Patient Safety: Opportunities for Value-based Procurement

In the past decade, much emphasis has been placed on the quality of medical care, and great efforts have been put forward to identify patient safety improvement opportunities. These efforts have generated many different indicators of safety events and low quality of care, including PSIs, HACs, and readmission penalty programs. Additionally, as consumerism has grown, ranking systems and marketing therein have exploded throughout all domains of health care. The COVID-19 pandemic caught us by surprise and turned our world upside down. We all learn how to do our job more efficiently and, most of all, safely - safely for our patients but also for their families, for our staff, for those we teach and train, and for ourselves.

Federally Facilitated Quality and Patient Programs

The Centers for Medicare and Medicaid Services (CMS) aimed at promoting high-value and high-quality care using a program that is targeted at a specific set of preventable infection events (surgical site, bloodstream and catheter-associated urinary tract infection), and conditions that occur in the inpatient setting, referred to as **hospital-acquired conditions (HAC)**. Similar to CMS value-based purchasing and readmissions reduction programs, this HAC reduction program has significant implications particularly for major teaching hospitals performing complex surgery, who are 2.9 times more likely to be penalized in this program than non-teaching hospitals [1], 56% of which are subject to payment reductions [2]. Indeed, it was shown that patients with at least one HAC have a 54% higher likelihood of dying during an inpatient hospital stay than patients without a HAC. Additionally, the odds of patients with at least one HAC having a prolonged hospital stay and excessive charges are 1.64 and 1.85 times that of patients without, respectively (Table 1). There is no doubt, therefore, that HACs provide challenges for hospitals and payers, all magnified by the resource pressures associated with an ongoing COVID-19 pandemic.

Table 1. Effects of At Least One Hospital-Acquired Condition on Mortality, Prolonged Length of Stay, and Excessive Hospital Charges

Effect of HAC	None n (%)	At Least 1 n (%)	Crude OR (95% CI)	Adjusted OR (95% CI)	*p* Value
Mortality	590,845 (1.73)	82,205 (3.67)	2.17 (2.12–2.22)	1.54 (1.51–1.58)	<0.0001
Prolonged LOS	9,304,176 (27.17)	965,170 (43.04)	2.03 (1.99–2.06)	1.64 (1.61–1.66)	<0.0001
Excessive charges	8,012,581 (23.40)	919,405 (41.00)	2.28 (2.22–2.34)	1.85 (1.79–1.90)	<0.0001

Odds ratios are adjusted for age, sex, race, insurance status, household income, Elixhauser comorbidity score, hospital size, hospital type, and hospital region.

CI = confidence interval; HAC = hospital-acquired condition; LOS = length of stay; OR = odds ratio.

98,000 patient deaths and over $19.5 billion of added healthcare costs are caused by preventable medical error [3].

The average U.S. mortality rate for a punch cystostomy procedure is 4.4% resulting in added cost of $8,756.00 per procedure performed (Table 2).

A single patient death to a hospital results in approximately $198,979.00 in added healthcare costs.
Most of these costs are absorbed directly by the healthcare facility.

U.S. MORTALITY RATES AND COST FOR IN-PATIENT HOSPITAL PROCEDURES		
Procedure (based on CCS, ICD-9-CM codes)	**Avg. Hospital Mortality Rate**	**Added Healthcare Cost**
Heart Valve Procedures	5.04%	$6,017.00
Percutaneous Punch Cystostomy	4.40%	$8,756.00
All procedures (combined)	2.26%	$2,698.00
Coronary Artery Bypass Graft	2.09%	$2,495.00
Hip Replacement	0.96%	$1,146.00
Urethral Catheterization	0.83%	$991.00

Table 2. Cost of preventable Medical Error
Source: National and Regional Estimates on Hospital use from the HCUP Nationwide Inpatient Sample (NIS) 2000-2010. www.Hcupnet.ahrq.gov

Urethrotech is in a strong position to offer a urethral catheter solution for healthcare providers focused on patient safety and workflow efficiency.

Incidence of Iatrogenic Urethral Catheterization Injury

Iatrogenic urethral catheterization injury is reported to occur in 0.7 per 1,000 adult **male** hospital admissions [4] which amounts to about **11,988** cases across all U.S. Community Hospitals, calculated on a presumed equal distribution between gender admissions (Table 3). National U.S. Audit Data on the true incidence of Catheterization-associated Urethral Injury (CAUI) are not available.

Avoiding catheterization related complications is an obvious and significant service improvement opportunity, particularly as difficult catheterization is mostly encountered unexpectedly. Healthcare Services who will identify the Urethrotech innovation as a win-win opportunity include high-cost elective surgical services, such as, but not limited to, Cardiothoracic, Orthopaedic and General surgery where pre-operative urethral catheterization is an essential part of safe peri-operative care and Emergency Departments where front-line healthcare professionals are called upon to do the catheterization procedure.

staffed Beds in Community Hospitals	6,146
Number of U.S. Community Hospitals	5,198
Number of Nongovernment Not-for-Profit Community Hospitals	2,937
Number of Investor-Owned (For-Profit) Community Hospitals	1,296
Number of State and Local Government Community Hospitals	965
Number of Federal Government Hospitals	209
Number of Nonfederal Psychiatric Hospitals	616
Other 2 Hospitals	123
Total Staffed Beds in All U.S. Hospitals	924,107
Staffed Beds in Community Hospitals	792,417
Medical-Surgical Intensive Care 4 Beds in Community Hospitals	55,663
Cardiac Intensive Care 5 Beds in Community Hospitals	15,160
Neonatal Intensive Care 6 Beds in Community Hospitals	22,721
Pediatric Intensive Care 7 Beds in Community Hospitals	5,115
Burn Care 8 Beds in Community Hospitals	1,198
Other Intensive Care 9 Beds in Community Hospitals	7,419
Total Admissions in All U.S. Hospitals	36,353,946
Admissions in Community Hospitals	34,251,159
Total Expenses for All U.S. Hospitals	$1,112,207,387,000
Expenses for Community Hospitals	$1,010,271,112,000
Number of Rural Community Hospitals	1,821
Number of Urban Community Hospitals	3,377
Number of Community Hospitals in a System 10	3,491

Table 3. 2020 Hospital Statistics in U.S.
Source: https://www.aha.org/statistics/fast-factsus-hospitals

Urethrotech UCD - Coding Guidance Facility Fees - Inpatient Hospital

CMS/Medicare:
As a general rule, catheterization procedures with the Urethrotech Urethral Catheterisation Device (UCD) currently are absorbed into DRG reimbursement and do not give rise to additional reimbursement. There are two exceptions: increased complexity of DRG and special supplies. Increased complexity in DRG is justified because catheter placement for difficult urinary complications (DUC) is not contemplated in the DRG regimen and thus may justify additional reimbursement to the existing primary or secondary DRG(s) for which the patient was admitted. Alternatively and if increased complexity of DRG is not appropriate, special supplies such as the Urethrotech UCD may be justified as special supplies.
In addition, the Urethrotech UCD is expected to avoid and/or reduce the number of complex procedures (also not reimbursable in most cases) for catheter placement, such as filiforms/followers, rigid cystoscopy in the OR, or suprapubic placement. Avoiding or reducing these expensive procedures is expected to improve operating margins.
Private Payors: Reimbursement is carrier and content specific. Generally, reimbursement is a percentage of charges.

Urethrotech UCD - Coding Guidance Facility Fees - ER

The ER is considered a hospital outpatient setting. The hospital outpatient setting utilizes APCs for reporting and reimbursing facility fees. For services provided in the ER, the hospital will report and be reimbursed for the space, personnel, equipment and supplies associated with the APC code that maps to the corresponding CPT code that is reported by the physician. The APC codes are applicable for the hospital/ED to bill when the catheterization procedure with the Urethrotech Urethral Catheterisation Device (UCD) is performed by nurses or staff on the order of a physician, or by a physician.
Payment rates for APC Codes: Most supplies are "packaged" into the APC for a procedure. However, hospitals are encouraged to list all supplies used so that they can be accounted for and eventually bundled into the APC if appropriate.

Suggested APC Code: APC 0126 – Level I Urinary and Anal procedures (maps to CPT code 51703)
SI – T
RW – 1.1497
Payment Rate - $81.99
National Unadjusted copayment - none listed
Minimal unadjusted copayment – $16.40

Urethrotech UCD - Coding Guidance Facility Fees – ACS / Outpatient Surgery

The outpatient and ASC settings utilize APCs for reporting and reimbursing facility fees. For services provided in the outpatient or ASC setting, the facility will report and be reimbursed for the space, personnel, equipment and supplies associated with the APC code that maps to the corresponding CPT code reported by the physician. These codes are applicable for the hospital/ED to bill when the catheterization procedure with the Urethrotech Urethral Catheterisation Device (UCD) is performed by nurses or staff on the order of a physician, or by a physician.

Suggested APC Code: APC 0126 – Level I Urinary and Anal procedures (maps to CPT code 51703)
SI – T
RW – 1.111
Payment Rate - $75.52
National Unadjusted copayment – $16.21
Minimal unadjusted copayment – $15.31

Urethrotech UCD - Coding Guidance Facility Fees – Office

For services furnished in the physician's office, payment for the space, equipment, and personnel is valued into the CPT code. For services performed in the office, the payment will be made at the total Non-Facility fee rate. This payment amount will cover the physician work as well as the costs for the space, personnel, equipment and supplies associated with the procedure.
Suggested CPT Code: 51703 Insertion of temporary indwelling bladder catheter; complicated (eg, altered anatomy, fractured catheter/balloon)
Total Non-Facility Fee - $139.64

Urethrotech UCD - Coding Guidance Physician / Provider – Inpatient Hospital, ER, ACS/Outpatient, Office

Suggested CPT Code: 51703 Insertion of temporary indwelling bladder catheter; complicated (eg, altered anatomy, fractured catheter/balloon).

Considerations for code selection

Report code 51703 utilizing one of the following options to capture additional work involved in the procedure:
1. Report the appropriate catheterization or procedure code (51703) along with the unlisted code 53899 – Unlisted procedure, urinary system. The Unlisted code value recommendation should be based on the extra physician work and practice expense of using the Urethrotech UCD.
2. Report the appropriate catheterization (51703) or other procedure code (if catheterization is bundled) along with a -22 (increased services) modifier. Documentation must support that the procedure is around 20% - 30% more work than the base procedure. Work includes increased time, complexity, intensity, and risk to the patient and the physician.

Diagnosis Coding:
A list of current diagnosis codes that may be used if appropriate to support a complicated catheterization based on altered anatomy include the following:

598 – 598.9	Urethral Stricture
599.4	Other Disorders Of Urethra And Urinary Tract > Urethral False Passage
600.01 – 600.02	Hyperplasia Of Prostate
996.31	Complications Peculiar To Certain Specified Procedures > Mechanical Complication Of Genitourinary Device, Implant, And Graft > Due To Urethral [indwelling] Catheter
996.64	Complications Peculiar To Certain Specified Procedures > Infection And Inflammatory Reaction Due To Internal Prosthetic Device, Implant, And Graft > Due To Indwelling Urinary Catheter

Additional Considerations and information for recommended code
51703 Insertion of temporary indwelling bladder catheter; complicated (eg, altered anatomy, fractured catheter/balloon)
MUEs - 2 (Maximum number of procedure code 51703 allowed per day)

Medicare RBRVS Relative Values

Work Relative Value Unit (RVU)	1.47
Facility Practice Expense	0.74
Malpractice	0.14
Facility Total	2.35
Medicare Fees	
Facility Fee	$79.95

Urethrotech UCD - Cost Saving Analysis

Cost saving analysis demonstrates obvious advantages using the Urethrotech UCD compared to established alternative procedures to manage difficult or failed urethral catheterization such as percutaneous trochar punch suprapubic catheterization or cystoscopy (Table 4 +5). The Urethrotech UCD provides a ready to use second line catheterization solution when needed to save time and avoid complications. Minimizing HACs has long-term impacts on mortality, morbidity, return to hospitals, long-term care, quality of life, return to work and family. These are clinical, social and economic benefits that go beyond safety and have tangible value.

		Percutaneous Trochar Punch Suprapubic Catheterisation			Urethrotech UCD® Catheterisation		
Complications	Cost per Complication	Rate (AHRQ)	Cost per 100 Patients	Cost per SPC	Rate (AHRQ)	Cost per 100 Patients	Cost per UCD®
Anestetic-related complications	$57,727.00	1.80%	$103.909.00	$1,039.00	0.00%	$0.00	$0.00
Bowel Injury	$57,727.00	2.30%	$132,772.00	$1,327.72	0.00%	$0.00	$0.00
Septicaemia (Sepsis)	$57,727.00	4.60%	$265,554.00	$2,655.54	0.00%	$0.00	$0.00
Mortality	$199.000.00	4.40%	$875,600.00	$8,756.00	0.00%	$0.00	$0.00

Table 4: Complication costs associated with traditional procedure approach to manage failed urethral catheterization.

TOTAL PROCEDURE COST COMPARISON FAILED URETHRAL CATHETERISATION (Traditional Methods versus Innovation)								
	Percutaneous Trocar Punch		Open Cystostomy		Flexible Cystoscopy		Urethrotech UCD®	
Item	Quantity	Cost	Quantity	Cost	Quantity	Cost	Quantity	Cost
Physician Time	10 minutes (30)	$29.00	60 minutes (30)	$174.00	10 minutes (30)	$29.00	5 minutes (30)	$14.50
Clinical Staff Time	30 minutes (30)	$11.00	60 minutes (30)	$22.00	30 minutes (30)	$11.00	–	
OR Time (@$66/min)	30 minutes (30)	$990.00	60 minutes (30)	$1,980.00	30 minutes (30)	$990.00	–	
Misc.Supplies (General Surgical)	Various (30)	$25.00	Various (30)	$25.00	Various (30)	$25.00	–	
Supplies	Procedural: (30) 1000mL Saline for Bladder Distension Percutaneous Trocar Punch Kit Foley Catheter Spinal Needle Syringe	$238.00	Procedural: (31) 1000mL Saline for Bladder Distension Foley Catheter Catheter Introducer Syringe	$138.00	Procedural: (31) 1000mL Saline for Bladder Distension Foley Catheter Guidewire Syringe	$163.00	Procedural: 2 Syringes 1 Lubrication gel Urethrotech UCD®	$269.90
Additional	30 minutes Ultrasound guidance	$73.00	4.6 post-operative days Inpatient length of stay	$24,247.00		–	–	
SUBTOTAL PROCEDURE COST								
Procedure Cost		$1,366.00		$26,586.00		$1,218		$284.40
COST OF COMPLICATIONS & MORTALITY PER PROCEDURE								
Per procedure costs associated with complications (See Complications and Mortality Rates and Costs)		$14,949.00	General Surgery complication rate ǂ	$6,108.00	–	–	–	–
TOTAL COSTS								
		$16,315.00		**$32,694.00**		**$1,218**		
Urethrotech UCD® System Savings		$16,030.60		$32,409.60		$933.60		
ADDITIONAL COSTS TO CONSIDER								
Balloon Dilator to manage simple stricture		1	$600.00				–	–
Multiple catheter changes of different size and tip		3	$ 81.00				–	–
Guidewire		1	$ 25.00				–	–
Fluoroscopic guidance (10,32) Not reimbursed seperately		1	$2,923.00				–	–

Table 5: Time, cost and practice expense data of procedure costs associated with traditional procedure approach to manage failed urethral catheterization.
ǂ Includes complications and mortality rate from AHRQ

When Donald Berwick, KBE, former Administrator of the Centers for Medicare and Medicaid Services (CMS) and President and Chief Executive Officer of the Institute for Healthcare Improvement, was asked by the British prime minister to review the state of the NHS, he reiterated,

"Hospitals, not individuals, must be held accountable for poor outcomes.
Measurement is best used for learning rather than for selection, reward or punishment.
Real improvement comes from changing systems not change within systems.
Concentrate on meeting the needs of patients rather than the needs of organizations.
Lastly, effective leaders challenge the status quo by offering clear ideas about superior alternatives."

References

1 Medicare program. Hospital inpatient prospective payment systems for acute care hospitals and the long-term care hospital prospective payment system and fiscal year 2015 rates; quality reporting requirements for specific providers; reasonable compensation equivalents for physician services in excluded hospitals and certain teaching hospitals; pro- vider administrative appeals and judicial review; enforce- ment provisions for organ transplant centers; and electronic health record (EHR) incentive program. Final rule. Federal Register 2014;79:49853–50536.
2 Medicare. Hospital-acquired condition reduction program.Available at https://www.medicare.gov/hospitalcompare/hac-reduction-program.html. Accessed November 22, 2015.
3 Andel, C., et al. (2012). "The economics of health care quality and medical errors." J Health Care Finance 39(1): 39-50.
4 Kashefi C, Messer K, Barden R, Sexton C, Parsons JK (2008) Incidence and prevention of iatrogenic urethral injuries. J Urol 179(6):2254–22
5 Alkhouli M, Alqahtani F, Cook CC. Association between surgical volume and clinical outcomes following coronary artery bypass grafting in contemporary practice. J Card Surg. 2019;34:1049 - 1054
6 Özkan B et al (2014) Difficult Urethral Catheterization in Cardiovascular Surgery Patients: do you have a Road Map? J Neph Urol Res 2:32–36
7 Bugeja, S., et al., A new urethral catheterisation device (UCD) to manage difficult urethral catheterisation. World J Urol, 2019. 37(4): p. 595-600

Disclaimers