Healthcare Failure Modes and Effects Analysis and Cost Benefit Analysis of a Fecal Management System for the Adult Intensive Care

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The Clinical Nurse Specialist (CNS) student was charged with evaluating a new product being introduced into an Adult Intensive Care Unit (ICU). Recent contract changes required nursing staff to utilize a new fecal management system (FMS). As a driver of improved patient outcomes and an expert in cost-effective care, the CNS is identified as the ideal person to evaluate products for safety and cost-effectiveness. To accomplish this task, a Healthcare Failure Modes and Effects Analysis was undertaken, followed by a cost-benefit analysis.

The product was to be used in an ICU housed in a tertiary care facility in the Midwest, consisting of 22 beds, and caring for an adult patient population with a mean age of 68 years. This age of patients is identified as being at the most risk for complications[1], at risk for fecal incontinence[2], and thus an increased risk for healthcare-acquired skin injuries[3]. The HFMEA (Appendix A) was conducted first to evaluate product safety. The CNS student assembled a team of herself, the unit manager, a unit charge nurse, and two hospital-employed CNSs. After completion of the HFMEA, a cost-benefit analysis comparing traditional methods of fecal management with the FMS device was done.

The HFMEA revealed that there were 43 total failure modes for the fecal management system. Of those 43 modes, four were identified as high risk. The first was verification of a physician order in the medical record prior to FMS placement. The team decided that this mode would be easily controlled with policy and education. The second identified mode was location of the fecal management system cuff during inflation which could result in rectal

trauma. The team evaluated this risk and decided that policy, procedure education, and competency verification would control this mode. The third mode resulted in complications due to FMS irrigation. This failure mode could result in several patient complications, such as burns from too hot of water during irrigation or trauma from water instilled via the incorrect port. The team analyzed this mode and decided that education and competency verification would provide sufficient control. The fourth failure mode identified as high risk was related to proper documentation to ensure that the device was not left in longer than indicated. Policy and procedure require dating of the FMS directly and daily documentation of insertion date in the electronic medical record by nursing staff were identified as controls.

After evaluating the literature and the HFMEA data, the product was determined as safe for use in the indicated patient population. Nursing staff would obtain a physician order prior to insertion and physicians would be educated on proper indications for use. In addition, all staff would be educated on the new device through product representative in-services in conjunction with facility policy and procedure education. Learning would be verified by evaluation of nursing competencies by nursing education staff.

The cost-benefit analysis also supported use of the product (Appendix B). The FMS was compared with traditional methods of incontinence management over the course of 1400 device days, 20% of the unit's average yearly census since it is estimated that 20% of adult ICU patients will experience fecal incontinence3.

Supply costs and costs of nursing time for both methods were calculated. For the FMS, nursing time was calculated based on two hours needed for care and maintenance of the system. The potential benefits of reduced patient complications from FMS use were also

calculated based on the prevention of one hospital-associated pressure injury and prevention of 50% of the average number of cases of incontinence-associated dermatitis. For traditional incontinence management, nursing time and supply cost were calculated based on one bed change per day and application of barrier cream to protect patient skin.

The results of the cost-benefit analysis supported the use of the fecal management system when clinically indicated. The FMS was estimated to save four hours of nursing time per day resulting in a savings of $151,667. The FMS was also found to have a $62,202 savings for supply costs. To those savings, the benefit of wound and dermatitis was monetized and added. The total savings estimated by using the FMS was calculated to be $235,768 over the course of one year.

The results of the HFMEA and cost-benefit analysis were shared with stakeholders. Nursing staff will be encouraged to advocate for product use when clinically indicated to prevent complications in the unit's elderly patient population. The product will be evaluated by the hospital-based CNS to ensure that the cost savings are realized and that patient safety is maintained.

References

1. Joyce, & Reich. (2015). Critical Care Issues of the Geriatric Patient. Anesthesiology Clinics, 33(3), 551-561.
2. Nelson, R.L. (2004). Epidemiology of fecal incontinence. Gastroenterology, 126(1), S3-S7.
3. Langill, M., Yan, S., Kommala, D., Michenko, M. (2012). A budget impact analysis comparing use of a modern fecal management system to traditional fecal management methods in two Canadian hospitals. Ostomy Wound Management, 58(25).

Appendix A

Process Step	Potential Failure Mode(s)	Potential Causes of Failure	Potential Effects of Failure	Severity	Probability	Hazard Score
Verify the physician order	a.) No order obtained b.) Order obtained without proper indication	a1.) Unfamiliarity with the policy a2.) Cultural deviations from policy b1.) Lack of knowledge related to proper indications for use	a.) Practice outside of scope b.) Patient receives improper treatment modality	4	Frequent	8
Explain the procedure to the patient	a.) Step omitted b.) Inadequate Explanation	a1.) Education not given to patient due to patient's illness state b.) Education not sufficient to inform patient about procedure, risks, benefits, and process	a.) Patient and family not satisfied with care b.) Patient/family not satisfied with care	1	Occasional	3
Obtain the product and don appropriate personal protective equipment (PPE)	a.) Product not available b.) Personal protective equipment not worn	a1.) Stock of product on unit not maintained b1.) Unit norms b2.) Unfamiliarity with PPE policies	a.) Patient unable to receive proper treatment modality b.) Staff at risk for contact with hazardous materials	4	Occasional	6
Connect the collection bag to the catheter tube assembly	a.) Collection bag not appropriately attached	a1.) Lack of familiarity with product a2.) Defective product	a1.) Leakage of stool a2.) Portal of entry for infection created a3.) Product defect identified	1	Uncommon	2
Deflate the cuff by attaching the empty syringe to the inflation port and removing air	a.) Step omitted b.) All air not removed from cuff c.) Syringe is attached to the incorrect port	a1.) Human error b1.) Human error b2.) Defect in product c1.) Human error c2.) Lack of familiarity with the product	a.) Cuff inserted into patient with excess air present causing rectal trauma b.) Cuff inserted into patient with excess air present causing rectal trauma c1.) Air not fully removed from cuff c2). Cuff inserted into patient with excess air present causing rectal trauma	4	Uncommon	4
Squeeze retention cuff to ensure all air has been removed	a.) Step omitted	a1.) Lack of familiarity with the policy for insertion a2.) Human error a3.) Unit culture/norms	a.) Excess air present in cuff at time of insertion	1	Frequent	4
Flatten the cuff between thumbs and index fingers	a.) Step omitted	a1.) Lack of familiarity with the policy for insertion a2.) Human error a3.) Unit culture/norms	a.) Cuff not properly positioned for steps later in the process	1	Frequent	4
Fold the cuff by bending the top right corner backward and down at a 45 degree angle	a.) Step omitted b.) Step not completed as instructed	a1.) Lack of familiarity with the policy for insertion a2.) Human error a3.) Unit culture/norms b1.) Lack of familiarity with the policy for insertion b2.) Competency in proper folding of cuff not verified b3.) Unit culture/norms b4.) Human error	a.) Cuff not appropriately sized for insertion b.) Cuff not appropriately sized for insertion	1	Frequent	4
Hold the folded cuff between the thumb and index finger	a.) Step omitted b.) Step not followed as instructed	a1.) Lack of familiarity with the policy for insertion a2.) Human error a3.) Unit culture/norms b1.) Lack of familiarity with the policy for insertion b2.) Competency in proper holding of cuff not verified b3.) Unit culture/norms b4.) Human error	a1.) Cuff not in the proper position for insertion a2.) Fold in cuff for insertion not maintained b1.) Cuff not in the proper position for insertion b2.) Fold in cuff for insertion not maintained	1	Frequent	4

Deploy the cuff into the rectal vault, cuff should unfold on it's own	a.) Cuff does not properly unfold b.) Proper deployment not verified	a1.) Lack of familiarity with the policy for insertion a2.) Human error a3.) Unit culture/norms b1.) Lack of familiarity with the policy for insertion b2.) Lack of familiarity with the product b3.) Unit culture/norms b4.) Human error	a.) Cuff unable to be properly inflated b.) Cuff unable to be properly inflated	4	Occasional	6
Inflate the cuff by depressing the plunger of the attached syringe	a.) Cuff is inflated in rectum instead of rectal vault	a1.) Lack of familiarity with the policy for insertion a2.) Proper placement not checked prior to inflation a3.) Human error	a.) Rectal trauma	7	Occasional	9
Use the pilot balloon as a guide, adjusting the amount of water infused into the cuff if over or under inflation is present	a.) Step omitted, cuff remains over-inflated b.) Step omitted, cuff remains under-inflated	a1.) Lack of familiarity with the policy for insertion a2.) Human error b1.) Lack of familiarity with the policy for insertion b2.) Human error	a.) Tubing is blocked due to built in safety features causing back-up of liquid stool b1.) Leakage occurs around cuff causing skin exposure to fecal material b2.) Staff believes product doesn't function properly	4	Occasional	6
Remove the syringe from the inflation port	a.) Step omitted, syringe remains attached	a1.) Lack of familiarity with the policy for insertion a2.) Human error	a1.) Syringe remains attached allowing fluid to escape from the cuff a2.) Syringe may cause device pressure injury if patient is positioned onto syringe	4	Uncommon	4
Fill syringe with 45ml tap water and attach to the inflation port	a.) Step not completed at this point in the process b.) Syringe filled in excess of 45ml c.) Syringe filled with less than 45ml d.) Water temperature not checked e.) Syringe attached to the incorrect port	a.) Lack of familiarity with the policy for insertion b1.) Human error b2.) Unit culture/norms	a.) Inefficiency during the insertion process b.) Potential for over-inflation of the cuff c1.) Potential for under-inflation of the cuff c2.) Inefficiency during the insertion process to add additional water to the syringe d.) Water is too hot, causing burns to the patient e.) Cuff will not inflate during later steps in the process	7	Uncommon	6
Position the patient	a.) Patient not positioned correctly b.) Suggested position is not appropriate for the patient c.) Patient safety not maintained during positioning	a1.) Lack of familiarity with policy for insertion b1.) Patient condition does not allow for proper positioning c1.) Policy not followed c2.) Human error	a.) Causes difficulty during the insertion process b1.) Alternate position will need to be identified prior to insertion b2.) If patient positioned per policy, despite contraindications, patient could suffer harm c1.) Unplanned Extubation c2.) Unplanned central or peripheral venous catheter removal c3.) Unplanned indwelling urinary catheter removal c4) Patient falls	7	Uncommon	6
Lubricate the cuff generously	a.) Step omitted b.) Cuff not sufficiently lubricated	a1.) Lack of familiarity with the policy for insertion a2.) Human error a3.) Unit culture/norms b1.) Lack of familiarity with the policy for insertion b2.) Human error b3.) Varying definition of "generous"	a.) Friction on insertion leading to rectal trauma b.) Friction on insertion leading to rectal trauma	4	Occasional	6
Insert the folded cuff into the patients sphincter, removing thumb as tube is inserted, using index finger to push cuff into the rectal vault	a.) Cuff is inserted with excess air in place b.) Cuff is inserted unfolded c.) Thumb is not removed properly d.) Index finger is not used to ensure accurate placement e.) Tube is not fully inserted into the rectal vault	a1.) Lack of familiarity with the policy for insertion a2.) Human error a3.) Unit culture/norms b1.) Lack of familiarity with the policy for insertion b2.) Human error b3.) Variance from process in earlier steps c1.) Human error c2.) Lack of familiarity with the policy for insertion d1.) Human error d2.) Lack of familiarity with the policy for insertion d3.) Discomfort with process e1.) Lack of familiarity with the policy for insertion e2.) Placement not verified e3.) Human error	a.) Cuff is larger than intended, rectal trauma occurs b.) Cuff is larger than intended, rectal trauma occurs c.) Thumb is inserted with cuff and index finger, stretching sphincter muscle more than recommended resulting in trauma d.) Placement is incorrect e.) Tube cuff is not incorrect position for inflation	4	Occasional	6

Gently pull on the catheter to ensure cuff is seated against rectal floor	a.) Step omitted, cuff is not properly seated against rectal floor b.) Pull on catheter too aggressive, tube is pulled out	a1.) Lack of familiarity with the policy for insertion a2.) Human error b.) Human error	a.) Leakage of fecal material around cuff b.) Rectal trauma	4	Occasional	6
Flush the catheter tube via the flush port with 45ml tap water once per shift	a.) Catheter is not flushed as recommended b.) Catheter is flushed via the incorrect port c.) Temperature of water is not checked	a1.) Lack of familiarity with the policy for maintenance a2.) Human error b1.) Lack of familiarity with the product b2.) Human error	a1.) Catheter has foul odor due to fecal material build up a2.) Catheter tubing becomes clogged with fecal material b1.) Water inadvertantly added to the cuff b2.) Water directly instilled into rectal vault c.) Patient exposure to water that is too hot leading to burns	7	Occasional	9
Documentation -Do not leave the catheter in place longer than 29 days	a.) Documentation not per policy, including a date and time of insertion b.)Guideline for removal is not followed	a1.) Human error a2.) Omission of date and time of insertion indocumentation b1.) Lack of familiarity with the policy for maintenance b2.) Human error b3.) Indications for removal not recognized b4.) Proper documentation not maintained, staff not familiar with length of time catheter is in place b5.) Inadequate hand-off during care transition	a.) Rectal trauma b.) Rectal trauma	10	Uncommon	8

Appendix B

Cost Benefit Analysis: Fecal Management System vs. Traditional Incontinence Management

100 patients, 14 days = 1400 device days

FMS Costs	
Nursing Time = (120 min/day x 1400 days)/(60 minutes)x($25/hr)	$ 70,000.00
Supplies:	$ 39,564.00
Sheets $2.92/day	$ 4,088.00
Gowns $0.32/day	$ 448.00
Pads $6.20/day	$ 8,680.00
Barrier Cream $1.72/day	$ 2,408.00
Bags for FMS $1.14/day	$ 1,596.00
Actual FMS Device $14.28/day	$ 19,992.00
Gloves $1.68/day	$ 2,352.00
FMS Costs Total	$ 109,564.00

Traditional Costs	
Nursing Time = (380 min/day x 1400 days)/(60 minutes)x($25/hr)	$ 221,667.00
Supplies:	$ 101,766.00
Sheets $13.86/day	$ 19,404.00
Gowns $1.95/day	$ 2,688.00
Pads $37.22/day	$ 52,108.00
Barrier Cream $16.33/day	$ 22,862.00
Gloves $3.36/day	$ 4,704.00
Traditional Costs Total	$ 323,433.00

FMS Benefits	
Reduction in Nursing Time	$ 151,667.00
Reduction in Supply Cost	$ 62,202.00
Reduction if One Pressure Injury was Prevented	$ 20,000.00
Reduction if IAD was prevented 1/2 the x's it occurs	$ 1,859.00
Cost Savings generated by FMS	$ 235,728.00
Cost Savings per day	$ 168.00

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Introduction

A CNS student led product evaluation to prevent adverse outcomes from fecal management system use and to conduct a cost comparison to traditional fecal incontinence management methods.

Background Data

- 33% of Adults over age 64 admitted to the ICU experience fecal incontinence [4]
- Fecal incontinence increases skin injury development [1, 3]
- Traditional methods of incontinence management are labor intensive, supply intensive, and often an aspect of missed nursing care [2]

Methods

- Healthcare Failure Modes and Effects Analysis (HFMEA)
  - Process to be evaluated: Fecal management system use
  - Team included the CNS student and 2 hospital employed CNS's
  - Creation and evaluation of a process diagram (Figure 1)
  - Creation and evaluation of a hazard analysis (Table 1)
  - Determination of process controls for high risk modes.
- Cost-Benefit Analysis (Table 2)
  - Cost calculation for the fecal management system
  - Cost calculation for traditional fecal incontinence management
  - Benefit calculation of fecal management system use
    - Cost benefit if one healthcare acquired skin injury was prevented
    - Cost benefit if half of the occurrences of incontinence associated dermatitis were prevented

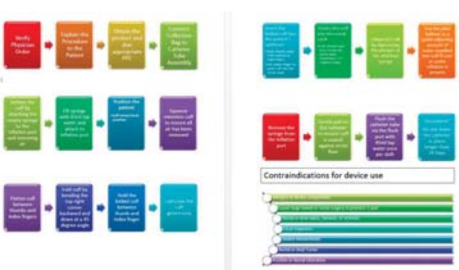

Figure 1. Fecal Management System Process Diagram

Process Step	Potential Failure Mode(s)	Potential Causes of Failure	Potential Effects of Failure	Severity	Probability	Hazard Score

Table 1. HFMEA Fecal Management System Hazard Analysis

Findings

- Healthcare Failure Modes and Effects Analysis (HFMEA)
  - 43 total failure modes identified during hazard analysis
  - 4 high risk modes identified during hazard analysis
    - Verification of a physician order in the medical record
    - Location of fecal management system cuff during inflation
    - System irrigation
    - Proper documentation
- Cost-Benefit Analysis
  - Cost and savings based on estimations of 1400 patient device days over the course of 1 years time
  - Total cost of fecal management system use $109,564
  - Total cost of traditional fecal incontinence management $323,433
  - Use of fecal management system would generate a cost savings of $235,728
  - Where savings occur:
    - Estimated to save 4 hours of nursing time per day generating a savings of $151,667 per year
    - Reduction in supply costs by $62,202
    - Reduction in cost due to healthcare acquired skin injuries and prevention of incontinence associated dermatitis

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Table 2. Cost Benefit Analysis

Conclusions

The results of the Healthcare Failure Modes and Effects Analysis led to the determination that fecal management systems are reasonably safe for use.

Cost Benefit Analysis provided information attesting to the cost-effectiveness fecal management system use.

The CNS, as a driver of positive outcomes and cost effectiveness, is the ideal evaluator for products and interventions.

References

1. Brunner, M., Droegemueller, C., Rivers, S., & Deuser, W. E. (2012). Prevention of incontinence-related skin breakdown for acute and critical care patients: Comparison of two products. (Research)(Report). Urologic Nursing, 32(4), 214-219.
2. Kalisch, B. J., Tschannen, D. H., & Lee, K. (2012). Missed Nursing Care, Staffing, and Patient Falls. Journal of Nursing Care Quality, 27(1), 6-12.
3. Langill, M., Yan, S., Kommala, D., Michenko, M. (2012). A budget impact analysis comparing use of a modern fecal management system to traditional fecal management methods in two Canadian hospitals. Ostomy Wound Management, 58(25).
4. Nelson, R.L. (2004). Epidemiology of fecal incontinence. Gastroenterology, 126(1), S3-S7.

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