



RCA Name Sologic_Clinical Example_Drug Reaction
 Report Number Example - no number
 Report Date 4/6/2013
 RCA Owner Brian Hughes

Root Cause Analysis Report

Problem Statement

Focal Point Patient adverse Fentanyl reaction unrecognized 12 hours

When

Start Date 7/25/2010 End Date 7/26/2010
 Start Time 8:00PM End Time 8:00AM
 Unique Timing After abdominal surgery, during night shift

Where

Facility Hospital XYZ
 System Pain management - Fentanyl epidural, self-administered
 Site Fourth floor South, Room 5

Actual Impact

	Cost
Safety None	\$0.00
Customer Service Patient experienced extreme discomfort	\$0.00
Other... Loss of confidence in hospital, staff by patient and family	\$0.00
Other... Added unnecessary stress	\$0.00
Actual Impact Total:	\$0.00

Frequency ?

Frequency Notes Unknown how often this happens - hospital does not track this type of event.

Potential Impact

Safety Potential failure to recognize more serious condition (est.)	\$1,000,000.00
Revenue Potential lost revenue due to damage to reputation (est.)	\$1,000,000.00
Cost Potential large payouts from lost lawsuits (est.)	\$2,500,000.00
Potential Impact Total:	\$4,500,000.00

Report Summaries

Executive Summary

On 7/25/2010, a patient was transferred to her room from post op. Over the course of 12 hours, the patient developed a persistent, extremely uncomfortable itch throughout her body. This was due to an adverse, yet non-lethal, reaction to Fentanyl. Nighttime hospital staff did not recognize the reaction. When the Pain Management team came on duty in the morning, the issue was recognized and resolved.

Recommendations:

1. Monitor patients closely for all adverse reactions including discomfort - particularly if they have never had major surgery before.
2. Monitor for other conditions besides anaphylaxis or other life-threatening issues.
3. Train nurses to recognize symptoms of adverse Fentanyl reaction.
4. Train patient and family members to watch for symptoms of adverse reactions.
5. Someone from pain management needs to be on call during night shifts and must respond to extreme patient discomfort cases.

Cause and Effect Summary

On 7/25/2010, a patient was transferred to her room from post op. Over the course of 12 hours, the patient developed a persistent, extremely uncomfortable itch throughout her body. This was due to an adverse, yet non-lethal, reaction to Fentanyl. She had been administered a Fentanyl epidural as the standard of care for major abdominal surgery.

Fentanyl can cause an itching reaction in some patients. In this case, the situation became increasingly worse because it was unrecognized by the night time hospital staff as the patient continued to self-administer doses every 10 minutes. It is the standard of care to prescribe self-administered pain management in many types of surgery. The patient was in pain due to her recent abdominal surgery, and therefore was actively attempting to manage the pain level. This increased the serum level of Fentanyl over time to a maximum level, which was then sustained.

The night-time staff (nurses and fellows making rounds) did not recognize the problem as a reaction to Fentanyl. Itching is not uncommon after surgery, but it normally subsides. Also, they are primarily concerned with life-threatening problems such as anaphylaxis. The patient was not experiencing life-threatening symptoms. Basically, the hospital staff thought it might be an uncomfortable, but still relatively normal, experience that would pass over a relatively short period of time.

Pain management arrived in the morning to find the patient in extreme discomfort, in tears, and upset that the staff was not responding to her needs. The family was also upset. The pain management nurse immediately recognized the problem and switched drugs to Lidocaine. Within a very short period of time, the itching subsided. The patient remained on Lidocaine until the epidural was removed a few days later.

Anesthesiology did not perform tests for non-lethal reactions - and this is the standard practice. By the time the Fentanyl was administered, the patient was already under general anesthesia and therefore would not be able to inform the surgical team of her condition.

Solutions

ID	Label	Description		
1	Solution	Train nurses to recognize symptoms of adverse Fentanyl reaction		
	Cause	Night time medical staff did not recognize symptoms		
	Note	The reaction was known and relatively common. The pain management team knew exactly what was happening. Nursing staff needs to be able to recognize and respond to it.		
	Assigned	Jon Boisoeneau	Criteria	Pass
	Due	7/30/2010	Status	Selected
	Term	Short	Cost	
2	Solution	Pain management on call for night time		
	Cause	Night shift - pain management arrives in morning		
	Note	Someone from pain management needs to be on call during night shifts and must respond to extreme patient discomfort cases.		
	Assigned	Arielle Furtado	Criteria	Pass
	Due	7/30/2010	Status	Selected
	Term	Short	Cost	
3	Solution	Monitor patient closely for adverse reactions - including discomfort - if they have never had major surgery before.		
	Cause	Anesthesiologist unaware of sensitivity		
	Note	If a patient has no prior experience with major surgery, they should be monitored proactively for a longer period of time after surgery is complete.		
	Assigned	Brian Hughes	Criteria	Pass
	Due	7/30/2010	Status	Selected
	Term	Short	Cost	
4	Solution	Monitor for other conditions besides anaphylaxis		
	Cause	Anesthesiologists don't monitor for itching.		
	Note	Simply not killing the patient isn't good enough. Doctors should be actively seeking to make the recovery period as comfortable as possible.		
	Assigned	Brian Hughes	Criteria	Pass
	Due	7/30/2010	Status	Selected
	Term	Short	Cost	

5	Solution	Train patient and family members to watch for symptoms of adverse reaction.		
	Cause	Patient unaware of sensitivity to Fentanyl - believed it would help		
	Note	Patients and family members are very watchful and generally capable of identifying deterioration in the patient's comfort or condition. Get them involved.		
	Assigned	Arielle Furtado	Criteria	Pass
	Due	7/30/2010	Status	Selected
	Term	Short	Cost	

Team

ID	Label	Description	Label	Description
1	First Name	Brian	Last Name	Hughes
	Phone (1)	206-282-7703	Phone (2)	
	Role	Hospital Quality Director	Group	Sologic
	Email	brian.hughes@sologic.com		
2	First Name	Jon	Last Name	Boisoneau
	Phone (1)	206-206-588-1818	Phone (2)	
	Role	Pain Management NP	Group	Sologic
	Email	jon.boisoneau@sologic.com		
3	First Name	Arielle	Last Name	Furtado
	Phone (1)	360-333-2323	Phone (2)	
	Role	Floor Nursing Supervisor	Group	Sologic
	Email	arielle@mandell.com		
4	First Name	Marcus	Last Name	McCoy
	Phone (1)	989-835-3402	Phone (2)	
	Role	Floor NP	Group	Sologic
	Email	marcus.mccoy@sologic.com		

Evidence

ID	Label	Description
1	Evidence Cause(s)	<p>Statement: Patient & Family</p> <p>Adverse non-lethal reaction to Fentanyl Reaction went untreated for 12 hours Extreme patient discomfort - 12 hour duration Patient self-administered every 10 minutes Patient in pain Self-administration device used Patient had abdominal surgery Patient unaware of sensitivity to Fentanyl - believed it would help Patient experienced extreme itching Never had surgery before - no history, never prescribed Fentanyl .</p>
	Location	Electronic Asset File
	Link	C:\Sologic\Investigations\PatientXYZ\Electronic_Assets
	Contributor	Arielle Furtado
	Type	Direct Statement
	Quality	★★★★☆
2	Evidence Cause(s)	<p>Statement: Pain management staff</p> <p>Adverse non-lethal reaction to Fentanyl Patient received Fentanyl epidural Fentanyl prescribed Anesthesiologist unaware of sensitivity Tests are not performed prior to operation No pain management nurse on staff Night shift - pain management arrives in morning Pain management arrived in morning Fentanyl can cause itching reaction Standard of care for this type of surgery Patient sensitive to Fentanyl Anesthesiologists don't monitor for itching. Not life-threatening condition Anesthesiologists watch for anaphalactic reaction</p>
	Location	Electronic Asset File
	Link	C:\Sologic\Investigations\PatientXYZ\Electronic_Assets
	Contributor	Jon Boisoneau

Type Direct Statement
Quality ★★☆☆☆

3 **Evidence** Medical Records
Cause(s) Fentanyl prescribed
 Patient had abdominal surgery
 Fentanyl level in system maintained consistent levels over time
Location EMRS
Link C:\Sologic\Investigations\PatientXYZ\Electronic_Assets
Contributor Marcus McCoy
Type Document
Quality ★★★★★

4 **Evidence** Statement: Nursing staff
Cause(s) Fellows on duty did not recognize reaction
 Nurses did not recognize reaction
 Reaction went untreated for 12 hours
 Night time medical staff did not recognize symptoms
 Thought this reaction was normal
 Didn't know what to do, but patient wasn't in obvious danger
Location Electronic Asset File
Link C:\Sologic\Investigations\PatientXYZ\Electronic_Assets
Contributor Brian Hughes
Type Choose
Quality ★★★★★

