Challenges in Clinical Translation



Jennifer Meddings MD, MSc CAUTI Technology Workshop March 12, 2019



Disclaimer: The views expressed in this presentation are my own, and do not represent the views of the University of Michigan, the Department of Veterans Affairs, or my research funders (AHRQ, VA National Center for Patient Safety, HRET/AHA, CDC, UM).

Outline

- My Background in CAUTI prevention
- Facility-related Challenges to Clinical Translation
- Clinician-related Challenges to Clinical Translation
- Patient-related Challenges to Clinical Translation
- Measurement-related challenges to Clinical Translation
- Expect a priority change from "CAUTI Prevention" to "Safer Urinary Management"... preventing urinary harms other than CAUTI
- CAUTI prevention in the world of imperfect urinary catheters

My Background in CAUTI Prevention

Clinician: Physician, General Internal Medicine & Pediatrics

University of Michigan (Michigan Medicine)

Ann Arbor VA Medical Center

Hospitalized adults (for heart failure, pneumonia, etc)

Outpatient adults & kids (many with chronic disease)

CAUTI prevention committee for ~10 years

My Background in CAUTI Prevention

Investigator: Preventing CAUTI and Pressure Ulcers

- Impact of "Value-based purchasing" programs for Medicare that use public reporting and Medicare payment changes/penalties
- Developing, implementing, and evaluating clinical interventions in the acute-care (ICU and non-ICU) and nursing home settings:
 - Interventions to reduce inappropriate catheter use and increase aseptic insertion/maintenance: reminders/stop orders, bundles, human factors designed catheter kits, socioadaptive strategies for changing clinician practice

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- My team has a provisional patent for a device to improve aseptic insertion of urinary catheters, and has applied for device patent to reduce hospital-acquired pressure ulcers. *None discussed today.*
- My team and I have NO associations with any companies, have no ownership in a commercial entity, and receive no royalties.

- Hospitals and Nursing Homes have CAUTI and urinary catheter use publicly reported - no exceptions, even in patients in a study of new devices.
 - The same CAUTI data is used in 2 different Medicare programs for assessing hospital complication penalties - as a reduction in ALL Medicare payments received by hospital.
- Hospitals and Nursing Homes often have several levels of review and approval needed for device studies:
 - IRB (of individual facilities, and/or multi-site IRB)
 - Multiple committees: CAUTI prevention/policy, Compliance, BME
 - Nursing Research and Translation Committee: Nurse leadership and unit-level approval (even for surveying nurse)
 - Nursing home ownership/administration many nursing homes are now in chains, with additional layers of oversight

- Many competing priorities, even within safety/quality arena!
 - Sepsis early recognition/management
 - Fall prevention
 - Delirium prevention
 - CLABSI prevention
 - Surgical Site Infection prevention
 - C. Difficile prevention
 - Reduce readmissions to the hospital
 - Manage high occupancy of ER and inpatient beds
 - ICU care bundles including early patient mobility
 - CAUTI prevention may be priority #10

- Is CAUTI or urinary catheter use still a problem for that specific Hospital, unit, or nursing facility?
 - Hospitals: ~15-20% patients with urinary catheters during hospitalization....but most are in the ICU or OR
 - 5-10% in non-ICU setting in many hospitals, but 40-80% in the ICU setting
 - Nursing homes have been using fewer urinary catheters for years compared to hospitals, so expect ~5% catheterized & usually prolonged use
 - Some hospitals have been very successful already in reducing urinary catheter use and CAUTI
- Multiple or changing electronic health records for data review

Characteristics of Healthcare Organisations Struggling to Improve Quality: Results from a Systematic Review of Qualitative Studies

Domains Characterising Struggling Healthcare Organisations (Review of 30 Studies)



Poor
Organisational
Culture



Inadequate Infrastructure



Lack of Cohesive Mission and Vision



System Shocks (New EHR, Scandals, Leadership Turnover)



Dysfunctional External Relations

Vaughn, Saint, Krein, Forman, Meddings, Ameling, Winter, Townsend, Chopra. *BMJ Qual Saf.* July 2018.



Clinician-related Challenges to Clinical Translation

- High turnover in many hospitals and nursing homes:
 - Hmm, the people who finally approved your study, and championed it have disappeared....and new person is overwhelmed with learning job!
- Physicians now often work with shift schedule rather than weeks-month - harder to get multiple data points per physician!
- Most patients who received urinary catheters were NOT admitted primary for urinary catheter need....they were admitted for "bigger" problem(s) like heart failure, sepsis, or pneumonia, and the need for urinary catheter came up as an "extra" decision during the busy hospitalization...while trying to treat or diagnosis another problem.

Clinician-related Challenges to Clinical Translation

- Catheters often ordered by physicians or routine surgery protocol, but are placed/removed by nurses.
- Nurse scope of practice/protocols for catheter care are highly regulated - expect nurses to be reluctant about a project that changes their usual insertion/maintenance steps/supplies.
- A "study" urinary catheter can get removed for reasons of:
 - Patient no longer has an appropriate indication for indwelling catheter, so alternative non-indwelling product is used by nursing protocol (usually no orders required!)
 - Has been in more than 7-14 days, and UTI suspected so fresh catheter placed before urine culture sample obtained

- Patients for whom urinary catheters are commonly placed tend to be older, frail, with complex medical issues.
 - Harder to consent ICU patients and nursing home residents for studies related to communication and cognitive challenges.
 - Guardians/Family often NOT physically on site to discuss or sign a consent.
 - VERY difficult logistically to collect clean-catch urine specimens due to incontinence rates, difficulty following instructions, mobility limitations.
 - Nurses are busy enough with other tasks have a place for collecting research specimens that is not dependent on the busy bedside nurse!
- Men and women have different UTI risks and urinary microbiomes!

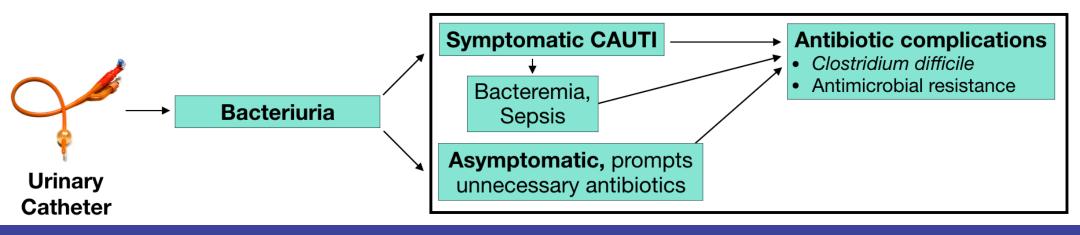
Measurement Challenges to Clinical Translation

Which CAUTI outcome is the study outcome?

- The National Healthcare Safety Network (NHSN) symptomatic CAUTI <u>surveillance</u> event used for public reporting/hospital penalty: standard collection by hospital infection preventionist, using CDC criteria...but fever qualifies for CAUTI even if have another diagnosis (e.g., pneumonia) causing fever.
- Clinician-diagnosed/treated CAUTI is only reliably measured using chart abstraction which is resource intensive (NOT reliably measured in claims data!)
- Asymptomatic bacteriuria does NOT = symptomatic CAUTI

Beware that CDC surveillance as well as acute-care (IDSA) and nursing home (McGeer's) clinical definitions for CAUTI can change during your project.

Heads up: expect priority change by funders and regulators from "CAUTI Prevention" to "Safer Urinary Management"



MANY Urinary Catheter Complications

BMJ Quality & Safety

ORIGINAL RESEARCH



Michigan Appropriate Perioperative (MAP) criteria for urinary catheter use in common general and orthopaedic surgeries: results obtained using the RAND/UCLA Appropriateness Method

Jennifer Meddings,^{1,2,3} Ted A Skolarus,^{1,4} Karen E Fowler,¹ Steven J Bernstein,^{1,2,5} Justin B Dimick,^{5,6} Jason D Mann,² Sanjay Saint^{1,2}

Link to access "Figure 1. Infectious and non-infectious urinary catheter complications": https://qualitysafety.bmj.com/
content/qhc/28/1/56/F1.large.jpg

Genitourinary Trauma! Ouch...

False passage, multiple insertions needed, PAIN!, Bleeding,

Urethra and prostate injury during placement/removal

Sequelae: strictures, penile gangrene

More procedures: cystoscopy, surgical repair

Prolonged catheter placement while healing -> strictures, bladder stones, bladder cancer, and bladder dysfunction after removal

THE JOURNAL UROLOGY®

May 2011

National Incidence and Impact of Noninfectious Urethral Catheter Related Complications on the Surgical Care Improvement Project

David S. Aaronson,* Alex K. Wu, Sarah D. Blaschko, Jack W. McAninch and Maurice Garcia

From the Department of Urology, University of California San Francisco, San Francisco (DSA, AKW, SDB, JWM, MG), and Kaiser Permanente Medical Group, Oakland (DSA), California

- Retrospective secondary data analysis of 2007 hospital discharge diagnosis codes (HCUP National Inpatient Sample)
- 1420 catheter-related complications billed in 7 surgeries
- Associated with increased length of stay, and UTI risk!

THE JOURNAL UROLOGY®

May 2012

Complications of Foley Catheters—Is Infection the Greatest Risk?

Anne-Marie Leuck Deborah Wright LeAnn Ellingson Linda Kraemer Michael A. Kuskowski James R. Johnson

From the VA Medical Center (AML, DW, LE, LK, MAK, JRJ), Department of Medicine (AML, JRJ) and Department of Psychiatry (MAK),
University of Minnesota, Minnesota

- Prospective study, 16 months, Minneapolis VA
- 100 Foley catheter-related traumatic events,
- 116 possible UTIs
- "...Foley catheter-related genitourinary trauma was as common as symptomatic UTI."

JAMA Internal Medicine | Original Investigation

A Multicenter Study of Patient-Reported Infectious and Noninfectious Complications Associated With Indwelling Urethral Catheters

Sanjay Saint, MD, MPH; Barbara W. Trautner, MD, PhD; Karen E. Fowler, MPH; John Colozzi, BA; David Ratz, MS; Erica Lescinskas, MD; John M. Hollingsworth, MD, MS; Sarah L. Krein, PhD, RN

Link to access "Figure 2. Percentage of 2076 Patients Reporting Infectious or Noninfectious Complications During the Month After Urethral Catheter Insertion": https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2686144

CAUTI prevention in the world of imperfect catheters

That is, what you should know about what hospitals are already investing resources in for CAUTI prevention

Lifecycle of the Urinary Catheter

- 1. Catheter Placement
- 2. Catheter Care
- 3. Catheter Removal
- 4. Catheter Re-Insertion

Link to access "Lifecycle of the urinary catheter" figure: https://
academic.oup.com/cid/article/

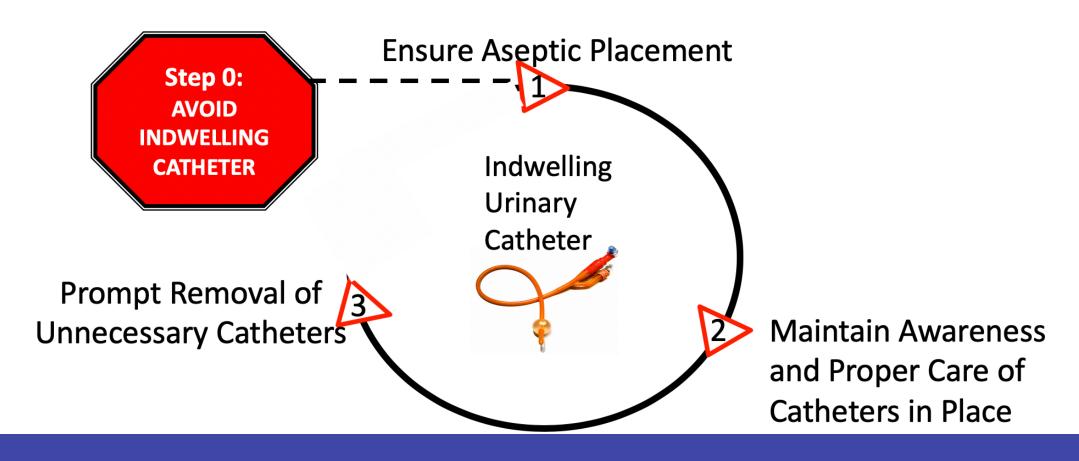
academic.oup.com/cid/article/

52/11/1291/408167



This conceptual model illustrates 4 stages of the urinary catheter lifecycle as targets for intervention to decrease catheter use and subsequent CAUTI.

Disrupting the Lifecycle of Urinary Catheter



Adapted from Meddings J, Saint S. *Clin Infect Dis*. 2011;52(11):1291-1293, for Patel P, et al. *J. Hosp. Med*. 2018 February;13(2):105-106.

Restricting to "Appropriate" Use Only

Step 0:
AVOID
INDWELLING
CATHETER

Also known as "Catheter Stewardship"

Ensure Aseptic Placement

Place only for appropriate reasons

Use alternatives

Prompt Removal of Unnecessary Catheters

Reminders/Stop orders that employ appropriate criteria

Indwelling Urinary Catheter

Daily review of continued need for urinary catheter

and Proper Care of Catheters in Place

Annals of Internal Medicine

Supplement

May 2015

The Ann Arbor Criteria for Appropriate Urinary Catheter Use in Hospitalized Medical Patients: Results Obtained by Using the RAND/UCLA Appropriateness Method Available by free access at annals.org

- Refined urinary catheter criteria based on challenges that nurses and physicians have expressed when applying 2009 CDC criteria such as difficulty turning, patient requests, multiple medical problems, vulnerable skin, etc.
- Multidisciplinary panel of 15 nurses and physicians who reviewed literature and discussed/rated 299 clinical scenarios about catheter use

Annals of Internal Medicine

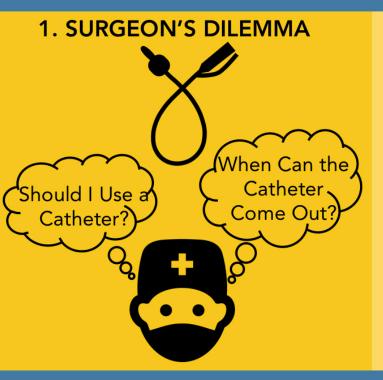
SUPPLEMENT

May 2015

The Ann Arbor Criteria for Appropriate Urinary Catheter Use in Hospitalized Medical Patients: Results Obtained by Using the RAND/UCLA Appropriateness Method Available by free access at annals.org

- Table 2. Guide for Foley Catheter Use
- Table 3. Guide for Intermittent Straight Catheterization
- Table 4. Guide for External Catheter Use
- Table 5. Side-by-side comparison of appropriateness of urinary management strategies (Foley, ISC, External non-catheter) for common uses of urinary catheters.
- Figure 4. ICU Daily Checklist for Foley Catheter Use

Michigan Appropriate Perioperative (MAP) Criteria for Urinary Catheter Use in Common General and Orthopaedic Surgeries: Results Obtained Using the RAND/UCLA Appropriateness Method









Panel of Experts

- 3. PERIOPERATIVE URINARY CATHETER GUIDELINES (examples)
- A. No Catheter Needed:
 - elective hip replacement
 - elective knee replacement
 - · laparoscopic cholecystectomy
- B. Remove Right After Surgery:
 - hemicolectomy
 - hip replacement to repair fracture

Meddings, Skolarus, Fowler, Bernstein, Dimick, Mann, Saint. *BMJ Qual Saf.* August 2018. **Open Access**.



Alternatives to Indwelling Catheters



Male, female urinals



Bedside commode, bedpans



Scale



External catheters



Incontinence care supplies



Intermittent straight catheters (ISC)

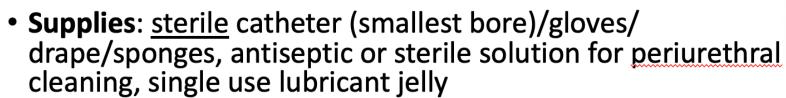


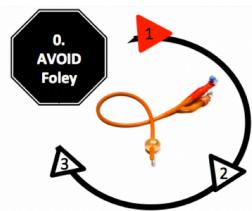
Bladder ultrasound

Pictures are not intended to imply recommendation or endorsement for specific products or brands.

1. Ensure Aseptic Placement

Ensure only properly trained persons insert catheters, and insert using aseptic technique and sterile equipment."1-3





- Hand Hygiene immediately before and after insertion
- Secure catheter to leg to prevent movement, urethral trauma/irritation
- Position bag below bladder ("dependent") with closed unobstructed tubing

¹Gould C, et al. Infection Control & Hospital Epidemiology, 2010;31:319-326. ²Hooton T, et al. IDSA Urinary Catheter Guidelines, CID 2010. ³North Carolina Manual to Prevent CAUTI, Version 2.0, February 2008.

35

Give periodic in-service training of correct insertion technique to all hospital personnel who insert urinary catheters.

Sterile catheter insertion in patients is complicated!

- MANY steps: most kits ~20 steps.
- Many hospitals are using comprehensive urinary catheter insertion kits, incorporating human factors research to reduce human error with insertion.
- Hospital purchase and clinician training for using a kit is resourceintensive - expect reluctance for trying a different catheter than the one already in their purchased kits!
- Link to instructions: http://m.bardmedical.com/media/629623/
- ud ft surestep dfu.pdf

How good are we at sterile catheter insertion? Awful!

Indwelling Urinary Catheter Insertion Practices in the Emergency Department: An Observational Study

Manojlovich M, et al. Infection Control & Hospital Epidemiology. January 2015

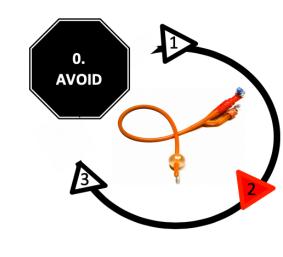
At least one Major Break of Sterility	48 of 81 (59%) insertions	
Sterile field contamination	22 of 81 (27%) insertions	Nurse touched sterile items with bare non-sterile hands. Garment touched field.
Catheter contamination	25 of 81 (31%)	Tip touched genitalia before insertion and nurse did not get a new catheter
Breach of sterile barrier	31 of 81 (38%)	Sterile gloved hand used to swab genitalia without tongs with same hand used to insert catheter; sterile gloves ripped but not replaced for insertion

Expect that even a more perfect catheter will often be inserted with breaks in sterile procedure

- It is difficult even for experienced clinicians to insert catheters without MAJOR breaks in sterility...even with 2 nurses performing together.
- Perform periodic in-services including observed competency assessments.
- Consider insertion checklists and catheter kits designed to be comprehensive, with reminders for the correct steps

2. **Maintain Catheter Awareness** and Proper Catheter Care

Level of Training	Proportion Unaware of Catheter Status ¹
Medical Students	18%
House Officers	25%
Attending Physicians	38%



¹Saint et al. The American Journal of Medicine, Oct 15 2000; 109(6):476-480.

Options: Daily care <u>checklists</u>, more obvious catheter documentation, Routine reminders of catheter presence to physicians/nurses

2. Maintain Catheter Awareness

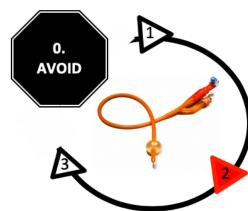
and Proper Catheter Care

Catheter Maintenance Care:

- Properly secured catheters
- Maintain closed drainage system
- Obtain urine samples aseptically
- Maintain unobstructed urine flow
 - No kinking of catheter tube, Keep bag below bladder at all times
 - Empty into separate clean container for each patient
 - Routine perineal cleansing
- Literature does not support antimicrobial catheters, and is mixed for use
 of topical chlorhexadine bathing or tube care for maintenance care

Who impacts this?

Nurses, patient care assistants, patient, family members, transporters



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Urine Culture Stewardship: BUT, only send urine tests for guideline-supported symptoms of UTI.

Option: Urinalysis with reflex to culture

Who influences urine culture ordering: nurses, patients/family, physician habits

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Antibiotic Stewardship Programs:

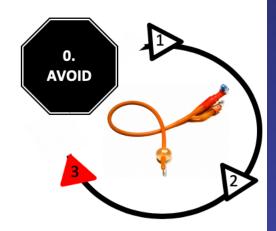
No kinking of catheter tube, Ke Guidelines for testing and antibiotic starts, narrowing, duration, pharmacist decision support.

> Note: clinician receiving urine culture result often NOT the one that ordered it, so hard to improve comfort with NOT treating with antibiotics.

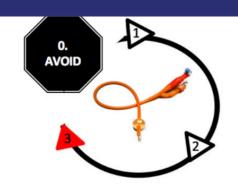
3. Prompt Removal of Unnecessary Catheters

Traditional Steps to Catheter Removal:

- 1. Physician recognizes catheter is present
- 2. Physician recognizes catheter no longer needed
- 3. Physician writes order to remove catheter
- 4. Nurse sees order and plans to remove the catheter
- 5. Urinary catheter is removed



3. Prompt Removal of Unnecessary Catheters



Reminder: reminds that a catheter is still in use; may also remind of appropriate indications

Stop Order: prompts removal of catheter based upon specified time after placement (e.g., 24 h) or based on clinical appropriateness criteria

Catheter Reminders & Stop Orders: Impact on CAUTI rates

Overall, the rate of CAUTI (episodes per 1000 catheter-days) was reduced by 53% with use of a reminder or stop order (rate ratio 0.47; 95% CI 30% to 64% reduction, p<0.001) in a metaanalysis of 11 studies.



The *key* intervention is having the bedside nurse assess daily whether the catheter is still necessary.

Supplement this assessment with periodic Foley "Catheter Rounds" of the unit, to ensure uniform interpretations of appropriate indications and care, by real-time feedback to clinicians

So how effective are these types of CAUTI preventive interventions?

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812

JUNE 2, 2016

VOL. 374 NO. 22

A Program to Prevent Catheter-Associated Urinary Tract Infection in Acute Care

Sanjay Saint, M.D., M.P.H., M. Todd Greene, Ph.D., M.P.H., Sarah L. Krein, Ph.D., R.N., Mary A.M. Rogers, Ph.D., David Ratz, M.S., Karen E. Fowler, M.P.H., Barbara S. Edson, R.N., M.B.A., M.H.A., Sam R. Watson, M.S.A., C.P.P.S., Barbara Meyer-Lucas, M.D., M.H.S.A., Marie Masuga, R.N., M.S.N., Kelly Faulkner, M.S.P.A., Carolyn V. Gould, M.D., M.S.C.R., James Battles, Ph.D., and Mohamad G. Fakih, M.D., M.P.H.

926 units in 603 hospitals in the US:
Daily assessment of catheter need
Use alternatives to indwelling catheters
Emphasize aseptic insertion/maintenance care
Feedback catheter use and CAUTI rates to units

Non-ICU CAUTI and urinary catheter use significantly decreased, but not in ICUs.

HOSPITAL MEDICINE

2018 February; 13(2):105-106.

Review of Strategies to Reduce Central Line-Associated Bloodstream Infection (CLABSI) and Catheter-Associated Urinary Tract Infection (CAUTI) in Adult ICUs

Payal K. Patel, MD, MPH^{1,2*}, Ashwin Gupta, MD^{1,3}, Valerie M. Vaughn, MD³, Jason D. Mann, MSA³, Jessica M. Ameling, MPH³, Jennifer Meddings, MD, MSc^{1,3,4,5}

Systematic literature review, yielding 28 CAUTI prevention studies with control group, including only 2 RCTs, and often not powered to detect statistically significant change.

- Post-intervention CAUTI rates lower (mean 49%) in 25 studies (11 statistically sig)
- Post-intervention urinary catheter utilization: reported in 11 studies, lower use (mean 16%) reported in 7 studies (4 statistically sig reductions)
- Most used interventions to disrupt multiple lifecycle stages of the urinary catheter.
- Many successful studies included strategies to facilitate and sustain behavior change, such as catheter audits and frequent feedback to bedside clinicians.

REVIEW

Systematic Review of Interventions to Reduce Urinary Tract Infection in Nursing Home Residents

Jennifer Meddings, MD, MSc^{1-3*}, Sanjay Saint, MD, MPH^{1,3}, Sarah L. Krein, PhD, RN^{1,3}, Elissa Gaies, MD, MPH⁴, Heidi Reichert, MA¹, Andrew Hickner, MSI^{1,5}, Sara McNamara, MPH⁶, Jason D. Mann, MSA¹, Lona Mody, MD, MSc^{1,3,6}

19 intervention studies: 8 RCTs, 10 pre-post nonrandomized studies, 1 non-randomized study with concurrent control Several practices, most implemented in bundles, appear to reduce UTI or CAUTI in nursing home residents:

- Improving hand hygiene,
- Reducing and improving catheter use,
- Managing incontinence without catheters, and
- Enhanced barrier precautions.

Preventing Catheter-Associated Urinary Tract Infections (CAUTI) in Nursing Home Residents

INTERVENTION

CAUTI Bundle: (training & tools)

C atheter removal
A septic insertion
U sing regular assessments

T raining for catheter care
I ncontinence care planning



404 Nursing Homes across the nation

OUTCOMES

Decreased Infections



6.4**→**3.3

(Catheter-associated UTI/ 1000 catheter-days; p=0.001)

54% Reduction

Decreased Urine Cultures



 $3.5 \implies 3.1$

(Urine cultures ordered/ 1000 resident-days; p=0.001)

15% Reduction

Mody et al. JAMA Intern Med May 2017 doi:10.1001/jamainternmed.2017.1689

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IMPLEMENTATION RESOURCES





https://www.cdc.gov/hai/prevent/tap/resources.html

Catheter-Associated Urinary Tract Infection (CAUTI) Guide to Patient Safety (GPS)

https://www.catheterout.org/cauti-gps.html

Take Home Points

- There are important potential challenges to clinical translation of a new technology for preventing CAUTI at that are facility-related, clinician-related, patient-related, and measure-related.
 - Many are related to multiple competing priorities and invested resources/regulation in place related to mandatory CAUTI public reporting and risk of financial penalty.
- Expect a priority change from funders, regulators, and manufacturers from "CAUTI Prevention" to "Safer Urinary Management" to prevent other urinary harms in addition to CAUTI
- Hospitals are currently using bundles of technical/skill, educational, and socioadaptive interventions to reduce CAUTI by avoiding inappropriate catheter placement, improving aseptic insertion and maintenance care, and promptly removing unnecessary catheters.

Thank you!

meddings@umich.edu

www.catheterout.org

