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Einstein

A nurse-driven, evidence-based project: How CNS collaborative partnerships facilitated the introduction and implementation of an FDA-cleared bowel management system at one healthcare network

Background and Problem Statement

Fecal incontinence is associated with perianal dermatitis and pressure ulcer formation. Hospitalized patients with low albumin levels and/or limited mobility who are also incontinent are at highest risk for these pressure ulcers. Recent nursing literature supports that the use of an indwelling bowel catheter in these patients reduces the incidence of skin damage and pressure ulcers,¹ limits infectious waste exposure, and reduces overall related cost to the hospital and patient.² Skin and soft tissue infection prevalence was reduced 26.4% with the use of an indwelling bowel catheter in one study.³

Watson's Caring Theory

The Nursing Department for the Albert Einstein HealthCare Network chose Watson's Caring Theory as the framework for its nursing practice in 2005. This theory aligns with its mission: "With humanity, humility and honor, to heal by providing exceptionally intelligent and responsive healthcare and education for as many as we can reach."

In Watson's Caring Theory, the Caritas Nursing Framework, the human need for elimination is considered an essential part of human survival and existence.¹ The Caritas Nurse's plan of care related to elimination includes preserving the patient's dignity when most vulnerable and dependent. Preserving body image by containing bowel incontinence and preventing the development of a pressure ulcer with an indwelling bowel catheter is representative of Caritas Process 9: Administering Sacred Nursing Acts of Caring–Healing by Tending to Basic Human Needs (formerly Carative Factor 9: Assistance with Gratification of Human Needs).

Methods

The Iowa Model states that change of practice should be piloted on a specific unit.⁵ Two FDA-cleared indwelling bowel catheters were available in April 2008 when Network approval was sought to do a pilot value analysis in ICUs. Thus, the performance of two

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different indwelling bowel catheter systems was compared between June and July 2008, after in-depth in-servicing on both products in May 2008. Nurses caring for patients during the trial were invited to submit an evaluation form. Ten catheters each were utilized (20 total) and 18 completed evaluation forms per bowel catheter system (36 total) were received.

Results and Evaluation

Product evaluations revealed staff preference for one system* because there was less leakage, no odor, and no catheter displacement. Albert Einstein HealthCare Network is a regional leader in kidney, liver, and pancreas transplantation. Thus, the overwhelming advantage noted with the chosen product was the FDA clearance and ease of medication administration (lactulose) rectally with this device.* The Value Analysis Committee approved network-wide usage of this product in winter 2008.

Educational/Clinical Rollout

In-services were provided on all appropriate units and shifts by the manufacturer’s clinical educator and the unit CNS. Evidence-based order

sets with guidelines were created by the CNS and a fellow staff nurse by working closely with the manufacturer and pharmacy. Quarterly Super User training began in February 2009. This training is open to all RN staff, managers, educators, and CNSs, and is approved for four Continuing Education units. Course curriculum includes: description of the order sets with guidelines; presentation on product characteristics; inclusion criteria; contraindications; nursing interventions for pre-insertion, maintenance, and removal; aspects of stool modification; and troubleshooting for leakage if it occurs. Demonstration of insertion, maintenance, and removal is performed on a simulation model and the indwelling catheter. After passing a written test, the nurse completes return demonstration of psychomotor skills competency. This is comprised of two parts: return demonstration of product insertion, maintenance, and removal, along with staff and patient teaching simulation. Upon passing, the RN receives a certificate and is designated as a Super User for their unit. To date, 43 Super Users are in the hospital network. Super Users support the CNS and staff by acting as an expert resource and partnering to educate the staff on the new order sets and guidelines.

Conclusions and Future Plans

In 2009, a lecture and demonstration of this indwelling bowel management system was incorporated into the New RN Skin Day Class. This product competency is also now becoming a required station at Unit-Based Skills Days. Continuing Education with quarterly Super User training is planned for 2010-2011. An evidence-based policy and procedure document is currently being created in collaboration with a staff RN, and will be reviewed and approved by the Nursing Policy and Procedure Committee of the Shared Governance System. Product evaluations by the end users are currently being collected and reviewed for a one-year post analysis.

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ActiFlo Indwelling Bowel Catheter System

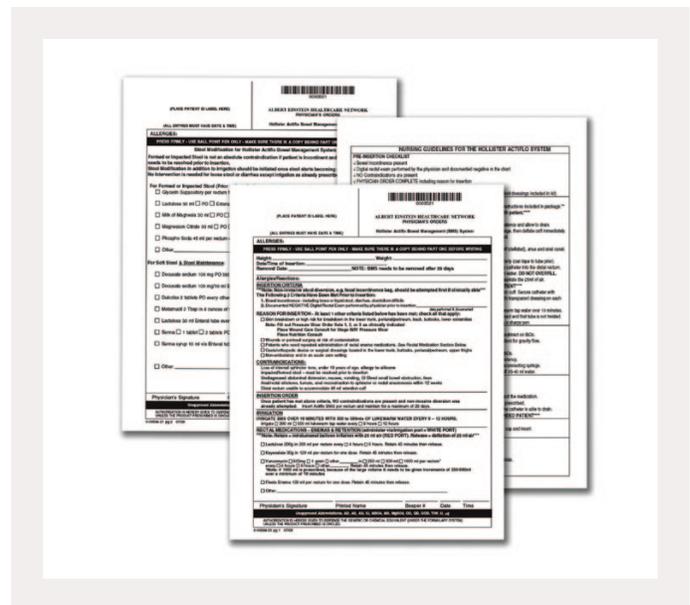


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Acknowledgements

Without the true collaboration of the following AEHN departments, this project would not have been a success: Department of Critical Care Nursing; Value Analysis, Pharmacy, Forms and CIMOC Committee; and Nursing Education and Professional Development.



Product evaluations by the end users were collected and reviewed for a one-year post analysis

ActiFlo Indwelling Bowel Catheter System Product Information

NON STERILE: Single patient use only. Latex-free.

CAUTION: Federal (USA) Law restricts this device to sale by or on the order of a physician. Prior to use of the ActiFlo indwelling bowel catheter system, be sure to read the entire ActiFlo indwelling bowel catheter system Instructions for Use package insert supplied with the product for device Intended Use, Description, Contraindications, Warnings, Precautions, Adverse Events, and Instructions for Use.

INTENDED USE

The ActiFlo indwelling bowel catheter system is intended for diversion of fecal matter to minimize contact with the patient's skin, to facilitate the collection of fecal matter for patients requiring bowel management, to provide access for colonic irrigation, and to administer enema/medications.

CONTRAINDICATIONS

- Do not use in patients having known sensitivities or allergies to the materials used in this device.
- Do not use if the patient's distal rectum cannot accommodate the inflated volume of the retention cuff or if the distal rectum/anal canal is severely strictured (e.g., secondary to tumor, inflammatory condition, radiation injury, scarring).
- Do not use on patients having impacted stool.
- Do not use on patients with a recent (less than 6 weeks old) rectal anastomosis, or a recent (less than 6 weeks old) anal or sphincter reconstruction.
- Do not use on patients with compromised rectal wall integrity (e.g., ischemic proctitis).

WARNINGS

(Failure to comply with the following warnings may result in patient injury)

- Do not use if package is open or damaged.
- Do not use improper amount or type of fluids for irrigation or cuff/balloon inflations. NEVER use hot liquids.
- Do not over inflate retention cuff or intraluminal balloon.
- Inflation of the intraluminal balloon causes complete catheter occlusion. Do not leave intraluminal balloon inflated in an unattended patient. To verify complete deflation of the intraluminal balloon, aspirate all air until RED connector (STOP FLOW 25 mL AIR) pilot balloon is collapsed when the syringe is removed from the connector.
- Use only gravity or slow manual irrigation. Do not connect manual pumping devices to catheter irrigation lumen. Do not irrigate patient with compromised intestinal wall integrity.
- Extreme caution should be exercised in patients at risk for the development of toxic megacolon. Occluding the tube by inflating the intraluminal balloon could aggravate this situation.

- Perform irrigations, and enema/medication administrations, via the CLEAR connector (IRRIG/Rx) AND NOT via the BLUE connector (CUFF 35-40 mL H₂O) or RED connector (STOP FLOW 25 mL AIR).
- Blood per rectum should be investigated to ensure no evidence of pressure necrosis from the device. Discontinue use of the device if evident.
- Abdominal distention that occurs while using the device should be investigated.
- The section of the catheter that crosses the anal canal (transsphincteric zone) is made of softcollapsible material designed to help avoid impact on the rectal sphincter. Excessive prolonged traction on the catheter, resulting in the retention cuff migrating into the anal canal, could result in temporary or permanent clinical sphincter dysfunction, or catheter expulsion.

PRECAUTIONS

- Do not sterilize.
- The ActiFlo indwelling bowel catheter is not intended for use longer than 29 days.
- The ActiFlo indwelling bowel catheter is not recommended for pediatric use.
- To avoid damage to retention cuff or intraluminal balloon, DO NOT contact either with ANY sharp edge including the enclosed lubricating jelly packets.
- The ActiFlo indwelling bowel catheter may not be effective in individuals who have had their distal rectum significantly altered by surgical resection or reconstruction.
- Patients with very weak sphincter function may expel the catheter under normal use, or may have increased leakage of stool or irrigation fluids compared to patients with normal sphincter function.
- Caution should be observed in patients whose rectum may be altered by stricture due to radiation or affected with radiation proctitis.
- Patients with severe tenesmus, or patients who experience tenesmus or severe pain after insertion of device, may not tolerate the catheter in place.
- Avoid inserting anything (e.g., thermometer, suppository, etc.) into the anal canal with the catheter in place to minimize patient injury or catheter damage.
- Care should be taken when disconnecting syringe from the CLEAR connector (IRRIG/Rx). Fluids that are retained in the rectum and colon may drain or splatter from the connector when it is disconnected.
- Use water only to inflate retention cuff. Do not use saline solution, which may adversely affect valve function.
- Use air only to inflate the intraluminal balloon. Do not use water or any other fluid.
- Do not use vigorous aspiration to remove fluid from the retention cuff or to remove air from the intraluminal balloon. Vigorous aspiration may collapse the inflation lumen and/or pilot balloon and prevent retention cuff or intraluminal balloon deflation.
- Do not allow ointments or lubricants having a petroleum base (e.g., Vaseline®, petroleumbased hand/body lotion) to contact the catheter. They may damage the silicone and may compromise the integrity of the device.

- Use only ActiFlo collection bags with the ActiFlo indwelling bowel catheter.
- Feces contains infectious material. Protect caregiver and others from splatter which may occur when disconnecting or emptying the collection bags or during catheter removal.
- After use, this system is a biohazard. Handle and dispose of in accordance with institutional universal precautions for contaminated waste.

ADVERSE EVENTS

The following adverse events may be associated with the use of any rectal device:

- Perforation
- Pressure necrosis
- Loss of sphincter tone
- Obstruction
- Infection
- Excessive leakage of fecal contents



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