

Reversal Agent Incident Report Initiative

Incident report to be completed for the following reversal agents: naloxone (Narcan), flumazenil (Romazicon) and prothrombin complex concentrate, 4-factor, unactivated (Balfaxar, Kcentra)

Opioid reversal	Benzodiazepine reversal	Vitamin K antagonist (warfarin) reversal Direct factor Xa inhibitor (e.g. apixaban, rivaroxaban) reversal
Naloxone (Narcan)	Flumazenil (Romazicon)	Prothrombin complex concentrate, 4-factor, unactivated (Balfaxar, Kcentra)

How to enter an incident report?

Step 1: Intranet Home Page → Scroll to the bottom right hand corner

Step 2: Click on [Vigilanz Safety Event Reporting](#)

Step 3: Select Facility

SEARCH AND SELECT YOUR FACILITY

East Florida - HCA Florida Aventura Hospital - Aventura, FL ▼

Go Log Off

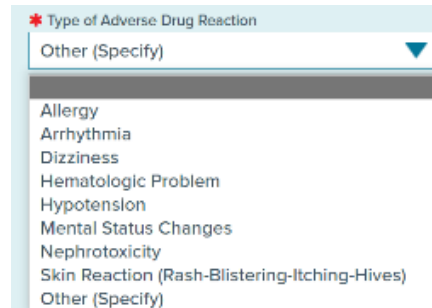
Step 4:

The screenshot shows a navigation menu with two main sections: 'Report' and 'Review'. The 'Report' section is highlighted with a red box and contains the following items: Behavior, Close Call/Near Miss, Environmental/Facilities, Non-Patient, Patient Event, Security, and SVG External Reporting. The 'Review' section contains: AMA/LWBS/LWOT/LBTC, Blood Products, Code BERT, Equipment/Supplies/Medical Device, Fall, Infection, IV/Vascular Access Device/Tubes/Drains, Medication Event, Patient Experience, Patient ID/Documentation/Consent, Patient Self Harm, Perinatal, Procedure/Treatment/Test, Provision of Care, and Skin/Tissue. The 'Medication Event' item is highlighted with a red box and has a sub-menu open, showing 'Adverse Drug Reaction/Allergy (Not Med Error)' and 'Medication Error'. A red arrow points to the 'Adverse Drug Reaction/Allergy (Not Med Error)' option.

Information Required in the Incident Report:

Complete all blanks with red asterisks *

Type of Adverse Drug Reaction



* Type of Adverse Drug Reaction

Other (Specify) ▼

- Allergy
- Arrhythmia
- Dizziness
- Hematologic Problem
- Hypotension
- Mental Status Changes
- Nephrotoxicity
- Skin Reaction (Rash-Blistering-Itching-Hives)
- Other (Specify)

Hartwig Scale (likely one from level 3 to level 7)

Mild (Level 1) The ADR Required No Change in the treatment with the Suspected Drug

Mild (Level 2) The ADR Required that the Suspected Drug be Withheld/Discontinued or Otherwise Changed – No Antidote or Other Treatment Required

Moderate (Level 3) The ADR Required that the Suspected Drug be Withheld/Discontinued or Otherwise Changed and/or an Antidote or Other Treatment is Required

Moderate (Level 4) Any Level 3 ADR that increases the Length of Stay by at Least One Day or the ADR is the Reason for Admission

Severe (Level 5) Any Level 4 ADR that Requires Intensive Medical Care

Severe (Level 6) The ADR Causing Permanent Harm to the Patient

Severe (Level 7) The ADR Either Directly or Indirectly Leading to the Death of the Patient

Offending Drug: Which opioid, anticoagulant or benzodiazepine was involved?

Brief objective description: Medication that caused the use of the reversal agent. Sign and symptoms noted before reversal agent administration. Resolution of signs and symptoms after the reversal agent was administered? Notification of the incident to attending physician?

Patient Example:

Patient over-sedated after administering lorazepam. Physician entered an order for flumazenil. Patient responded; patient now alert and oriented. Informed physician

Information Required in the Incident Report:

Complete all blanks with red asterisks *

* Facility	HCA Florida Aventura Hospital ▼	Facility COID	30920
* Reporter's Profession	▼	* Reporting From Location	Select an Option ▼
* Type of Adverse Drug Reaction	▼		
* Hartwig Scale	▼		
Offending Drug	* Medication Name / Actual Medication Select an Option ▼		
Medication Dose	Actual Route of Administration	Rate of Administration	
▼	▼	▼	
* Patient Last Name	* Patient First Name	Patient Account Number	
▼	▼	▼	
Gender	▼		
* Date of Event	* Event Time	* Location Event Occurred	Location Type
▼	▼	Select an Option ▼	Select an Option ▼
* BRIEF Objective Description (150 character limit)			Reporter Additional Comments
▼			▼
* Employee Witness to Event	▼		
* Non-Employee Witness to Event	▼		
* Patient Significant Other/Guardian Notified	▼		

Reversal Agent Incident Report Meditech Alert

Meditech alert for nursing reminding them to follow up with incident report.

Example of Meditech screen:

PTCP0E24A, LIVEAV 44/U 01/01/80 70 kg V.CPOETEST - PRE IN CrCl NO RESULT AVAILABLE

Allergy No Known Allergies AdvReac No Adr Entered

Sunday March 24, 2024 1525 Allergies

A	Start	Medication	Sched Time	Today		
				Sat	Sun	Mon
✓	03/24/24 1523	flumazenil 0.2 mg IV ONCEPRN (BENZ REV)				
	04/23/24 1522	flumazenil ... (Give 2 ml of 0.1 mg/ml)				
	Active					
	New Order					

Document | Ack | Preferences | Drug Data | eMAR Reports | Change Order | Other | Submit

PTCP0E24A, LIVEAV 44/U 01/01/80 PRE IN AVAILABLE

Allergy No Known Allergies AdvReac No Adr Entered

Sunday March 24, 2024 1525 Allergies

Instructions

Special Instructions

INCIDENT REPORT DOCUMENTATION REQUIRED AFTER REVERSAL AGENT IS ADMINISTERED

OK

A	Start	Medication	Sched Time	Today		
				Sat	Sun	Mon
✓	03/24/24 1523	flumazenil 0.2 mg IV ONCEPRN (BENZ REV)				
	04/23/24 1522	flumazenil ... (Give 2 ml of 0.1 mg/ml)				
	Active					
	New Order					

Document | Ack | Preferences | Drug Data | eMAR Reports | Change Order | Other | Submit | Exit

Reversal Agent Incident Report Meditech Alert

Meditech alert for provider entering the order reminding them to follow up with incident report.

Example of Meditech screen:

The screenshot displays the Meditech interface for reviewing patient orders. At the top, the window title is "Review Patient's Orders" and the date is "Sun, Mar 24". The patient information bar shows "PTCPOE24A,LIVEAU - 44/U", "DOB 01/01/80", "PRE IN", and "U.CPOETEST". Below this, it indicates "70 kg" and "U/A U00938734/U041824557". A red text alert states "Allergies/ADRs: No Known Allergies".

The main area shows a medication order for "Flumazenil Inj (Romazicon Inj)" with the instruction "IV 0.2 MG ONCEPRN PRN (Benzodiazepine Reversal/Protoc)" and "<see Instructions>". The order details table is as follows:

Rate/Dose	Directions	PRN	Start	Stop
0.2 MG	ONCEPRN	Y	03/24 1523	

An "Edit Special Instructions" modal window is open, titled "Special Instructions". It contains a list of instructions with the following text highlighted:

- 0.1
- 0.2
- 0.2
- 0.2 INCIDENT REPORT DOCUMENTATION REQUIRED AFTER REVERSAL AGENT IS ADMINISTERED
- 0.2

The modal window has "OK", "Cancel", and "Delete All" buttons. The main window also has "Remove Favorite", "Monograph", and "Show All Locations" buttons. At the bottom, there are "More", "Done", "Cancel", and "Help" buttons.