

Safety flows
through

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Urological Drainage – Management with the LUBRI-SIL[®] Comprehensive Care Foley Tray

Spain Value Brief

Overview of Urine Drainage Management

Urine drainage management is a common component of healthcare.

Urine drainage management may be delivered through the use of following options:^{9:10}

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

- Urological drainage management is often required in hospitalised patients and the community-dwelling population^{1:2:3}
- Patients requiring urine drainage management may include those that are critically ill, have impaired mobility, or are incontinent^{1:2}
- Urinary Incontinence (UI) is highly prevalent in the adult population and the management of UI is typically done through external absorbent products (E.g., pads and protective underwear) or indwelling catheters. As per the annual report 2018 on the National Health System in Spain, the most used medical products were UI pads, both in terms of the number of packaging units consumed and expenditure^{7:8}
- Urine drainage management using urinary catheters is an option in selected acute care patients. It is estimated that approximately 15.5% of all patients admitted to hospitals will receive a urethral catheter during their hospital stay^{11:12:13}

Clinical indications and purpose for urethral catheterisation.¹³

- Treatment of acute urinary retention
- Allowing bladder irrigation/lavage
- Bypassing an obstruction/voiding difficulty
- Monitoring renal function hourly during critical illness
- Allowing instillation of medications, such as chemotherapy
- Treatment of chronic urinary retention, only if symptomatic and/or with renal compromise
- Enabling bladder function tests, such as urodynamic assessment
- Monitoring, recording, and draining residual urine volume (wherever possible, a bladder scanner is the preferred option to measure residual urine volumes)

DIAGNOSTIC USES OF URINARY CATHETERISATION	
	Obtaining a sample for urine or culture analysis
	Measuring post-voidal residual volume and conducting urodynamic studies
	Instillation of radiographic contrast to visualise the bladder or urethral pathology
	Distending the bladder with saline to form a sonolucent structure through ultrasound
THERAPEUTIC USE OF SHORT-TERM (0-2 WEEKS) OR INTERMEDIATE (2-4 WEEKS) URINARY CATHETERISATION	
	During labour with epidural anaesthesia and fluid management in patients with pre-eclampsia and eclampsia
	Patients undergoing abdominopelvic and hip surgery
	Measurement of intra and post-operative urine production
	Treatment of bladder neoplasms (cytotoxic drugs and intravesical BCG)
	Primary care for any patient with acute urinary retention, until resolution of the main cause of the retention (long-term indwelling catheter)
Intermittent or short-term catheterisation	Urethropexy or sling procedure for bladder neck Obstruction
	Other organic causes of obstructed urination in women (neoplasms, inflammatory causes)
	Incomplete relaxation of the pelvic floor with dysfunctional urination
	Ulcers (grade III or V) in the sacral or trochanter region contaminated with urine in incontinent patients
THERAPEUTIC USES OF LONG-TERM URINARY CATHETERISATION (> 4 WEEKS)	
Clean intermittent catheterisation	In selected cases of urinary incontinence that does not respond to conservative treatment. Not responsive to behavioural or pharmacological therapy.
	Spinal cord injury patients
	In patients with hypotonic bladder, to prevent excessive distension, infection and detrusor muscle damage.
	In incontinent patients, subject to terminal illness, it may be useful, although continuous drainage should be used only rarely.
Condom catheter or long-term suprapubic drainage	In patients with spastic bladder after a spinal injury

Limitations with Urine Management Options and Hospital Acquired Infections (HAIs)

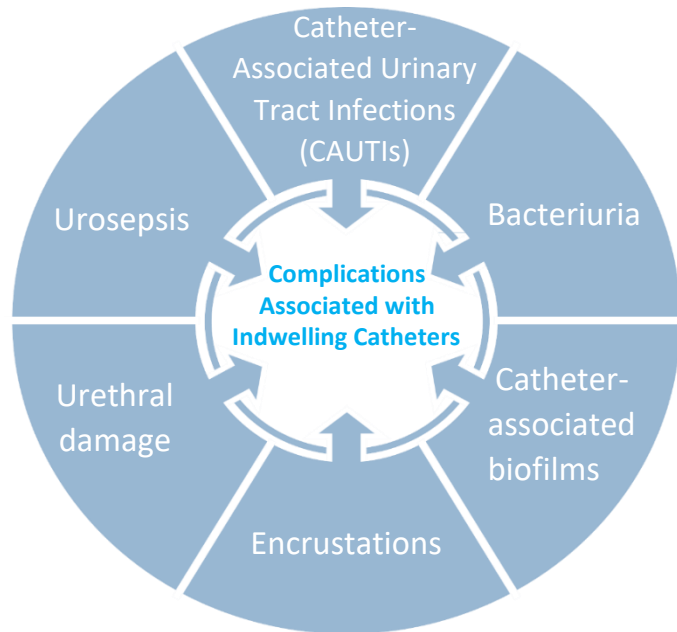
Urine drainage management through indwelling catheters is associated with several challenges.

Indwelling urinary catheters cause mechanical and pathogenic issues for patients with UI, urinary retention, and those who have undergone surgery and have limited mobility.^{44;45}

There is a wide range of materials used for catheters such as latex, hydrogel coating, silicone, antimicrobial-coating, and silver alloy coating.^{13; 46;48;49;50;52}

The risk of UTI increases with each additional day of urinary catheterisation.¹²

Use of indwelling catheters is associated with infectious and non-infectious complications that affect the patient's quality of life and increase hospital resource use⁶



Urinary tract infections, the most common type of HAI.

8.9 Million

HAIs estimated to occur each year in European hospitals.²¹

7%–8%

of patients receiving healthcare in Spain affected by HAI.¹¹

15%–20%

of HAIs in Spain is accounted by UTI.¹²

Urinary Tract Infections (UTIs) are defined as a combination of clinical features and the presence of bacteria in the urine.¹⁵

Gram-negative bacteria are the most common cause of UTIs. Escherichia coli and Pseudomonas aeruginosa are the dominant causative agents in most of the UTIs.^{12;15}

Approximately 70% of UTIs at the hospital level and up to 95% of UTIs in ICUs are associated with use of indwelling urinary catheters.¹²

The risk of UTI increases with each additional day of urinary catheterisation.¹²

A HAI, also known as a nosocomial infection, is an infection that occurs in a hospital or other health-care setting.

UTIs can have serious consequences, since they have been linked to the following outcomes:

- Significantly increase mortality¹²
- Prolong hospitalization¹²
- Cause severe sepsis or septic shock²²
- Increase cost of treatment²³
- Instigate greater patient discomfort²⁴
- Decrease patient safety²⁵

Burden of Hospital Acquired Infections (HAIs)

ITU-Zero project — Reducing usage of urinary catheters, a common cause of CAUTIs, is an important goal.

The ITU-Zero project was undertaken by the Ministry of Health, Consumer Affairs, and Social Welfare to reduce CAUTI incidence in Spain's acute treatment centers. The project's aims are as follows:



- To reduce the incidence of CAUTIs to less than 2.7 episodes per 1,000 device days, representing a 40% reduction of the national average rate



- To reduce the use of urinary catheters to a ratio of less than 0.7; reduce antibiotic and antimicrobial usage in the treatment of CAUTIs



- To provide training to healthcare personnel of the hospitals participating in the project



- To update the protocols of the procedure of insertion and maintenance of urethral catheters in ICUs^{12,26}

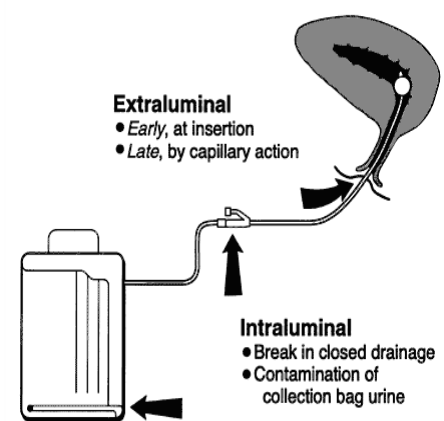
The deployment of ITU-Zero initiatives has resulted in a drop in CAUTI rates. When compared to 2018, the rate of CAUTIs declined marginally, from 2.85 to 2.58 episodes per 1,000 days of urethral catheter use in 2019.²⁸

The pathway by which the bacteria reaches a patient's bladder can be:¹²



The source of microorganisms causing CAUTIs can be endogenous, i.e., via meatal, rectal, or vaginal colonization or exogenous such as via equipment or contaminated hands of healthcare personnel.¹⁷

If the correct infection prevention practices are implemented: → Up to 70% of CAUTIs are considered avoidable.²⁹



Entry channels of microorganisms into catheterised urinary tract causing CAUTI.¹⁷

Burden of Hospital Acquired Infections (HAIs)

Causative factors contributing to high incidence of CAUTIs.

The following are the care-related factors:^{30,31}

- Devices left in situ for extended periods when they were not required
- Staff not following policy/guidance at the time of urinary catheterisation
- Catheters not changed in a timely manner
- Wrong sizes of urinary catheters used
- An open drainage system was utilised
- Stabilization devices were not employed

The following are the patient related factors:

- Female sex, as women are more likely to develop UTIs than men due to differences in anatomy³³
- Comorbidities such as diabetes³²
- Patient compliance

The most important risk factor for developing a CAUTI is prolonged use of the urinary catheter. Indwelling catheter that remains in situ increases the daily risk of CAUTI by 5%.^{34,35}

Preference of using closed drainage system over open drainage system.

The Spanish Urology Association considers the use of urinary catheterisation kits, which include pre-connected and sealed urinary catheter systems, ensuring that the system always remains closed, thereby eliminating the risk of CAUTIs.¹³

There are recommendations from different organizations for the use and maintenance of closed-collection systems as the best practice to reduce the number of CAUTI cases.

Based on the type of circuit, the rate of CAUTI development differs. It is estimated that bacteriuria appears in 100% of patients with closed circuit in 30 days after catheterisation. Whereas, in an open system, bacteriuria appears in 100% of patients within 72 hours after catheterisation.¹²

The World Health Organization (WHO) recommends maintaining a closed drainage system and avoiding open system as much as possible.³⁷

The usage of closed drainage systems over open systems reduces the infection rate associated with indwelling urinary catheter, generally from 100% to 25% for up to 2 weeks of catheterisation.³⁸

Burden of Hospital Acquired Infections (HAIs)

CAUTIs are associated with additional antibiotic use and antimicrobial resistance.



Increase in antimicrobial-resistant organisms, specifically Gram-negative bacteria, represents a major challenge for urologic practices.⁴²⁻⁴³

HAIs are caused by multidrug-resistant bacteria that require treatment with last-line antibiotics.³⁹

There was progressive increase in multi-resistance bacteria in CAUTIs with significant increase in resistance in Gram-negative bacteria between 2007 to 2013. However, since 2014 there has been a decrease in resistance in Gram-negative bacteria due to the implementation of ITU-Zero project in Spain.³⁰

Strains of CAUTI causing agents will become resistant to antibiotics, which requires the use of alternative antibiotics in many occasions as rescue treatment.¹²

CAUTI is one of the major reasons for dispensing antibiotics in hospitals.¹³

According to the WHO, every infection prevented is an antibiotic treatment avoided.⁴¹

CAUTIs comprise the largest institutional reservoir of nosocomial antibiotic resistant organisms, which include Gram-negative bacteria such as *Escherichia coli* (25.66%), *Pseudomonas aeruginosa* (11.68%), *Klebsiella pneumoniae* (10.44%), and *Acinetobacter baumannii* (0.18%).¹²

Resistance to several first-line antibiotics is on the rise and has become a worldwide problem.

Klebsiella pneumoniae strains showed high resistance to cefotaxime and ciprofloxacin.^{12:15}

Carbapenem antibiotics should be used in patients with high risk of multidrug-resistant bacteria.⁴⁰

Escherichia coli has shown increasing resistance to several first-line antibiotics and high resistance to ciprofloxacin and cefotaxime.^{12:15}

High resistance is observed for antibiotics such as Piperacillin/Tazobactam.⁴⁰

Piperacillin/Tazobactam are not recommended in monotherapy if a multidrug-resistant bacteria is suspected.⁴⁰

Quinolone antibiotics have shown resistance of up to 20% in Spain.⁴⁰

Key Guidelines and Recommendations to Prevent CAUTIs

Guidelines provide best practice recommendations for urine drainage management and prevention of CAUTIs.

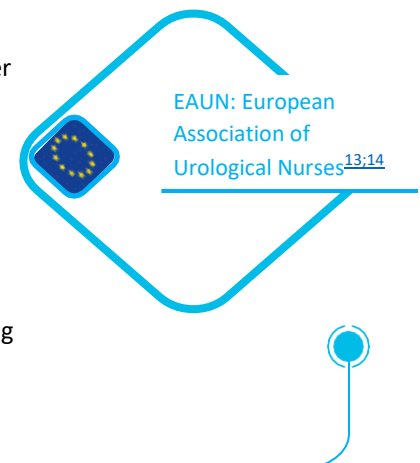
- Use a closed urinary drainage system
- Avoid unnecessary catheterisation and insert a catheter only for appropriate indications
- Use silver-coated catheters when catheterisation is required for less than a week and remove the catheter as soon as possible
- Use preconnected drainage systems to reduce the risk of disconnections
- Do not use chlorhexidine in urine bag and povidone-iodine for genital washing. Avoid offering antibiotic prophylaxis routinely



- A pre-treatment urine culture should be obtained when Urinary Tract Infection diagnosis is not clear or antimicrobial resistance is suspected
- Indwelling catheter should be replaced before obtaining urine for culture if placed for more than two weeks
- Indwelling catheters should be placed only when they are indicated and should be removed as soon as they are no longer required
- Indwelling catheters should be inserted using the aseptic technique and sterile equipment. Closed catheter drainage system should be maintained
- Systemic antibiotic prophylaxis should not be routinely used



- Prefer using suprapubic catheter, male external, or intermittent catheter over indwelling urethral catheter when appropriate
- Follow hand hygiene before and after handling the urinary catheter or the drainage system
- Use silicone catheter in long-term catheterized patients
- Use and maintain aseptic closed drainage system
- Maintain unobstructed urine flow with catheter and drainage system free of kinks. Keep the collection bag below the level of the bladder, avoiding the bag in contact with the floor
- Use urinary catheter attachments or stabilization devices to secure the catheter after insertion to prevent movement and traction on the urethra



- Minimize the usage and duration of catheterisation in all patients, particularly for those at high risk of being affected by CAUTI such as women, the elderly, and patients with impaired immunity
- Unless there is an appropriate indication of continued use, remove the catheter as soon as possible, preferably within 24 hours
- Use aseptic technique and sterile equipment
- Consider using urinary catheter systems with pre-connected, sealed catheter tubing junctions



Key Guidelines and Recommendations to Prevent CAUTIs



EVIDENCE-BASED POSITION RECOMMENDATION ON THE PREVENTION OF URINARY TRACT INFECTIONS (UTI) RELATED TO THE USE OF URINARY CATHETERS (UC)

Approved by:



Table 8. Materials that should be included in the urinary catheterisation set/kit.

URINARY CATHETERISATION SET/KIT	
HYGIENE/STERILITY	MUST / RECOMMENDED
Latex-free 100% silicone urinary catheter	MUST
Availability of kits/sets with different catheter sizes and lengths	MUST
Urinary catheter with lubricous coating on silicone substrate	RECOMMENDED
Outer wrap (preferably sterile)	MUST
Sterile, latex-free gloves	MUST
Sterile apron	MUST
Sterile underpad sheet with waterproof moisture barrier layer	RECOMMENDED
Fenestrated drape	MUST
Gauze Squares for cleaning	MUST
Clamp/clip	MUST
Two syringes of sterile water for cleaning	MUST
Syringes pre-filled with sterile/distilled water (sterile recommended) for catheter inflation	MUST
Pre-filled syringe of lubricant gel (recommended without anaesthetic or antiseptic)	MUST
Empty syringe to facilitate catheter removal in catheter exchange	RECOMMENDED
Catheter inflation valve cap clearly labelled with size in Charrière and balloon inflation volume in ml	RECOMMENDED
Plastic protective bag surrounding the catheter to prevent direct handling	RECOMMENDED
Closed drainage system: pre-connected, sealed and security banded catheter tube and bag connections	MUST
Bag with anti-reflux valve or chamber and needle-free sample port.	MUST
Stabilisation/securement device	MUST
Stabilising/securement devices for the catheter without tape, including a rotating securement mechanism with a breathable patch and alcohol-soluble adhesive. The swivel-type securement with hermetic seal stabilises the catheter to protect it from accidental movement and ingress of the catheter.	RECOMMENDED

THE 5 MOMENTS

Consensus Recommendations WHO Guidelines on Hand Hygiene in Healthcare (Year 2019)

1. Before contact with the patient.	D.a) Before and after touching the patient (IB).
2. Before a clean/aseptic procedure.	D.b) Before handling an invasive device for patient care, regardless of whether or not gloves are used (IB). D.d) If there is relocation from a contaminated part of the body to another part of the body during care of the same patient (IB).
3. After a risk of exposure to bodily fluids.	D.c) After contact with excretions or bodily fluids, mucous membrane, non-intact skin or wound dressing (IA). D.d) If there is relocation from a contaminated part of the body to another part of the body during care of the same patient (IB). D.f) After removing the sterile (II) or non-sterile gloves (IB).
4. After contact with the patient.	D.a) Before and after touching the patient (IB). D.f) After removing the sterile (II) or non-sterile gloves (IB).
5. After contact with the patient's environment.	D.e) After contact with inanimate objects and surfaces (including medical equipment) in the vicinity of the patient (IB). D.f) After removing the sterile (II) or non-sterile gloves (IB).

LUBRI-SIL® Comprehensive Care Foley Tray Benefits Features and Specifications

LUBRI-SIL® Comprehensive Care Foley Tray is a 'All in One' kit

All in one place – Easy to use
All in one system – Reduced risk of infection
All in one price – Cost effective solution³⁶



(7) (8) Not shown here

The LUBRI-SIL® Comprehensive Care Foley Tray contains everything required to either catheterise or re-catheterise, allowing optimisation of clinical practice and reduction of risk to the patient in one handy pack.

The Spanish Urology Association recommends the use of urinary catheterisation kits for all Spanish hospitals as they prevent the uncontrolled variation in clinical practice and promote compliance with the existing guidelines for best urinary catheterisation practice. The LUBRI-SIL® Comprehensive Care Foley Tray is a 'All in One' kit uniquely designed for the prevention of CAUTIs. It contains the following items:¹³

- | | |
|--|--|
| ① One empty 10mL syringe to deflate the balloon during re-catheterisation | ⑤ Two pairs of latex free gloves |
| ② One prefilled 10mL syringe of sterile water to inflate the newly inserted catheter balloon | ⑥ Cleansing solution and gauze |
| ③ LUBRI-SIL® Hydrogel Coated All Silicone Foley Catheter preconnected to the choice of collection system | ⑦ An apron for the healthcare professional |
| ④ Protective waterproof sheet and fenestrated drape | ⑧ Refuse bag to dispose of items |
| | ⑨ Syringe of lubricating gel |
| | ⑩ STATLOCK® Foley Stabilisation Device |

LUBRI-SIL® Comprehensive Care Foley Tray Benefits Features and Specifications

Key features of the LUBRI-SIL® Comprehensive Care Foley Tray include the following:

- STATLOCK® Foley Stabilisation device is a lock-tight, swivel design for proper securement of indwelling catheter to prevent movement and urethral traction
- Clear construction permits visualization of mucous build-up, clots, and initial urine flow
- Pre-connect closed drainage system reduces the risk of disconnections¹³
- Removable Tamper Evident Seal prevents accidental bag disconnection and discourages misguided breakage of the sterile closed system
- Can remain in situ for up to 12 weeks
- Hydrogel coating creates a "cushion" between the catheter surface and the delicate urethral tissue, reducing friction and improving patient comfort

Benefits associated with the use of the LUBRI-SIL® Comprehensive Care Foley Tray are as follows:

- Enhances nursing staff efficiency¹³
- Offers smooth catheter insertion¹⁰
- Maintains a closed system, thus reducing the risk of infection. This reduces the consumption of antibiotics and the costs associated with such consumption, and prevents antibiotic resistance¹³
- Enhances safety and comfort for latex-sensitive patients
- Offers instant protection for clinicians and patients
- Allows standardisation of the process in all healthcare units and encourages best practices¹³

LUBRI-SIL® Comprehensive Care Foley Tray Specifications

Catheter	Collection system	Product code (Standard length)
Hospital		
LUBRI-SIL® Hydrogel Coated All Silicone Foley Catheter	Preconnected to 500mL Leg Bag	TR17585M (12-16)
	Preconnected to a 2 Litre Bed Bag	TR17582L (12-16)
	Preconnected to a Urinometer	TR1758UM (12-16)



You're preparing to **catheterise** and can't find all the **essential items**



Why take the risk when there is a **better way**



Clinical Outcome of the LUBRI-SIL® Comprehensive Care Foley Tray

Observational data and user experiences with the BARD® Foley Tray demonstrate numerous clinical and patient benefits.

Several studies are depicting the reduction in the incidence of CAUTIs on using the BARD® Foley Tray. These studies are from the UK, which is a pioneer in the use of urinary catheter kits.

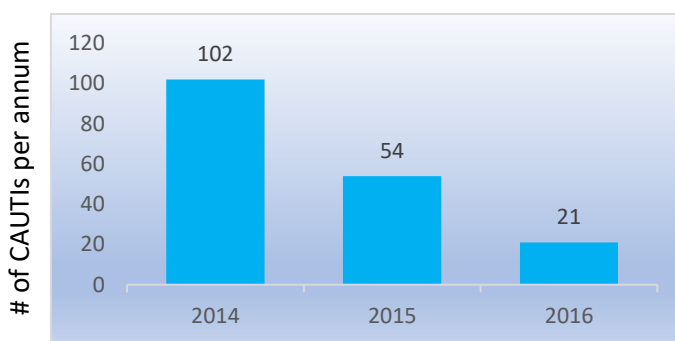
Evidence

Reducing catheter-associated urinary tract infections.²⁰

Amy Cartwright

- 80% reduction in CAUTIs post tray implementation
- Standardise catheterisation practice across the Trust
- When opposed to purchasing separate catheterization components, Trust saved roughly EUR 1.17 on each tray
- Trust also saved an estimated EUR 185,836 from reductions in CAUTIs

Change in CAUTI incidence over time



Nottingham University Hospitals NHS Trust: CAUTI rates across the Trust between 2014 and 2016

Year	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
2014	10	12	5	11	8	8	8	9	9	9	7	10	102
2015	8	8	2	7	4	1	5	5	5	4	6	1	54
2016	4	1	2	4	1	3	2	1	1	1	0	1	21

* Data was collected locally for NHS Safety Thermometer monitoring. The catheterisation tray was fully introduced across the Trust by January 2015

Evidence

Reducing catheter-associated urinary tract infections through best practices.³¹

Palmer, S., and Dixon, R

- More than 80% reduction in CAUTIs post tray implementation
- Standardise catheterisation practice across the Trust
- The Trust saved EUR 38,570 as a result of standardisation

Sherwood Forest Hospitals NHS Trust: Change in CAUTI rates over time following the introduction of the BARD® Foley Tray

	March 2016	June 2016	March 2017	June 2017	March 2018
Catheters in situ	143	69	105	96	115
CAUTIs	19	9	7	2	2

Economic Value of the LUBRI-SIL® Comprehensive Care Foley Tray

The LUBRI-SIL® Comprehensive Care Foley Tray may provide economic benefits by avoiding costly complications.

The economic impact associated with the treatment of CAUTIs can be significant due to the incidence and cost of treating each episode.



CAUTI increases the length of hospital stay by two to four days¹⁹



Each year, the healthcare attributable spend for CAUTIs in the US amounts to EUR 285 million¹⁸



CAUTI is estimated to cost hospitals EUR 2,300 per episode, with overall annual costs in the UK amounting to EUR 115.7 million²⁷



The cost per patient with CAUTI in Spain was EUR 3,957 in 2005²³



The cost of treating a CAUTI includes the length of stay in the hospital with healthcare worker cost, antibiotic therapy costs, and diagnostic tests²³



Implementing government strategies and adherence to CAUTI preventive measures might cut CAUTI expenditures by up to 50%¹²

The economic burden of CAUTIs is well-established, with healthcare reform measures encouraging hospitals to reduce HAI.

There are proven economic benefits of using the BARD® Foley Tray. Purchasing the catheter along with the additional equipment included in the tray is shown to be cost effective.⁵¹



The LUBRI-SIL® Comprehensive Care Foley Tray is expected to free resources and reduce costs associated with urine drainage management.

The urine drainage management through indwelling catheters includes several costly components of care:

- Staff time spent on gathering all necessary catheterisation equipment⁵¹
- Catheter care
- Antibiotic therapy^{47;13}
- Registered nurse hourly wage in Spain: EUR 16^{4;5}

Use of the BARD® Foley Tray, which includes all the equipment necessary for an aseptic catheterisation, results in the reduction on nursing time constraints, with an average of 12 minutes saved on getting all necessary catheterisation equipment together. This will release more of the nurses' time and enhance their efficiency, thereby helping them focus more on direct patient care.^{51;13}

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