/clauvulanic acid.

1. **Protocol Adverse Event with IND (Unanticipated Problem)**

Subjects with essential hypertension are enrolled in a phase 2, nonrandomized clinical trial testing a new investigational antihypertensive drug. At the time the clinical trial is initiated, there is no documented evidence of gastroesophageal reflux disease (GERD) associated with the investigational drug, and the IRB-approved protocol and informed consent document do not describe GERD as a risk of the research. Three of the first ten subjects are noted by the investigator to have severe GERD symptoms that began within one week of starting the investigational drug and resolved a few days after the drug was discontinued. The investigator determines that the GERD symptoms were most likely caused by the investigational drug and warrants modification of the informed consent document to include a description of GERD as a risk of the research.

<http://www.ohsu.edu/xd/research/about/integrity/irb/upload/UP-Case-Studies.pdf>

1. **Patient Safety Incident**

A 75 year old woman Mrs. Jones was admitted to an in-patient oncology service for treatment of Non-Hodgkins lymphoma because of a persistent fever. The patient used a cane for ambulation because “she felt unsteady on her feet” and therefore, a fall-risk protocol was implemented. During the second night of her in-patient stay Mrs. Jones awoke and rather than ringing the nurse call bell, decided to ambulate on her own to the bathroom. After getting out of bed, Mrs. Jones fell and broke her hip. The broken hip extended Mrs. Jones’ stay by one week and required an admission to a rehabilitation facility for physical therapy. The hospital documented the incident in the occurrence reporting system, and Mrs. Jones’ care and treatment was documented in her electronic health record.

**Patient Safety Incident -- Monitoring Error?**

**Overview:** Physicians are prescribing contraindicated drugs

**Story**:  The Prescribing Information for Entresto indicates it is contraindicated to take it with an ACEI like lisinopril.  Since Entresto was approved, we have seen 6 patients in the emergency room with angioedema and renal complications because they are on both an ACEI and Entresto.  I think physicians aren’t aware that patients shouldn’t take an ACEI and Entresto at the same time.  FDA should issue a drug safety communication to warn physicians about this important interaction.

1. **Near Miss Incident**

Dr. Smith was entering orders into the electronic health record after rounds in a skilled nursing facility. Mr. Blue and Mr. Bloom both residents in the facility had been seen on the morning of October 21. First Dr. Smith opened both records in order to document the results of both physical exams – he finished Mr. Blue first and then entered data on Mr. Bloom. Dr. Smith then was interrupted by Ms. Green, the nurse to answer a question about another resident. Upon returning to the computer, Dr. Smith was viewing the chart for Mr. Bloom but began to enter a new medication order for Mr. Blue. The system fired an alert noting a drug-drug interaction with an existing medication, and Dr. Smith realized he was entering the order on the incorrect patient.

The order for Mr. Bloom was given a status of “entered in error” and Dr. Smith entered the medication order for Mr. Blue on the correct chart. No entry was made into the occurrence reporting system.

**Patient Safety Near Miss -- Wrong Drug**

**Overview:**  Patient receives the wrong drug because of established (generic) name similarity

**Story:** A patient in our HIV clinic was prescribed Genvoya   
(tenofovir **alafenamide**/emtricitabine/elvitegravir/cobicistat).  When he filled the prescription at his local retail pharmacy, he received Stribild   
(tenofovir **disoproxil fumarate**/emtricitabine/elvitegravir/cobicistat).  Thankfully, he noticed the error and contacted the clinic about it.  The generic components of these products appear very similar, differing only by the formulation of tenofovir contained within each.  However, the differences between these two forms of tenofovir are substantial in terms of safety.  We are not only concerned about the potential for error due to their similar sounding generic names, but also because of the similar sizes, shapes, and markings of the tablets, differing only by a shade of green (see attached photo).  Both products are manufactured by Gilead Sciences.  We suggest the addition of tallman lettering to the formulation of tenofovir in each of these tablets (eg: tenofovir ALAFENAMIDE) as well as a change in tablet appearance to facilitate prevention of future medication errors with these two single tablet regimens for HIV.



**Patient Report Near Miss --    Wrong Dosage Form**

**Overview:** A pharmacist dispensed 120 cyclosporine modified 100 mg capsules instead of 120 ml of the cyclosporine modified oral liquid (100 mg/ml) because the prescriber didn’t specify the dosage form.

**Story:** A pharmacist received a prescription for cyclosporine modified 100 mg, dispense 120, take as directed, and filled this prescription with the 100 mg capsules.  However, the family later called the pharmacist and reported that they thought the prescriber had written for a liquid preparation since the patient has difficulty swallowing anything but liquids.  Upon follow-up with the prescriber, she confirmed with the pharmacist that that she meant for the pharmacy to dispense 120 ml of the 100 mg/ml cyclosporine modified suspension instead of the capsules.  The patient didn’t take the wrong dosage form.

**Patient Safety Near Miss - Wrong Patient**

**Overview:** Pharmacy gave me the medications that belonged to another patient.

**Story:** I’m a dentist, and have been on atenolol 50 mg once daily for years.  A few days after getting a refill on my prescription, I noticed an increase in urination and a slight uptick in my pulse.  I looked at my pharmacy vial, and realized that I had been taking Hydrochlorothiazide – the pharmacy vial had somebody else’s name on it.  I contacted the pharmacy, and my provider.  I’m switching pharmacies.

1. **Unsafe Condition Incident**

**Overview**: Facility with slippery floors causes employee to slip and spill liquids.

A rehabilitation facility routinely polishes the floors once per month, providing staff with adequate notice regarding this activity. Following the prescribed floor maintenance routine the floors are more slippery. A nutrition services worker was delivering trays to patients the following day and slipped while carrying a tray. While the employee did not fall, several cartons with liquids spilled onto the floor. Housekeeping was called to clean the floor. An occurrence report was not entered.

**Overview:** Look alike carton labeling can result in wrong strength errors

**Story:** No actual error (near miss).  Akorn’s cyclopentolate eye drops look identical.  FDA should require Akorn to use different colors.

