

External Urine Collection Devices: Protecting Incontinent Patients from Infections, Wounds and Falls

Driven in part by increased obesity and an aging population, the rate of female urinary incontinence has risen dramatically in the US over the past two decades, with one recent study finding that nearly 62% of adult U.S. women – aged 20 and older – suffer from the condition. That's up from 49% in 2004. Researchers further estimate that 40% of those 78 million women have weekly incontinence, and 27% suffer from moderate or severe incontinence.ⁱ

In other words, "every person in the US has urinary incontinence or knows somebody that has urinary incontinence, and it's somehow still a restricted topic," says Ushma J. Patel, MD, a PGY-4 obstetrics and gynecology resident who co-authored a recent study on female urinary incontinence.ⁱⁱ

Urinary incontinence is a functional disability that impacts hygiene and takes a social, financial, and emotional toll on many women – including more than 50% of women over age 70. It has grown into a \$10 Billion market dominated by indwelling catheters and diapers, options that cause severe discomfort for many women and carry significant health risks including skin injuries from extended exposure to urine and urinary tract infections (UTI).

An Inpatient Crisis

For hospitals, managing adult patient incontinence is a significant clinical concern with implications that impact care quality, outcomes, and patient safety, and carry a potentially heavy regulatory compliance and financial burden. Patients suffering from incontinence have higher Braden Scale scores, indicating a higher risk for pressure sores,ⁱⁱⁱ and are at high risk of developing incontinence-associated dermatitis (IAD) and moisture-associated skin damage (MASD).

By the numbers, 42.5% of patients have some type of observable skin injury^{iv} and nearly 1 in 5 develop IAD.^v They are nearly 5 times more likely to have a sacral area pressure injury upon admission, are over 5 times more likely to acquire one while hospitalized, and 5.8% more likely to see an increase in severity – contributing to an average length of stay (LOS) of 6.4 days compared to 4.4 days for their continent counterparts. Incontinent patients also experience a 30-day readmission rate of 12.8%, compared to 8.8% for continent patients.^{vi} Among critically ill adults in the intensive care unit, 36% developed MASD in just four days and 81% still suffered from IAD at discharge.^{vii}



Urinary incontinence also increases the risk of falls – one of five geriatric syndromes or multifactorial conditions associated with high morbidity and poor quality of life among older adults. Falls represent an important and increasing public health problem as many result in serious injuries, pain, depression, and other comorbidities requiring medical attention. One study determined an overall odds ratio of 63% for



recurrent falls and a probability excess odds ratio of 65% among people with urinary incontinence compared to those without.^{viii}

Options for managing incontinence are limited and far from ideal. Diapers and absorbent pads are popular because cost of use is low. However, their use results in increased nursing workloads and carries a heightened risk of adverse events.^{ix} Also commonly used are indwelling catheters, which contribute significantly to UTIs – the most common type of healthcare-associated infection reported to the National Healthcare Safety Network.

Among hospital-acquired UTIs, approximately 75% are associated with a urinary catheter. Further, catheter-associated urinary tract infections (CAUTIs) can lead to more serious complications such as sepsis and endocarditis, while healthcare-associated UTIs are responsible for more than 13,000 annual deaths annually.[×]

Managing urinary incontinence, which is a primary measure used by the Centers for Medicare and Medicaid Services (CMS) to assess quality of care, also represents a heavy financial burden for hospitals. The direct cost of urinary incontinence in the US is an estimated \$16.3 Billion annually, \$12.4 Billion of which relates directly to female incontinence.^{xi} At \$17,020, the total costs per incontinent patient is \$3,307 higher than continent patients. That figure includes labor costs and costs associated with longer LOS, readmissions, and secondary conditions such as pressure injuries from IAD.

Further, hospitalization with a primary diagnosis of UTI costs \$6,424 per case, or \$2.8 billion annually^{xii}, while CAUTI costs hospitals \$450 million annually^{xii} and range from \$1,764-\$10,197 per inpatient case^{xiv} – which is not reimbursed by CMS.

Nursing Home Challenges and Continuity of Care

The challenges associated with urinary incontinence are felt far beyond a hospital's four walls – long-term care (LTC) providers also struggle with effective management. An estimated 25% of older adults in the U.S. – a population for whom UTI is the second most common infection – are expected to reside in an LTC facility at some point in their lives.

Further, about 50% of all nursing home residents also suffer from incontinence.^{xv} The residents rely on incontinence pads and briefs as well as indwelling urinary catheters. While absorbent pads are a common management strategy, residents' reliance on nursing staff to assist with changing them as needed creates many of the same issues as seen in hospitals in terms of prolonged exposure to urine – including increased risk of UTIs^{xvi} and skin damage such as MASD and IAD CITE.



Thus, nursing homes turn to indwelling catheters to manage incontinence in 7% to 10% of cases. As with their acute care counterparts, doing so increases the risk of UTI, hospitalizations, antibiotic resistance,



and death. One study found CAUTI rates as high as 5.5% among LTC residents, compared to just 1.1% for non-catheterized residents.^{xvii}

Nursing homes, hospitals, and healthcare providers must collaborate and cooperate in care management to achieve the goal of consistent, high-quality care, avoiding the complications of incontinence. Continuity of care results in improved outcomes, higher satisfaction rates, and improve cost of care and promotes dignity as it related to incontinence care.

Across the continuum of care – home, nursing home, outpatient, and acute care – now is the time to address the incontinence care crisis. ^{xviii}

An Innovative Alternative

The growing importance of finding safer alternatives to pads and indwelling catheters to manage urinary incontinence has given rise to one innovative alternative that minimizes the risk for skin injury and infection: the external urine collection device.

As with indwelling catheters, external devices collect urine via tubing and rely on gravity or suction to drain it into a container. Unlike indwelling catheters, however, external devices are not inserted into the bladder or urethra. Rather, they adhere to the genitalia or pubic area.^{xix}

In one study, nurses reported greater satisfaction caring for female patients with external urine collection devices due to their ability to capture and record output, practicality for protecting against infections, IAD and MASD, and the decreased workload related to less frequent linen changes. Patients also expressed heightened satisfaction, reporting a sense of cleanliness, increased comfort, and less pain and discomfort. External devices for women also prevent residual pooling of urine at the urethral opening, which further mitigates skin damage and UTI.^{xx}

There are two main types of external urine collection devices for women. The first is a suction-based system which, as the name implies, attaches to the wall suction device and uses low continuous suction near the perineal area, between the labia and near the urethra, to keep it in place. This approach provides a sump mechanism to collect and measure urine output, while continuous airflow helps to promote proper temperature, humidity, and airflow to the perineum region.^{xxi}

While suction-based external urine collection devices are effective and help reduce infection rates, they have several important limitations. Patients are unable to ambulate or be moved out of their room, for example for tests or procedures, while suction-based devices are in place. This limits their use to bedridden patients. Data on skin outcomes also does not suggest that these types of external devices contribute to avoidance of pressure injuries, with researchers noting that ongoing surveillance is needed to ensure they are not associated with increased device-associated pressure injury.^{xxii}

Finally, because of their reliance on the wall suction unit, suction-based external collection devices prohibit its use for other important purposes such as respiratory management for nasopharyngeal suctioning, chest tube maintenance, or nasogastric management for gavage or lavage. Units that do not operate on battery power are also at risk for disruption should the facility experience a power outage.



The second type of external urine collection device for women is a disposable single-use silicone cap which covers the opening of the urethra and is stabilized by a guide. The cap is connected to a standard catheter and urine collection bag and can stay in place up to 24 hours.

Unlike their suction-based counterparts, these external devices can be used by full or partially ambulatory and/or bedridden patients and do not require dedicated utilization of the wall suction system. Studies have found them to be 100% effective, without associated side effects on the skin or mucosa. Nor were there any observed adverse events or apparent risk for device-associated pressure injury.^{xxiii}

Adopting Innovation

Despite clinical studies validating the safety and efficacy of external urinary collection devices for women, they struggle for broad uptake among healthcare providers due to the same "innovation hesitation" that has impeded preceding advances. While their reasons for this hesitation may be valid, the reality is that innovation is a critical component of clinical and organizational success – particularly in terms of mitigating the impact of incontinence on CAUTI, IAD, MASD and sepsis rates.

As such, nurses should be encouraged to explore, test, and adopt clinically relevant innovations to improve patient care, safety, and outcomes related to incontinence care. Doing so will impact catheter per-day use, unacceptable CAUTI rates, and/or skin complications that lead to reduced reimbursements and quality scores.

Adoption of innovation is complex, and barriers include a lack of financial, human, and material resources, and a lack of integration and organizational readiness.^{xxiv} Nurses need



time to properly explore and evaluate external urine collection devices and need the material support including training/professional development and institutional resources to facilitate adoption, to ultimately sustain the changes in practice.

To facilitate the adoption of innovation, hospital and LTC facility leadership should create a supportive culture and recognize the anticipated added value from adopting the external device on all aspects including nursing workflow and workload. They should design an adoption strategy that:

- Facilitates high-quality training for high-use, high-consequence areas first to measure the impact of change
- Focuses on Leadership, Champions, Expert Clinicians, and Super Users to systematically lead change using small tests of change
- Incorporates the external device at critical communication points, including admission incontinence screening, rounds, shift and safety huddles, signage, and white boards
- Facilitates documentation/informatics changes and promote data-driven decisions for the high ROI, reducing per capita healthcare costs



Within healthcare, innovation is the application of ideas or products new to the stakeholder, designed to significantly benefit individuals, groups, or society.^{xxv} External urine collection devices designed specifically for women are an innovation that arose out of necessity to address the critical safety and clinical needs of incontinent females who were limited by the quality and function of existing clinical options.



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