Failure Mode Effect Analysis of Patient Controlled Epidural Analgesia
D Sanjekar, C Shekhar, H Stevens, N Mussadi

Citation

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Abstract
Objectives To increase patient safety by focusing on most vulnerable steps in the process flow implemented for PCEA, thereby applying proper corrective measures so as to avoid near misses, critical incidents and sentinel events.

Methods We applied Pareto principle of “useful many but vital few” [80:20] to the process of PCEA for vaginal births right from patients admission till discharge. Pre FMEA and post FMEA process flows were studied over three months. In a sequential ten steps of FMEA Process. Final RPN scoring was done to analyze if failure modes are reduced or eliminated

Results We found that with efficient and timely application of corrective measuresthe RPN score can be reduced drastically resulting in more patient safety and satisfaction.

Conclusion FMEA is a systematic, proactive method for evaluating a process to identify where and how it might fail, and to assess the relative impact of different failures in order to identify the parts of the process that are most in need of change

Practic Guidelines for PCEA during labour
- PURPOSE: To assure the safe and effective use of patient controlled epidural analgesia (PCEA) for the epidural administration of opioids and local anesthetics.
- POLICY: PCEA will be used for the treatment of patients in moderate to severe pain during labour. Only the patient can push the PCA button. A patient must be able to physically push the PCA button, no nurse, family member, or healthcare provider is authorized to push the patient’s button (no PCEA by proxy) at any time. If a patient requires supplemental doses to achieve analgesia, the doctor will administer the dose through the pump as ordered.
- Anaesthesiologist as a PCEA provider will approve initiation of PCEA and order PCEA using the electronic infuser set. Only provider can amend the PCEA settings if necessary depending on pain score and patient satisfaction. Anaesthesiologist will assess the patient as and when felt necessary.
- Nursing will instruct each patient selected for PCEA on the correct method of use, how pain will be assessed, and monitoring expectations. Upon initiation of PCEA and in timely manner nursing will assess and document BP, pulse, RR, pain score, sedation score plus an assessment of motor/sensory function.

Implications Meticulous following of post FMEA process flow of PCEA which was already proven and time tested; has resulted in considerable reduction in near miss events and improvement in patient satisfaction levels. Corrective measures were included into policies and processes of the hospital.

FMEA is acronym used for Failure Mode Effect Analysis.
Failure Modes and Effects Analysis (FMEA) is a systematic, proactive method for evaluating a process to identify where and how it might fail, and to assess the relative impact of different failures in order to identify the parts of the process that are most in need of change.
- Systematic method of identifying and preventing product and process problems before they occur
- Proactive approach.
- Quality improvement tool – but unlike many tools it does not require complicated statistics.
- Team based activity.

Patient-controlled Epidural analgesia (PCEA) is a method of allowing a person in pain to control their own pain. Patient-controlled epidural analgesia has proven to be both safe and effective. PCEA has many advantages when compared with continuous epidural infusion (CEI) techniques. Although the analgesia provided is similar, PCEA reduces the incidence of unscheduled clinician interventions and the total dose of local anesthetic. PCEA also reduces the incidence of lower extremity motor block. It is a corner stone to pain management. PCEA can be used for Labour, post-surgical and medical acute pain management. Continuous monitoring is vital in ensuring patient safety and care.

- Reason for selecting this topic is Introducing “Patient Controlled Epidural Analgesia” as a new service to the facility.
- Potential Patient harms if safety measures not adequately implemented.

INTRODUCTION

Patient-controlled Epidural analgesia (PCEA) is a method of allowing a person in pain to control their own pain. Patient-controlled epidural analgesia has proven to be both safe and effective. PCEA has many advantages when compared with continuous epidural infusion (CEI) techniques. Although the analgesia provided is similar, PCEA reduces the incidence of unscheduled clinician interventions and the total dose of local anesthetic. PCEA also reduces the incidence of lower extremity motor block. It is a corner stone to pain management. PCEA can be used for Labour, post-surgical and medical acute pain management. Continuous monitoring is vital in ensuring patient safety and care.

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Failure Modes and Effects Analysis (FMEA) is a systematic, proactive method for evaluating a process to identify where and how it might fail, and to assess the relative impact of different failures in order to identify the parts of the process that are most in need of change.

THE 10 STEPS OF FMEA PROCESS

1. Review the process
2. Brainstorm the potential failures
3. List potential effects of each failure mode
4. Assign a severity rating for each effect
5. Assign a frequency (occurrence) rating for each failure mode
6. Assign a detection rating for each failure mode
7. Calculate the risk priority number (RPN) for each effect
8. Prioritize the failure modes for each action
9. Take action to eliminate or reduce the high-risk failure modes (Including RCA)
10. Calculate the resulting RPN as the failure modes are reduced or eliminated.

Step 1: Review the Process: Construct a detailed flow chart of the process.
- Multi-disciplinary participation of all those involved in the process
- Allocate plenty of time for this step
- Be as detailed and complete as possible
- Learn the flowchart process and symbols.

Step 2: Brainstorm the Potential Failures: Determine each step that can “fail” and how it can “fail”.

Step 3: List Potential Effects of Each Failure Mode: Determine the “effect” of each possible “failure”.

Steps 4, 5, 6, 7: Determining how serious the possible effect(s) could be on the patient – “criticality”.

For each effect:
- Estimate likelihood of failure (frequency/occurrence scale rank)
- Estimate severity of failure (severity scale rank)
- Estimate probability that failure is detected (detection scale rank)
- Find the Criticality Index (CI) or Risk Priority Number (RPN) - Compute criticality index (CI) or Risk Priority Number. CI is the product of three indexes or Occurrence Rank X Severity Rank X Detection Rank.

**Step 8: Prioritize the failure modes for each action.**

**Step 9: Take Action to Eliminate or Reduce the High-Risk Failure Modes (Including RCA):**

Brainstorm actions that could reduce the criticality index starting with failure modes that have the highest CI value that:
- Decrease likelihood of occurrence.
- Decrease the severity of effects.
- Increase the probability of detection.

**Step 10:** Calculate the resulting RPN as the failure modes are reduced or eliminated.

**PCEA (PATIENT CONTROLLED EPIDURAL ANALGESIA)**

**Reason: Reasons for Selection of PCEA for this study:**

[Start Date – 23rd June 2016 End date – 17th Sep 2016].

Introducing “Patient Controlled Epidural Analgesia” as a new service to the facility.

Potential Patient harms if safety measures not adequately implemented.

**Benefits:**
- Appropriate patient education.
- Safety measures implemented.
- Regime selected cross checked by the nurse.

- Medication preparation - witnessed by second staff.
- Labeling of prepared medication.
- Pump alarms – medication level and battery.
- Do’s and Don’ts leaflet.
- Availability of resources ensuring continuity of care.
- Limited access to Protocol and history software.

**Abbreviations:**

FMEA: Failure Mode effective Analysis.
PCEA: Patient Controlled Epidural Analgesia.
CEI: Continuous Epidural Infusion.
CI: Clarity Index.
RCA: Root Cause Analysis.
RPN: Risk Priority Number.
MRP: Most Responsible Physician.
PAC: Pre Anesthesia Check.
MDS: Multi Disciplinary Sheet.
DDA: Deputy Director Administration.
ADON: Assistant Director Of Nursing.

**References:**


**Related Documents:**

- PCEA policy – ZH Portal > Policies> ASC.
- Forms- ZH Portal > Forms > Doctors > Epidural analgesia prescription form > Consent form.
- ZH Portal > Forms > Nurses > Epidural analgesia monitoring Record.
- PCEA Education leaflet.
- PCEA pump Do’s and Don’t.
Failure Mode Effect Analysis of Patient Controlled Epidural Analgesia

- Epidural Analgesia Patient Feedback Form.
- Epidural Analgesia Cart Checklist.

### Table 1

<table>
<thead>
<tr>
<th>No.</th>
<th>Problem Area</th>
<th>FMEA</th>
<th>FMEA</th>
<th>Recommended Action</th>
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### Table 5

**Table 5**

<table>
<thead>
<tr>
<th>Quantity</th>
<th>Description</th>
<th>Failure Probability</th>
<th>Failure Impact</th>
<th>Rating</th>
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<td>Very high severity ranking when a potential failure mode affects safe system operation without warning</td>
<td>10</td>
<td>Low</td>
<td>9</td>
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<tr>
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<td>Very high severity ranking when a potential failure mode affects safe system operation with warning</td>
<td>10</td>
<td>Low</td>
<td>9</td>
</tr>
<tr>
<td>Very High</td>
<td>System impossible with destrucive failure without compensatory safety</td>
<td>10</td>
<td>Low</td>
<td>9</td>
</tr>
<tr>
<td>High</td>
<td>System impossible with minor mishaps</td>
<td>9</td>
<td>Low</td>
<td>9</td>
</tr>
<tr>
<td>Very Low</td>
<td>System operable with slight degradation of performance</td>
<td>8</td>
<td>Low</td>
<td>9</td>
</tr>
<tr>
<td>Low</td>
<td>System operable with minimal interference</td>
<td>7</td>
<td>Low</td>
<td>9</td>
</tr>
</tbody>
</table>

### Occurrence / Probability

- Probability: LOW
- Likelihood: Unlikely (R10)
- Likelihood: Likely (R7)
- Likelihood: Very likely (R5)
- Likelihood: Almost certain (R1)

### Severity

- Severity: Minor
- Severity: Significant
- Severity: Critical
- Severity: Catastrophic

### Rating

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<th>Likelihood</th>
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<tr>
<td>Catastrophic</td>
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<td>R1</td>
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</tr>
</tbody>
</table>

### Prevention

- Prevention: Low
- Prevention: High
- Prevention: Very high
- Prevention: Extreme

### Uptime

- Uptime: 99.99%
- Uptime: 99.9999%
- Uptime: 99.99999%
- Uptime: 100%

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References
Author Information
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