

Urinary Output Monitoring and Management in Acute Care: Clinical Pathway for CMS 1533 Compliance and Positive Economic Impact of Compliance

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Abstract

Catheter-associated urinary tract infections (CAUTI) are the most common nosocomial infections in U.S. hospitals and nursing homes, accounting for more than 1 million cases annually¹. Unresolved nosocomial UTI's may account for as many as 56,000 deaths per year.² The estimated annual cost of treating nosocomial UTI in the U.S. is \$558 to \$593 million³; cases of sepsis add significant additional cost. The patient risk of developing a decubitus ulcer (pressure ulcer) in an acute care hospital can be as high as 38%.⁴ The cost of treating pressure ulcers is estimated at \$11 billion per year.⁵ Pressure ulcers are frequently caused by the moisture trapped against a patient's skin by a diaper.⁶ As of October, 2008, hospitals must bear the costs for increased length of stay and treatment costs for CAUTI and pressure ulcers.⁷

A hydrocolloid-based external continence device for men provides a new, fully external option for urinary output monitoring and management in acute care hospitals. The device forms a paramental seal on the glans, directing all urine away from the body. Patients' skin remains dry, reducing the risk of breakdown and UTI.⁸ The device is applicable for any size male anatomy, including uncircumcised, circumcised⁹, large, small or retracted¹⁰ and works for all forms of incontinence where retention or urinary obstruction are not present. Intermittent catheterization can be performed with the device in place. Accurate application is essential to utilize the device.¹¹

Execution of a recommended Clinical Care Protocol to establish guidelines for implementing use of the hydrocolloid-based external continence device will significantly reduce the number of male patients receiving indwelling catheters and diapers (absorbent pads) and reduce the annual estimated costs of treating CAUTI and sepsis, which exceeds \$6.8 billion in the hospital setting (Figure 3). A similar reduction in the use of diapers and pads among male patients in the hospital setting could reduce the \$11 billion annual cost for treatment of pressure ulcers that occur in areas where diapers and pads trap moisture against the skin (Figure 4). The total potential cost savings from a 50% reduction of both indwelling catheters and diapers among male patients approaches \$2.8 billion (Figures 3 & 4).

Problems with Current Methods of Urinary Monitoring and Management: A Massive Public Health Issue

Catheter-associated urinary tract infections (CAUTI) are the most common nosocomial infections in U.S. hospitals and nursing homes, accounting for at least 1 million cases annually.¹ The acquisition of urinary tract infections associated with indwelling bladder catheterization has been linked to a threefold greater risk of mortality in hospitalized patients. Unresolved nosocomial UTIs may account for as many as 56,000 deaths per year.² Once catheters are in place for three to four days, most clinicians and infectious disease experts believe urinary tract infections (UTI) are unpreventable.⁷ For male patients, these catheters

promote catheter-associated UTI rates ranging from 38%-70%.^{12, 13, 14} The Centers for Medicare and Medicaid Services (CMS), citing a study in the American Journal of Medicine¹, estimates each episode costs \$676, or \$558 to \$593 million per year.³ If CMS had included the costs of treating sepsis as a secondary diagnosis, which averages \$40,000 per episode¹⁵, the total cost would exceed \$6.8 billion (Figure 3). Acute care hospitals will also face rising risks of wrongful death litigation, as CAUTI and decubitus ulcers will now be considered a preventable medical error.

Decubitus ulcers are frequently caused by the moisture trapped against the skin by a diaper.⁶ The cost of treating pressure ulcers is estimated at \$11

billion per year.⁵ Each year in the U.S., 2.5 million incidents of pressure (decubitus) ulcers occur in acute care hospitals.¹⁶ Sixty-two percent of pressure ulcers occur at the sacrum, trochanter and ischium, all areas covered by a diaper, exposing the skin to persistent moisture.¹⁷ In hospitals, the incidence of pressure ulcers has been recorded as high as 29.5%.¹⁸ Cases of pressure ulcers as secondary diagnoses in an acute care hospitals cost an average of \$43,180 each.¹⁹ The failure to prevent pressure ulcers is now considered a reliable indicator of medical error and may lead to litigation.²⁰

In 2008, CMS took action. The Center promulgated Medicare rule 1533⁷ which will take effect on October 1, 2008. In June 2011, this rule was expanded to include all state Medicaid. Under the rule, CMS will not pay for treating hospital-acquired CAUTI, nor will CMS pay for associated increases in length of hospital stay. Additionally, according to 1533, CMS will no longer reimburse for the cost of pressure ulcers acquired during hospital stay as they “could reasonably have been prevented through the application of evidence-based guidelines.” To comply with the new standard, hospitals must reduce their rates of nosocomial UTIs and decubitus ulcers, or be faced with absorbing the treatment costs and risk management into their already razor-thin revenue margins.

The Costs of Care

Indwelling Catheters

Studies beginning in the 1970s confirmed indwelling catheters used for as little as one day increase hospital morbidity and mortality²¹ and increase the rates of hospital-acquired infection. Kunin²² found CAUTI accounts for 40% of all nosocomial infections and increases costs by adding unnecessary days and treatment costs. A separate study of nosocomial infections in the elderly found a linear relationship between the average duration of urinary catheterization and the rate of catheter-associated UTI²³. The excessive use of antibiotics to treat these infections contributes to the massive public health problem of emerging antibiotic-resistant microorganisms such as methicillin-resistant *Staphylococcus aureus* (MRSA) and vancomycin-resistant enterococcus (VRE).²²

Even indwelling urinary catheters impregnated with antibiotics or coated with silver alloys do not prevent gram-negative (i.e. stool bacteria) catheter-associated UTI, according to a recent study in *Emerging Infectious Disease*²⁴. The majority of CAUTIs are caused by gram-negative stool bacteria; *Escherichia coli* accounts for 46% of hospital-acquired UTI.²⁵ Moreover, impregnated catheters cost approximately 60% more than standard indwelling catheters, according to industry costs supplied for a study published in the *Archives of Internal Medicine*.²⁶ Although efficacy is not established, some manufacturers price these catheter kits at up to \$50.

Several studies have examined the cost of hospital-acquired UTI. While CMS used Foxman’s 2002 estimate of at least \$676 per episode, Maki estimated the cost to be at least \$1,000 based on extending length of stay by one day.²⁴ Cox estimates an additional cost of \$1,875 based on 2.5 extra days of care.² These estimates do not include the cost of treating sepsis complications, which are estimated at \$5.2 billion annually (Figure 3).

Under CMS 1533, hospitals will incur all charges for treating CAUTI that develops within 72 hours of patient discharge from an acute care hospital stay.⁷ Post-discharge costs may be significant. Only 52% of patients with CAUTI were actually diagnosed and treated by an Ann Arbor teaching hospital.¹² If the remaining 48% had experienced UTI symptoms within 72 hours of discharge and returned to the hospital, additional readmissions would not have been covered by Medicare or many other private insurers.

Indwelling catheters may also lead to significant costs when dislodged by critically ill or uncomfortable patients. Urethral catheters dislodged with the balloon inflated may cause severe hemorrhage and cost \$21,000 per episode.²⁷

Condom Catheters

Condom catheters do not help patients avoid catheter-acquired UTI, nor are they very useful for urinary measurement. A recent randomized study published in the *Journal of the American Geriatric Society*

compared men using indwelling catheters to those using condom catheters in an acute care setting. The study spanned 3.5 years with an average length of stay of 3 days per patient after enrollment. Results found men over 40 years of age without dementia were almost as likely to develop bacteriuria when randomized to the condom catheter (38.2%) as those using an indwelling urinary catheter (41.5%).¹⁴ A retrospective study of geriatric patients comparing condom catheters to a control group not using a catheter found a 63% condom catheter-associated UTI rate.²⁸ Both studies confirm that switching to condom catheters will not help hospitals comply with CMS's new rule to reduce CAUTI's.

In a second, similar study, Saint et al. found high condom catheter pop-off rates made their usefulness for accurately measuring urine output in a hospital setting highly questionable.²⁹

Disposable Briefs / Absorbent Pads / Adult Diapers

By creating an environment that makes the skin extremely susceptible to breakdown (maceration), diapers (including under pads, adult briefs, and disposable absorbent incontinence products) are a major contributor in the incidence of complications resulting from urinary output management methods. Sixty-two percent of pressure ulcers occur in the areas affected by moisture present in a diaper.¹⁷ A prospective study of 139 patients found that diapers rapidly cause pressure ulcers by trapping urine against the skin.⁶

The incidence and prevalence of pressure ulcers are high enough to warrant concern for hospitalized populations. In hospitals, the incidence of pressure ulcers ranged from 2.7%³⁰ to 29.5%.¹⁸ Several subpopulations are at higher risk:

- Quadriplegic patients (60%)³⁰
- Elderly patients admitted for femoral fracture (66%)³¹
- Critical care patients (33%)³²

Each case of pressure ulcer as a secondary diagnosis in an acute care hospital costs an average of \$43,180.¹⁹

The Braden Scale³³ is the most commonly used tool for assessing and reducing pressure ulcers in the U.S.

The scale includes moisture trapped against the skin as a key risk factor in the cause of pressure ulcers. The Braden Scale recommends using alternative urine collection methods in lieu of diapers to prevent or alleviate persistent moisture against the skin.³³

New Methods for Urinary Output Monitoring and Management

BioDerm, Inc. manufactures *Liberty3.0*, a hydrocolloid-based male external continence device that may often replace indwelling catheters, condom catheters and diapers for urinary output monitoring and management in the acute care setting. The device, manufactured in the U.S., is fully external and non-invasive. This device employs a hydrocolloid faceplate with a central urine outlet opening to make a seal around the meatus and direct all urine into a leg or bedside collection bag. This device functions like an ostomy device for normal male anatomy, directing all urine immediately away from the meatus to establish an environment where the skin (including penile shaft and glans) is consistently protected from moisture or exposure to urine. By keeping the skin dry, the device prevents skin maceration, breakdown, and wounds. Perineal hygiene is required prior to application, thus reducing ambient bacteria. The perineal hydrocolloid seal establishes an occlusive dressing that can prevent access of bacteria to the urinary meatus.³⁵



Figure 1

The hydrocolloid seal will adhere to clean, dry skin for an average of 24 to 72 hours. Although initial applications may have a shorter wear time, the device may be worn up to 3 days. The seal turns a milky-white color when the device is ready to be changed. Soaking the seal in warm water will allow the device to slide off easily.⁸

The device's central urine outlet channel permits direct access to the meatus for patients who require intermittent catheterization and have overflow

incontinence / urine leakage between catheterization episodes.

Proper application is essential for successful utilization of the device. If application is not performed correctly, the device may be more likely to come off early or leak.¹¹

The device is highly effective for all normal male anatomy. Unlike other external methods (condom catheters), the design works with retracted anatomy. The device allows the foreskin to return to the natural, forward position making it equally suitable for both circumcised and uncircumcised anatomy.⁹ Figure 2 identifies appropriate candidates for the hydrocolloid-based external continence device.

Candidates for a Hydrocolloid-Based External Continence Device

A hydrocolloid-based external continence device is appropriate for male patients who:

- spontaneously void urine or are capable of prompted voiding
- do not have urinary obstruction or retention
- do not exhibit anatomic abnormalities such as severe hypospadias or urethral fistula
- are free of wounds, infection or purulent discharge at the application site
- do not have gross hematuria or trauma to the urinary tract

Figure 2

Clinical Trials and Case Reports

A prospective clinical trial of 43 patients with a total of 420 applications of the device found urine contact with the skin was completely eliminated. There was no significant skin breakdown or irritation from the latex-free hydrocolloid adhesive of the collection device. Average wear time was 48 hours per application and there were no infections or adverse events.³⁶

Patients who have been using the device in the UK include those with Parkinson's disease, multiple sclerosis, and spinal cord injury. These patients have reported that it is easy to apply, comfortable, and easy to remove. Patients have reported a benefit from a feeling of increased security.¹¹

Conclusion

Improved Outcomes

Based on preliminary data, utilizing a hydrocolloid-based external continence device can significantly reduce complications associated with indwelling catheters such as CAUTI, sepsis and damage to the urinary tract. Since coming on the market in 2005, over 1 million Liberty devices have been used with zero reported adverse events, including urinary tract infection and skin injury. By directing all urine away from the skin, risks of diaper-associated pressure ulcers resulting from persistent moisture and skin breakdown are greatly reduced as well as the risk of UTI. By adhering to only the glans with a hydrocolloid seal, skin damage, risk of pop-offs, and latex and adhesive allergic reactions associated with condom catheters are alleviated.

Randomized, prospective clinical studies comparing a hydrocolloid-based male external continence device to indwelling catheters, condom catheters and diapers are required to confirm improvements in care and outcome costs, and should be pursued. Clinical studies may also satisfy continuous improvement requirements for accreditation by the Joint Commission on Accreditation of Healthcare Organizations.⁴⁰

Potential Cost Savings

Acute care hospitals have a significant cost-savings opportunity to replace indwelling urinary catheters with the hydrocolloid-based external continence device. Replacing 50% of indwelling catheters in men with the hydrocolloid-based device will save \$1.37 billion, or \$4,250 annually per staffed male-patient bed (table 2). For a typical 400 bed acute care hospital with 80% occupancy, this represents \$556,000 in annual savings. Figure 3 outlines the costs associated with indwelling catheters and complications, as well as the potential savings from a proposed reduction in use.

Cost Savings from Indwelling Catheter Reduction in US Acute Care Hospitals

Data		
Male Patient (Pt) Discharges (millions, annually)	13.9 ³⁷	
Total Pt Discharges (millions, annually)	34.7 ³⁷	
% Catheterized	40.0% ⁷	
Probability (P), Development of Bacteriuria w/Catheter, 2-10 Days	26.0% ³⁸	
P, Progression to Symptomatic UTI w/o Bacteremia	24.0% ³⁸	
P, Progression to Bacteremia	3.6% ³⁸	
Staffed Beds, US Community Hospitals (millions)	0.803 ³⁹	
Additional Length of Stay to Treat Symptomatic UTI (days)	2.5 ²	
Cost of Additional Days to Treat Symptomatic UTI (per incident)	\$1,875 ²⁶	
Cost to Treat Incident of Sepsis (Bacteremia)	\$40,000 ¹⁵	
Calculations		
	All Patients	Males
Catheterized (millions, annually)	13.88	5.56
Developing Bacteriuria (millions)	3.61	1.45
Acquiring Symptomatic UTI w/o Bacteremia (millions)	0.87	0.35
Acquiring Bacteremia (millions)	0.13	0.05
Annual Cost to Treat Symptomatic UTI (millions)	\$1,624	\$651
Annual Cost to Treat Bacteremia (millions)	\$5,197	\$2,082
Total Costs UTI + Sepsis (millions)	\$6,821	\$2,732
Annual Savings from Replacing 50% of Indwelling Catheters in Male Pts		
	(millions)	\$1,366
	(per staffed, male-patient bed)	\$4,247

Figure 3

Replacing 50% of the diapers and pads used in male patient beds in the acute hospital setting with the hydrocolloid-based device potentially saves \$1.4 billion in pressure ulcer treatment costs annually (Figure 4).

Cost Savings from Diaper / Pad Reduction in US Acute Care Hospitals

Cost of Treating (billions, annually)	\$ 11.0 ⁵
Proportion of Ulcers in Diaper Areas	62.0% ¹⁷
Cost to Treat Ulcers Caused by Diapers/ Pads (billions, annually)	\$ 6.8
Proportion of Patients, Male	40.0% ⁷
Potential Cost Savings Replacing 50% of Diapers/ Pads Among Male Patients (billions, annually)	\$ 1.4

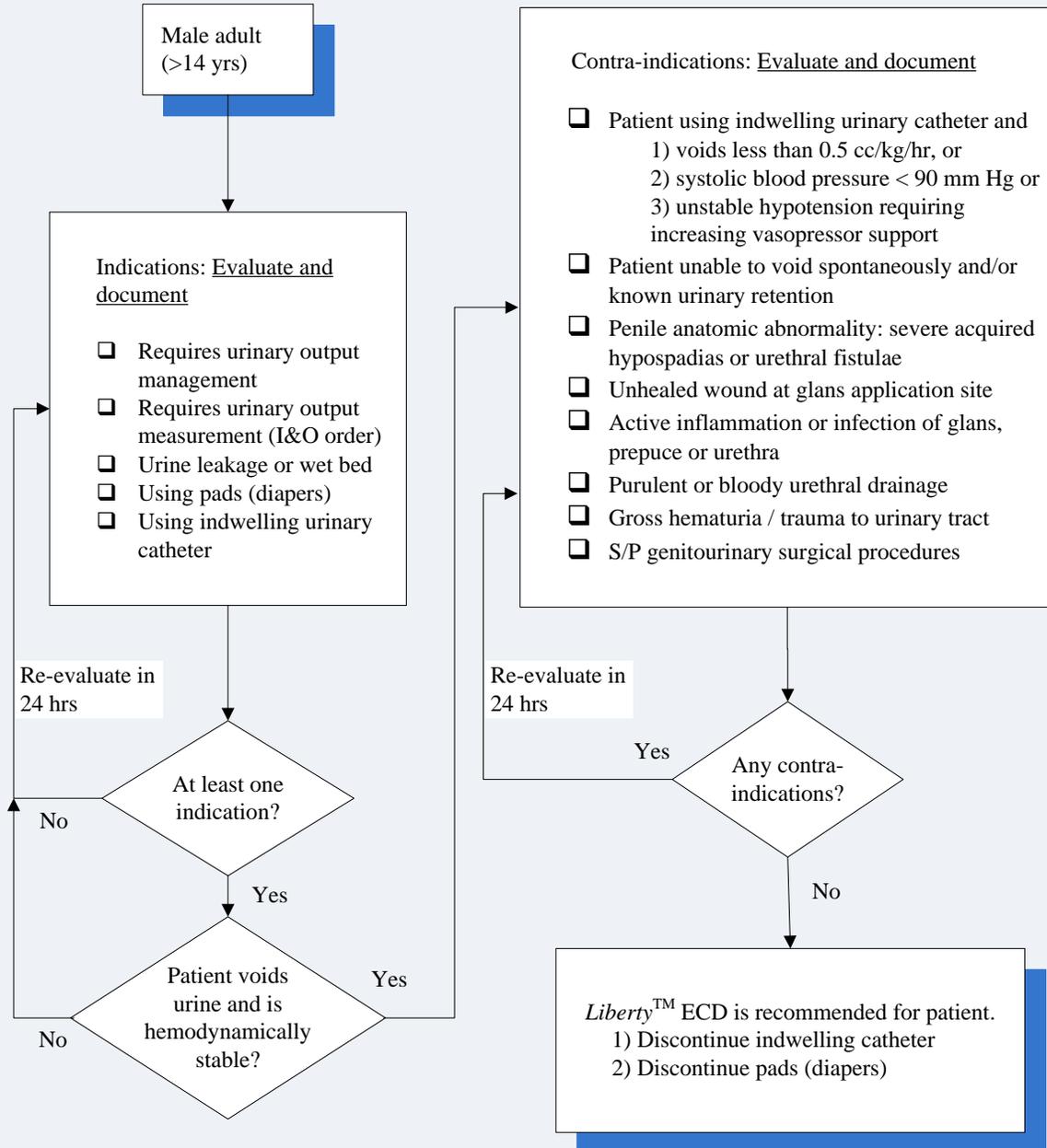
Figure 4

By utilizing a hydrocolloid-based external continence device for urinary output monitoring and management for all applicable male patients, hospitals have the opportunity to significantly reduce payor costs and the number of hospital days per patient while improving the quality of care provided to these patients. The total potential cost savings from a 50% reduction of both indwelling catheters and diapers among male patients approaches \$2.8 billion.

Recommended Clinical Care Protocol

The findings of initial clinical studies suggest that the hydrocolloid-based external continence device for men may significantly reduce the cost of urinary monitoring and management in the acute care setting.^{11, 34, 36} Figure 5 is a protocol for urinary monitoring and management to determine when use of the external continence device is appropriate in the acute care setting.

Protocol for Use of the *Liberty*TM Male External Contenance Device in Acute Care



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Figure 5

Implementing this program will significantly reduce the number of patients receiving indwelling catheters, condom catheters and diapers in the hospital setting. By improving the standards of care, participating facilities can provide a greater level of quality for their patients while reducing treatment times and costs.⁴⁰

Current methods for urinary monitoring and management have an extremely high rate of complications and associated outcome costs. With the onset of new Medicare Mandate CMS-1533, hospitals must quickly address the dangerous complications such as pressure ulcers and CAUTI associated with absorbent pads and indwelling catheters or face millions of dollars in treating these complications without reimbursement. Such complications and their associated treatment expenses can be greatly reduced, and in some cases, potentially eliminated with alternative methods for urinary output monitoring and management. In addition, both the episodes of wrongful death from catheter associated UTI and pressure ulcers from diapers are substantial risk management issues for acute and long term care facilities. Acute care hospitals can clear the regulation hurdle, improve patient outcomes, and reduce the risk of litigation by implementing protocols using a hydrocolloid-based male external continence device as a replacement to indwelling catheters and diapers.

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