OPEN

External Collection Devices as an Alternative to the Indwelling Urinary Catheter

Evidence-Based Review and Expert Clinical Panel Deliberations

Mikel Gray ◆ Claudia Skinner ◆ Wendy Kaler

ABSTRACT

Multiple evidence-based guidelines have suggested clinicians consider external collection devices (ECD) as alternatives to indwelling catheters. Nevertheless, there is a dearth of evidence-based resources concerning their use. An expert consensus panel was convened to review the current state of the evidence, indications for ECDs as an alternative to an indwelling urinary catheter, identify knowledge gaps, and areas for future research. This article presents the results of the expert consensus panel meeting and a systematic literature review regarding ECD use in the clinical setting.

KEY WORDS: CAUTI prevention, External collection device

INTRODUCTION

Catheter-associated urinary tract infections (CAUTIs) are the most frequently reported hospital-acquired infection in the National Health Safety Network.1 They are associated with multiple clinically relevant complications such as pyelonephritis, urosepsis, and bacterial endocarditis.²⁻⁴ In addition to concerns over patient safety associated with CAUTI development, there is a growing concern over the prevalence of multidrug-resistant infections. A national study analyzed the number of CAUTIs associated with multidrug-resistant organisms in long-term acute care hospitals, and found vancomycin resistance among Enterococcus faecalis in 44% of cases reported in 2010, and 25% of Pseudomonas aeruginosa infections.⁵ It is estimated that at least 13,000 deaths are attributable to urinary tract infections (UTIs) each year. 4,6 Based on these associations, the Centers for Medicare and Medicaid Services named hospital-acquired UTI as one of the original "never events."

Mikel Gray, PhD, FNP, PNP, CUNP, CCCN, FAANP, FAAN, Department of Urology, University of Virginia School of Medicine, Charlottesville, Virginia. Claudia Skinner, DNP, RN, CCRN, CNML, NE-BC, St. Joseph's Health, Irvine, California.

Wendy Kaler, MPH, Center of Excellence, Dignity Health, San Francisco, California.

Eloquest Healthcare granted funds for the facilitation of the APIC consensus round table, and the medical writing and editorial development of this document provided by MedBio Publications LLC. The consensus round was moderated by Dr Ahnal Purohit. The authors maintained total editorial control throughout manuscript development.

This is an open-access article distributed under the terms of the Creative Commons Attribution-Non Commercial-No Derivatives License 4.0 (CCBY-NC-ND), where it is permissible to download and share the work provided it is properly cited. The work cannot be changed in any way or used commercially. The authors declare no conflict of interest.

Correspondence: Mikel Gray, PhD, FNP, PNP, CUNP, CCCN, FAANP, FAAN, Department of Urology, University of Virginia, PO Box 800422, Charlottesville, VA 22902 (mg5k@virginia.edu).

DOI: 10.1097/WON.0000000000000220

Effective prevention of CAUTI relies on an intervention bundle, similar to prevention guidelines for other never events such as facility-acquired pressure ulcers. A bundle is defined as 3 to 5 interventions that, when implemented collectively, improve patient outcomes.8 Saint and colleagues identified 4 elements of an intervention bundle for prevention of CAUTI: (1) urinary catheter reminders or stop orders; (2) nurse-initiated discontinuation of indwelling urinary catheters; (3) portable ultrasound to determine postvoid residual; and (4) external continence devices (ECDs) in men.9 The 2009 Centers for Disease Control and Prevention CDC Guidelines also included a statement about use of ECDs, "Consider using external catheters as an alternative to indwelling urethral catheters in cooperative male patients without urinary retention or bladder outlet obstruction [pg.38]."10 This statement is categorized as category II, indicating the recommendation is supported by weak evidence suggesting a reasonable balance of likely benefits versus harm.¹⁰ External collection devices are also advocated in guidelines from the Infectious Diseases Society of America,¹¹ European and Asian infection control societies,12 Wound Ostomy and Continence Nurses Society, Society for Urologic Nurses and Associates, and the American Nurses Association.¹³

External Collection Devices

External collection devices are defined as a category of devices that adhere to the external genitalia or pubic area and collect urinary output (Figure 1). They are distinguished from indwelling catheters that are inserted into the bladder vesicle using a transurethral or suprapubic route. They can be divided into several device categories, condom catheters, reusable body-worn urinals, and a nonsheath, glans-adherent ECD.

Originally constructed of latex, many condom catheters are now constructed from one of several alternative substrates such as silicone. Single-use condom catheters (sometimes referred to as Texas catheters) adhere to the penile shaft via an adhesive applied to the interior surface of the device, or a

Category	Description	Image	Application	Image Url
Latex-based sheathed devices	External catheter with latex sheath. Available with and without separate adhesive liner. ^A		Sheath is held at the tip of the penis and rolled down the penile shaft.	http://www.coloplast.us/conveen-latex- urisheaths-en-us.aspx#section=product- variants_4
	External catheter with latex sheath and adhesive lining. ^B		Appropriate sizing is necessary.	https://www.hollister.com/us/products/popup_l arge_product_photo.asp?photo=large_960x_174.jp g&groupid=3
	External catheter with foam adhesive strap. ^c	26	Sheath is held at the tip of the penis and rolled down the penile shaft. An adhesive strap is wrapped around the device to provide securement. Appropriate sizing is necessary.	http://www.exmed.net/images/Product/large/ru sch-texas-style-male-external-latex-condom- catheter-GHWWQYPHB.jpg
Non-latex based sheath devices	External catheter with sheath made of PSX silicone material and adhesive lining. ^A			http://www.coloplast.us/conveen-optima-en- us.aspx
	External catheter with silicone sheath and adhesive lining. ^A			http://www.coloplast.us/freedom-clear-advantage- en-us.aspx
	External catheter with silicone sheath and adhesive lining.8		Sheath is held at the tip of the penis and rolled down the penile shaft.	https://www.hollister.com/us/products/popup_larg e_product_photo.asp?photo=large_975xx_527.jpg& groupid=3
	External catheter with hydrocolloid sheath and adhesive lining. ^C	SPIRIT	Appropriate sizing is necessary.	http://www.exmed.net/p-3769-rochester-spirit- silicone-male-external-condom-catheter-style-3- wideband.aspx
	External catheter with silicone sheath and adhesive lining. ^c	inch.		http://www.blowoutmedical.com/ultraflex-external- condom-catheter-by-rochester- medical.html?utm_source=google&utm_medium=ba se&utm_campaign=products&feed_special=google
	External catheter with silicone sheath and adhesive lining. ^c			http://www.allegromedical.com/browse/ViewProductLargelmage.do?productId=8ab281020bb66dff010bb67f037a64a9
	External catheter with silicone sheath. Adhesive free. ^c	1467	Sheath is held at the tip of the penis and rolled down the penile shaft. A foam velcro strap is wrapped around the device to provide securement. Appropriate sizing is necessary.	http://www.exmed.net/p-2059-rochester-catheter- latex-free-male-external-condom- catheter.aspx?DefaultVariantID=20896&utm_source =Google&utm_medium=cse&utm_term=ROC38304E ACH&gclid=CjwKEAjwxMetBRDJx6Sz2p7DsQOSJADJH AQNYhd6XHC23- XvLzlTtgmniY9meE9pOYky50Tqsom_CxoCgsPw_wcB
	Inflatable external catheter with silicone sheath. Adhesive free. D		The inflatable retention ring secures the catheter and can be easily deflated for removal. Appropriate sizing is necessary.	https://www.cookmedical.com/products/uro_30230 _webds/#!
Retracted Penile Pouch	Integrated hydrocolloid ring with adhesive and collection pouch. ⁸		The penis is placed in the opening of the pouch and the wafer adheres to the skin at the base of the penis. Wafer can be cut to accommodate different sized anatomies.	http://www.elderstore.com/retracted-penis- pouch.aspx
Glans- adherent device	Non-sheath, glans- adherent ECD with integrated hydrocolloid and adhesive. ^E	*	The device secures to the glans only by first adhering the faceplate, then overlapping and securing with the seal straps. One-size-fits-all and no sizing necessary.	http://eloquesthealthcare.com/reliafit/

Figure 1. External collection devices on market analysis—2015.

double-sided adhesive strap that wraps around the penis. ¹⁴ In addition, condom catheter straps are available that wrap circumferentially around the penile shaft; they are usually manufactured of foam or other materials with variable elasticity in order to accommodate changes in penile shaft size with erectile activity. ¹⁴ A single-use condom catheter is available that adheres to the penile shaft via an internal ring that is inflated

with air to enable urinary containment.¹⁴ Most condom catheters come in multiple sizes to accommodate variability in the circumference of the penile shaft.¹⁴ Urinary drainage is accomplished by attaching the distal end (catheter tip) of the device to a urinary drainage bag (leg bag or overnight bag). A device should be chosen that has a nonkinking junction between the catheter tip and drainage bag.¹⁴ Correct application requires

measuring the penile diameter at the base of the penile shaft, gently cleansing and drying the penile skin, and clipping any hair growing on the shaft to enhance adherence between the condom catheter or adhesive strap and skin. ¹⁴ Some clinicians use a liquid polymer acrylate (liquid skin barrier) to protect the underlying skin and promote adherence; our literature review identified no studies supporting or refuting the need for adding this step to the application process. Anticipated wear times for condom catheters are 24 to 72 hours. ¹⁴

The nonsheath, glans-adherent ECD is a fully external, one-size-fits-all, device that can be applied to males who are circumcised and uncircumcised, as well as those who have smaller penile circumferences or leaks and obese men with retracted penile shafts. This device differs from traditional condom catheters because of the one-size-fits-all design with technology that bypasses the need to cover the penile shaft and associated risk of skin damage. 15,16 A brief overview of device application is presented in Table 1.

Obese men and those with shorter penile shafts also may be fitted with a 1- or 2-piece penis pouch, sometimes referred to as a retracted penis pouch. These devices attach to the pubis via a hydrocolloid wafer barrier. The base of the penile shaft is assessed and a hole is cut in the barrier wafer that allows the penis to pass through the pouch. The skin at the base of the penis is held taut to enhance adherence. Urine drains into a collection pouch that is incorporated into the product, or a pouch that is attached to the wafer barrier via a flange. The pouch has a distal port that attaches to a drainage bag. Preparation of the skin requires cleansing and removal of pubic hair. Anticipated wear time is 2 to 3 days for a 1-piece system and 5 to 7 days for a 2-piece system. The

External collection devices have been developed for women, but none have gained widespread use in the clinical setting. ^{18,19} Despite a number of innovative designs, the considerable challenges of designing a device that effectively contains urinary output while avoiding damage to the pubic skin or vaginal mucosa remains elusive. As a result, commercially available ECDs are currently limited to male patients.

TABLE 1.

Application Procedure

- 1. If the patient is uncircumcised, retract foreskin to expose the glans.
- 2. Clean and dry the glans.
- Use alcohol wipe to remove cleanser's moisturizing agents and natural oils from the skin.
- Apply small amount nonwater-soluble liquid adhesive^a to the glans, avoiding urethral opening and allow to dry for 30 s.
- Remove paper tabs from faceplate ("daisy") and apply the device to ensure primary securement.
- Remove paper tabs from one section of the seal ("bowtie") at a time and apply circumferentially by overlapping the exposed petals.
- 7. Apply gentle pressure with one hand around the new seal, holding for 10 s to promote device adherence.
- 8. For uncircumcised anatomy, return the foreskin to natural resting position, which may overlap the seal.
- Attach drainage bag to universal adapter at distal end of device and secure with the hydrocolloid stabilization securement device.

From Lucas and colleagues. 16

In addition to its indication as part of a care bundle for prevention of CAUTI, ECDs have been used in a variety of other situations (Table 2). These indications include long-term drainage in men with neurogenic bladder dysfunction and reflex urinary incontinence, short-term drainage in men who experience cognitive dysfunction due to acute or chronic illness, and short-term drainage in the ambulatory surgical setting or diagnostic suite. ²⁰⁻²⁵

While evidence-based intervention bundles have been shown to reduce CAUTI incidence, a 2014 analysis by the National Hospital Safety Network revealed that only 6% to 27% of hospitals reported adherence to CAUTI prevention policies.¹ This disparity between evidence and practice may be due, in part, to patient and caregiver preference based on discomfort, application challenges associated with appropriate application for small and retracted male anatomy, and difficulties with leak prevention.³¹

In order to more fully address widespread adoption of ECDs as an alternative to the indwelling catheter, a round-table discussion of clinicians with expertise in indwelling catheter management, prevention and treatment of CAUTI, and use of ECDs was convened. The purpose of that meeting was to identify ECD knowledge gaps and indications for ECD use as an alternative to the indwelling urinary catheter.

EXPERT PANEL PROCEEDINGS

Eight clinicians were selected to serve on the round table based on their complementary areas of expertise to serve as consensus panel members (Table 3). The majority of consensus panel members (n = 7, 87.5%) were RNs; the panel member who was not an RN has expertise in epidemiology and infection control. The expertise represented by this panel was broad and included 1 member with expertise in urology, 2 in quality improvement, 5 in infection prevention, and 1 in epidemiology.

The expert panel met in Anaheim, California, on June 8, 2014, to consider the current state of the science and evidence-based literature surrounding ECDs, and to identify knowledge gaps and indications for usage. Each individual provided rationales and recommendations, and consensus on agenda

TABLE 2.

Indications for ECD Use in Men

- Patients requiring ECD when indwelling catheter is not appropriate^{21-23,26-29}
- Long-term care patients who experience urinary incontinence without retention²⁴
- Long-term urinary containment for selected men with neurogenic bladder dysfunction and incontinence without sensory awareness due to paralyzing spinal disorders such as spinal cord injury, transverse myelitis, or progressive multiple sclerosis²⁵
- Patients with delirium tremens
- Patients on powerful diuretic medications such as furosemide who require accurate documentation of fluid intake and urinary output (vs strict intake and output)^{22,30}
- Patients requiring procedural drainage such as after outpatient surgeries such as discectomy, arthroscopic surgeries
- Patients on observation for 6- to 8-h period postprocedure when deemed appropriate (observation for urinary retention)

^aMastisol Liquid Adhesive, Eloquest Healthcare, Inc, Ferndale, Michigan.

^bCathGrip, Bioderm, Inc, Largo, Florida.

TABLE 3. Clinicians, Credentials, Affiliations, and Facilities of Consensus Panel Members

First name	Last Name	Credentials	Title/Role	Facility/Organization
Mikel	Gray	PhD, APRN, FNP-BC, CUNP, CCCN	Nurse practitioner and professor	University of Virginia School of Nursing
Claudia	Skinner	DNP, RN, CCRN, CNML, BC-NE	Director of Center of Excellence	St. Jude Medical Center
Shannon	Davila	RN, MSN, CIC, CPHQ	Clinical quality improvement manager	New Jersey Hospital Association
Brenda	Helms	RN, BSN, MBA/HCM, CIC	Manager infection prevention, employee health, accreditation	Baylor Medical Center at McKinney
Wendy	Kaler	CLS, MPH, CIC	Manager infection control	St. Francis Memorial Hospital
Valerie	Lowe	RN, BSN, CIC	Infection preventionist	California Hospital Medical Center
Susan	Viker	RN, CIC	Manager of infection prevention	California Hospital Medical Center
Vicki	Warnock	RN, CIC	Director of infection prevention	Dignity Health

topics was achieved. The agenda included 3 main topics: (1) urinary management and the impact on overall wellness; (2) current urinary management algorithms; (3) the benefits of implementation of male ECDs within a urinary management algorithm. They reviewed evidence-based literature on ECDs as an alternative for incontinence management prior to the round-table discussion.

A moderator guided the discussion, she was selected based on expertise in the process of consensus construction, and was an individual who was neutral to the topic. Consensus for each statement was obtained based on general principles outlined by Murphy and colleagues,³² using 80% agreement as a minimum criterion for consensus. If consensus was not achieved after initial discussion, the statement was modified based on panel member input and a second, and sometimes third, consensus votes were taken until consensus was achieved.³²

Discussion initially focused on ECD as part of an evidence-based care bundle for prevention of CAUTI. Panel members recognized that current evidence demonstrates effective prevention of CAUTI primarily relies on a reduction in the number of indwelling urinary catheter days. For example, a study on the relationship between indwelling urinary catheter use and the incidence of CAUTI showed a strong linear correlation (r[2])

0.79; P < .0001).³³ Additional articles were reviewed regarding the negative outcomes associated with CAUTI, such as increased morbidity, extended hospital length of stay, decreased health-related quality of life, and increased costs.^{2-4,14,25,31}

Discussion then turned to the use of ECDs as an alternative for indwelling catheterization. Panel members concurred that evidence concerning the efficacy of ECD as an alternative to the indwelling urinary catheter is sparse, especially when compared to the current focus on timely catheter removal protocols. Given the dearth of existing research on the use of ECD and the poor uptake for intervention bundles for CAUTI prevention, the group discussed strategies for improving ECD use (Table 4). 34-39 These strategies include incorporating ECD use into education about CAUTI prevention, and emphasizing the ability of ECD use in reducing indwelling catheter days while maintaining the ability to accurately measure fluid intake and urinary output.

Individual panel members observed that introduction of ECDs into their facilities sometimes met with resistance from nursing staff owing to concerns about application of an ECD, its ability to effectively contain urinary output, and prevention of potential complications such as urethral obstruction or local tissue damage if devices were applied too tightly. Panel members with experience introducing ECDs in acute care facilities

TABLE 4.

Recommendations for Improving Use of ECD as a Component of an Intervention Bundle for Prevention of CAUTI

- 1. Incorporating ECDs into discussions of CAUTI prevention, emphasizing the need to avoid unnecessary Foley catheters while maintaining the ability to capture accurate intake and output. 22,30
- Ensuring adequate buy-in of clinical team members when introducing an ECD; addressing key stakeholders and team at correct time points; engaging medical director and nursing director, WOC nurses as stakeholders, nurse educators, and CAUTI prevention champions.^{34,35}
- 3. Identifying champions/superusers as part of the quality improvement initiative. 1,28
- 4. Setting appropriate expectations regarding the learning curve for application of ECDs by nurses and presentation of the device as an evidence-based solution for CAUTI prevention; presenting the learning curve associated with ECDs as investment, which is part of the solution vs part of the problem.
- 5. Setting appropriate expectations regarding duration of ECD use and potential changes on a case-by-case basis; emphasizing evidence-based nursing. 36,37
- 6. Setting appropriate expectations for ECDs in unique patient populations in which application may be more complex (eg, obese/uncircumcised).
- 7. Develop a customizable nurse-driven protocol for ECD usage in clinically appropriate situations. 34,35
- 8. Develop tools to demonstrate value of ECDs (cost avoidance). 49,52
- 9. Develop tools to ensure education/re-education on an every 6-mo basis (potentially annual basis) focused on appropriate ECD application to avoid rare complications. 43,50
- 10. Collect patient survey information in ambulatory patients (satisfaction, comfort, health-related quality of life) to measure patient satisfaction. 38,39

Abbreviations: CAUTI, catheter-associated urinary tract infection; ECD, external collection device.

emphasized the need to set appropriate expectations regarding the learning curve required for application of ECDs by nurses, identifying indications for their use, appropriate application methods, expected wear time for a typical device, and anticipated duration for ECD use in acutely or critically ill patients.

Panel members also recognized the need for policies that allow individualization of ECD use based on patient needs, body habitus, and preferences. Several panel members reported improved staff acceptance of regular ECD use when they emphasized its role as an essential component of an evidence-based CAUTI prevention bundle, and when the associated learning curve was presented as an investment in the overall program's success.

Panel members who had introduced ECDs in their facilities also discussed the need to develop a nurse-driven protocol for their use based on standardized indications, and data collection documenting its impact on CAUTI occurrences and associated costs. Nurse-driven protocols have been shown to be effective in empowering nurses to adhere to CAUTI prevention best practices. P.34-40 Reeducation focusing on techniques for effective and appropriate application of ECDs was recommended initially every 6 months.

Based on their collective experiences, the panel concurred that ensuring adequate buy-in among clinical team members is essential when introducing regular use of ECDs as part of a CAUTI prevention bundle. Recommended strategies included identifying and addressing key stakeholders and the team at strategic time points; and engaging support from key persons in administration such as the medical and nursing directors. Panel members also advocated early involvement of key clinical leaders within the facility such as WOC nurses, nurse educators, and CAUTI prevention champions. Identification of unit-based CAUTI prevention champions or superusers of these devices is recommended, as these individuals are ideally situated to teach others to successfully apply and manage ECD as they gain experience in their use.

Panel members practicing in ambulatory care settings also shared experiences regarding teaching patients and lay-caregivers on how to safely and effectively apply ECD, including setting expectations for a realistic learning curve, and a greater average wear time as skills applying these devices matured. In addition to collecting data about the long-term effects of ECD use on UTI rates, they also advocated investigating data on the impact of these devices on satisfaction, comfort, and health-related quality of life.

Scoping Literature Review

Given the lack of literature associated with ECD use, and the comparatively low uptake of CAUTI bundles in acute care facilities discussed earlier, the panel recommended appointing an editorial committee comprising 3 panel members (CS, MG, WK). The panel identified 3 aims for the literature review: (1) review evidence concerning the efficacy of ECD for prevention of CAUTI when compared to the indwelling urinary catheter, (2) review evidence concerning cost analyses associated with a CAUTI prevention bundle versus no formal program, and (3) identify knowledge gaps and prioritize research needs concerning use of ECD for prevention of CAUTI.

METHODS

We queried the MEDLINE database using the following parameters: research in humans published within the last 10 years, English language, both sexes, adults aged 19 years

and older. Given the limited amount of research in this area, the search included all levels of studies: systematic review with and without meta-analysis of pooled data, randomized clinical trials, nonrandomized trials, prospective cohort studies and retrospective case-control studies, multiple case series, and case studies. The search also included best practice statements, clinical practice guidelines, comprehensive, and integrative reviews. MeSH terms queried were catheters; urinary catheterization; catheters, indwelling; cross infection; evidence-based nursing; and nursing assessment. Additional key words queried were condom catheters; penile sheath; nurse-driven protocols; CAUTI; prevention; and incontinence. When searching for articles on safety of ECDs, the date range was expanded to "all dates" because of the importance of reviewing all individual reported case studies.

Findings

The literature review identified 86 potentially relevant articles. The editorial team then conducted a title review to eliminate duplicate articles, and articles unrelated to the stated aims, yielding 36 relevant titles. The editorial group then completed an abstract review of the 36 relevant articles, and 32 articles^{1,2,5,7,19,21-23,25,26,28,29,31,32,34-50} were selected that were relevant and were read used for the review. An additional 20 articles^{3,4,6,8,10-18,20,24,27,30,33,51,52} were identified as relevant on bibliographic (ancestry) review (Figure 2).

Efficacy and Safety of ECD

One of the objectives of the focused (scoping) literature review was to identify clinical studies discussing the efficacy and safety of ECDs. We used the definition provided by the Cochrane: "The extent to which an intervention produces a beneficial result under ideal conditions. Clinical trials that assess efficacy are sometimes called explanatory trials and are restricted to participants who fully co-operate." One randomized controlled trial²⁶ was retrieved and 3 individual case histories^{47,48,50} were identified that discussed the safety of ECD use.

Saint and colleagues²⁶ compared CAUTI occurrences associated with ECD use to infections in patients managed by indwelling catheterization. The study compared indwelling urinary catheters to ECDs in 75 men aged 40 years or more who required urinary drainage during hospitalization.²⁶ Men allocated to drainage with an ECD had a lower incidence of bacteriuria than did men randomized to the indwelling catheter group (70/1000 patient days vs 131/1000 patient days); this difference was statistically significant when adjusted for other risk factors (P = .04), including presence of dementia.²⁶ When compared to men managed by an indwelling catheter, men using ECD has a lower hazard ratio for bacteriuria or



Figure 2. Flowchart of scoping literature review.

symptomatic UTI (hazard ratio = 4.84; 95% confidence interval = 1.46-16.02). Men without dementia using an ECD also reported higher levels of comfort and less pain associated with urinary drainage (P = .02) on a questionnaire designed for the study than men with indwelling catheters. Meaning the study that the study

Three case studies were published that focused on the safety of ECD use. 47,48,50 Vaidyanathan and colleagues 47 reported a case of localized necrosis of the scrotum in a man with a spinal cord injury. Ozkan and colleagues 48 reported isolated gangrene of the penis in a paraplegic patient, and Kawoosa 50 described penile strangulation and necrosis.

In the first case study,⁴⁷ the necrosis was attributed to several factors, including lack of understanding regarding the impact of urine leakage and resultant skin damage, improper personal hygiene coupled with a neurogenic bowel, and an impaired immune system. Based on these findings, the authors discussed the importance of patient and caregiver education for appropriate application, and care of an ECD in the treatment of incontinence. In the second and third case studies, 48,50 adverse outcomes were attributed to improper application of the ECD; these findings highlight the importance of proper application and patient observation. Considered collectively, these case studies illustrate the importance of appropriate application of the ECD and adherence with proper care and hygiene. 47,48,50 In addition, the lack of cases reported reinforces the clinical experiences of panel members that dispel the myth that ECDs are inherently dangerous when applied and cared for properly.

Cost Analysis of an Evidence-Based CAUTI Prevention Bundle

We did not find any studies that reported on the costs associated with an entire CAUTI prevention bundle of care, nor were there any articles reporting cost analyses of ECD versus IDC for CAUTI prevention. An economic analysis conducted by the CDC assessed the costs of hospital-acquired infections and the benefits of prevention, and found the attributable costs per CAUTI infection ranged from (US) \$589 to \$1007. The economic analysis estimated if 20% of hospital-acquired infections were prevented using evidence-based best practices, the cost benefits of prevention would reach approximately (US) \$5.7 billion. Leading the costs associated with an entire cost analysis estimated if 20% of hospital acquired infections were prevented using evidence-based best practices, the cost benefits of prevention would reach approximately (US) \$5.7 billion.

Clarke and colleagues⁴⁹ analyzed the effectiveness of a CAUTI bundle of care with 4 interventions, and reported the annualized investment of \$23,924 for implementing the 4 interventions resulted in significantly higher savings as a result of CAUTI avoidance. Collectively, these studies suggest that the cost associated with an effective CAUTI prevention program is less than the cost of anticipated infections in the absence of an effective prevention program is instituted.

Knowledge Gaps and Research Needs

There is a significant paucity of evidence-based literature associated with ECD indications and usage. There are multiple knowledge gaps, including efficacy studies and cost analyses of CAUTI prevention bundles that incorporate ECDs. Future research should include well-designed comparative effectiveness studies to compare ECDs with indwelling urinary catheters, assessing efficacy, safety, costs, patient satisfaction, and health-related quality of life. Evidence-based guidelines should be developed to assist facilities with incorporating ECDs into CAUTI prevention bundles utilizing nurse-driven protocols.

CONCLUSION

This expert consensus round-table meeting resulted in a clinically meaningful discussion regarding the promotion of widespread adoption of ECDs as an alternative to the indwelling catheter. The consensus panel members successfully identified ECD knowledge gaps and indications for ECD use as an alternative to indwelling urinary catheters. An additional scoping literature review revealed existing evidence regarding the safety and efficacy of ECDs. There is a substantial clinical need for large, well-designed comparative effectiveness research studies and cost analyses, and evidence-based guidance for developing nurse-driven CAUTI prevention bundles of care, which incorporate ECDs into decision making.

REFERENCES

- Stone PW, Pogorzelska-Maziarz M, Herzig CT, et al. State of infection prevention in US hospitals enrolled in the National Health and Safety Network. Am J Infect Control. 2014;42(2):94-99.
- Ramanathan R, Duane TM. Urinary tract infections in surgical patients. Surg Clin North Am. 2014;94(6):1351-1368.
- Jacobsen SM, Stickler DJ, Mobley HL, Shirtliff ME. Complicated catheter-associated urinary tract infections due to Escherichia coli and Proteus mirabilis. Clin Microbiol Rev. 2008;21(1):26-59.
- Centers for Disease Control and Prevention. Urinary Tract Infection (Catheter-Associated Urinary Tract Infection [CAUTI] and Non-Catheter-Associated Urinary Tract Infection [UTI]) and Other Urinary System Infection [USI]) Events. http://www.cdc.gov/nhsn/PDFs/pscManual/ 7pscCAUTIcurrent.pdf
- Chitnis AS, Edwards JR, Ricks PM, Sievert DM, Fridkin SK, Gould CV. Device-associated infection rates, device utilization, and antimicrobial resistance in long-term acute care hospitals reporting to the National Healthcare Safety Network, 2010. *Infect Control Hosp Epidemiol*. 2012;33(10):993-1000.
- Klevens RM, Edwards JR, Richards CL, Jr, et al. Estimating health care-associated infections and deaths in U.S. hospitals, 2002. *Public Health Rep (Washington, DC: 1974)*. 2007;122(2):160-166.
- Gray M. Reducing catheter-associated urinary tract infection in the critical care unit. AACN Adv Crit Care. 2010;21(3):247-257.
- 8. Institute for Healthcare Improvement. Definition Evidence-Based Care Bundles. http://www.ihi.org/topics/bundles/Pages/default.aspx
- Saint S, Kowalski CP, Kaufman SR, et al. Preventing hospital-acquired urinary tract infection in the United States: a national study. *Clin Infect Dis*. 2008;46(2):243-250.
- Gould CV, Umscheid CA, Agarwal RK, Kuntz G, Pegues DA. Guideline for prevention of catheter-associated urinary tract infections 2009. *Infect Control Hosp Epidemiol*. 2010;31(4):319-326.
- 11. Hooton TM, Bradley SF, Cardenas DD, et al. Diagnosis, prevention, and treatment of catheter-associated urinary tract infection in adults: 2009 International Clinical Practice Guidelines from the Infectious Diseases Society of America. Clin Infect Dis. 2010;50(5):625-663.
- Tenke P, Kovacs B, Bjerklund Johansen TE, Matsumoto T, Tambyah PA, Naber KG. European and Asian guidelines on management and prevention of catheter-associated urinary tract infections. *Int J Antimi*crob Agents. 2008;31(Suppl 1):S68-S78.
- Conway LJ, Larson EL. Guidelines to prevent catheter-associated urinary tract infection: 1980 to 2010. Heart Lung J Crit Care. 2012; 41(3):271-283.
- Lekan-Rutledge D. Management of urinary incontinence: sin care, containment devices, catheters and absorptive products. In: Doughty DB. 3rd edn. *Urinary and Fecal Incontinence*. St. Louis: Elsevier; 2006: 309-339.
- 15. Urinary Output Monitoring and Management in Acute Care. Clinical Pathway for CMS 1533 Compliance and Positive Economic Impact of Compliance Sponsored by the Center for Excellence in Healthcare Outcomes. http://bioderminc.com/wp-content/uploads/2013/10/Urinary-Output-Monitoring-and-Management-in-Acute-Care.pdf
- Lucas LM, Iseler J, Gale L. Evaluation of a new, novel male external urinary management device. Poster presented at: Cleveland Clinic's Spring 2013 WOC Nursing Symposium; April 12, 2013; Cleveland, OH.

- Lekan-Rutledge D. Management of urinary incontinence: skin care, containment devices, catheters, absorptive products. In: Doughty DB. 3rd ed. *Urinary and Fecal Incontinence*. St. Louis: Mosby-Elsevier; 2000:309-340.
- 18. Pieper B, Cleland V. An external urine-collection device for women: a clinical trial. *J ET Nurs.* 1993;20(2):51-55.
- Simaika YS. The "trio" condom catheter: a modification of the condom catheter in the management of postpartum haemorrhage. *Int J Obstet Gynaecol.* 2010;117(3):372.
- Gray M. Neurogenic bladder dysfunction. In: Doughty DB, Moore KN, eds. Wound, Ostomy and Continence Nursing Society Core Curriculum. 1st ed. Philadelphia: Wolters-Kluwer; 2016.
- Jamison J, Maguire S, McCann J. Catheter policies for management of long term voiding problems in adults with neurogenic bladder disorders. Cochrane Database Syst Rev. 2013;11:Cd004375.
- 22. Tambyah PA, Oon J. Catheter-associated urinary tract infection. *Curr Opin Infect Dis.* 2012;25(4):365-370.
- 23. Chenoweth CE, Saint S. Urinary tract infections. *Infect Dis Clin North Am.* 2011;25(1):103-115.
- 24. Gammack JK. Use and management of chronic urinary catheters in long-term care: much controversy, little consensus. J Am Med Dir Assoc. 2003;4(2 Suppl):S52-S59.
- Cameron AP, Wallner LP, Forchheimer MB, et al. Medical and psychosocial complications associated with method of bladder management after traumatic spinal cord injury. Arch Phys Med Rehabil. 2011;92(3):449-456.
- Saint S, Kaufman SR, Rogers MA, Baker PD, Ossenkop K, Lipsky BA. Condom versus indwelling urinary catheters: a randomized trial. *J Am Geriatr Soc.* 2006;54(7):1055-1061.
- Ribby KJ. Decreasing urinary tract infections through staff development, outcomes, and nursing process. J Nurs Care Qual. 2006;21(3):272-276.
- Saint S, Kowalski CP, Forman J, et al. A multicenter qualitative study on preventing hospital-acquired urinary tract infection in US hospitals. *Infect Control Hosp Epidemiol.* 2008;29(4):333-341.
- 29. Nicolle LE. Urinary catheter-associated infections. *Infect Dis Clin North Am.* 2012;26(1):13-27.
- Pratt RJ, Pellowe CM, Wilson JA, et al. epic2: National evidence-based guidelines for preventing healthcare-associated infections in NHS hospitals in England. J Hosp Infect. 2007;65(Suppl 1):S1-S64.
- 31. Fink R, Gilmartin H, Richard A, Capezuti E, Boltz M, Wald H. Indwelling urinary catheter management and catheter-associated urinary tract infection prevention practices in Nurses Improving Care for Healthsystem Elders hospitals. *Am J Infect Control*. 2012;40(8):715-720.
- 32. Murphy MK, Black NA, Lamping DL, et al. Consensus development methods, and their use in clinical guideline development. *Health Technol Assess (Winchester, England)*. 1998;2(3):i-iv, 1-88.
- 33. Titsworth WL, Hester J, Correia T, et al. Reduction of catheter-associated urinary tract infections among patients in a neurological intensive care unit: a single institution's success. *J Neurosurg*. 2012;116(4):911-920.

- Alexaitis I, Broome B. Implementation of a nurse-driven protocol to prevent catheter-associated urinary tract infections. J Nurs Care Qual. 2014;29(3):245-252.
- 35. Oman KS, Makic MB, Fink R, et al. Nurse-directed interventions to reduce catheter-associated urinary tract infections. *Am J Infect Control.* 2012;40(6):548-553.
- 36. Sahel A, DeBrouwere V, Dujardin B, Kegels G, Belkaab N, Alaoui Belghiti A. Implementing a nationwide quality improvement approach in health services. Leadersh Health Serv (Bradford, England). 2015;28(1):24-34.
- 37. Baier RR, Keough L, McDonald J. Transitions of care: professional expectations. *Rhode Island Med J.* 2013;96(11):26-32.
- Challenor R, Perry R. Measuring patient satisfaction: three years' data and experience of using a validated patient questionnaire. *Int J STD AIDS*. 2015;26(9):667-671.
- 39. Ahmed F, Burt J, Roland M. Measuring patient experience: concepts and methods. *The Patient*. 2014;7(3):235-241.
- Mori C. A-voiding catastrophe: implementing a nurse-driven protocol. Med Surg Nurs. 2014;23(1):15-21.
- Andreessen L, Wilde MH, Herendeen P. Preventing catheter-associated urinary tract infections in acute care: the bundle approach. J Nurs Care Qual. 2012;27(3):209-217.
- Grigoryan L, Abers MS, Kizilbash QF, Petersen NJ, Trautner BW. A comparison of the microbiologic profile of indwelling versus external urinary catheters. Am J Infect Control. 2014;42(6):682-684.
- Conway LJ, Pogorzelska M, Larson E, Stone PW. Adoption of policies to prevent catheter-associated urinary tract infections in United States intensive care units. Am J Infect Control. 2012;40(8):705-710.
- 44. Kyle G. The use of urinary sheaths in male incontinence. *Br J Nurs* (Mark Allen Publishing). 2011;20(6):338.
- Saint S, Kowalski CP, Kaufman SR, et al. Preventing hospital-acquired urinary tract infection in the United States: a national study. *Clin Infect Dis*. 2008;46(2):243-250.
- Magill SS, Hellinger W, Cohen J, et al. Prevalence of healthcareassociated infections in acute care hospitals in Jacksonville, Florida. *Infect Control Hosp Epidemiol.* 2012;33(3):283-291.
- 47. Vaidyanathan S, Soni BM, Hughes PL, et al. Localised necrosis of scrotum (Fournier's gangrene) in a spinal cord injury patient—a case report. *BMC Fam Pract.* 2002;3:20.
- 48. Ozkan HS, Irkoren S, Sivrioglu N. Penile strangulation and necrosis due to condom catheter. *Int Wound J.* 2015;12(3):248-249.
- Clarke K, Tong D, Pan Y, et al. Reduction in catheter-associated urinary tract infections by bundling interventions. *Int J Qual Health Care*. 2013;25(1):43-49.
- Kawoosa NU. Isolated gangrene of the penis in a paraplegic patient secondary to a condom catheter. *Indian J Surg.* 2011;73(4):304-306.
- Cochrane Collaboration. Cochrane Community Glossary. http://community.org/glossary/5#lettere
- Scott DR. The direct medical costs of healthcare-associated infections in U.S. hospitals and the benefits of prevention. http://www.cdc.gov/ HAI/pdfs/hai/Scott_CostPaper.pdf

Call for Authors: Continence Care

Original research, case studies and case series addressing, in particular:

- Urinary or fecal stream diversion: indwelling urethral, suprapubic catheters or fecal/bowel management system.
- Pelvic floor muscle rehabilitation protocols for stress, urge and mixed urinary incontinence in men or women.
- Current state of the science presented in systematic reviews and/or meta analyses.
- Evidence based management of incontinence associated dermatitis or moisture associated skin damage.
- Incidence and prevalence of incontinence in understudied populations.
- Quality of life issues associated within continence, care-giving, catheter management, prevention of incontinence.