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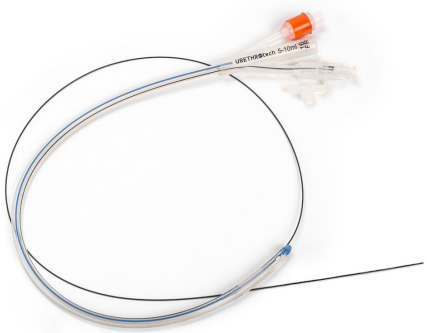
NHS Foundation Trust

Value based Procurement Briefing

Urethrotech® Urethral Catheterisation Device (UCD®) – A solution for difficult or failed urethral catheterisation



Reference / Version: UCD/ V4.3

DD / MM / YYYY

Directorate Manager: *Name Name*
Clinical Director: *Name Name*
CBU Accountant: *Name Name*
Executive Sponsor: *Name Name*

1. Executive Summary

Summary of the Case	The Urethrotech® Urethral Catheterisation Device (UCD®) is a NICE-approved innovative solution to manage difficult or failed urethral catheterisation in the outpatient or inpatient setting. The adoption of the device is directly associated with improvements in cost, quality, patient experience, finance and workforce.
Financial Impact	Income: Same as traditional urethral catheter placement. PBR income is £297 (£309 - including bladder irrigation). Revenue Expenditure: £233 rather than £640 (flexible cystoscopic catheterisation) or £676 (Inpatient suprapubic catheterisation). Capital Expenditure: None Surplus of £65 - £76 rather than £54 using traditional methods.
Workforce Impact	The device can be used by any healthcare professional competent in performing the procedure of male urethral catheterisation and is suitable for use in any clinical environment, avoiding hospital admission and usage of specialist resources.
Quality Impact	Reduced Urethral Catheterisation Injury and it's complications; Reduced infection risk (single use device); Fewer emergency theatre usage; Reduced Length of Stay (alleviates need to wait for theatre slots or endoscopy space); Improved patient setting.

Risks Mitigated	A&E waiting times RTT Target Iatrogenic Injury Hospital Acquired Infections Financial Balance		
Implementation and Delivery	**Milestone Activity**	**Lead**	**Target Date**
	To be determined	TBC	DD/MM/YYYY
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2. Introduction

Incidence and Indication of Urethral Catheterisation: Urethral catheterisation is an indispensable medical procedure, routinely performed in a variety of healthcare settings. Four million urethral Foley catheters are used annually in the UK alone and it is estimated that up to a quarter of hospitalised patients, and 1 in 14 patients in community care have a urinary catheter in place. It is therefore the most commonly placed indwelling medical device.

Clinical indications for urethral catheter placement are broadly categorised into the following scenarios:

- Pre-operative catheter placement (urine output measurement)
- Acute Medical illness (urine output measurement)
- Relief of urinary retention (prostatic obstruction (acute/chronic), urethral stricture)
- End of life urinary and incontinence management (home care, palliative care and nursing homes)

All urethral catheters require

- **Placement:** is usually performed by non-medical or junior medical healthcare professionals at the patients bedside adhering to clean antiseptic procedure principles and should be done without causing trauma to the urethra and prostate
- **Removal** (long term catheter replacement or 'trial-without-catheter' (TWOC) after episode of urinary retention): all catheters should be removed at the earliest possible opportunity to reduce infective complications.

Workforce: Urethral Catheters are inserted by a spectrum of healthcare professionals of all grades. Although urethral catheterisation is a routine procedure, a level of skill and expertise is required to perform the procedure consistently without causing injury. In the United States, nursing staff perform the majority of catheterisations for both male and female patients. This is in contrast to the UK, where doctors are more likely to insert male urethral catheters in hospitalised patients. The task usually falls on the most junior members of the team who have the least experience of inserting them [1].

Catheterisation associated Urethral Injury (CAUI): In recent years, there has been a considerable amount of energy and resources directed towards reducing catheter associated urinary tract infections (CAUTIs) [2], but traumatic catheterisation has not received the same attention despite contributing significantly to catheter related morbidity [3].

The male urethra is more susceptible to injury than the female urethra due to its longer length, pendulous anatomy and the presence of an enlarged prostate in elderly men. Published data on CAUI is limited probably due to the absence of hospital 'reimbursement codes' for de-facto procedure complications and the true incidence of CAUI is difficult to establish. Many injuries will go unreported. In retrospective studies CAUI is reported between 0.3 - 3% [1]. Hospital wide prospective studies report an incidence of traumatic urethral catheterisation of 13.4 per 1000 catheters inserted in male patients [4]; whereas 4-9% of high-risk men undergoing cardiac surgery experience some form of adverse event related to pre-operative urethral catheterisation [5].

Each case of CAUI is associated with significant short-term morbidity; 80% experience Clavien 2 or greater complications and a third of patients develop urosepsis of whom 5% require inotropic support in the Intensive Care Unit [4]. In the worst-case scenario, patients can develop Fournier's gangrene with a mortality rate of 7.5 - 40% after a misplaced urethral catheter.

Although difficult catheterisation occurs only in a small percentage of urethral catheterisations overall, it is an important Quality and Patient Safety issue due to the large number of catheterisations that take place on a daily basis throughout the NHS. Often multiple catheterisation attempts are made, with the mean number of attempts ranging from 1.6 – 3.2, before Urology consultation is requested [6], causing significant urethral injury in 32% of men [7]. It is therefore astonishing that there is no widely accepted 'Male Catheterisation Algorithm' or Hospital Policy for the management of 'Difficult Male Urethral Catheterisation' available.

3. Case for Change and Proposal

3.1. Current Position

A catheterisation emergency occurs when a standard urethral catheter doesn't slide into the bladder but gets stuck with palpable 'resistance' which occurs most commonly at the level on an enlarged prostate in elderly men. The patient is at risk of Catheterisation associated Urethral Injury (CAUI) if the healthcare professional applies undue force in the attempt to overcome the resistance, rather than stop.

Patient care pathways can become unpredictable and easily escalate out of control.

To manage the catheterisation emergency, traditionally patients have to be referred to a Urologist for specialist interventions. As most situations arise unpredictably at any time of day or night, standard treatments, such as cystoscopic insertion of the catheter, require access to the endoscopy suite or otherwise emergency theatre. Cystoscopy relies on a general or local anaesthetic and procedure time in theatre or the endoscopy department is often not readily available. Alternatively, a transabdominal suprapubic catheter can be inserted under ultrasound control, but again requiring specialist equipment and specialist surgical skills. Blind (without ultrasound guidance) suprapubic catheter placement is contraindicated particularly in men with a history of previous abdominal surgery due to the risk of bowel injury associated with a high mortality rate.

Recently, NICE has evaluated the innovative Urethral Catheterisation Device (UCD®) which was specifically developed by Urethrotech to solve difficult urethral catheterisation at the patient's bedside[9]. NICE acknolwedged that the UCD® could be used in any healthcare setting by appropriately trained healthcare professionals who would otherwise perform urethral catheterisation[9].

3.2. Strategic Context and Drivers for Change

In the context of increasing financial pressures on the NHS, Referral-To-Treatment (RTT) pathway targets, A&E waiting times, staffing shortages and ambitions to improve patient experience, whilst driving down hospital-acquired infections, all urological procedures must be evaluated against alternatives.

Costs of CAUI: The acute consequences of CAUI are significant with bleeding, pain, urinary infection, sepsis, or urinary retention, all leading to longer in-patient hospital stays, let alone the high risk of long-term complications. The average cost of UCI is £8000 per patient, making CAUI an estimated £215Mio/year problem in the UK (based on an incidence of 0.67%) [4]. These costs are exclusive of managing iatrogenic CAUI strictures with repeated urological interventions and follow-up appointments [4], and exclusive of any potential medico legal costs, which would lead to an even greater cost burden to the healthcare service.

3.3. Proposal for Future

The NICE-approved Urethrotech UCD® was developed to manage cases of difficult or failed urethral catheterisation safely. The device is ready-to-use in any clinical environment whenever needed and the UCD® enables the solo operator to proceed with catheterisation as planned. The non-traumatic UCD®-guidewire bypasses enlarged prostate lobes and drags the catheter safely behind into the bladder. The guidewire is removed once the Foley balloon is inflated as per current practice. The UCD® has several unique benefits listed in the following table.

4. Options Appraisal

	Option 1: standard management for difficult urethral catheterisation	Option 2: UCD® to solve difficult urethral catheterisation
Administration	Managing patients without breaching the A&E 4-hour treatment targets is often a challenge. When difficult urethral catheterisation is encountered, delays caused by late specialist attendance and/or unavailability of specialist equipment and/or clinical specialist areas (e.g. endoscopy space) lead to unnecessary hospital admissions for specialist surgical interventions to solve the problem of failed or even traumatic urethral catheterisation injury. There is no choice to defer the catheterisation emergency.	NICE-approved ready-to-use sterile medical device (5-year shelf life), which can be used by any healthcare professional (HCP) who would otherwise perform urethral catheterisation requiring minimal additional training. The UCD® can be used independently in any clinical setting (A&E, outpatients, ward) solving the problem of difficult urethral catheterisation wherever and whenever it occurs; hence this risk is mitigated against.
Cleaning / Maintenance	Current standard treatments to manage difficult or failed urethral catheterisation are invasive and require specialist equipment which need to be maintained and re-processed between patients and require specialist skills to operate. The main issue is unavailability of these resources during day-time and out-of-hours requiring admission to hospital to manage patients via the emergency theatre route.	Single use sterile equipment and so no cleaning / maintenance required.

Financial Cost	Larger staffing, consumable and sterilisation costs, with potential risk of medical litigation costs. Further information provided in following financial sections.	Single use equipment in the outpatient/ward setting, therefore minimising costs on staffing, consumable and sterilisation costs.
Infection Prevention	CAUI is contributing to catheter associated morbidity as significantly as catheter associated UTI's [3]. 80% of patients experience Clavien 2 or greater complications and a third of CAUI patients develop urosepsis of whom 5% required inotropic support in the Intensive Care Unit [4]. Patients can develop Fournier's gangrene with a mortality rate of 7.5 - 40% after a misplaced urethral catheter.	Single use equipment designed to prevent CAUI.
Length of Stay	Patient experiencing difficult urethral catheterisation may have to wait for surgical specialist attendance, operating theatre slots or endoscopy availability to be catheterised utilising standard care (sometimes for considerable time if there are competing clinical priority cases). If A&E waiting times are breached, patients are admitted in any case whether or not they came to harm by repeated attempts to place a standard urethral catheter. If iatrogenic CAUI was caused as the result of patient care error, emergency surgical interventions are necessary to control and contain the damage with unpredictable outcomes.	No inpatient stay is required and planned care proceeds as planned with the UCD®.
Patient Experience	Patients are at risk of being harmed at multiple levels: 1. escalation of difficult catheterisation into traumatic catheterisation injury. 2. further risk of delays of managing the complications of CAUI due to competing operating theatre demands or waiting for endoscopy availability. 3. traditional 2nd-line catheter insertion manoeuvres (suprapubic or cystoscopic catheterisation) are more invasive and painful and require anaesthetic. 4. uncontrolled septic complications of CAUI may lead to long ITU stay and even loss of life 5. long-term sequalae of CAUI may require life-long surgical interventions for traumatic urethral stricture, or long-term urethral catheterisation in surgically unfit elderly men, which could cost them social independence if unable to do catheter care [4].	Well tolerated and more pleasant 2nd-line catheterisation experience utilising natural way into bladder and avoidance of harm.
Patient Safety	Catheterisation associated urethral injury is a reportable incident and causes moderate to severe harm, 78% long-term stricture complications and reported mortality of 5%.	The UCD® was developed to improve patient safety by solving difficult urethral catheterisation and prevent CAUI.
Risk of RTT Target Breach	Alternative standard treatments to manage failed urethral catheterisation may be delayed if superseded by more clinically urgent operating theatre cases.	Due to the outpatient / ward or clinic setting, this risk is mitigated against.
Workforce	Surgeon, assistant and theatre staff required. Nursing resource also needed in pre-operative and post-operative care.	The UCD® device is used by one healthcare professional and an assistant is not required.

4.1. The Preferred Option

Based on the above cost, quality, patient experience, finance and workforce factors, the preferred option is Option 2: the adoption of the UCD® catheterisation solution.

5. Detailed Analysis of the Preferred Option

5.1. Financial Impact

The Urethrotech UCD® is a purpose developed and NICE-approved medical device to manage difficult or failed urethral catheterisation in order to prevent Catheterisation associated Urethral Injury (CAUI). It is difficult to cost CAUI as the incidence of the problem is not recorded in National Databases. The cost of managing CAUI is reported as costing £8000/case excluding the costs of managing long-term complications [1].

1 Inpatient night costs +- £300
1-hour Main-Theatre-Time costs +- £600

- The UCD® costs: £198.98 (ex VAT) (ready-to-use sterile single use product)
- There are no other associated specialist equipment requirements
- It is assumed that when patients are being catheterised as part of their care the cost of the standard catheter will be contained within the associated HRG

5.1.1 Income

1. **Urethral Catheterisation**

Urethral Catheterisation is classified under various OPCS[1] procedure codes and descriptions:
M479 – Insertion of Catheter
M478 – Other specified urethral catheterisation of bladder
M472 – Change of Catheter
M473 – Trial without Catheter (removal of urethral catheter from bladder)
M471 – Irrigation through Catheter

M479 coded alone groups to LB15E Minor Bladder Procedures, 19 years and over, which attracts a tariff of £297 per procedure for both inpatient and outpatient settings, based on national PBR Tariff 2016/17 [1]. If a specific device (Urethrotech UCD®) was being used to catheterise the patient, one could argue that the M478 code would be a more accurate and differentiate between a standard catheterisation. M478 coded alone groups to LB42A Dynamic Studies of Urinary Tract, 19 years and over, which has tariff of £219 for both inpatient and outpatient settings.

2. **Failed TWOC using UCD® for difficult re-catheterisation:**

M473 and M478 coded together group to LB15E Minor Bladder Procedures, 19 years and over, which has a tariff £297 for both inpatient and outpatient settings and if bladder irrigation was performed, the code M471 could be added, which would cause the appointment to group to LB18Z Attention to Suprapubic Bladder Catheter, which has tariff of £309 for both inpatient and outpatient settings.

[1] Urethrotech has made reasonable efforts to provide accurate coding advice, but this advice should not be construed as providing clinical advice, dictating reimbursement policy or substituting for the judgment of a Practitioner. It is always the provider's responsibility to determine and submit appropriate codes, charges and modifiers for services that are rendered. Urethrotech assumes no responsibility for the timeliness, accuracy and completeness of the information contained herein. Since reimbursement policy and regulations change frequently, it is recommended that providers consult with the relevant coding department regarding reimbursement coverage.

5.1.2 *Expenditure*

The UCD® catheterisation solution requires no capital investment. Revenue consequences are outlined below and the comparison table illustrates the variances between Option 1: Current Practice and Option 2: Adoption of UCD® catheterisation solution.

Option	Option 1: current practice		Option 2: UCD®
Description	Traditional surgical procedures		UCD®-catheterisation
Income Per Case	Cystiscopic catheterisation	Suprapubic catheterisation +- Ultrasound guided +- GA cystoscopy	second-line Urethral Catheterisation
NHS National Tariff 2017/8	**£694**	**£297**	**£297-£309**
Hospital Admission required	yes	yes	no
Length of Stay	variable	mean 4.1 days (1-85) [10]	0
Procedure Codes	M459 (flexible cystoscopy)	M382 (Cystostomy and insertion of suprapubic tube into bladder)	M473 (removal of urethral catheter from bladder) M478 (other specified urethral catheterisation of bladder) M371 (bladder irrigation)
HRG-codes	LB72A	LB15E (Minor Bladder Procedures)	LB15E (Minor Bladder Procedures) LB18Z (attention to suprapubic bladder catheter)
Expenditure Per Case			
Suprapubic catheter set (MediPlus)		£36	
Theartre Consumables, instruments, capital equipment	variable (covered in Tariff)		£0.00
Urethrotech UCD®			£198.98
Sterilisation	£40	£40.00	£0.00
Emergency Theatres, inc staff	£600	£600.00	£0.00
Clinic, inc staff (£280/hour)	£0.00	£0.00	£35.00
Subtotal	**£640**	**£676.00**	**£233.00**
Profit per Case (no CAUI)	£54	-£379.00	£64 - £76
Multiple catheterisation attempts can lead to ..	Catheterisation Associated Urethal Injury (CAUI) [4, 11]		purpose developed medical device to manage difficult urethral catheterisation and to avoid CAUI [9]
Incidence	13.4 /1000 catheters inserted in male patients		
Length of Stay	mean 9.4 plus minus 10 days (2-53)		
Costs / CAUI case	£8,000		
Death	5%		
Urethral Stricture	78%		
Admission to long-term residental home as unable to manage an indwelling long-term catheter [3]	16%		
Cost per CAUI-Case	-£7,946	-£8,379	n/a
Current est. annual activity	100		0
Current Annual Profit/Loss	£5,400		£0
Projected Annual Activity	20		80
Projected Annual Profit/Loss	£1,160		£5,120 - £6,080

Assumptions:

- On an annual basis, 100 failed or difficult urethral catheterisation have to be managed by the provider.
- 80% of urethral catheterisation cases per annum are suitable for the UCD®
- One UCD® procedure lasts 5 minutes on average [2] .

[2] Theatres - Costs - Detailed Tables http://www.isdscotland.org/Health-Topics/Finance/Costs/Detailed-Tables/Theatres.asp

5.2 Workforce Impact

- Staffing: There are no extra staffing resource requirements for the Trust
- The UCD® can be used by any healthcare professional (doctor or nurse) who are currently performing the urethral catheterisation procedure
- The UCD® can be used in any clinical environment, unlike other 2nd-line bladder drainage procedures such as cystoscopy or insertion of supra-pubic catheter which require specialist medical staff and equipment and are often performed in an operating theatre environment
- The UCD® is a solo-procedure and does not require an assistant
- UCD® Training Programme: The Advanced Male Urethral Catheterisation (AMUC) Training Course module was established to teach doctors and nurses to manage difficult urethral catheterisation safely, which is easy to integrate into established catheter training programs

5.3 Impact on Other Internal Departments

There is a relief on Emergency Department, Operating Theatres, Radiology Departments and In-patient beds.

5.4 Quality Impact

The UCD® is an innovative product manufactured by Urethrotech Ltd and has been available to the market since June 2017. It has achieved the necessary standards to be CE marked and is NICE approved [9].

5.5 Risk Analysis

- Financial: There is no financial risk to the Trust due to the translocation of the management of failed or difficult catheterisation to a lower cost environment with no requirement for capital investment.
- Clinical: Clinical risk is low as the pathway of care for the UCD® delivers no risk of cross contamination and in addition prevents sharp-injury associated with alternative procedures. There is no change in overall clinical practice.
- Patient: There is no additional risk to the patient.

6 Conclusion & Recommendation

In summary, the UCD® catheterisation solution provides an excellent alternative to traditional more invasive procedures to manage difficult or failed urethral catheterisation and demonstrates outstanding clinical benefits, system cost savings and an improved patient experience. The adoption of the UCD® is therefore recommended to the Trust Board for approval at the earliest opportunity.

References:

1. Kashefi C, Messer K, Barden R et al: Incidence and prevention of iatrogenic urethral injuries. J Urol 2008; 179: 2254

2.Eliminating CAUTI: Interim Data Report, 2013. Available at https://www.ahrq.gov/professionals/quality-patient-safety/cusp/cauti-interim/index.html. Accessed April 30, 2018

3. Leuck AM, Wright D, Ellingson L et al: Complications of Foley catheters - Is infection the greatest risk? J Urol 2012; 187: 1662

4. Davis NF, Quinlan MR, Bhatt NR, Browne C et al: Incidence, Cost, Complications and Clinical Outcomes of Iatrogenic Urethral Catheterization Injuries: A Prospective Multi-Institutional Study. J Urol 2016; 196: 1473-1477

5. Bugeja, S., Mistry, K., Yim, I.H.W. et al. World J Urol (2018). https://doi.org/10.1007/s00345-018-2499-9

6. Villanueva C et al. The Approach to the Difficult Urethral Catheterisation among Urology Residents in the United States. Int Br J Urol 2010; 36 (6): 710-717

7. Thomas AZ et al. Avoidable iatrogenic complications of urethral catheterisation and inadequate intern training in a tertiary-care teaching hospital. BJU Int. 2009; 104: 1109-1112

8. Zammit PA, German K, The difficult urethral catheterisation: use of a hydrophilic guide wire. BJUI Int. 2004; 93: 883-4

9. Urethrotech UCD for difficult or failed catheterisation. Medtech innovation briefing. Available at https://www.nice.org.uk/advice/mib116/resources/urethrotech-ucd-for-difficult-or-failed-catheterisation-pdf-2285963278125253. Accessed April 30, 2018

10. Khan A, Abrams P. Suprapubic catheter insertion is an outpatient procedure: cost savings resultant on closing an audit loop. BJUI 2008

11. Davis NF, Bhatt NR et al. Long-term outcomes of urethral catheterization injuries: A prospective multi-institutional study. J Urol 2019 (in press)