ORIGINAL ARTICLE

A proactive risk assessment by utilizing 'Healthcare Failure Mode and Effect Analysis' (HFMEA) for safe implementation of peripheral nerve catheters in pediatric patients

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ABSTRACT

Introduction: In 2011, Nationwide Children's Hospital began using peripheral nerve catheters (PNC) to provide postoperative analgesia to patients undergoing select orthopedic and abdominal surgeries. While PNCs provide a significant improvement in the quality of care that our patients receive, introducing this new technology and process within our hospital presents an inherent risk.

Methodology: In order to assure that our patients received the safest care, we assembled a multi-disciplinary team to complete a proactive risk assessment by utilizing Healthcare Failure Mode and Effect Analysis (HFMEA). HFMEA was designed by the VA National Center for Patient Safety to identify potential failure modes within systems, and to study the consequences the failure modes have on customers. The result of this process identified and evaluated 96 failure modes and therefore 19 specific interventions were developed and deployed.

Conclusion: The HFMEA process gives us confidence that new pain management techniques and their related processes can be safely and effectively implemented in order to provide the safest and highest quality care to our patients.

Keywords: Failure Modes; Quality Assurance; Pain; Pain Catheters; Pediatric

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INTRODUCTION

In 2011, the Department of Anesthesiology and Pain Medicine at Nationwide Children's Hospital in Columbus, OH began using continuous peripheral nerve catheters (PNC) to provide localized analgesia to pediatric patients undergoing select orthopedic and abdominal surgeries. Knowing the inherent risk associated with the procedure as well as the consequences that may arise in the pediatric patient with a PNC, a thorough investigation of the process was initiated. Since this was unusual in pediatric healthcare delivery and few if any pediatric institutions in the country were performing such a technique, extra caution was taken in examining many aspects of the process that could result in complications before implementing the program. It was suggested by our Quality and Safety Team that we utilize the HFMEA™ (Healthcare Failure Modes and Effects Analysis) tool.

METHODOLOGY & DISCUSSION

JCAHO *Standard LD.5.2* requires hospitals to select at least one high-risk process for proactive risk assessment on an annual basis. HFMEA™ (Healthcare Failure Modes and Effects Analysis) has been designed by the VA National Center for Patient Safety (NCPS) specifically for healthcare. HFMEA™ utilizes the traditional hazard analysis steps found in the Failure Modes and Effects Analysis (FMEA) process. The FMEA process was one of the first systematic techniques for failure analysis developed in the 1950's by reliability engineers. It was used to investigate and evaluate problems that might arise from malfunctions of military

Table 1: Step 3: Conduct hazard analysis; 'Hazard matrix table'

Process step	Column 3.1 Failure Modes (What might happen)	Column 3.2 Cause (Why it happens)	Column 3.3 Effects (What could happen to the patient)	Column Scoring			
				3.4 Severity	3.5 Probability	3.6 Intercept-ability	3.7 Hazard score
Physician – Request pain pump	Pain pump is not scheduled with surgery	Surgeon forgets, lack of knowledge, resistance to change of practice	Delay of On-Q, delay in surgical process	1	3	2	6
	Anesthesia staff unavailable to place catheter	Not enough staff	Delay of On-Q, delay in surgical process	1	2	2	4
	Incorrectly requests pain pump for N/A case	lack of knowledge, error in scheduling	Patient harm	4	4	2	32
	pain pump is scheduled for a patient with allergy to a drug to be used	Patient allergy unknown	Patient harm	4	1	4	16
Scheuler – Schedule procedure with pain pump	pain pump is not scheduled with surgery	lack of knowledge,	Delay of On-Q, delay in surgical process	1	3	2	6
	pain pump is scheduled for surgery that should not have it	lack of knowledge, error in scheduling	Patient harm	4	4	2	32

systems. It involves reviewing as many components, assemblies, and subsystems as possible to identify failure modes, and their causes and effects. For each component, the failure modes and their resulting effects on the rest of the system are recorded in a specific FMEA worksheet calculating risk priority number (RPN). However this process is unique because it replaces calculation of the RPN with a hazard score that is read directly from the *Hazard Matrix Table* (Table 1). This table was developed by NCPS specifically for this purpose.

PNCs are wire-reinforced plastic tubes that are placed under ultrasound guidance in the operating room to deliver local anesthetic to a specific nerve to enhance intra-operative and post-operative analgesia. These have been used in the adult population for years, but until 2011 had been used sparingly in the pediatric population. While PNCs provide a significant improvement in the quality of care our patients receive, introducing this new technology and process within our hospital presents an inherent risk. In addition to the known risks of infection, nerve injury and local anesthetic toxicity which some may argue are even more likely in the pediatric population, there are unknown risks which may be due to the process of procuring the drug, securing the catheter and preventing accidental removal in the pediatric patient. In order to assure that our patients received the safest care, we assembled a multi-disciplinary team to complete a proactive risk assessment by utilizing Healthcare Failure Mode and Effect Analysis (HFMEA). HFMEA enhances the ability to identify potential failure modes within systems, and to study the consequences the failure modes have on patients.

Our multi-disciplinary team involved anesthesiologists, pharmacists, nursing staff, surgeons, members of the pain team as well as quality and safety members. We met on a monthly basis until the PNC program was initiated, then had follow-up meetings and debriefings. During monthly meetings, the team initially graphically outlined the process using process flow maps. The process flow maps allowed the team to identify potential failure modes related to each process step. Each failure mode was then evaluated for the likelihood of occurrence, severity and our ability to intercept the failure. Utilizing a score generated by the product of these evaluation criteria (severity, probability and ability to intercept) an overall hazard score was developed.

The process identified and evaluated 96 failure modes and subsequently19 specific interventions were developed and deployed (Table 2). The interventions included developing patient instructions as well as home-going instructions, designing new labels for the pain pump and tubing, designing an electronic order-set, formulating surgeon and family education, using videos to enhance family education, changes to pharmacy code kits, as well as modifying hand-offs between services. Overall, many of these interventions and improvements would not have been implemented at the time of the initiation had we not utilized the HFMEA process.

Table 2: Specific interventions decided

Action Item	Responsible	Due date	Updated due date	Status
Make final decision on the specific PNC we will be using.	Chairman	06/01/2011	07/15/2011	Complete
Develop paging protocol for Pharmacy to use when filling a PNC order	Pharmacy Coordinator	07/01/2011	07/31/2011	Complete as of 3/5/12
Develop a policy related to the proper use of the PNC that addresses the specific failure modes identified.	Nurse Practitioner Supervisor/ Director of Acute Pain	07/01/2011	07/31/2011	Complete
Work with QIS Coordinator (Clinical) to develop necessary label for the PNC tubing.	Manager QI	06/01/2011	Samples available 07/08/2011	Complete
Investigate availability of specialized lure-locks for use with PNC only.	Chairman	07/01/2011		Complete - nothing available
Develop an EPIC order set for PNC.	NP Supervisor/ Pharmacy Coordinator/ Dir. Acute Pain	07/01/2011	08/31/2011	Complete
Develop EPIC hard stops related to PNC and other EPIC safety parameters.	NP Supervisor/ Pharmacy Coordinator/ Dir. Acute Pain/ IS Systems Analyst	07/01/2011	08/31/2011	Complete
Develop education for surgeons concerning proper use of PNC and present this to the surgeons' group	Director Acute Pain	07/01/2011	08/31/2011	Complete
Develop education for surgeons concerning proper use of PNC and add to the standard surgeon on-boarding process.	Director Acute Pain/ Education Nurse Specialist	07/01/2011	08/31/2011	Complete
Develop education for the nursing groups. Use PCA education as a template.	NP Acute Pain	07/01/2011	08/31/2011	Complete via CHEX™
PACU education about 5P changes and accompanying patient to ICU/floor	Staff RN PACU	08/01/2011	08/31/2011	Complete
Video for families to review regarding PNCs	Director Acute Pain / NP Supervisor	09/01/2011	08/31/2011	Video completed and posted to the web at a later date
Intra-lipids are part of pharmacy code kit	Pharmacy Coordinator	08/01/2011	09/01/2011	Approved by P&T; will be added to code kit before go-live
Lock bag on the floor - education	Director Acute Pain	08/31/2011		Complete APN education
Lock bag and flow rate for discharge - education	Director Acute Pain	08/31/2011	by 12/31/12	Will not send patients home with bag until 12/31/12
Add bar code label from Pharmacy to bag	Pharmacy Coordinator	08/31/2011		Complete
Physician exclusively (not Pharmacy) will prime pump and set flow rate-Education	Director Acute Pain	08/31/2011		Complete - via education of Pain Team
Weekend protocol if an Acute Pain Team physician is not in-house - Education	Director Acute Pain	08/31/2011		Attending Pain physician on call will cover
Helping Hands™	Director Acute Pain			Complete

PNC = peripheral nerve catheter
CHEX™ is NCH's web-based computer training program for health care personnel education
Helping Hands™ are standardized information sheets given to families about their surgery, procedures, catheters etc

The first PNC was placed on November 1, 2011. Initially the PNCs were placed in patients who were staying in the hospital as inpatients following surgery. This was mainly for safety reasons to allow us the ability to monitor the catheter as well to identify any fail-safe measures that would need to be implemented. Following the success of inpatient pain catheters, we made a transition to home-going PNCs following outpatient surgery.

These catheters in outpatients are placed in the operating room and the patient goes home the same day with the catheter in place. The pain service calls the patient and family daily until the catheter is pulled out by the family. To date, over 100 PNCs have been placed both for inpatients as well as outpatients. No significant events have been

associated with continuous PNC infusions. The HFMEA process gave us confidence that new pain management techniques and their related processes could be safely and effectively implemented in order to provide the safest and highest quality care to our patients.

CONCLUSION

A comprehensive approach to a successful implementation of a PNC service is necessary. In the pediatric population the potential for malfunction, local anesthetic toxicity, and non-compliance may be higher than adults. HFMEA is a systematic method of identifying and preventing process problems before they occur. In our institution, it was utilized to safely and effectively implement this new pain management technique and its related logistics, and to provide the safest and highest quality of care to our patients.

Conflict of Interest: None of the authors have any conflict of interest to disclose.

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★★★★★

A profession of love and trust

Claire Clavier once said, "We usually just treat the human body, but it may be that we should heal the soul…that's when you put a little of yourself in, so that the job is well done".

Being a nurse is a truly rewarding and an exciting job because it imparts a feeling to me of being useful and active by devoting all of my time to the patients and patient care.

Doctors prescribe and reassure and we console and relieve the suffering and often play the role of being a confidant of the patients.

Our work will not be appreciated unless we do a good job and only when we truly believe in what we do.

We, nurses or future nurses, must have the ability to forget our privacy at work. We have to think only about our job, which not only requires our mere presence, but also full concentration and especially devotion, and it is in this way that we can manage to bring a little smile to our patients faces and lead them to trust us.

Just like a small child who had a thorn pricked into her foot and she still smiles to you through her tears. We have to earn the trust of our patients and their commitment to us that rewards our untiring efforts.

Being a nurse is not only to heal the body but also to heal the soul.

A patient who insists that you are the only nurse to treat him and no other…

These are few moments of joy that reward our efforts and make us more bound to our profession ….

…. and lead us to do a good work and love this profession which is based on love and trust….

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