

**Conference Sponsored
by Hollister Incorporated**

The support of Hollister Incorporated for this clinical presentation is gratefully acknowledged.

As Presented at

Clinical Symposium on Advances in Skin & Wound Care

October 22 – 25, 2009, San Antonio, TX



Cathy Downey, BSN, RN, CWOCN
Timothy Goedvolk, RN, BSc.N, MSN

**University Medical Center
of Southern Nevada
Las Vegas, NV**



Economical and clinical advantages of better bowel management in hospitalized patients

Introduction

Fecal incontinence is a significant problem in hospitalized adults, affecting 33% of patients overall, and as high as 58% of patients in intensive care units.¹ Uncontrolled stooling contributes to the development of nosocomial pressure ulcers² and incontinence associated dermatitis.³ Other hospital acquired conditions may also result from fecal soiling, including urinary tract infections and skin and soft tissue infections.⁴ Bowel catheters are a growing disposable expense in acute care, thus clinicians are asked to justify the value of this product category. The selection of one product over another should include considerations about clinical outcomes in addition to cost effectiveness measures.

Our Skin Care and Infection Control Council was asked to help improve the management of patients with fecal incontinence. The nursing staff had concerns about the current bowel catheter in use, including frequent leakage, difficulty keeping the device in place, and patients complaining of pain during use.

Providing product education had not resulted in positive change, thus a quality improvement process was initiated by our multidisciplinary team.

Steps in the Improvement Process

Completed a literature review, including:

- Published literature about bowel catheters
- Product data supplied by manufacturers

Collaborated with distribution team to learn which areas of the hospital were the highest users of the product:

- 16 bed Medical Intensive Care Unit (MICU)
- 24 bed Step Down Unit (3S)

Established key objectives for the product evaluation, which included data on:

- Ease of use
- Comfort for the patient
- Improved patient outcomes

Completed a value analysis.

“RN staff reported that the new tube was easy to use, and that the use of gravity irrigated allowed them to keep the tube functioning well.”

Value Analysis

Financial impact report generated on current bowel catheter system:

- All products associated with the bowel catheter were identified and a cross comparison with the proposed product* was made
- Literature review on usage was conducted
- GPO contact pricing was used in cost comparison analysis

The proposed product* was projected to save costs based on duration of usage as compared to current system.

Recommendation from Value Analysis was to conduct a controlled trial in two high usage areas to evaluate true duration of use at UMCSN.

Product for the evaluation was paid for by UMCSN.

Product Evaluation Process

The two nursing units with the highest usage of bowel catheters participated in the product evaluation.

Product education was provided to all shifts and days for the first week. The manufacturer's Clinical Nurse Educators were available for support and follow-up as needed for the duration of the evaluation period.

22 bowel catheter kits were used during the evaluation.

RNs completed written evaluations which included questions about:

- Ease of use
- Product performance
- Patient comfort
- Preference of the new system* or the prior system

Clinical Results

- 92% of respondents rated the new system* as excellent or better with regard to leakage and stool containment
- 88% rated the new system* as excellent or better in odor control
- 69% of respondents rated the new system* as excellent or better in patient acceptance and comfort
- 79% of respondents rated the new system* as easy to use
- 91% of respondents recommended switching to the new system*

Clinical Impact: Case Example

57-year-old male, admitted 11/17/2008 with peri-gluteal mass

The wound was surgically debrided 11/18/2008.

Topical treatment: Dakins soaked dressings, changed every 4 hours.

Indwelling bowel catheter+ was placed to help prevent wound contamination.

Multiple subsequent surgical debridements.

Split thickness skin graft applied January 5, 2009.

Only 30% take due to frequent stool leakage.



Peri-gluteal wound, following debridement

There was constant leakage with the first bowel catheter system in place and the patient complained of discomfort, a feeling of constipation, with the tube in place. The tube was expelled one to two times per day.

Placement of new bowel catheter system* 1/13/09

Patient experienced an immediate decrease in the amount of leakage around the tube.

Following placement of the new tube, the patient reported increased comfort. RN staff reported that the new tube was easy to use, and that the use of gravity irrigated allowed them to keep the tube functioning well.

* Zassi bowel management system, now marketed as ActiFlo indwelling bowel catheter system, Hollister Incorporated, Libertyville, IL

+ Flexiseal FMS, ConvaTec, Skillman, NJ

Wounds Closed: 2/1/09



New bowel catheter system* in place

Economic Impact

Figure 1 shows the annual spend for bowel catheter products before and after the product change in two of the highest usage nursing units. Changing to a different bowel system+ also resulted in decreased costs overall. While economic impact was not the principal reason for the project, the financial results were significant.

Summary

Product performance, staff satisfaction, patient satisfaction and economic value were integral components of this quality improvement process.

Keys to success in this project were: reviewing the existing evidence about bowel catheters, involving the nurses on units where the highest bowel

catheter usage occurs, collaborating on the goals of the project, and including clinical and economic end points for evaluation. By using this process, our decisions resulted in effective change and improvement of patient care, along with cost savings.

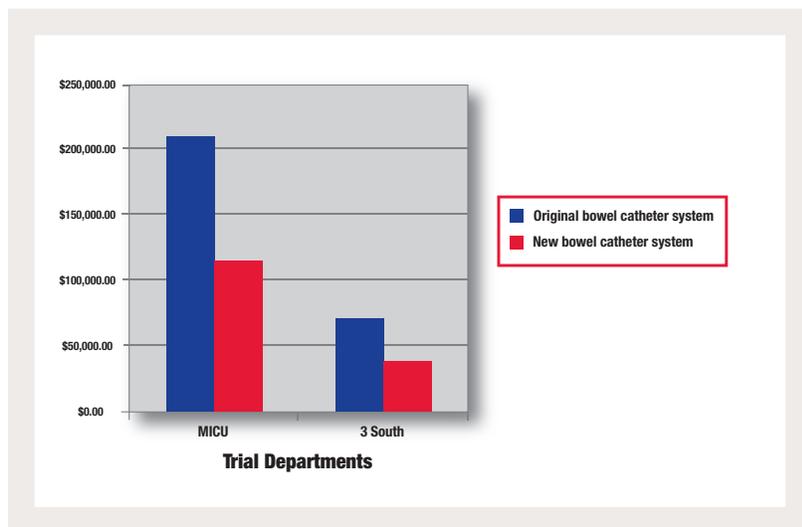


Figure 1 Hospital Costs by Unit Before and After Change

References

- Bliss DZ, Johnson S, Savik K, Clabots CR, Gerding DN. Fecal incontinence in hospitalized patients who are acutely ill. *Nurs Res* 2000; 49(2): 101-108.
- Benoit RA & Watts C. The effect of a pressure ulcer prevention program and the bowel management system in reducing pressure ulcer prevalence in an ICU setting. *J Wound Ostomy Continence Nurs* 2007; 34(2), 163-177
- Junkin J, Selekof J. Prevalence of incontinence and associated skin injury in the acute care inpatient. *J Wound Ostomy Continence Nurs* 2007; 34(3): 260-269.
- Echols J, et al. (2007). Clinical utility and economic impact of introducing a bowel management system. *J Wound Ostomy Continence Nurs* 34(6): 664-670.

Product Information

NON STERILE: The ActiFlo indwelling bowel catheter is constructed primarily of silicone materials. All system components are latex-free. Single patient use only.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician or other healthcare practitioner licensed under state law to order this product. Refer to the complete ActiFlo indwelling bowel catheter system Instructions for Use supplied by the manufacturer for directions on how to properly use this product.

INTENDED USE: The ActiFlo indwelling bowel catheter system is intended for diversion of fecal matter to minimize external contact with the patient's skin, to facilitate the collection of fecal matter for patients requiring stool 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).
- Do not connect irrigation bag to an IV.
- Do not use irrigation bag for enteral feeding.

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 stop-flow balloon.
- Inflation of the stop-flow balloon causes complete catheter occlusion. Do not leave stop-flow balloon inflated in an unattended patient. To verify complete deflation of the stop-flow 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 stop-flow 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.
- 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 system is not intended for use longer than 29 days.
- Caution should be used in patients who may bleed easily due to anticoagulant/antiplatelet therapy or underlying disease conditions. Immediately consult a physician if rectal bleeding is suspected.
- The ActiFlo indwelling bowel catheter system is not recommended for pediatric use.
- To avoid damage to retention cuff or stop-flow balloon, DO NOT contact either with ANY sharp edge including the enclosed lubricating jelly packets.
- The ActiFlo indwelling bowel catheter system 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 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 stop-flow 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 stop-flow balloon. Vigorous aspiration may collapse the inflation lumen and/or pilot balloon and may prevent retention cuff or stop-flow balloon deflation.

- Do not allow ointments or lubricants having a petroleum base (e.g., Vaseline®, petroleum-based hand/body lotion) to contact the catheter. They may damage the silicone and may compromise the integrity of the device.
- Use only Hollister branded bowel catheter collection bags with the ActiFlo indwelling bowel catheter.
- Feces contains infectious material. Protect 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 protocol and 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



Hollister Incorporated
2000 Hollister Drive
Libertyville, Illinois 60048 USA

For detailed clinical questions:
1.888.740.8999

For orders only:
1.800.323.4060

Distributed in Canada by
Hollister Limited
95 Mary Street
Aurora, Ontario L4G 1G3
1.800.263.7400

www.hollister.com

Hollister and logo, and ActiFlo are trademarks of Hollister Incorporated. All other trademarks and copyrights, are the property of their respective owners.

©2012 Hollister Incorporated.
910979-1112