Complicated Urinary Tract Infections (cUTI): Clinical Guidelines for Treatment and Management

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You are asked to see this patient:

- 80 y/o man with ASIA A paraplegia below T12
- Neurogenic bladder with chronic indwelling Foley
- Temp of 100.1F with rigors
- SOFA score = 2
- No pressors needed (sepsis, without shock)
- Urine cultures within past 12 months
  - *E. coli* and *Klebsiella* resistant to TMP/SMX, cefazolin, and ceftriaxone
  - No fluoroquinolone exposure within the past year
- No allergies or contraindications to any antibiotics

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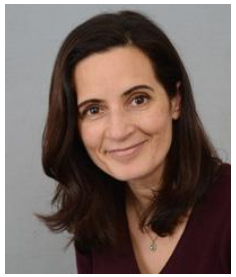

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IDSA Methodology

- Volunteer panel of **19** experts
- GRADE methodology
- **3** clinical questions
- Screened **11,428** articles
- Included **255** studies
- **118** pages of guidelines
- **160** pages of supplemental materials
- *Time to develop*: **4+1 years**
- Included patient representatives
- **Focused on complicated UTI**

GRADE methodology

Population: In patients with complicated UTI
Intervention: Fluoroquinolones for empirical therapy
Comparison: Any Other Abx for empirical therapy
Outcome: Clinical cure

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Fluoroquinolones	Any Other Abx *	Relative (95% CI)	Absolute (95% CI) &		
Clinical cure (at Test-Of-Cure (TOC))												
3[1,2,3]	randomised trials	serious[a]	not serious	not serious	not serious[b]	none	615/697 (88.2%)	682/747 (91.3%)	**RR 0.96** (0.93 to 0.99)	**37 fewer per 1,000** (from 64 fewer to 9 fewer)	⨁⨁⨁◯ Moderate	CRITICAL
Microbiological cure (at TOC)												
3[1,2,3]	randomised trials	serious[a]	not serious[c]	serious[d]	not serious[b]	none	528/696 (75.9%)	587/741 (79.2%)	**RR 0.96** (0.86 to 1.06)	**32 fewer per 1,000** (from 111 fewer to 48 more)	⨁⨁◯◯ Low	IMPORTANT

IDSA reviewers

- IDSA Board of Directors
- IDSA Standards and Practice Guidelines Subcommitee (SPGS)
- IDSA Quality Subcommitee
- Centers for Disease Control
- 3 external reviewers
  - Mac Hooton, Emily Spivak, Bryan Alexander
- 9 societies
  - SIDP, AAFP, SHM, AUA, ASM, SAEM, ACOG, AMMI-CA, ESMID
- Patient representatives
- General public

Initial response to reviews: 89 pages

Clinician areas of controversy

- Definition of uUTI and cUTI
- Scope of the guidelines
- Why we didn’t address diagnosis
- Focus on RCTs
- Role of antibiogram
- Beta-lactams for cUTI
- Fluoroquinolones, aminoglycosides, ceftriaxone

Public comment controversies

- UTI classifications
- Next generation sequencing
- Chronic or embedded UTI
- Scope of the guidelines
- Role of the antibiogram
- Oral antibiotics for cUTI

IDSA cUTI guideline in a nutshell

- New classification of cUTI
  - Includes febrile UTI, pyelonephritis, CAUTI, bacteremic UTI
- Selection of empiric antibiotic therapy for cUTI
  - **Four-step process:** Review (1) severity of illness, (2) risk factors for resistant organisms, (3) patient factors, and (4) antibiogram (only if septic)
  - **Preferred agents (select from remaining options AFTER completing steps above):** third- or fourth-generation cephalosporins, carbapenems (if septic), piperacillin-tazobactam, or fluoroquinolones
- Route of antibiotic therapy
  - Oral switch recommended versus continuing IV
- Duration of antibiotic therapy
  - 7 days recommended versus longer courses

Choice of empiric agent for cUTI

Condition of the Patient	Preferred	Alternative
Sepsis with or without shock	Third or fourth generation cephalosporins, carbapenems, piperacillin-tazobactam, fluoroquinolones	Novel beta lactam-beta lactamase inhibitors, cefiderocol, plazomicin, or older aminoglycosides
Without sepsis, IV route of therapy	Third or fourth generation cephalosporins, piperacillin-tazobactam, or fluoroquinolones	Carbapenems, newer agents (novel beta lactams-beta lactamase inhibitors, cefiderocol, plazomicin), or older aminoglycosides
Without sepsis, oral route of therapy	Fluoroquinolones or trimethoprim-sulfamethoxazole	Amoxicillin-clavulanate or oral cephalosporins

IDSA & WikiGuideline – Classification

New classifications of uUTI and cUTI

Old Classifications

Uncomplicated UTI: Acute cystitis in afebrile nonpregnant premenopausal women with no diabetes and no urologic abnormalities

Acute Pyelonephritis: Acute kidney infection in women otherwise meeting the definition of uncomplicated UTI above

Complicated UTI: All other UTIs

New Classifications

Uncomplicated UTI: Infection confined to the bladder in afebrile women or men

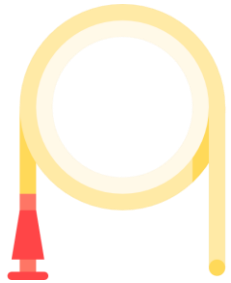
Complicated UTI: infection beyond the bladder in women or men

- Pyelonephritis
- Febrile or bacteremic UTI
- Catheter-associated (CAUTI)
- Prostatitis* (*not covered by these guidelines)

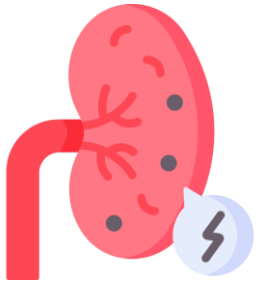
IDSA Classification of cUTI and uUTI

Areas of controversy

What about…



CAUTI



Stones

Prostate

IDSA treatment approach

Step 1

- **Consider severity of illness:**
  - Sepsis with shock, sepsis without shock, no sepsis

Step 2

- **Evaluate patient-specific risk factors for resistant organisms:**
  - Avoid antibiotics to which patient has had resistant pathogen previously isolated
  - Avoid fluoroquinolones (FQ) if patient exposed to FQ in past 12 months

Step 3

- **Assess other patient-specific factors:**
  - Risk of allergic reaction, contraindications, drug–drug interactions

Step 4

- **If septic use antibiogram to tailor empiric therapy:**
  - Consider at least 90% susceptibility threshold for sepsis with shock
  - Consider at least 80% susceptibility threshold for sepsis without shock
  - Patients not septic have lower (<5%) risk of mortality and initial inappropriate empiric choice has little impact on mortality

Severity of illness

Step 1: Assess severity of illness: Is the patient in sepsis (+/- shock)?

- Narrower margin for error in sepsis
- More emphasis on stewardship in absence of sepsis

Risk factors for resistant organisms

Step 2: Evaluate risk factors for uropathogens resistant to specific antimicrobial agents:

- Review urine cultures in prior 12 months; avoid empiric treatments to which recent uropathogens have been resistant
- Assess for exposure to fluoroquinolones in past 12mo; avoid empiric FQ if present

Rationale: Observational studies across a range of patient populations consistently identify uropathogen susceptibilities from prior cultures and recent fluoroquinolone exposure as independent predictors of uropathogen resistance in cUTI

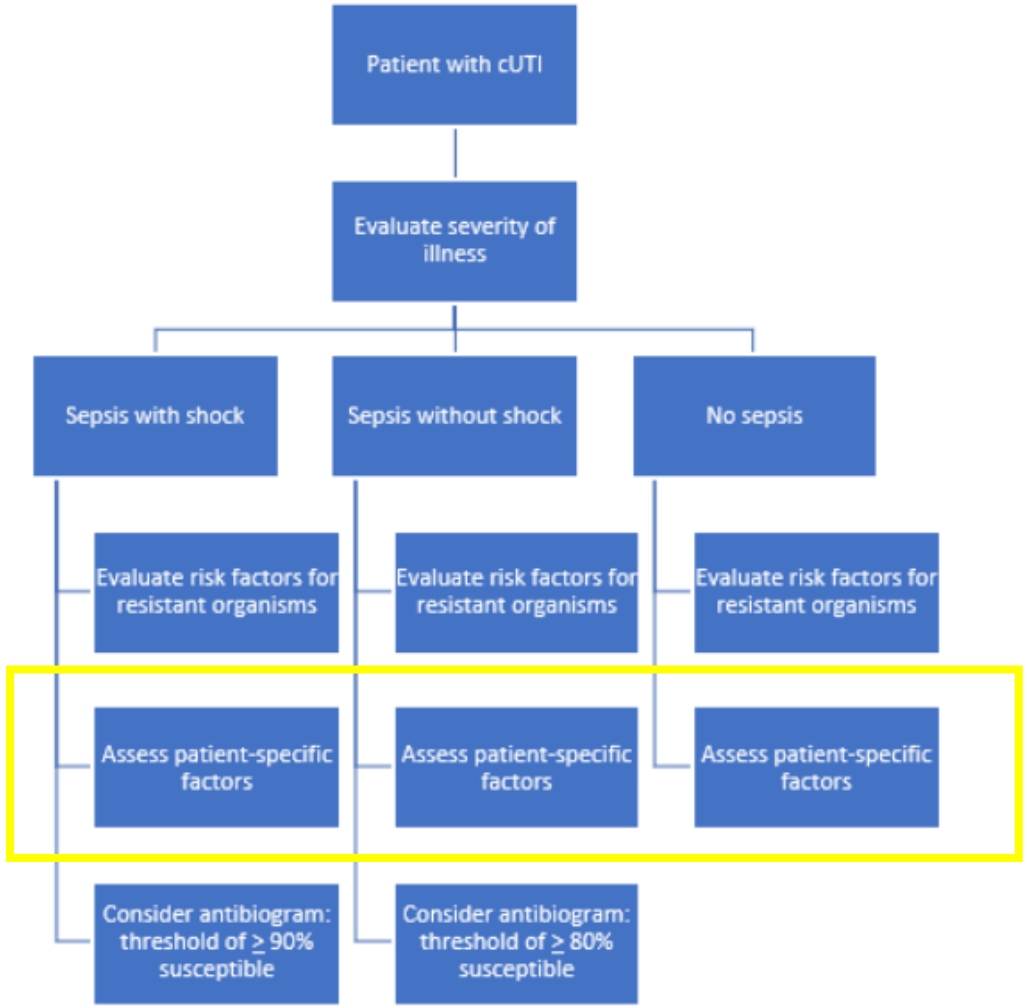
Patient-specific factors

Step 3: Consider patient-specific factors

Avoid empiric treatments that pose undue risk on account of the patient's individualized needs:

- Allergies
- Drug-drug interactions
- Toxicity risk profile (e.g. avoiding aminoglycosides in CKD)
- *C. difficile* infection risk
- Preferred route of delivery & cost

Rationale: Guidelines cannot replace your clinical decision-making for individual patient scenarios

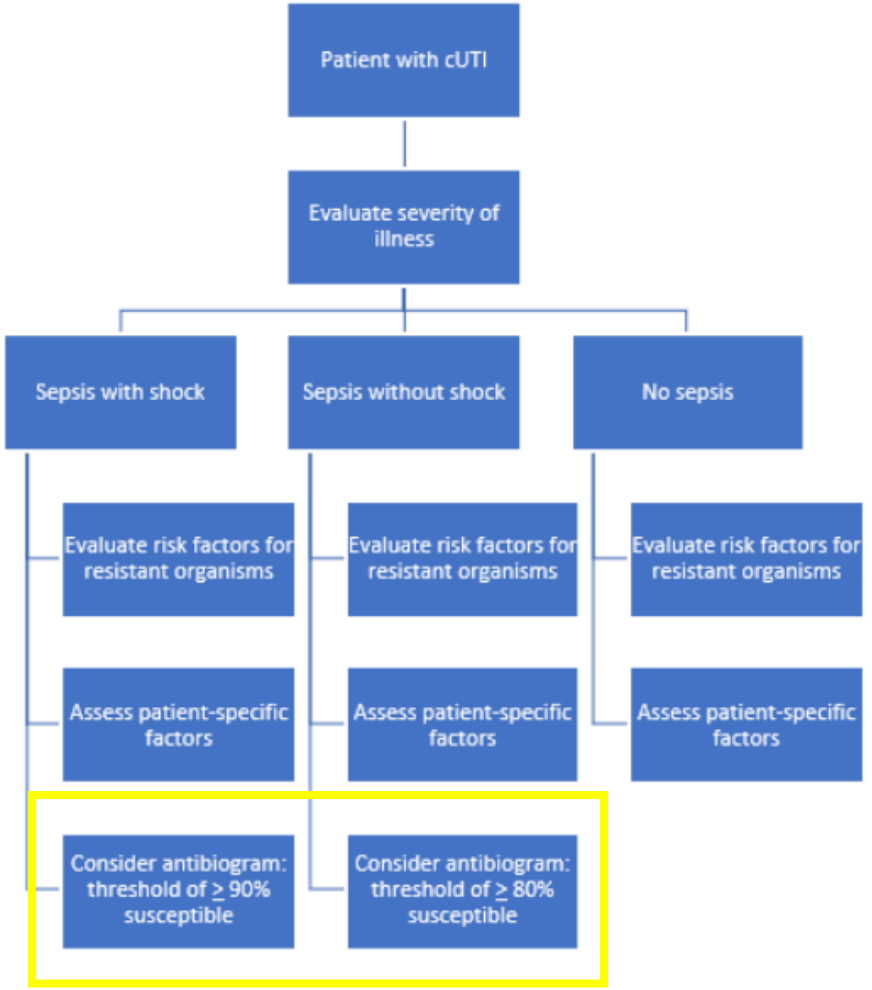


Considering the antibiogram

Step 4 (ONLY in patients with sepsis): Consider the antibiogram

- Limited evidence that antibiograms improve clinical outcomes; may promote overprescribing
- In cUTI, inappropriate empiric antibiotic therapy only modestly impacts mortality due to low baseline mortality risk → likely only relevant for highest-risk pts (i.e. the critically ill)
  - Septic shock: aim for ≥ **90%** susceptibility
  - Sepsis w/o shock: aim for ≥ **80%** susceptibility

Rationale: Modeling identified susceptibility thresholds at which inappropriate therapy would contribute >1% excess mortality, which the panel deemed unacceptable



Let's apply the 4 steps to our patient:

- 80 y/o man with ASIA A paraplegia below T12
- Neurogenic bladder with chronic indwelling Foley
- Temp of 100.1F with rigors
- SOFA score = 2 (STEP 1)
  - No pressors needed (sepsis, without shock)
- Urine cultures within past 12 months (STEP 2)
  - *E. coli* and *Klebsiella* resistant to TMP/SMX, cefazolin, and ceftriaxone
- No fluoroquinolone exposure within the past year (STEP 2)
- No allergies or contraindications to any antibiotics (STEP 3)

Applying the antibiogram (step 4)

Susceptibilities:	Levofloxacin	Ceftriaxone	Ertapenem	Ceftazidime-Avibactam	Amikacin
E. coli	82%	85%	90%	95%	99%

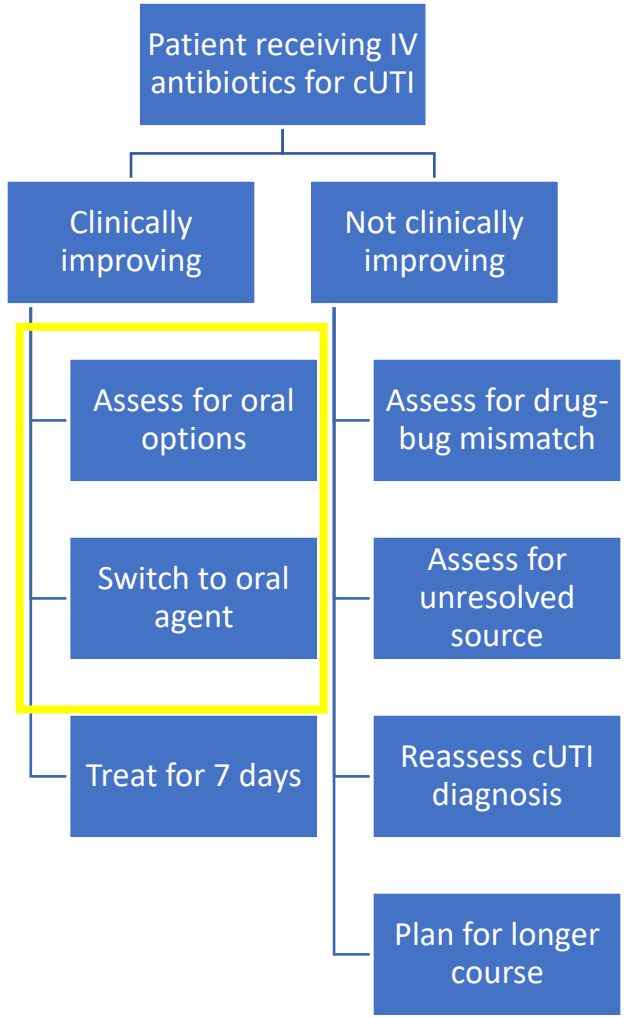
- Consider the source of the antibiogram isolates
- Consider how recent the antibiogram is
- For sepsis without shock, the target is at least 80% susceptibility
- Best choices for this patient with sepsis, no shock
  - Levofloxacin
  - Ertapenem
  - (Prior organism was ceftriaxone resistant)
  - Other choices are less preferred

Urine grew ESBL+ *E. coli*, treated with ciprofloxacin

Using oral antibiotics

Question 2: IV to PO switch for cUTI

In patients with cUTI (including those with pyelonephritis and/or associated GNR bacteremia) treated initially with IV therapy who are now clinically improving, able to take oral medications, and have an appropriate oral option, **we suggest transitioning to oral antibiotics rather than continuing IV antibiotics**

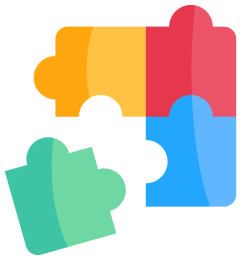


Using oral antibiotics – PK/PD

Table 1.2: Dosing of oral antibiotics for complicated UTI (in alphabetical order)			
Drugs	**Oral absorption (%)**	**Urinary excretion (%)**	**Dose for patients with normal renal function**
Amoxicillin-clavulanate	80 (amoxicillin)[22] variable (clavulanate)[23]	50-70 (amoxicillin)[22] 25-40% (clavulanate)[22]	875mg-125mg every 8 to 12 hours[24-32] Other regimens may be more effective[a]
Cefixime	50[33]	50[33]	400mg once daily[34]
Cefpodoxime	50[33]	80[33]	200mg to 400mg every 12 hours[31,35,36]
Ceftibuten	75-90[33]	73[33]	9mg/kg daily (children)[b] 400mg daily or 200mg every 12 hours (adults)[37,38]
Cefuroxime	52[33,39]	90[33,39]	500mg every 12 hours[31,40]
Cephalexin	90[33]	90[33]	500mg to 1000mg every 6 hours[24-29,32,41,42] Other regimens may be more effective[a]
Ciprofloxacin	70[43]	40-50[43]	500mg to 750mg every 12 hours [28,31,41,44,45]
Levofloxacin	99[46]	64-100[46]	500mg to 750mg daily[19,36,41,45]
Other oral beta-lactams (e.g. amoxicillin, cefadroxil, cefaclor, cefdinir)	Comparative clinical outcomes data vs highly bioavailable oral alternatives are more limited and/or discouraging; consider use with infectious disease pharmacist consultation if alternatives are not available.		
Trimethoprim-sulfamethoxazole	70-90[47]	84 (sulfamethoxazole), 66 (trimethoprim)[47]	800mg-160mg every 12 hours[31,44]

Most observational studies seeking to define relationship between antimicrobial selection and outcomes in GN-BSI **compare "high bioavailability" agents versus "low bioavailability" agents**.

Using oral antibiotics – PK/PD



Bioavailability is only one piece of the puzzle…

Patient | MIC | [antibiotic] | Half-life

Table 22. Pharmacokinetic comparison between oral cephalosporins with varying bioavailability and likelihood of target attainment when used for Gram-negative bacteremia.[453]

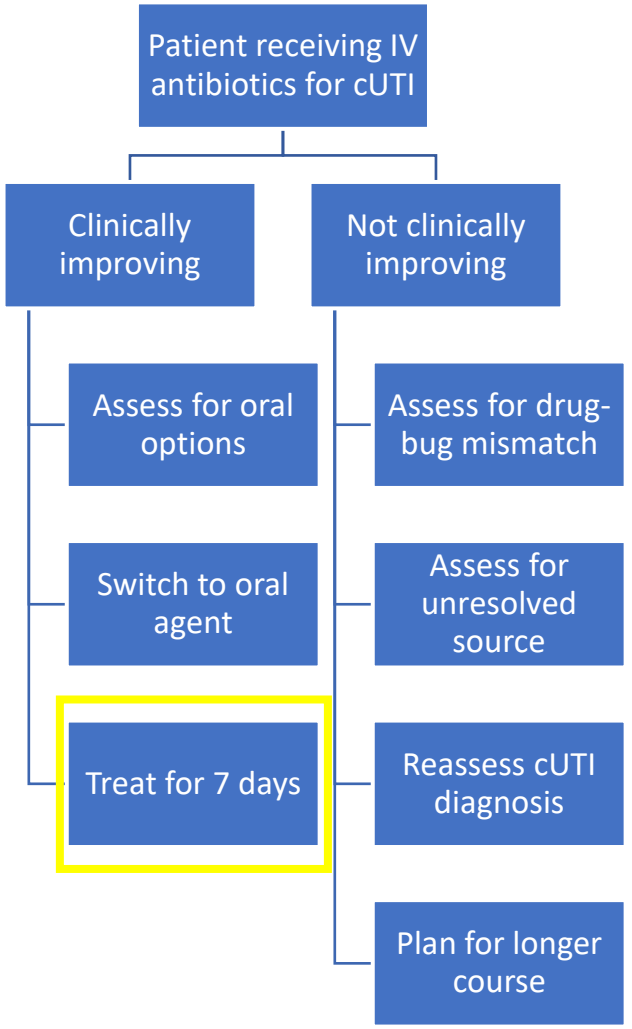
	Cefprozil	Cefpodoxime
Bioavailability	94% (high)	30-50% (low-medium)
Plasma C_{max}	18.3 mcg/mL (1,000 mg)	3.8 mcg/mL (400 mg)
Half-life	1.2 hours	2.7 to 4.2 hours
Reported MIC_{90} vs. *Escherichia coli*	8 mcg/mL	1 mcg/mL
Estimated %fT>MIC_{90} (goal: 60-70% for cephalosporins vs. Gram-negative organisms)	Dosed 500 mg twice daily: **Approximately 12%**	Dosed 400 mg twice daily: **Approximately 50%**

In many existing studies, oral β lactam selection and dosing is suboptimal

Duration of treatment

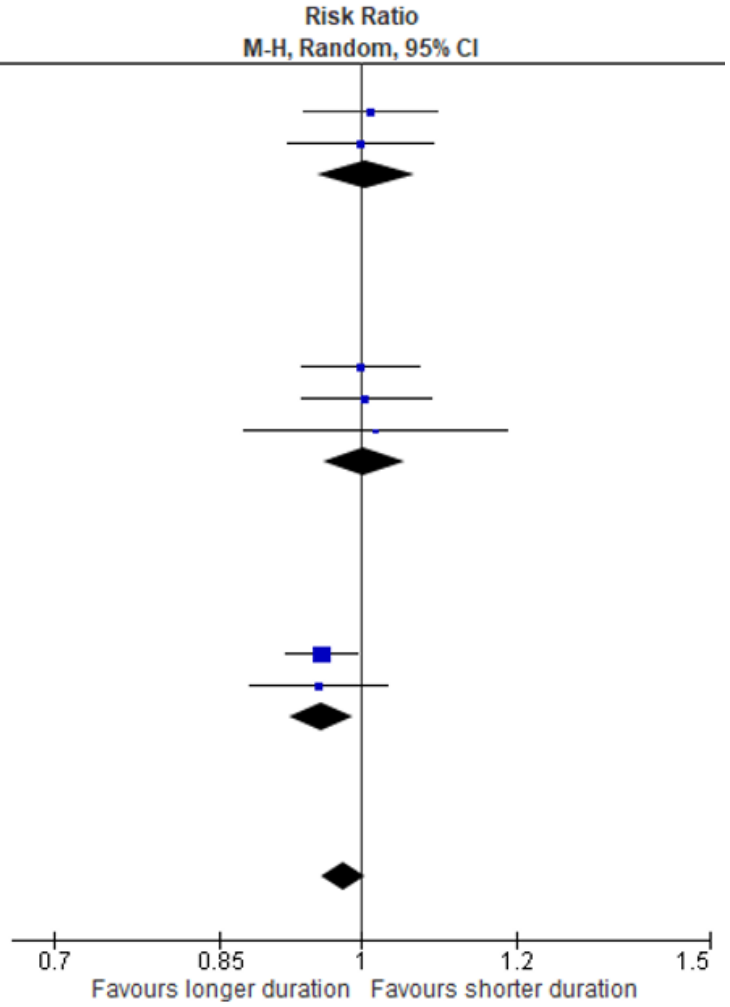
In patients with cUTI (including those with pyelonephritis and/or associated GNR bacteremia) who are clinically improving on effective therapy, we suggest treating with a shorter course of antibiotics (7 days) rather than a longer course (10-14 days)

- Moderate-certainty evidence supports as little as 5 days of therapy for cUTI if a FQ is used
- Men with febrile UTI in whom acute bacterial prostatitis is suspected might benefit from larger durations (e.g. 10-14 days)



Treatment of cUTI: Caution with shorter in men

Study or Subgroup	Shorter duration Events	Total	Longer duration Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
8.1.1 Exclusion criteria: Acute Bacterial Prostatitis was excluded						
Peterson 2008	257	317	242	302	11.5%	1.01 [0.94, 1.09]
Rudrabhatla 2018	22	22	23	23	9.6%	1.00 [0.92, 1.09]
Subtotal (95% CI)		**339**		**325**	**21.1%**	**1.01 [0.95, 1.07]**
Total events	279		265			
Heterogeneity: Tau² = 0.00; Chi² = 0.06, df = 1 (P = 0.80); I² = 0%						
Test for overall effect: Z = 0.22 (P = 0.83)						
8.1.2 No exclusion criteria based on presence or absence of Acute Bacterial Prostatitis						
Darouiche 2014	28	28	27	27	14.2%	1.00 [0.93, 1.07]
Ren 2017	142	158	142	159	12.2%	1.01 [0.93, 1.08]
Wagenlehner 2018	51	64	101	129	2.9%	1.02 [0.87, 1.19]
Subtotal (95% CI)		**250**		**315**	**29.4%**	**1.00 [0.96, 1.05]**
Total events	221		270			
Heterogeneity: Tau² = 0.00; Chi² = 0.08, df = 2 (P = 0.96); I² = 0%						
Test for overall effect: Z = 0.18 (P = 0.86)						
8.1.3 Inclusion criteria: Acute Bacterial Prostatitis was included						
Lafaurie 2023	110	115	125	125	38.8%	0.96 [0.92, 1.00]
van Nieuwkoop 2017	85	94	94	99	10.7%	0.95 [0.88, 1.03]
Subtotal (95% CI)		**209**		**224**	**49.5%**	**0.96 [0.92, 0.99]**
Total events	195		219			
Heterogeneity: Tau² = 0.00; Chi² = 0.01, df = 1 (P = 0.92); I² = 0%						
Test for overall effect: Z = 2.40 (P = 0.02)						
Total (95% CI)		**798**		**864**	**100.0%**	**0.98 [0.95, 1.01]**
Total events	695		754			
Heterogeneity: Tau² = 0.00; Chi² = 4.71, df = 6 (P = 0.58); I² = 0%						
Test for overall effect: Z = 1.49 (P = 0.14)						
Test for subgroup differences: Chi² = 3.60, df = 2 (P = 0.17), I² = 44.4%						



Re-centering on why we are here

Patient perspectives on chronic UTI

- Chronic UTI sufferers experience **debilitating symptoms** that negatively impact their quality of life
- Chronic UTI is caused by **insufficient antibiotic treatment upon initial acute infection** (wrong choice, wrong route of delivery, and/or wrong duration).
- **Longer courses of antibiotic therapy are needed** for subsequent bouts of acute UTI
- Healthcare providers should **listen to the patient's perspective** on UTI symptoms

Ending remarks

We still have lots to learn about one of the most common infections we see!

Is everything “clear” now?

Questions or discussion

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Bonus slides begin here

Impact of inappropriate empiric antimicrobial therapy (IEAT) on cUTI mortality

Search strategy

Criteria for inclusion:

- Studies of patients with cUTI (most populations with severe illness)
- Studies comparing rates of mortality with IEAT vs AEAT
    - "appropriateness" refers to in vitro susceptibility
    - "empirical" refers to the 48-72h before susceptibility testing is available
- **Studies reporting IEAT adjusted ratios for mortality (aOR or aHR)**

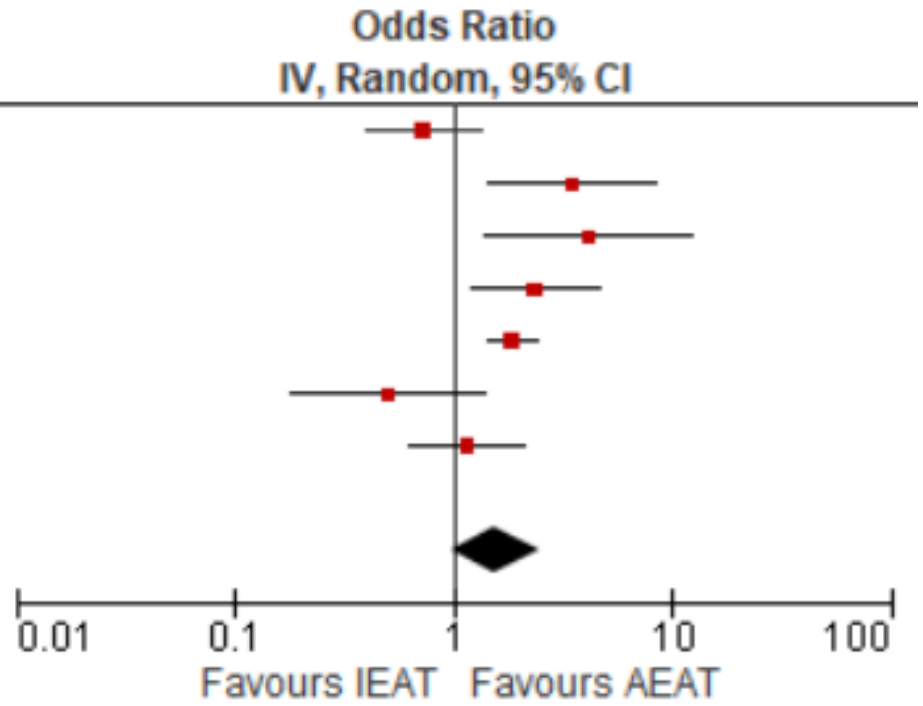
Key premise: We deemed an unacceptable rate of resistance to be one in which IEAT contributes >= 1% increase in mortality for cUTI patients hospitalized with sepsis and/or septic shock

Modeling impact of IEAT on cUTI mortality: adjusted ORs for the seven included studies

Study or Subgroup	log[Odds Ratio]	SE	Weight	Odds Ratio IV, Random, 95% CI
Babich 2017	-0.3285	0.30895	15.9%	0.72 [0.39, 1.32]
Esparcia 2014	1.24415	0.45588	12.0%	3.47 [1.42, 8.48]
Holmbom 2022	1.4327	0.55626	9.8%	4.19 [1.41, 12.47]
Korkmaz 2020	0.85866	0.345	14.9%	2.36 [1.20, 4.64]
Ortega 2013	0.62058	0.12754	20.8%	1.86 [1.45, 2.39]
Rigolt 2020	-0.69315	0.51401	10.7%	0.50 [0.18, 1.37]
Wiggers 2019	0.1484	0.3108	15.9%	1.16 [0.63, 2.13]
Total (95% CI)			**100.0%**	**1.56 [0.99, 2.46]**

Heterogeneity: Tau² = 0.25; Chi² = 21.31, df = 6 (P = 0.002); I² = 72%

Test for overall effect: Z = 1.90 (P = 0.06)



Modeling impact of IAET on cUTI in the setting of sepsis without shock (baseline ~10% mortality)

Sepsis without shock in cUTI: baseline 10% in-hospital mortality	5% Resistance		10% Resistance		15% Resistance		20% Resistance		25% Resistance	
	IEAT (NS)	AEAT (S)	IEAT (NS)	AEAT (S)	IEAT (NS)	AEAT (S)	IEAT (NS)	AEAT (S)	IEAT (NS)	AEAT (S)
	0.05* 10.0* 1.56	0.95* 10.0	0.1* 10.0* 1.56	0.9* 10.0	0.15* 10.0* 1.56	0.85* 10.0	0.20* 10.0* 1.56	0.80* 10.0	0.25* 10.0* 1.56	0.75* 10.0
	0.8	9.5	1.6	9.0	2.34	8.5	3.1	8.0	3.9	7.5
Total mortality given this resistance rate	**10.3%**		**10.6%**		**10.8%**		**11.1%**		**11.4%**	
							+ 1 death per 100 cUTI as compared to baseline of 10%			

Modeling impact of IAET on cUTI in the setting of septic shock (baseline ~20% mortality)

Septic shock in cUTI: baseline 20% in-hospital mortality	5% Resistance		10% Resistance		15% Resistance		20% Resistance		25% Resistance	
	IEAT (NS)	AEAT (S)	IEAT (NS)	AEAT (S)	IEAT (NS)	AEAT (S)	IEAT (NS)	AEAT (S)	IEAT (NS)	AEAT (S)
	0.05* 20.0* 1.56	0.95* 20.0	0.1* 20.0* 1.56	0.9* 20.0	0.15* 20.0* 1.56	0.85* 20.0	0.20* 20.0* 1.56	0.80* 20.0	0.25* 20.0* 1.37	0.75* 20.0
	1.6	19.0	3.1	18.0	4.7	17.0	6.2	16.0	7.8	15.0
Total mortality given this resistance rate	**20.6%**		**21.1%**		**21.7%**		**22.2%**		**22.8%**	
			+ 1 death per 100 cUTI as compared to baseline of 20%							

Strong risk factors of resistance to a specific antibiotic class

Risk factors	aORs of resistance	Timing
Risk factors for fluoroquinolone resistance		
Prior exposure to fluoroquinolones	4.62 (1.09-19.61) 15.73 (6.15-40.26) 30.35 (5.82-158.42)	Prior month (3 different studies)
	23.35 (8.20-76.85)	Prior 3 months
	21.8 (3.7 – 127.1)	Prior 6 months
	7.6 (2.1-27.5) 13.16 (3.11-68.43)	Prior 12 months
	1.95 (1.66 – 2.28)	Unclear

Weak risk factors of resistance to a specific antibiotic class

Risk factors	aORs of resistance	Timing
Healthcare exposure	Nursing home	
	1.93 (1.22 – 3.07)	Current
	2.80 (1.02-7.25)	Current
	4.41 (1.79-10.88)	Current
	Hospitalisation	
	2.0 (1.0-3.9)	Each prior week of hospitalisation
	2.19 (1.31-3.64)	Prior 2 weeks
	3.99 (2.38-16.30)	Prior 3 months
	0.97 (0.87 – 1.09)	Past year
	Nosocomial	
	2.56 (1.31-5.02)	Prior 3 months
Risk factors for TMP/SMX resistance		
Prior exposure to TMP/SMX	2.36 (1.94-2.88)	Unclear
	2.58 (1.13-5.89)	Prior 12 months

Prior urine culture and risk of current resistance

Antibiotics	aORs of resistance (range)	Interval between cultures
Fluoroquinolones	-If one prior culture Cipro-R: 5.51 (3.33-9.16) to 12.8 (8.5-19.0) -If 2 or more prior culture Cipro-R: 6.1 (2.73-14.08) to 28.4 (13.2-60.7)	Up to 6 years
Third generation cephalosporins	-If one prior culture C3-R: 21.7 (7-69.2) -If 2 or more prior culture C3: 32.5 (5.06-126.4)	Up to 6 years
TMP/SMX	-If one prior culture in the last 12 months TMP/SMX-R: 8.58 (3.92-18.81)	Last 12 months
	-If one prior culture TMP/SMX-R: 4.7 (3.5-6.5) to 4.78 (2.87-8.07) -If 2 or more prior culture TMP/SMX-R: 5.4 (3.1-9.4) to 6.66 (2.85-17)	Up to 6 years

Definitions of complicated UTI

UTI WikiGuideline	IDSA cUTI	Previous IDSA	EAU	AUA/CUA/SUFU
More precise terminology is strongly encouraged; reasonable to lump pyelonephritis, febrile, or bacteremic UTI together given similar treatment principles	**Any infection that extends beyond the bladder** (e.g., pyelonephritis, CAUTI, febrile or bacteremic UTI)	Urinary symptoms **PLUS** Functional or structural abnormalities of the GU tract✸	Urinary symptoms **PLUS** Functional or structural abnormalities of the GU tract✸ **AND/OR** Presence of diabetes or immune compromise	Urinary symptoms **PLUS** Functional or structural abnormalities of the GU tract✸ **AND/OR** Presence of diabetes or immune compromise **AND/OR** MDRO

✸ *Includes all biological males*

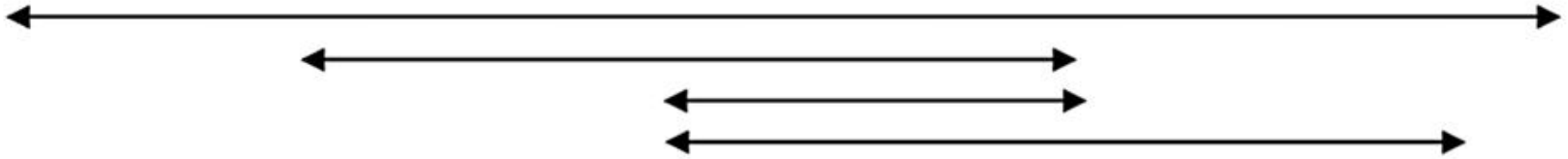
Additional definitions are recommended by FDA and EMA for inclusion in UTI clinical research studies

IDSA: Infectious Diseases Society of America
EAU: European Association of Urology
AUA: American Urological Association
CUA: Canadian Urological Association
SUFU: Society of Urodynamics, Female Pelvic Medicine, and Urogenital Reconstruction

Prostatitis impacts duration of treatment in men

Study	**Males included** *(No, %)*	**Prostatitis/ epididymitis**	**Relative estimate of clinical cure in the whole population (short vs. long)**
Peterson 2008	**427 (39%)**	Excluded	RR 1.05 (0.97-1.14)
Rudrabhatla 2018	24 (41%)	Excluded	RR 1.00 (0.92 to 1.09)
Darouiche 2014	52 (95%)	NR	RR 1.00 (0.93 to 1.07)
Ren 2017	40 (15%)	NR	RR 1.01 (0.93 to 1.08)
Wagenlehner 2018	40 (18%)	NR	RR 1.09 (0.96 to 1.23)
Lafaurie 2023 PROSTA-SHORT	240 (100%)	Included	RR 0.96 (0.92 to 1.00)
van Nieuwkoop 2017 FUTIRST	86 (43%)	Included	RR 0.95 (0.88 to 1.03)

The Continuum of UTI



	No detectable bladder bacteriuria	Asymptomatic Bacteriuria	Subclinical UTI	Symptomatic UTI
Pyuria	+/–	+/-	+/-	+/-
Urinary Symptoms	–	–	+	++
Bacteriuria	–	+	+	+

Trautner, Clin Infect Dis, 2020

IDSA & WikiGuidelines – Duration

Both the IDSA and WikiGuideline drive home these important points re: duration…

Additional research is needed!!!

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Patients with febrile UTI, pyelonephritis, CAUTI, and Gram-negative bacteremia likely lie on a **spectrum**

As few as **5** days?

As long as **14 or more** days?