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**
- **Safety**: None
- **Customer Service**: Patient experienced extreme discomfort
- **Other...**: Loss of confidence in hospital, staff by patient and family
- **Other...**: Added unnecessary stress

  **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
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 persistant, 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 anaphlaxis 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 persistant, 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 anaphlaxis. 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.
<table>
<thead>
<tr>
<th>ID</th>
<th>Label</th>
<th>Description</th>
<th>Cause</th>
<th>Note</th>
<th>Assigned</th>
<th>Criteria</th>
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<th>Cost</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Solution</td>
<td>Train nurses to recognize symptoms of adverse Fentanyl reaction</td>
<td>Night time medical staff did not recognize symptoms</td>
<td>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.</td>
<td>Jon Boisoneau</td>
<td>Pass</td>
<td>7/30/2010</td>
<td>Selected</td>
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<tr>
<td>2</td>
<td>Solution</td>
<td>Pain management on call for night time</td>
<td>Night shift - pain management arrives in morning</td>
<td>Someone from pain management needs to be on call during night shifts and must respond to extreme patient discomfort cases.</td>
<td>Arielle Furtado</td>
<td>Pass</td>
<td>7/30/2010</td>
<td>Selected</td>
<td>Short</td>
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<td>3</td>
<td>Solution</td>
<td>Monitor patient closely for adverse reactions - including discomfort - if they have never had major surgery before.</td>
<td>Anesthesiologist unaware of sensitivity</td>
<td>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.</td>
<td>Brian Hughes</td>
<td>Pass</td>
<td>7/30/2010</td>
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<td>4</td>
<td>Solution</td>
<td>Monitor for other conditions besides anaphylaxis</td>
<td>Anesthesiologists don't monitor for itching.</td>
<td>Simply not killing the patient isn't good enough. Doctors should be actively seeking to make the recovery period as comfortable as possible.</td>
<td>Brian Hughes</td>
<td>Pass</td>
<td>7/30/2010</td>
<td>Selected</td>
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<td>5</td>
<td><strong>Solution</strong></td>
<td>Train patient and family members to watch for symptoms of adverse reaction.</td>
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<td><strong>Cause</strong></td>
<td>Patient unaware of sensitivity to Fentanyl - believed it would help</td>
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<td><strong>Note</strong></td>
<td>Patients and family members are very watchful and generally capable of identifying deterioration in the patient's comfort or condition. Get them involved.</td>
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<td>1</td>
<td>Brian</td>
<td>Hughes</td>
<td>206-282-7703</td>
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<td>Hospital Quality Director</td>
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<td>Jon</td>
<td>Boisoneau</td>
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<td>Furtado</td>
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| 1  | Evidence | Statement: Patient & Family | 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. |

**Location**  
Electronic Asset File  
**Link**  
C:\Sologic\Investigations\PatientXYZ\Electronic_Assets

**Contributor**  
Arielle Furtado  
**Type**  
Direct Statement  
**Quality**  
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| 2  | Evidence | Statement: Pain management staff | 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 |

**Location**  
Electronic Asset File  
**Link**  
C:\Sologic\Investigations\PatientXYZ\Electronic_Assets

**Contributor**  
Jon Boisoneau
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<th>Type</th>
<th>Direct Statement</th>
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<tr>
<td>Cause(s)</td>
<td>Fentanyl prescribed</td>
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<td>Patient had abdominal surgery</td>
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<td>Fentanyl level in system maintained consistent levels over time</td>
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<td>Contributor</td>
<td>Marcus McCoy</td>
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<thead>
<tr>
<th>Evidence</th>
<th>Statement: Nursing staff</th>
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<tbody>
<tr>
<td>Cause(s)</td>
<td>Fellows on duty did not recognize reaction</td>
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<td></td>
<td>Nurses did not recognize reaction</td>
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<td></td>
<td>Reaction went untreated for 12 hours</td>
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<td></td>
<td>Night time medical staff did not recognize symptoms</td>
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<td>Thought this reaction was normal</td>
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<td>Didn't know what to do, but patient wasn't in obvious danger</td>
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<td>Location</td>
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<td>Brian Hughes</td>
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</table>
Patient sensitive to Fentanyl

- Patient sensitive to Fentanyl
  - Patient allergic to Fentanyl
  - Patient was allergic to Fentanyl
- Patient was on Fentanyl
- Patient was prescribed Fentanyl
- Patient received Fentanyl
- Fentanyl can cause itching
- Fentanyl reaction
- Fentanyl reaction went untreated
- Patient experienced extreme itching
- Patient had a reaction to Fentanyl
- Fentanyl reaction

Criteria
- Criteria for Fentanyl reaction
- Fentanyl reaction
- Fentanyl reaction in patient
- Fentanyl reaction in patient
- Fentanyl reaction in patient

Train nurses to recognize symptoms of Fentanyl reaction
- Train nurses to recognize symptoms of Fentanyl reaction
- Train nurses to recognize symptoms of Fentanyl reaction
- Train nurses to recognize symptoms of Fentanyl reaction
- Train nurses to recognize symptoms of Fentanyl reaction
- Train nurses to recognize symptoms of Fentanyl reaction

Pain management staff
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- Pain management staff

Nursing staff
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Patient & Family
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Medical Records
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Self-administered device used
- Self-administered device used
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Fentanyl prescribed
- Fentanyl prescribed
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Adverse non-lethal reaction
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- Adverse non-lethal reaction

Fentanyl epidural
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Fentanyl - believed never prescribed
- Fentanyl - believed never prescribed
- Fentanyl - believed never prescribed
- Fentanyl - believed never prescribed
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- Fentanyl - believed never prescribed

No pain management nurse on staff
- No pain management nurse on staff
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No prior surgery
- No prior surgery
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Anesthesiologists
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Anesthesiologist
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Standard of care for this type of surgery
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Criteria
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Terminated because:
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Other causal paths more productive
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Solutions
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Failed to adequately monitor
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Failed to monitor
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Anesthesia
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Night time medical staff
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Night shift - pain management arrives
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- Night shift - pain management arrives

Cheaper, faster
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Cheaper staff
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Cheaper staff on staff
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