Mini-Session II

2012 Research & EBP Saturday Morning Clinic

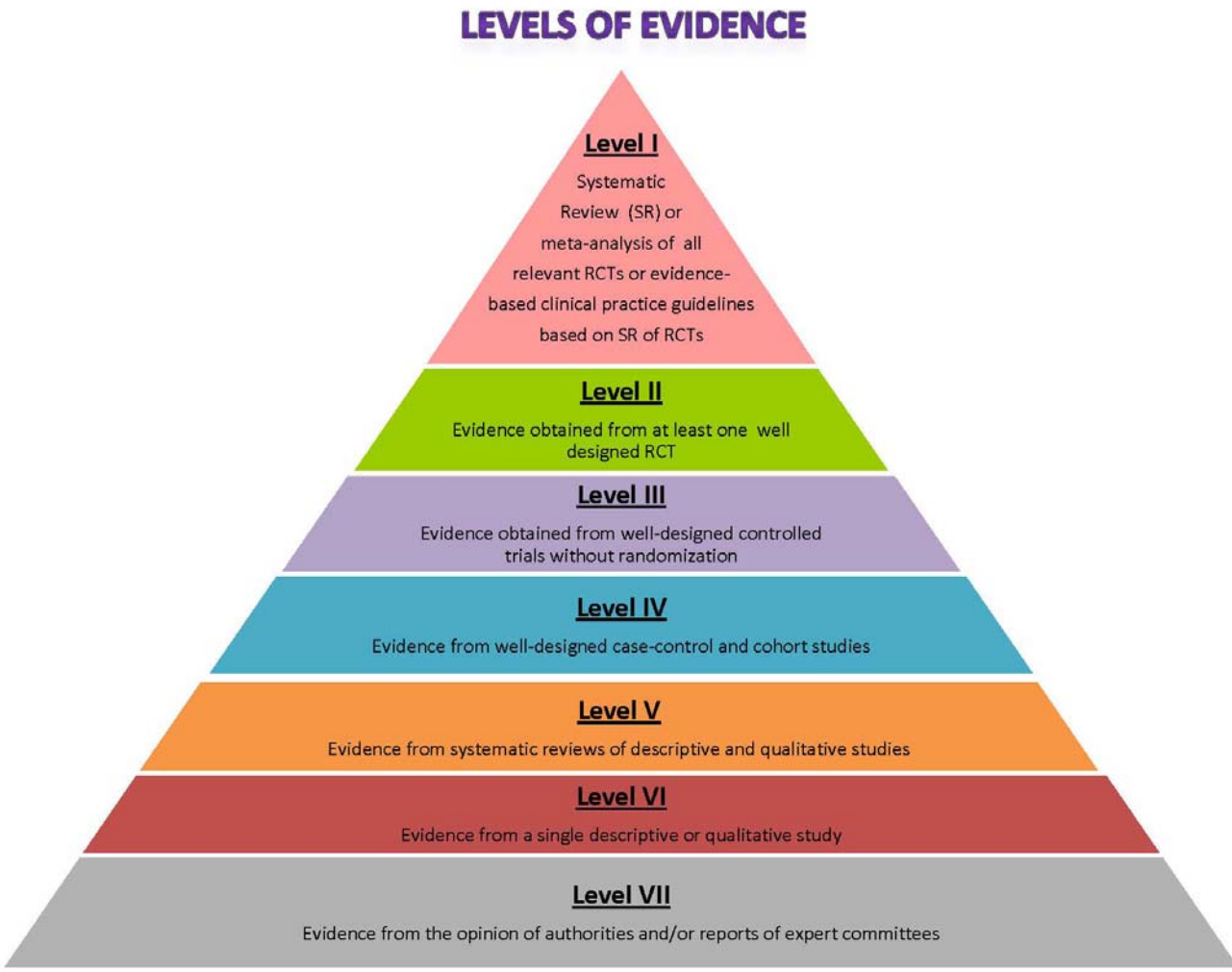
The Levels of Evidence

Why a pyramid?

A pyramid demonstrates the **hierarchy of evidence** used to guide practice in a visual way.

There is a smaller quantity of best evidence, which is located at the top of the pyramid. A decrease in quality along with an increase in quantity of evidence is shown as the pyramid expands toward its base.

The different colors of the levels help users to easily pick out the relative quality of the evidence when making decisions to guide practice.



modified from Melnyk & Fineout-Overholt, 2005

Key Definitions

Processes utilized in these methodologies minimize bias and foster objectivity

- **Systematic Review**
  - Summary of the evidence on a specific clinical topic
  - Rigorous process for identifying, appraising, and synthesizing research studies to draw conclusions
- **Meta-Analysis**
  - Summary statistics on the effect of an intervention or treatment across multiple studies
- **Randomized Controlled Trial**
  - Subjects are randomly assigned to control (placebo or no treatment/intervention) and experimental (treatment or intervention) groups
- **Evidence-Based Practice Guideline**
  - Recommendations for practice from team of experts
  - Outcome of an unbiased, exhaustive, and rigorous review of the best evidence on a specific topic

Level I

Types of Evidence

Systematic Review (SR) or Meta-Analysis of all relevant randomized controlled trials (RCT)

Evidence-Based Clinical Practice Guidelines based on SR and RCT

Relationship of catheter-associated urinary tract infection to mortality and length of stay in critically ill patients: A systematic review and meta-analysis of observational studies

Clarence Chant, PharmD, FCSHP, FCCP; Orla M. Smith, RN, MN; John C. Marshall, MD, FRCSC; Jan O. Friedrich, MD, DPhil, FRCPC

Objective: To determine whether catheter-associated urinary tract infections are associated with increased morbidity and mortality in critically ill patients.

Data Sources: MEDLINE, HealthStar, EMBASE, and CINAHL databases from inception to June 2010 and bibliographies of included studies without language restriction.

Study Selection: Studies reporting mortality or morbidity in adult intensive care unit patients with and without catheter-associated urinary tract infections.

Data Extraction: Two authors independently selected studies and extracted data on study methodology, quality, and patient outcomes using a standardized form. Meta-analyses were performed using random-effects models.

Data Synthesis: Of 720 citations, 11 studies enrolling 2,745 patients with and 60,719 patients without catheter-associated urinary tract infections met inclusion criteria. Catheter-associated urinary tract infection was associated with a significant increase in mortality (odds ratio [OR], 1.99; 95% confidence interval [CI], 1.72–2.31; $p < .00001$; $I^2 = 54\%$; eight studies; 62,063 patients) and length of stay in the intensive care unit (weighted mean difference of + 12 days; 95% CI, 9–15; $p < .00001$; $I^2 = 96\%$; seven studies; 13,011 patients) and hospital (mean difference + 21 days; 95% CI, 11–32; $p < .0001$; $I^2 = 98\%$; five studies; 10,183 patients). Restricting the analysis only to the two studies that adjusted for other outcome predictors, catheter-associated urinary tract infections were not associated with an increase in mortality (OR, 0.97; 95% CI, 0.82–1.16; $p = .77$; $I^2 = 0\%$; two studies; 5,626 patients). Although both studies individually demonstrated significantly increased intensive care unit length of stay after adjustment, pooled data showed that catheter-associated urinary tract infections were associated with a significant increase in intensive care unit length of stay using only a fixed effects model (mean difference + 2.6 days; 95% CI, 2.3–3.0; $p < .00001$) and not a random effects model (mean difference + 8 days; 95% CI, −13 to +28 days; $p = .46$) due to the high degree of heterogeneity for this outcome between the two studies ($I^2 = 99.6\%$) which results in a larger CI.

Conclusions: Catheter-associated urinary tract infection is associated with significantly increased mortality and length of stay in unmatched studies. Increased mortality and possibly increased length of stay appear to be consequences of confounding by unmeasured variables. These findings highlight the importance of evaluating risks and benefits of commonly used treatments such as antibiotics to manage catheter-associated urinary tract infection. (Crit Care Med 2011; 39:1167–1173)

KEY WORDS: catheter; urinary tract infections; mortality; critically ill

Catheter-associated urinary tract infection (CAUTI) is one of the most common nosocomial infections in intensive care units (ICUs) (1). Nosocomial CAUTI is associated with large antimicrobial use (3) emphasized the challenges associated with the management of CAUTI in the ICU: the need for urinary catheters, the lack of reliable diagnostic tests to differentiate between colonization and infection, the paucity of controlled studies to Despite this perception of minimal risk, CAUTI is frequently treated with antimicrobials even in asymptomatic patients (6, 7). This potentially inappropriate use of antimicrobials may contribute to the problematic issue of rising antimicrobial

Level I

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Systematic Review (SR) or Meta-Analysis of all relevant randomized control trials (RCT)

Evidence-Based Clinical Practice Guidelines based on SR and RCT

INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY APRIL 2010, VOL. 31, NO. 4

HICPAC GUIDELINE

Guideline for Prevention of Catheter-Associated Urinary Tract Infections 2009

Carolyn V. Gould, MD, MSCR; Craig A. Umscheid, MD, MSCE; Rajender K. Agarwal, MD, MPH; Gretchen Kuntz, MSW, MSLIS; David A. Pegues, MD; and the Healthcare Infection Control Practices Advisory Committee (HICPAC)

EDITOR'S NOTE

Following are the Executive Summary, Summary of Recommendations, and Implementation and Audit sections. The references for the entire guideline are available in the online edition of the journal. The entire guideline and the full citation apparatus have been previously published by HICPAC and are available at http://www.cdc.gov/hicpac/.

I. EXECUTIVE SUMMARY

This guideline updates and expands the original Centers for Disease Control and Prevention (CDC) Guideline for Prevention of Catheter-Associated Urinary Tract Infections (CAUTI) published in 1981. Several developments necessitated revision of the 1981 guideline, including new research and technological advancements for preventing CAUTI, increasing need to address patients in nonacute care settings and patients requiring long-term urinary catheterization, and greater emphasis on prevention initiatives as well as better defined goals and metrics for outcomes and process measures. In addition to updating the previous guideline, this revised guideline reviews the available evidence on CAUTI prevention for patients requiring chronic indwelling catheters and in-

staff, healthcare epidemiologists, healthcare administrators, nurses, other healthcare providers, and persons responsible for developing, implementing, and evaluating infection prevention and control programs for healthcare settings across the continuum of care. The guideline can also be used as a resource for societies or organizations that wish to develop more detailed implementation guidance for prevention of CAUTI.

Our goal was to develop a guideline based on a targeted systematic review of the best available evidence, with explicit links between the evidence and recommendations. To accomplish this, we used an adapted GRADE system approach for evaluating quality of evidence and determining strength of recommendations. The methodology, structure, and components of this guideline are approved by HICPAC and will be used for subsequent guidelines issued by HICPAC. A more detailed description of our approach is available in the Methods section.

To evaluate the evidence on preventing CAUTI, we examined data addressing three key questions and related subquestions:

1. Who should receive urinary catheters?

Level II

Evidence from at least one well designed randomized controlled trial (RCT)

Stop Orders to Reduce Inappropriate Urinary Catheterization in Hospitalized Patients: A Randomized Controlled Trial

Mark Loeb, MD, MSc[1,2,4,5], Derek Hunt, MD, MSc[3], Kelly O'Halloran, RN, MScN[4], Soo Chan Carusone, PhD[2], Nancy Dafoe, RN[1], and Stephen D. Walter, PhD[2]

[1]Department of Pathology and Molecular Medicine, McMaster University, Hamilton, Ontario, Canada; [2]Department of Clinical Epidemiology and Biostatistics, McMaster University, Hamilton, Ontario, Canada; [3]Department of Medicine, McMaster University, Hamilton, Ontario, Canada; [4]Hamilton Health Sciences, Hamilton, Ontario, Canada; [5]McMaster University, Hamilton, Ontario, Canada.

BACKGROUND: Hospitalized patients frequently have urinary catheters inserted for inappropriate reasons. This can lead to urinary tract infections and other complications.

OBJECTIVE: To assess whether stop orders for indwelling urinary catheters reduces the duration of inappropriate urinary catheterization and the incidence of urinary tract infections.

DESIGN: A randomized controlled trial was conducted in three tertiary-care hospitals in Ontario, Canada. Patients with indwelling urinary catheters were randomized to prewritten orders for the removal of urinary catheters if specified criteria were not present or to usual care.

PARTICIPANTS: Six hundred ninety-two hospitalized patients admitted to hospital with indwelling urinary catheters inserted for ≤48 h.

MEASUREMENTS: The main outcomes included days of inappropriate indwelling catheter use, total days of catheter use, frequency of urinary tract infection, and catheter reinsertions.

RESULTS: There were fewer days of inappropriate and total urinary catheter use in the stop-order group than in the usual care group (difference −1.69 [95% CI −1.23 to −2.15], $P<0.001$ and −1.34 days, [95% CI, −0.64 to −2.05 days], $P<0.001$, respectively). Urinary tract infections occurred in 19.0% of the stop-order group and

INTRODUCTION

Approximately one quarter of patients admitted to hospital have indwelling urinary catheters inserted[1–3]. In 30% to 50% of these patients, a urinary catheter is not medically indicated but have been inserted for either an unclear or inappropriate indication such as urinary incontinence[2,4–6]. Duration of urinary catheterization is often inappropriately prolonged because physicians forget that their hospitalized patients have catheters in place[7]. About 80% of hospital-acquired urinary tract infections occur in the presence of an indwelling urethral catheter[8]. Because bacteriuria develops in up to 50% of patients who have a catheter inserted for 5 days or more[9–11], reducing unnecessary use of such catheters may decrease urinary tract infections.

To reduce unnecessary urinary catheterization, we developed stop orders requiring removal of indwelling urinary catheters that did not have a justified indication to continue, based on published recommendations[4–6] and feedback from hospital urologists, internists, and nurses. Any one of the following criteria was considered justified to continue catheterization: urinary obstruction, neurogenic bladder and urinary retention, urological surgery, fluid challenge for acute renal failure, open sacral wound care for incontinent individuals, and comfort care for urinary incontinence in terminal illness. We conducted a randomized controlled trial to assess whether this strategy would reduce unnecessary urinary catheter use and lead to a reduction of urinary tract infections in hospitalized patients.

Level III & Level IV

Level III
Evidence from well designed controlled trials without randomization

Level IV
Evidence from well designed case control and cohort studies

- Non-Randomized Controlled Trial
  - Differs from a RCT in that a nonrandom method is used to assign subjects to control and experimental groups, e.g. even/odd numbers, days of the week
- Case Control Study
  - Retrospective comparison of a subject with a condition (e.g. hypertension) with one who does not
  - Designed to identify variables that might predict the condition (e.g. stressful lifestyle, sodium intake)
- Cohort Study
  - Involves two groups of patients (cohorts), one exposed and one not exposed (e.g. to a disease)
  - Prospectively, the cohorts are followed over time to tract outcomes

Level V

Level V
Evidence from SR of descriptive and qualitative studies

- Descriptive Study
  - Research aimed to describe characteristics of certain phenomena or selected variables
- Qualitative Study
  - Studies that collect data in non-numeric form such as personal interviews

Level VI

Evidence from a single descriptive or qualitative study

To cath or not to cath?

By Tina Wetzel, RN,C, BSN, MA; and the NICHE group at Memorial Medical Center, Springfield, Ill.

WHEN EVELYN GRAY, 89, was brought to the ED from a long-term-care (LTC) facility because of a change in mental status, lower extremity edema, and weight gain, she was diagnosed with worsening heart failure (HF). An indwelling urinary catheter was inserted, and she received I.V. furosemide (Lasix).

Mrs. Gray was admitted to the medical unit. Her peripheral edema decreased and her mental status improved, and plans were made for her discharge to the LTC facility on day six. On the evening of day five, she became confused; during the night, she fell and accidentally pulled out her urinary catheter. The catheter was reinserted, but the next day the nurses noted that her urine had a strong odor. A urine culture was positive for *Candida albicans*. Mrs. Gray responded to antifungal therapy, and her mental status improved. She returned to the LTC facility, where her urinary catheter was removed on day nine.

Unfortunately, Mrs. Gray's situation isn't unusual. Many patients have an indwelling urinary catheter throughout their hospital stay, often for no appropriate reason. To address the overuse of

Reading up

Our first step was to review the literature to determine appropriate reasons for using urinary catheters. Over 25 years ago, the Centers for Disease Control and Prevention (CDC) developed guidelines recommending that their use be limited, that they be used only for short periods, and that they not be used for convenience to manage incontinence.[1]

The CDC guidelines made little impact, and even though current literature still stresses limiting urinary catheter usage, up to 25% of hospitalized patients are catheterized.[2] From 8.5% to 10% of these patients develop urinary tract infections (UTIs) that account for at least 40% of health care–associated infections.[3]

The most important risk factor for UTI is duration of catheterization. At least 40% of patients who have a urinary catheter longer than 7 days will develop a UTI, extending their hospital stay 3 more days.[4]

Other complications of urinary catheter use include bladder spasms, hematuria, urethritis, periurethral abscesses, fistula formation, and obstruction.[3,5]

care provider may not even be aware that his patient has a urinary catheter. To add to the problem, the continued need for the catheter is rarely addressed during the remainder of the patient's hospital stay, so many urinary catheters aren't removed until discharge.

Developing a protocol

To address the overuse of urinary catheters, we developed an evidence-based protocol that allows urinary catheter insertion only for appropriate reasons identified in the literature. (See *When can you use a urinary catheter?*)

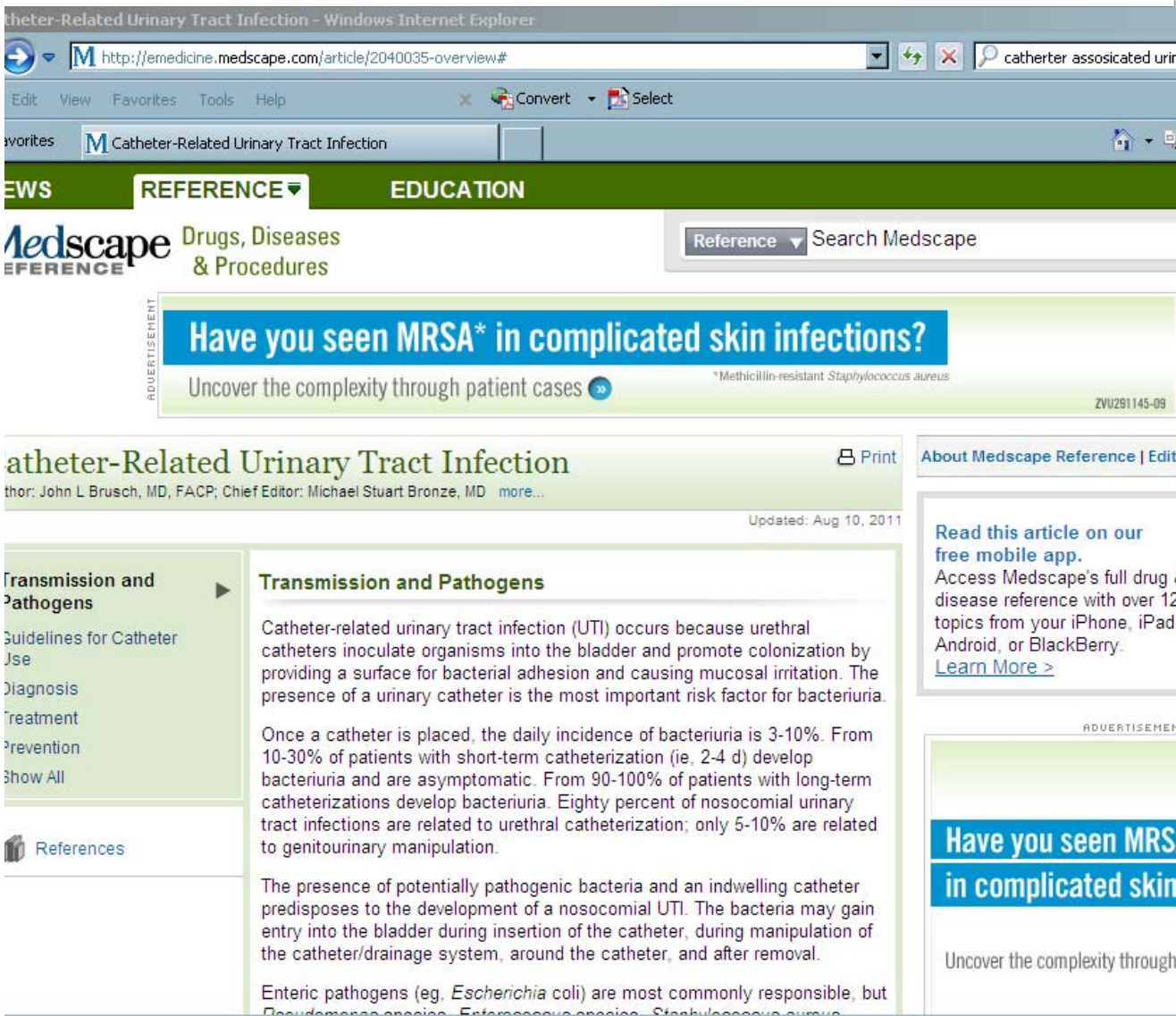
Conducting a pilot study

Once we'd developed the protocol, we implemented it on a medical unit. We compared records of two groups of hospitalized patients who had urinary catheters: those in the hospital 2 weeks before the protocol was implemented and those in the hospital 2 weeks after it was implemented. We found that using the protocol reduced the number of patients with urinary catheters from 35 to 15 and significantly reduced the number of mean catheter days from 8.57 to 4.3. The percentage of patients

Level VII

Evidence from the opinion of authorities and or reports of expert committees

http://emedicine.medscape.com/article/2040035-overview#

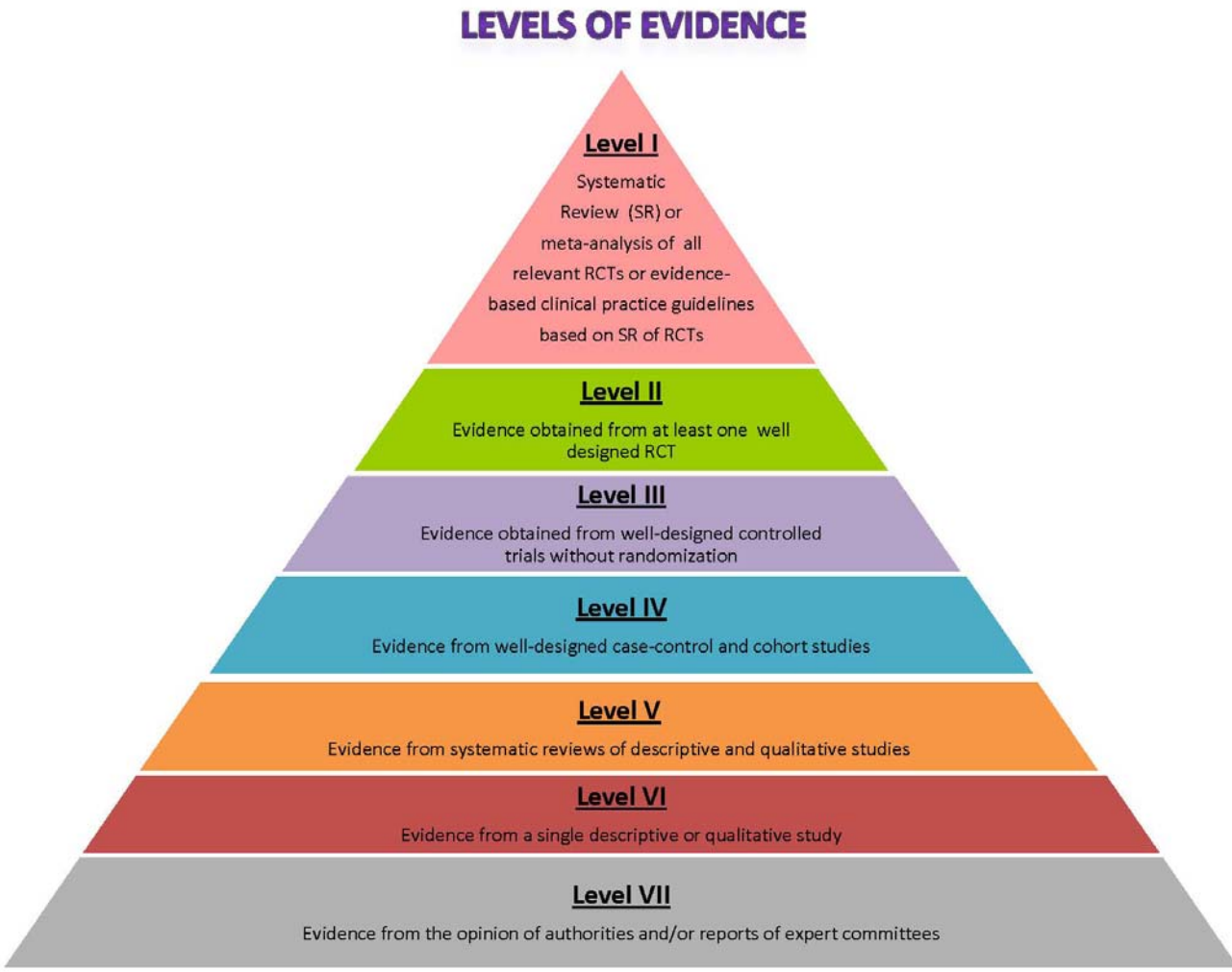


How to use the evidence pyramid

Where in the pyramid is the best evidence found?

Would you use evidence ranked near the base of the pyramid to make a practice change?

Why?
or
Why not?



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For assistance:
Contact the Department for Research and Evidence-Based Practice or
The CVMC Research & EBP Council
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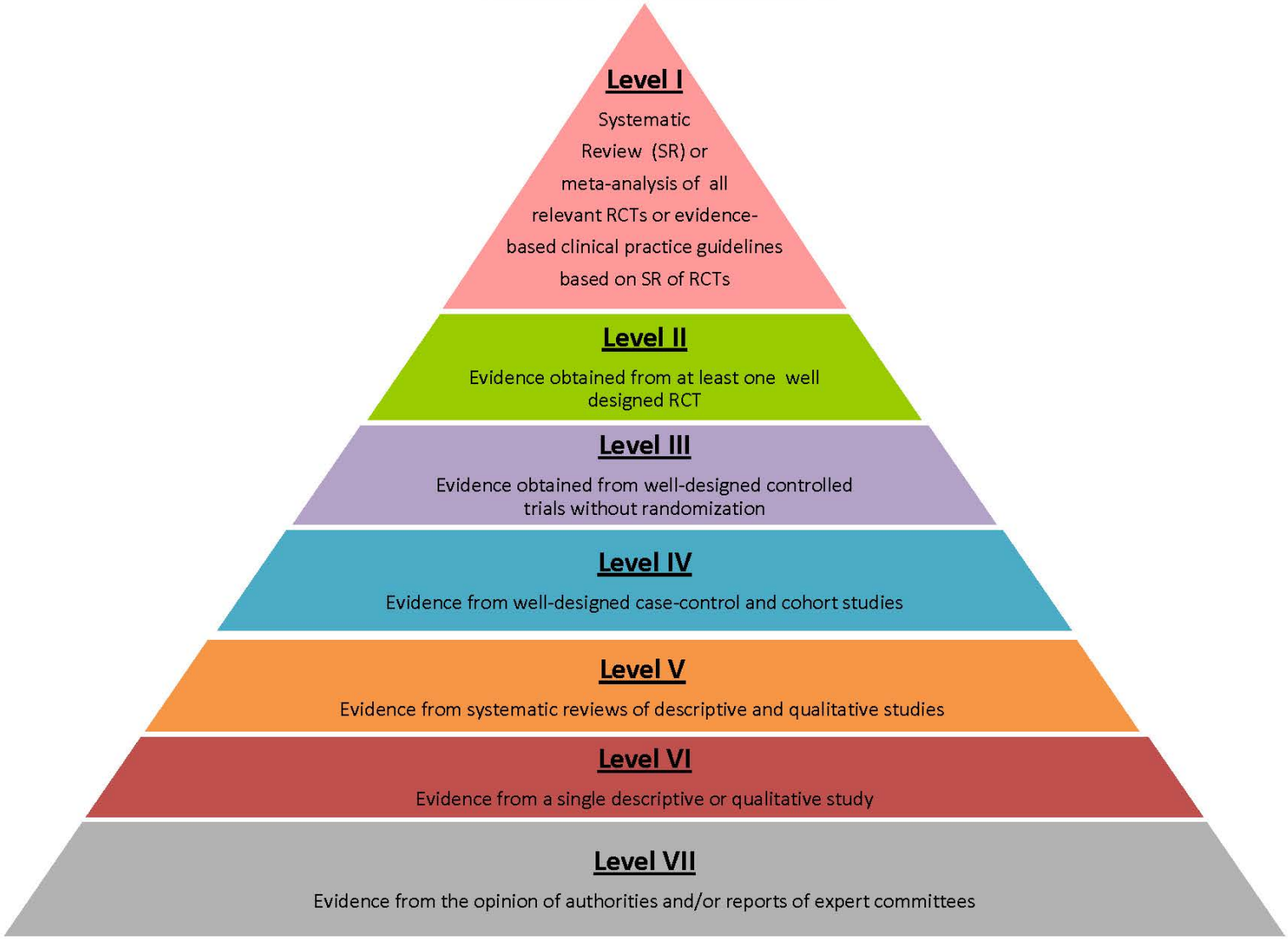
ThankYOU!

LEVELS OF EVIDENCE



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Level ?

WOCN FACT SHEET

Catheter-Associated Urinary Tract Infections

Fact Sheet

Clinical Practice Continence Subcommittee: Diana Parker ■ Laurie Callan ■ Judith Harwood ■ Donna Thompson ■ Marilyn-Lu Webb ■ Mary Wilde ■ Margaret Willson

Prevalence and Incidence

Catheter-associated urinary tract infections (CAUTI) are one of the most frequent infections today:

- The daily risk of developing CAUTI is 3% to 7% in the acute care setting.[1]
- CAUTI comprise 40% of all institutionally acquired infections.[2]
- There is an 8% prevalence of CAUTI in the home care setting.[3]
- There is limited evidence regarding the incidence of CAUTI in long-term suprapubic catheter users compared to urethral catheter users.[4]

The Centers for Medicare & Medicaid Services (CMS) identified hospital-acquired CAUTI as 1 of 8 conditions for which hospitals will not receive additional reimbursement.[5,6] Long-term care facilities also follow the CMS regulatory guidance. In the long-term-care federal regulation (F-315 Tag), the use of urinary catheters must be medically justified and care rendered to reduce the risk of infection for all residents with or without a catheter.[7] The CMS regulations emphasize the complications/risks of CAUTI

- People with catheters acquire bacteriuria at different rates. Incidence of conversion from sterile urine to bacteriuria occurs at the rate of 3% to 10% per day.[20]
- Asymptomatic bacteriuria will be present in virtually every long-term catheter user once the catheter has been in place > 30 days.[20,21]
- Asymptomatic bacteriuria should not be treated in long-term catheter users. Bacteriuria may be treated in selected cases of short-term catheter users such as patients who are immunocompromised, pregnant, or scheduled for urological surgery.[18]

Bacteremia: Blood stream infection

- Approximately 3% of all patients with a catheter will develop bacteremia, which is a serious and possibly life-threatening complication.[22]
- CAUTI is the second most common cause of nosocomial bloodstream infection.[4]

Diagnosis of CAUTI

The diagnosis of CAUTI is based on finding bacteriuria