Failure Mode Effect Analysis of Patient Controlled Epidural Analgesia

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Abstract

Objectives To increase patient safety by focusing on most vulnerable steps in the process flow implimented 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 that with efficient and timely application of corrective measuresthe RPN score can be reduced drastically resulting in more patient safety and stisfaction.

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 PECA 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 alredy proven and time tested; has resulted in to 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.

- A group brainstorming tool which identifies and prioritizes potential failures in high risk process.

- Systematic method of identifying and preventing product and process problems before they occur

- Pro active 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 is 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 is can be used for Labor, post-surgical and medical acute pain management. Continuous monitoring is vital in ensuring patient safety and care.

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.

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 flow chart 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:

- PCEA Pump Manual.

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.

- Epidural Analgesia Patient Feedback Form.

- Epidural Analgesia Cart Checklist.

Table 1

Sr. No	Process or Sub-process	Potential Failure Mode	Effect Potential Failure Effects	Potential Causes of Failure	RPN 1	Recommended Actions	RPN2
1	Booked patients visits Obstetrician/ surgeon / Physician for checkups and MRP informs about PCEA to patient	Inappropriate education/language barriers	Denial/ uninformed decision	Lack of standard source of education	144	1. Epidural leaflet to be updated/ session with GP's 2. Obstetricians and surgeon on PCEA	72
2	All orders for sedatives, analgesics, and anticoagulants will be reviewed by the anesthetist. If any contra indication anesthetist to discuss with MRP, document in file.	Failure to review the previous orders Orders on intra - partum opioids used not discussed with anesthetist	Drug overdose/ ADR / fatal	doctor busy / oversight/ reviewing the wrong file	210	Epidural analgesia prescription form updated incorporating review of sedatives, analgesics and anticoagulants. Form to be made available on portal/ circulation	40
3	Epidural catheterization done by the anesthetist - If Procedure Successful Patient re -medicated on the use of PCEA pump and documented in the patient education form by the anesthetist	Catheter fall out / kinking of catheter / catheter migration	Inability to provide pain relief / patient safety compromised	Patient factor/ catheter factor / doctor factor	72	Biomedical to check for epidural catheter fixator device (button) in UAE	18
		Inadequate patient re-education	Patient safety compromised / inadequate pain relief	Time constraint/l language barrier	105	Do's and Don'ts for PCEA pump to be prepared, laminated and given to patient and taken back after discontinuation	28
4	Pre-procedure programming of the pump / setting of the fixed protocols in the protocol software	Unauthorized access to software Access restricted (at the time pump setting) Unauthorized change in setting Software malfunction	Issues with patient safety Procedure delays	no log in id for the software	150	Software made available in Anesthetist desktop only All initial software entries and later updates to be done in presence of second anesthetist. Print out of the setting to be taken (snapshot) and signed by two anesthetists making the entry. Settings record to be circulated and signed by all other anesthetists. To maintain it in OT In case of software malfunction co provided by the supplier. software to be reinstalled	40

Table 2

5	PCEA pump settings done by the Anesthetist as per the regime (select one out of 3 regimes fed in the pump or completely enters a new regime)	Incorrect pump setting	Drug overdose/ ADR / inadequate analgesia	Anesthetist inadequate training about PCEA pump	180	Regime selection done in presence of a second licensed staff. Epidural Analgesia Prescription form updated columns for two signatures. To be incorporated in the policy	20
6	PCEA pump loaded with medication and PCEA initiated under directions of anesthetist	Desired reservoir bag not available	frequent change of bag/ medication wastage	out of stock/ no defined frequency of checking the epidural cart	108	Stock of PCEA medication bag to be made in labor room. Checklist for epidural cart to be prepared and monitoring frequency of the contents to be and documented after each use and once every month	12
		Medication preparation error	incorrect preparation / delay in procedure / IV injection given through epidural line	Oversight / human error no patient and epidural labeling done on the bag /infusion line	175	1. Medication preparation done in presence of a second licensed staff (High alert drug policy). Epidural Analgesia Prescription form updated columns for two signatures. To be incorporated in the policy 2. Drug bag to be labeled after preparation as per the infusion labeling. Nurses and anesthetist to be educated and incorporated in policy 3. Yellow sticker available in epidural set to be put on the infusion line - indicates epidural infusion is going, nurses to be educated	5
7	PCEA on going	Attendants operating the machine / pump switched off by attendants or patients	Sudden onset of the pain/leakage of medicine / dural injury / motor block	Uncooperative patient, relatives.	180	1. Do's and Don'ts for PCEA pump to be prepared (English and Arabic), laminated and given to each patient prior to starting PCEA and taken back after discontinuation Do not touch sticker to be put on the PCEA Pump bag	60

Table 3

		Interruption of PCEA - battery failure / device malfunction	sudden onset of the pain	battery not charged after previous use/ pump used for long time	105	1. Anesthetist to check battery before starting the procedure. To be included in the policy2. Visual inspection of pump to be done for any damage, moisture on the pump, clarity of display, correct date and time displayed on the pump. To be included in the policy3. Pump to be charged every use and if pump not used battery to be charged every 3 months. LR nurses to be educated.4. Alarm for the battery available. Alarm will ring 12hrs prior to battery life and near to empty also when empty. If there is an alarm the PCEA pump to be connected to the charger and patient to be informed .LR nurses to be educated.	14
		Medication bag empty	inadequate analgesia	small size bag used,/continued PCEA	144	Alarm for medication to be set in the software. Alarm for medication to be set in the software. Alarm set for 10ml drug remaining.	24
8	Written feedback taken from the patient	Filled by the patient and handed over to the nurses	integrity of feedback form compromised	process for feedback compilation not being followed	100	Feedback is handed over for analysis, corrective action taken and obtained score is sent to department. Staff to be educated	20

Table 4

Based on the corrective actions planned the following action plan was drafted and agreed upon by the team

Sr. No	Task	Completion date
1	Epidural leaflet to be updated/ session with GP's	Leaflet - 12th sep
2	Session with doctors for education of patient on PCEA	Training - 15th Oct
3	Do's and Don't for PCEA pump to be prepared, laminated and given to patient and taken back after discontinuation	15th Sep
4	Epidural analgesia prescription form to be updated incorporating - • Column for review done of sedatives and analgesics. • columns for signatures for staff witness regime selection and medication preparation	14th Sep 2016
5	History software to be made available in anesthetist desktop .All entries to be downloaded on a every 3 months (through history software) and saved in the anesthesia desktop.	15th Sep 2016
6	Protocol software (Therapy Manager) - Software to be made available in Anesthetist desktop only .All initial software entries and later updates to be done in presence of second anesthetist. Print out of the setting to be taken and signed by two anesthetist making the entry. Settings record to be circulated and signed by all other anesthetists. To maintain it in OT	13th Sep 2016
7	Checklist for epidural cart to be prepared and monitoring frequency of the contents to be and documented after each use and once every month	15th Sep 2016
8	Extra keys available with biomedical / PCA and PCEA pump keys compatible with each other	10th Sep 2016
9	When the pump is not in use, key to be kept in the PUMP box, when in use the keys to be kept with Labour room nurses	10th Sep 2016
10	Pump to be charged every use and If pump not used battery to be charged every 3 months. LR nurses to be educated	13th Sep2016
11	Anesthetist to check battery before starting the procedure. Visual inspection of pump to be done for any damage, moisture on the pump, clarity of display, correct date and time displayed on the pump. To be updated in the Policy	13th Sep2016
12	Alarm for the battery available. Alarm will ring 12hrs prior to battery life and subsequently every hour. If there is an alarm the PCEA pump to be connected to the charger and patient to be informed. .LR nurses to be educated	13th Sep2016
13	Drug bag to be labeled after preparation as per the infusion labeling. Nurses and anesthetist to be educated. To be updated in policy	15th Sep2016
14	Do Not Touch label to be put on top of the PCEA pump	13th Sep2016
15	Handover - nurses handover notes to include "PCEA protocols informed" Documented in MDS. WDRB to be followed for the anesthetist. Nurses and Anesthetist	15th Sep2016
16	Nurses can discontinue as per WDRB policy. Nurses to be educated and updated in the policy	15th Sep2016
17	Pump is cleaned by the nurse/assistants as per infusion pump cleaning protocols (Ref Equipment cleaning policy). Nurses to be educated. Reference to be made in policy	15th Sep2016
18	Biomedical to check for epidural catheter fixature device (button) in UAE	30th Sep 2016
19	Feedback to be handed over to CRE, CRE does the analysis, corrective action taken and obtained score is sent to department Staff to be educated	15th Sep 2016
20	Ongoing Epidural file audits. Reports of file audits presented in nurses CNE	21st Sep

1.Protocol Software (Therapy Manager) made available in Anesthetist desktop. All initial software entries and later updates to be done in presence of second anesthetist. Print out of the settings done to be taken and signed by both the anesthetist making the entry. Settings record to be circulated and signed by all other anesthetists. Record to be maintained it in Anesthesia department
2.History software - Pump entries downloaded every 3 months and saved in the Anesthetists desktop- Responsibility Anesthetist
3.Pump code to be changed every 3 months by the anesthetist and to be available only with the anesthetist
4.PCEA pump key kept in the PCEA box when not in use
5.Epidural cart checked and documented after each use and once every month with the help of the epidural cart checklist.
6.Alarm for battery will ring 12hrs prior to battery life and subsequently every hour.
7.If pump not used for 3 months battery to be charged once every 3 months

Table 5

SEVERITY		
Hazardous without warning	Very high severity ranking when a potential failure mode effects safe system operation without warning	10
Hazardous with warning	Very high severity ranking when a potential failure mode affects safe system operation with warning	9
Very High	System inoperable with destructive failure without compromising safety	8
High	System inoperable with minor damage	6
Low	System inoperable without damage	5
Very Low	System operable with significant degradation of performance	4
Minor	System operable with some degradation of performance	3
Very Minor	System operable with minimal interference	2
None	No effect	1

Occurrence - PROBABILITY		
Probability of Failure	Failure Probability	Ranking
Very High: Failure is almost inevitable.	>1 in 2	10
	1 in 3	9
High: Repeated failures.	1 in 8	8
	1 in 20	7
Moderate: Occasional failure.	1 in 80	6
	1 in 400	5
	1 in 2,000	4
Low: Relatively few failure.	1 in 15,000	3
Remote: Failure is unlikely.	1 in 150,000	2

DETECTABILITY		
Rating	Description	Definition
1	Certain to detect	Almost always detected immediately (10 out of 10)
2		
3	High Likelihood	Likely to be detected (7 out of 10)
4		
5	Moderate Likelihood	Moderate Likelihood of detection (5 out of 10)
6		
7	Low Likelihood	Unlikely to be detected (2 out of 10)
8	Almost certain not to detect	Detection not possible (0 out of 10)

References

Author Information

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