

Urine Output Management with the Purewick™ Female External Catheter

UK Value Brief



Overview of Urine Output Management

Urine output management is a common component of healthcare

Conventional urine output management may occur through use of:⁹

- *Indwelling urinary catheters*
- *Male external catheters*
- *Absorbent pads*
- *Bed pans*

Management of urine output is often required in hospitalised patients and the community-dwelling population.¹⁻³

- Patients requiring urine output management may include those that are critically ill, have impaired mobility, or are incontinent.^{1:2}

A major cause for patients to require urine output management is urinary incontinence (UI) where patients experience involuntary leakage of urine.⁴⁻⁶

The prevalence of UI in the UK is estimated to range up to 42%, and is especially common in women.³

In the community setting, management of UI typically occurs through the use of external absorbent products (e.g. pads) or indwelling catheters, with patients seeking assistance from healthcare professionals in 13% to 26% of cases.^{3:7}

A comprehensive analysis of all patients receiving NHS-funded care determined urine management through urinary catheters occurs in 18.6% of hospitalised patients, though usage can be as high as 76.6% in critical care settings.⁸

Guidelines provide best practice recommendations for urine output management

Organisations have outlined the best practices for managing urine output considerations to minimise the risk of healthcare-associated infections:

Guideline	Recommendations
NICE CG171 ¹⁰	<ul style="list-style-type: none">• Absorbent products, hand held urinals and toileting aids should not be considered as a treatment for UI, only as a temporary strategy or an adjunct to ongoing therapy• Intraurethral devices should not be used for the routine management of UI in women• Pad tests should not be used in the routine assessment of women with UI
NICE CG139 ¹¹	<ul style="list-style-type: none">• Indwelling urinary catheters should only be used after alternative methods of management have been considered• Patient's clinical need for catheterisation should be reviewed regularly, with urinary catheters being removed as soon as possible
epic ¹²	<ul style="list-style-type: none">• Use of short-term indwelling urethral catheters should only be used in clinically indicated patients and only after alternative methods have been assessed• Catheters are associated with significant risks of urinary tract infections, with the longer duration of use associated with increased risk
Joint Working Party ¹³	<ul style="list-style-type: none">• Interventions should be used to reduce the total antibiotic consumption, particularly broad-spectrum antibiotics in the community and care home setting• Use of antibiotic prophylaxis for urinary catheter insertion or changes should be avoided
RCN Catheter Care ¹⁴	<ul style="list-style-type: none">• When an indwelling catheter is inserted the nurse should consider and plan for early removal as the infection risk increases on a daily basis

¹³ Joint Working Party consists of the British Society for Antimicrobial Chemotherapy, the Healthcare Infection Society and the British Infection Association
Abbreviations: NICE = National Institute for Health and Care Excellence; RCN = Royal College of Nursing

Burden of Urine Output Management

Reducing Gram-negative infections, a common cause of catheter-associated urinary tract infections (CAUTIs), is an important goal

The consequences of UTIs can be serious as they have been found to:

- Significantly increase mortality^{12, 23}
- Prolong hospitalisation and increase readmissions^{12, 23}
- Cause additional use of NHS resources²⁴
- Instigate greater patient discomfort²⁴
- Decrease patient safety²⁴

The UK Secretary of State for Health has set a goal for 2021 to reduce the number of healthcare-associated Gram-negative bloodstream infections (BSIs) by 50%.¹⁵

- The initial focus of the NHS Improvement Resource was *Escherichia coli* (*E. coli*) BSIs – the most common source of which are the urogenital tract.^{15, 16}
- Public Health England requires reporting of all Gram-negative bacteraemia, with surveillance forms documenting bacteria type, source, and admission details.¹⁷

Urinary tract infections (UTIs) are the most common Gram-negative bacteraemia and account for the majority of infections acquired in hospitals and long-term care facilities.¹⁸⁻²¹

- Use of urinary catheters is the most significant independent predictor of UTI in hospitals, with 43% to 56% of UTIs found to occur with their use.^{12, 20, 22}

UTIs have been linked to the development of BSIs and sepsis – some of the most severe infections associated with increased morbidity, mortality, and costs.^{25, 26}

- UTIs have been found to be the one of the most common primary source of BSIs.²⁰
- Healthcare-associated UTIs have been associated with a secondary BSI in 1% to 12.5% of cases.^{20, 27}
- UTIs are one of the leading causes of severe sepsis (9%) and septic shock (31%), with over 70% linked to Gram-negative bacteria.²⁶

CAUTIs are associated with additional antibiotic use and antimicrobial resistance



Increases in antimicrobial-resistant organisms, specifically Gram-negative bacteria, represents a major challenge for urologic practices.^{30, 31}

The UK 5-Year Antimicrobial Resistance Strategy (2013 to 2018) was created to slow the development and spread of antimicrobial resistance with a focus on antibiotic use.²⁸

- “Increasing resistance in Gram-negative bacteria, for example, *E. coli* and *Klebsiella* spp., is a particular and growing public health concern because of the limited treatment options for infections caused by these bacteria, especially those that are resistant to carbapenem antibiotics, which are the last-line drugs used to treat those infections.”²⁸

The treatment of CAUTIs contributes to the emerging issue of antibiotic resistance in hospitals, with a leading source of antimicrobial-resistant organisms being uropathogens.¹³

- CAUTIs comprise the largest institutional reservoir of nosocomial antibiotic-resistant organisms, which include Gram-negative bacteria such as *E. coli* (26%), *Pseudomonas aeruginosa* (12%), and *Klebsiella* spp. and *Enterobacter* spp. (12%).²⁹

Burden of Urine Output Management

Hospital falls related to urine output management remain a serious concern



In the UK, falls related to bathroom use have been reported in up to **25.9% of cases**.³⁷

UI and bathroom-related activities are significant risk factors for falls:^{32; 33}

- Patients with urine management difficulties, in combination with reduced mobility, are at increased risk of falls when rushing to the toilet.^{4; 34-36}
- A systematic literature review of risk factors and risk assessment tools for falls in hospital inpatients found that urinary incontinence/frequency consistently emerged as a significant factor.³³

Unintentional falls and related injuries in hospitalised patients are a major concern as they are associated with injury (e.g. fracture), prolonged hospitalisation, or death.^{33; 38-40}

In the UK, falls were the most commonly reported type of incident in acute and community hospitals, and the third most commonly reported incident in mental hospitals.⁴¹

- Overall, 250,000 falls were reported across all 3 hospital types annually.⁴¹
- Over 28% of falls result in harm to the patients, with older patients 3X more likely to sustain serious harm.⁴¹

Skin complications, such as dermatitis and pressure ulcers, may result from sub-optimal urine output management

Rates of pressure ulcers are reported to be

4X higher

16.3% vs. 4.1%

with incontinent patients compared to similar continent patients.⁴⁹

Complications such as incontinence-associated dermatitis (IAD) and pressure ulcers may result from skin damage due to urine exposure.⁴²⁻⁴⁵

IAD is common (5.6% to 50% of patients) and may be associated with several negative consequences:^{42; 43; 45-47}

- Patients experience reduced quality of life due to discomfort, burning, itching, and pain at the affected areas, loss of independence, and disrupted activities/sleep.^{21; 23; 24}
- The damage to the skin barrier increases patient susceptibility to secondary skin infections.^{45; 46}
- Treatment of IAD can be difficult, time-consuming, and costly.⁴⁵

Skin moisture, UI, and IAD are risk factors for the development of pressure ulcers. Pressure ulcers are associated with additional complications.⁴²⁻⁴⁵

- Patients experience severe pain, physical and psychological discomfort, and restrictions in activities.^{44; 48}
- Incidence of pressure ulcer complications has been found to prolong hospitalisation and increase hospital costs/resource utilisation.^{44; 48}

UI is a key contributing factor in the formation of moisture lesions and has a profound effect on a person's social, physical, and psychological well-being.^{48; 50}

Burden of Urine Output Management

Fluid balance can be impacted by the method of urine output management



Diagnosed dehydration is associated with comorbidities, longer hospital stays, additional future hospitalisation, and increased mortality rates.⁵³

According to the UK Office of National Statistics, more than two hospital or care home patients die each day with dehydration or malnutrition noted on the death certificate.⁵¹

Mortality rates in hospitalised older adults suffering from dehydration are reported to be as high as 46%.⁵²

Long-term care residents are particularly vulnerable to developing dehydration, with patients reporting conscious reductions in fluid intake due to anxiety about incontinence and toileting assistance.⁵⁴

Proper assessment of fluid balance and hydration can be challenging as physical signs and urine markers have been shown to have little utility in determining dehydration of elderly patients.⁵³

Risk of healthcare worker injuries exist with urine output management

Urine management tasks, such as patient transfers between the toilet and chair or absorbent pad changes, have been identified as leading causes of stressful patient handling tasks by nurses.⁵⁹

According to the UK Health and Safety Executive, work-related musculoskeletal disorders account for 36% of illnesses acquired on the job by workers in the health and social work activities sector.⁵⁵

- Similarly, lifting and handling is involved in 25% of accidents that lead to non-fatal injuries to employees.⁵⁵

The Fourth European working conditions survey determined 43.4% of workers in the healthcare sector are required to lift or move patients.⁵⁶

- 26.3% of these workers report backache and 24.3% report muscular pains.⁵⁶

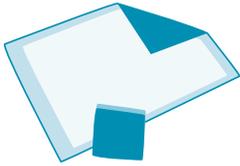
The Health and Safety Authority (2015) found the top accident trigger in the healthcare sector was manual handling, which encompassed 29.7% of reported accidents.⁵⁷

With urine output management, there is a risk for nurse or nursing aid injuries:

- Hospital workers are at a unique risk of injury as they are required to lift, reposition, and transfer patients who have limited mobility.⁵⁸
- Nurses have identified that the two most stressful patient-handling tasks performed in nursing homes involved transferring a patient to or from the toilet.⁵⁹

Limitations with Urine Management Options

Urine output management strategies for female patients, such as pads, are associated with several challenges



Conventional absorbent products can have designs that are prone to leakage, uncomfortable to patients, and be relatively expensive.⁶³

Conventional absorbent products, such as pads, are associated with complications that reduce patient quality of life and increase hospital resource use.⁴²⁻⁴⁵

There is a lack of external urine output management options for female patients, with conventional treatment typically consisting of absorbent products.⁶⁰⁻⁶²

- This can create concerns as pad changes can be difficult for patients with limited mobility and issues toileting.⁶²

Use of these products is associated with several limitations:

- Skin maceration and inflammation can occur due to overhydration from wet absorbent products resulting in increased skin permeability and susceptibility to irritants.^{43; 45}
- The occlusive nature of absorbent pads can change the microenvironment of the skin, potentially leading to increased mechanical irritation, microorganism growth, and immune responses that cause the symptoms of dermatitis.⁴³

Due to the prolonged contact of urine with the skin, complications can arise with external absorbent products, including IAD and urinary tract infections.^{42; 43; 64}

- Nursing home residents using absorbent pads were at an increased risk of developing UTIs compared to residents who did not use pads (41% vs 11%; $P = 0.001$).⁶⁴

Routine cleansing and application of skin protectants are often required to reduce the risk of complications associated with absorbent products.^{45; 47}

- However, a meta-analysis of 13 studies and 1,295 patients found limited evidence exists on the effects of skin care treatments and interventions for the prevention or treatment of IAD.⁴²

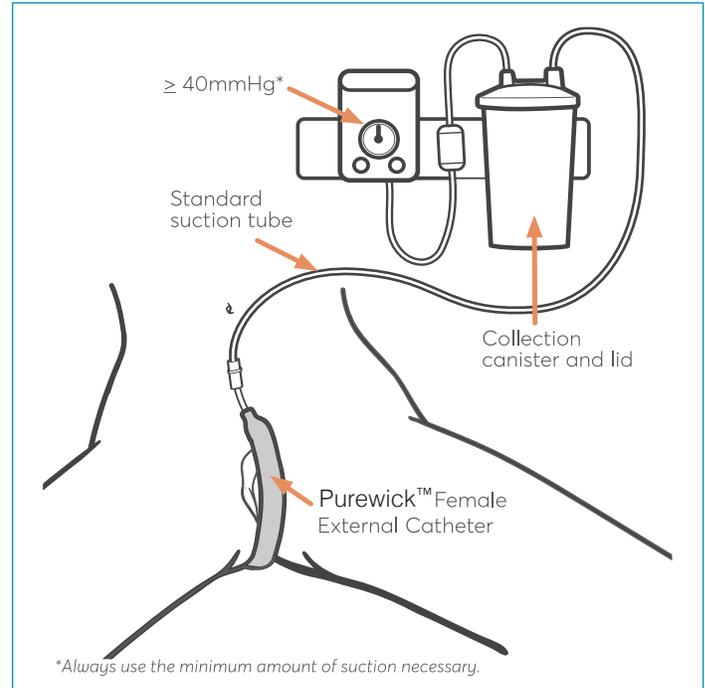
A new standard of care for female urine output management is needed

Historically, external female collection devices have been developed as an alternative to absorbent products, however, none have gained widespread adoption in clinical settings.⁶⁰

- Considerable design challenges exist for creating a device that effectively contains urinary output while avoiding damage to the pubic skin or vaginal mucosa.⁶⁰
- These challenges previously limited external continence devices to male patients.⁶⁰

Given the limitations associated with historical external urine output management options, there is a need for an effective, simple to use, non-invasive method for females.^{60; 65}

Purewick™ Female External Catheter (FEC) Design Features and Benefits



The Purewick™ FEC is the first female external catheter to address the need for an effective, non-invasive method of managing urine output in women

Key design features of the Purewick™ FEC include:

- Easily positioned between the labia, with the top end of the device aligned with the pubic bone and the other tucked gently between the gluteus muscles
- Low-pressure suction wicks urine away from the patient through soft material on the patient-facing side of the device
- The soft, flexible device stays comfortably in place without the need for tape or adhesives that may impact skin integrity

Benefits associated with the use of the Purewick™ FEC:

- Designed to reduce urinary catheter days, lowering CAUTI risk
- Provides non-invasive urine output measurement and the ability to obtain accurate shift outputs – critical to fluid balance calculations – without a Foley Catheter
- Protects skin by wicking away urine
- Minimizes the need for patients to attempt toileting and thus may lower the risk of falls
- Reduces the physically stressful patient handling tasks associated with conventional urine output management
- Flexibility to function while lying down or seated and works overnight during sleep

Clinical Value of the Purewick™ FEC

Observational data and user experiences with the Purewick™ FEC demonstrate numerous clinical and patient benefits

A prospective, observational, single-arm study of healthy volunteers (n=17) evaluated the performance and user acceptability of the Purewick™ FEC in a simulated acute care hospital setting.⁶⁵

- The primary efficacy measure was the percentage of urine capture per void episode, with the mean capture rate in devices with correct vacuum of 99.3% and a median rate of 100% (range 90.9% to 100%).
- Patient feedback* on the comfort of the Purewick™ FEC after voiding indicated the device was found to be comfortable or very comfortable, with most respondents being very likely to recommend the system to friends or family (Table 1).

Table 1: Patient Survey Results ⁶⁵

Assessment Question	Mean Assessment Score*
Comfort During Placement	4.6 out of 5.0
Comfort When Suction Applied	4.6 out of 5.0
Comfort While Voiding	4.5 out of 5.0
Comfort During Removal	4.8 out of 5.0
Likelihood of Recommending to Family/Friend	4.9 out of 5.0

* Patient feedback measured using a 5-point Likert scale, with: 5 = Very Comfortable/Likely; 1 = Very Uncomfortable/Unlikely

Additional feedback from nurses, as measured by a survey with 61 respondents from 6 hospitals, indicated the Purewick™ FEC was associated with numerous benefits:**

- 95% reported minimal to no leakage of urine
- 90% reported the Purewick™ FEC was easy to place and maintain
- 97% believed the device reduced labor and time due to less patient clean-up
- 89% believed patients may have improved dignity
- 95% believed patients may have increased satisfaction
- 92% believed there was reduced risk for moisture-associated skin damage



A two-year study in the neurosurgical intensive care unit of a large academic medical centre observed a 72% reduction in the CAUTI rate across all patients.⁶⁶

**Data on file at C.R. Bard, Inc.

Economic Value of the Purewick™ FEC

The Purewick™ FEC may provide economic benefits by avoiding costly complications



Potential complications arising due to urine output management are estimated to cost the NHS millions of pounds annually.^{12; 72-74}

Increased resource use due to UTIs include bed blocking, with their development resulting in an estimated 590,000 additional bed days to the NHS.⁷²

The economic impact associated with the treatment of skin-related complications can be considerable due to the prevalence and cost with treating each episode:

- The precise cost of managing IAD to the NHS is difficult to determine due to difficulty distinguishing the cost of IAD from the cost of treating pressure ulcers.⁶⁷
- Costs of IAD can be considerable due to staff time and consumables, with skin cleansings performed 8.5 times per day and annual spending on barrier creams and films estimated to be £33.3 million.⁶⁷⁻⁶⁹
- Treatment of Grade 1 pressure ulcers range from £1,064 to £1,214, with the total annual cost of pressure ulcers (all grades) to the NHS ranging from £1.4 to £2.1 billion annually.^{70; 71}

UTIs and BSIs are associated with substantial costs:

- CAUTI is estimated to cost hospitals £1,968 per episode, with overall annual costs to the NHS of £99 million.¹²
- BSI is estimated to cost hospitals £6,209 per episode, with overall annual costs to the NHS of £19 to £36 million.^{72; 74}

The economic impact of falls can be substantial, with the average hospital cost estimated ranging from £1,337 to £14,197 depending on the fall severity and age of the patient.⁴¹

Injuries to nursing staff, such as back-related injuries, has a large economic impact and has been reported to cost the NHS over £400 million annually.⁷⁴

- In general, the overall average cost for a non-fatal workplace injury in Britain is estimated at £8,200, but can range from £880 to £29,200 depending on severity.⁷⁵

The Purewick™ FEC may free resources traditionally associated with urine output management

UI and urine output management include several costly components of care:^{4; 43; 76}

- Staff time for assessment and toileting assistance
- Clothing/linen changes and laundry services
- Incontinence care and products
- Skin cleansers and protectants
- Catheter care
- Medications

The total annual NHS cost for managing UI is estimated to range from £354 to £536 million.^{77; 78}

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Safety Information

Purewick™ Female External Catheter

Indications: The Purewick™ Female External Catheter is intended for non-invasive urine output management in female patients.

Contraindications: The Purewick™ Female External Catheter should not be used on patients with urinary retention.

Warnings: To avoid potential skin injury, never push or pull the Purewick™ Female External Catheter against the skin during placement or removal. Never insert the Purewick™ Female External Catheter into the vagina, anal canal, or other body cavities.

Do not use the Purewick™ Female External Catheter with a bedpan or any material that does not allow for sufficient airflow.

Discontinue use if an allergic reaction occurs. After use, this product may be a potential biohazard. Dispose of in accordance with applicable local, state and federal laws and regulations.

Please consult the package insert for more detailed safety information and instructions for use.

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