

IDSA 2025 Guideline Updates for Complicated Urinary Tract Infections

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Alex Hodge, PharmD
PGY2 Resident, Infectious Diseases
HCA Healthcare



Isabelle Price, PharmD
PGY1 Resident, Managed Care
HCA Healthcare

Preceptor: Nickie Greer, PharmD, BCPS, BCIDP

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Objectives

Recall the rationale for the development of new guidelines and classifications for urinary tract infections (UTIs) from the Infectious Diseases Society of America (IDSA).

Identify updated recommendations for treatment selection for complicated UTIs based on IDSA guidelines.

Recognize clinical evidence for newly approved intravenous antibiotics for the treatment of complicated UTIs.

Purpose

Previous guidelines focused on uncomplicated cystitis and pyelonephritis in women

- With an aging US population, the risk of UTI in men is nontrivial
- Several randomized, controlled trials now assess complicated UTI in women and men

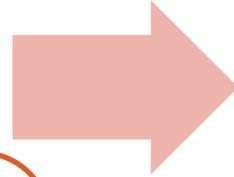
Gram-negative urinary organisms now have antimicrobial resistance rates above the thresholds for antibiotics recommended in previous guidelines

- Need for re-evaluation to guide empiric choice of antibiotics

UTI Definition Updates

Old Classifications

- **Uncomplicated UTI (uUTI)**
 - 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
- **Complicated UTI (cUTI)**
 - 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 bacteriemic UTI, catheter-associated UTI (CAUTI), prostatitis (not applicable in these guidelines)

UTI Classifications for Directed Therapy

Uncomplicated UTI

- **Presentation**
 - Localized bladder signs (dysuria, urgency, frequency, suprapubic pain)
 - No signs of systemic infection
- **Population**
 - Female or male, urologic abnormalities, immunocompromise, diabetes
 - Recurrent UTI can be uncomplicated

Complicated UTI

- **Presentation**
 - Signs of systemic infection (fever, chills, hemodynamic instability, flank pain costovertebral angle tenderness)
- **Population**
 - Female or male, urologic abnormalities, immunocompromise, diabetes
 - Indwelling catheter, neurogenic bladder, urinary obstruction or retention

***These guidelines do not apply to bacterial prostatitis, epididymitis, or orchitis**

Assessment Question 1

Which of the following is not included in the new classification of a complicated UTI?

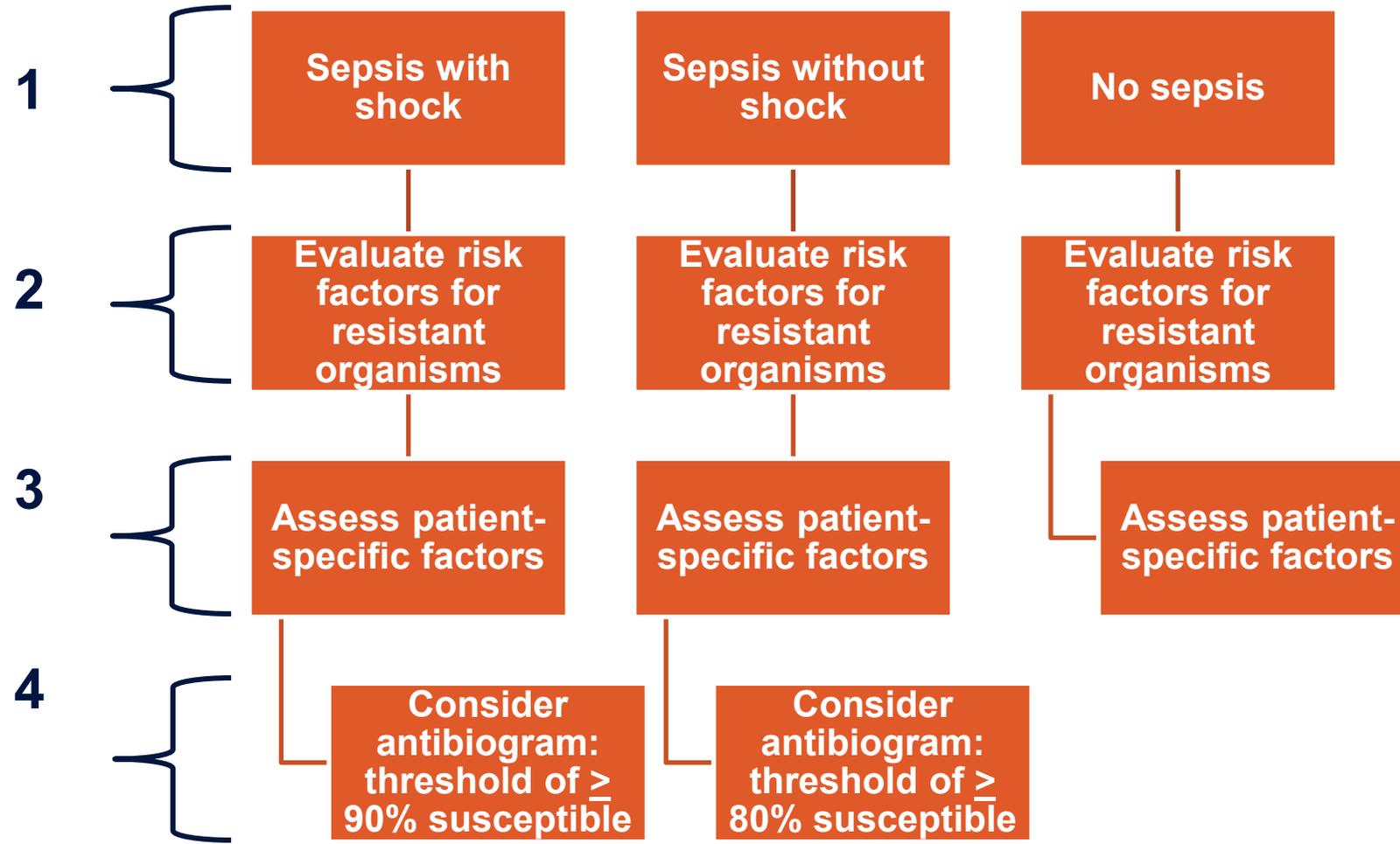
- a. Catheter-associated UTI
- b. Pyelonephritis
- c. Prostatitis
- d. Urosepsis in men

Assessment Question 1: Correct Response

Which of the following is not included in the new classification of a complicated UTI?

- a. Catheter-associated UTI
- b. Pyelonephritis
- c. Prostatitis
- d. Urosepsis in men

Four-step Approach of Antibiotic Selection



Step 1: Severity of Illness

Empiric antibiotic therapy guided by the severity of illness

- Patients with sepsis have increased risk of mortality (>10%)
- Higher value placed on appropriate therapy versus stewardship in septic patients
- Sepsis is identified by SOFA score increase of ≥ 2 points, or presumptively identified with screening tools such as SIRS or quick SOFA (qSOFA)

Step 2: Evaluate Risk Factors for Resistance

Suggest avoiding antibiotics to which a previous urinary pathogen was resistant

- More recent cultures may better guide therapy vs more distant urine cultures
- Median time frame for paired cultures was 3-6 months in referenced trials

Suggest avoiding fluoroquinolones if patient was exposed in the past 12 months

- More recent antibiotic exposure may better guide therapy vs more distant exposure

Step 3: Assess Patient Specific Factors

Account for patient-specific considerations to avoid preventable adverse events

- Allergic reactions (assess true allergies)
- Contraindications (comorbidities)
- Drug-drug interactions

Step 4: Consider Antibigram

Septic patients: suggest using an antibiogram ONLY IF local, recent, and relevant to the patient

- Local: same healthcare facility
- Recent: based on data from the prior 12 months
- Relevant: based on organisms from a similar patient population
- Consider antibiotic selection with $\geq 90\%$ sensitivity in septic shock and $\geq 80\%$ sensitivity in sepsis without shock

No recommendation of antibiogram use in non-septic patients

***Escherichia coli (E. coli)* is the default organism unless prior urine culture data is available**

Assessment Question 2

Which of the following was a consideration for the development of new guidelines for complicated urinary tract infections?

- a. To separate pyelonephritis from other cUTIs
- b. Inclusion of men in recent randomized controlled trials
- c. Resistance patterns decreasing since previous guideline publication
- d. None of the above

Assessment Question 2: Correct Response

Which of the following was a consideration for the development of new guidelines for complicated urinary tract infections?

- a. To separate pyelonephritis from other cUTIs
- b. Inclusion of men in recent randomized controlled trials
- c. Resistance patterns decreasing since previous guideline publication
- d. None of the above

Assessment Question 3

What factors are recommended to consider when evaluating an antibiogram?

- a. Data is based on the prior 12 months
- b. Data is derived from the same healthcare facility
- c. Data is relevant to the patient
- d. All of the above

Assessment Question 3: Correct Response

What factors are recommended to consider when evaluating an antibiogram?

- a. Data is based on the prior 12 months
- b. Data is derived from the same healthcare facility
- c. Data is relevant to the patient
- d. All of the above

Preferred Empiric Antibiotic Therapy for cUTI

Sepsis with or without shock

- Third or fourth generation cephalosporins, piperacillin-tazobactam, fluoroquinolones, carbapenems

Without sepsis, IV route

- Third or fourth generation cephalosporins, piperacillin-tazobactam, fluoroquinolones

Without sepsis, oral route

- Trimethoprim-sulfamethoxazole or fluoroquinolones

Alternative Empiric Antibiotic Therapy for cUTI

Sepsis with or without shock

- Aminoglycosides, novel beta lactam-beta lactamase inhibitors, or cefiderocol

Without sepsis, IV route

- Aminoglycosides, carbapenems, or novel beta lactam-beta lactamase inhibitors

Without sepsis, oral route

- Amoxicillin-clavulanate or oral cephalosporins

Empiric IV Antibiotic - Cephalosporins

Drug	Dosing	Indication	Formulary Status
Ceftriaxone	1-2 g IV daily*	First-line	F
Cefepime	1-2 g IV q8-12h* PD dosing: 1 g IV q6h or 2 g IV q8h	History of <i>P. aeruginosa</i>	F
Cefiderocol	2 g IV q8h (over 3 hours)*	DTR GNR	NF/NFR

*Doses used in clinical studies as noted in guideline

F: formulary

NF: non-formulary

DTR: Difficult to treat

20 | GNR: Gram negative rod

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Source: <https://www.idsociety.org/practice-guideline/complicated-urinary-tract-infections/>

Empiric IV Antibiotic - Penicillins

Drug	Dose	Indication	Formulary Status
Piperacillin-tazobactam	4.5 g IV q8h* PD dosing: 3.375 g IV q8h (over 4 hours)	History of <i>P. aeruginosa</i> (alternative)	F

*Doses used in clinical studies as noted in guideline
21 | F: Formulary

Empiric IV Antibiotic - Carbapenems

Drug	Dosing	Indication	Formulary Status
Meropenem	1 g IV q8h* PD dosing: 500 mg IV q6h (push) or 2 g IV q8h (over 3 hours)	History of ESBL	F
Ertapenem	1 g IV daily*	History of ESBL	NFR/FR

*Doses used in clinical studies as noted in guideline

F: formulary

NF: non-formulary

FR: formulary restricted

NFR non-formulary restricted

Empiric IV Antibiotic - Novel Beta Lactams

Drug	Dosing*	Indication	Formulary Status
Ceftolozane-tazobactam	1.5 g IV q8h	ESBL; CRE; MDR/DTR GNR	NFR/FR
Meropenem-vaborbactam	2 g/2 g IV q8h (over 3 hours)	ESBL; CRE; MDR/DTR GNR	NFR/FR
Ceftazidime-avibactam	2.5 g IV q8h (over 2 hours)	ESBL; CRE; MDR/DTR GNR	NFR/FR

Doses used in clinical studies as noted in guideline Doses used in clinical studies as noted in guideline

FR: formulary restricted

NFR: non-formulary restricted

MDR: multidrug-resistant

DTR: Difficult to treat

GNR: Gram negative rod

Empiric IV Antibiotic - Aminoglycosides

Drug	Dosing	Indication	Formulary Status
Gentamicin	7 mg/kg IV x1, followed by TDM	Alternative for ESBL GNR	F
Tobramycin	7 mg/kg IV x1, followed by TDM	Alternative for ESBL GNR	F

TDM: Therapeutic Drug Monitoring
ESBL: extended spectrum beta lactamase

24 | GNR: Gram negative rod

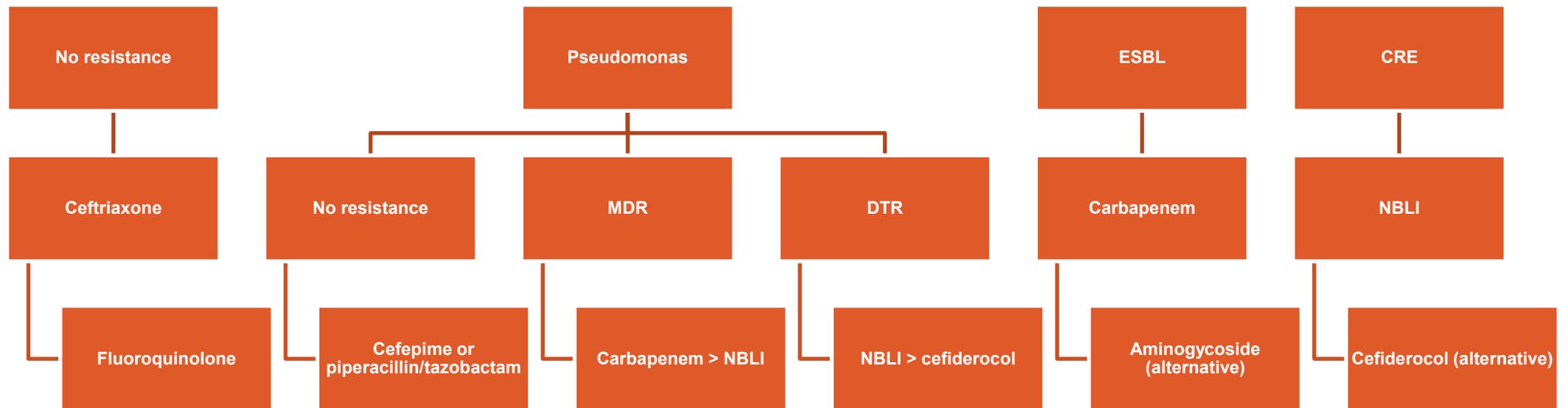
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Empiric IV Antibiotic - Fluoroquinolones

Drug	Dosing	Indication	Formulary Status
Ciprofloxacin	400 mg IV q12h	First line empiric alternative	F
Levofloxacin	750 mg IV daily	First line empiric alternative	F

Example Algorithm with Sepsis



MDR: multidrug-resistant
 DTR: Difficult to treat
 ESBL: Extended spectrum beta lactamase
 CRE: carbapenem resistant Enterobacterales
 NBLI: Novel beta lactamase inhibitor

Selection of Definitive Therapy

Selection of targeted spectrum based on urine culture once results are available

Other considerations

- Route of therapy, costs of treatment, required resources of administration, minimal collateral impact on intestinal microbiota

IV to PO Transition

Patients with cUTI clinically improving, able to take oral medications, with an effective oral option available

- Suggest transition to oral antibiotics for remaining treatment duration
- Supporting literature excluded patients with indwelling urinary catheters, sepsis/septic shock, immunocompromised state, severe renal insufficiency, and functional/structural abnormalities of the urinary tract

Patients with associated gram-negative bacteremia clinically improving, able to take oral medications, and with an effective oral option available

- Suggest transition to oral antibiotics for remaining treatment duration
- Supporting literature included patients who were afebrile, hemodynamically stable, and achieved source control

IV to PO Transition



Dosing of Oral Antibiotic Therapy

Drug	Oral absorption (%)	Urinary excretion (%)	Dose (normal renal function)
Amoxicillin-clavulanate	<ul style="list-style-type: none"> • 80 (amoxicillin) • Variable (clavulanate) 	<ul style="list-style-type: none"> • 50-70 (amoxicillin) • 25-40 (clavulanate) 	875 mg/125 mg q8-12h
Cefuroxime	52	90	500 mg q12h
Cephalexin	90	90	500-1000 mg q6h
Ciprofloxacin	70	40-50	500-750 mg q12h
Levofloxacin	99	64-100	500-750 mg daily
Trimethoprim-sulfamethoxazole	70-90	66 (trimethoprim) 84 (sulfamethoxazole)	800/160 mg q12h

Assessment Question 4

What is a preferred oral option for the treatment of cUTI without sepsis?

- a. Amoxicillin-clavulanate
- b. Cephalexin
- c. Cefdinir
- d. Trimethoprim-sulfamethoxazole

Assessment Question 4: Correct Response

What is a preferred oral option for the treatment of cUTI without sepsis?

- a. Amoxicillin-clavulanate
- b. Cephalexin
- c. Cefdinir
- d. **Trimethoprim-sulfamethoxazole**

Duration of Antibiotic Therapy

Patients with cUTI improving clinically on effective therapy

- Suggest shorter course of therapy rather than longer course (10-14 days)
 - Fluoroquinolone: 5-7 days
 - Non-fluoroquinolone: 7 days

Patients with cUTI with gram-negative bacteremia improving clinically on effective therapy

- Suggest shorter course (7 days) rather than a longer course (14 days)

Summary of Guidelines

Classification uUTI now includes male and female populations

Classification of cUTI now includes any infection beyond the bladder including pyelonephritis

Higher value of appropriate therapy in patients with increased mortality, while higher value of stewardship in patients with lower mortality

Four-step approach for selection of empiric therapy (severity of illness, risk factors of resistance, patient factors, and antibiogram)

Transition to definitive therapy and/or oral antibiotics when appropriate

Shorter duration of therapy is suggested (7 days vs 14 days)

FDA Approval of IV Fosfomicin: October 22, 2025

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Fosfomicin



Mechanism: inhibits bacterial wall synthesis by inactivating pyruvyl transferase enzyme



ADRs: QT prolongation, electrolyte disturbances, transaminase elevation, *Clostridioides difficile* infection



Monitoring: electrolytes, fluid balance, leukocyte count, renal function



Pearl: contains 330 mg sodium per gram of fosfomicin (IV formulation), CLSI breakpoints only listed for *E. coli* and *E. faecalis*, lacks adequate bloodstream and renal parenchyma penetration (PO only)

PO: oral route

36 | CLSI: Clinical & Laboratory Standards Institute

CrCl: creatinine clearance

Dosing in UTIs

- **IV (complicated):** 6 g q8h for up to 14 days
 - CrCl 41-50: 6 g load, 4 g q8h
 - CrCl 31-40: 6 g load, 3 g q8h
 - CrCl 21-30: 6 g load, 5 g q24h
 - CrCl 11-20: 6 g load, 3 g q24h
- **PO (uncomplicated):** 3 g once

Fosfomycin for Injection (ZTI-01) vs. Piperacillin-Tazobactam for the Treatment of Complicated Urinary Tract Infection Including Acute Pyelonephritis: ZEUS, A Phase 2/3 Randomized Trial

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Methods

- Multicenter, randomized, parallel-group, double-blind phase 2/3 trial from May 2016 to January 2017
- Assessed noninferiority of IV fosfomycin versus piperacillin/tazobactam (PIP/TAZ) in cUTI and acute pyelonephritis (AP)
- Primary endpoint: composite of clinical cure and microbiological eradication at test of cure (day 19-21)
- 1:1 randomization to fosfomycin 6 g IV q8h or piperacillin/tazobactam 4.5 g IV q8h for 7 days
 - Patients with CrCl <20 mL/min were excluded
 - Fosfomycin was renally dose adjusted; piperacillin/tazobactam was a fixed dose
 - Those with concomitant bacteremia could receive up to 14 days of therapy
 - No option of switch to oral antibiotics throughout fixed duration

Baseline Characteristics

	Fosfomycin (n = 184)	PIP/TAZ (n = 178)
Age, y, mean (SD)	49.9 (20.92)	51.3 (20.71)
Sex, n (%), Female:Male	119 (64.7):65 (35.3)	111 (62.4): 67 (37.6)
Race, white	184 (100)	178 (100)
Primary diagnosis		
AP	100 (54.3)	96 (53.9)
CUTI	84 (45.7)	82 (46.1)
SIRS at baseline	62 (33.7)	52 (29.2)
Bacteremia at baseline	19 (10.3)	13 (7.3)
CrCl, mL/min, mean (SD)	83.6 (32.85)	84.7 (32.35)
≥20-50 mL/min	26 (14.1)	20 (11.2)

Baseline Characteristics

	Fosfomycin (n = 184)	PIP/TAZ (n = 178)
Gram-negative Enterobacterales	177 (96.2)	169 (94.9)
<i>Escherichia coli</i>	133 (72.3)	133 (74.7)
<i>Klebsiella pneumonia</i>	27 (14.7)	25 (14.0)
<i>Enterobacter cloacae</i> complex	9 (4.9)	3 (1.7)
<i>Proteus mirabilis</i>	9 (4.9)	5 (2.8)
<i>Klebsiella oxytoca</i>	3 (1.6)	2 (1.1)
<i>Citrobacter amalonaticus/farmeri</i>	1 (.5)	0
Gram-negative non-Enterobacterales	10 (5.4)	9 (5.1)
<i>Pseudomonas aeruginosa</i>	8 (4.3)	9(5.1)
<i>Acinetobacter baumannii</i>	2 (1.1)	0
Gram-positive aerobes	4 (2.2)	8 (4.5)
<i>Enterococcus faecalis</i>	3 (1.6)	7 (3.9)
<i>Staphylococcus aureus</i>	1 (0.5)	0
<i>Staphylococcus saprophyticus</i>	0	1 (0.6)

Results – Primary Endpoint

	Fosfomycin (n = 184)	PIP/TAZ (n = 178)	Treatment Difference (95% CI)
Overall response			
Success	119 (64.7)	97 (54.5)	10.2 (-0.4, 20.8)
Failure	54 (29.3)	73 (41.0)	
Indeterminate	11 (6.0)	8 (4.5)	
Clinical response			
Cure	167 (90.8)	163 (91.6)	-0.8 (-7.2, 5.6)
Failure	9 (4.9)	12 (6.7)	
Indeterminate	8 (4.3)	3 (1.7)	
Microbiological response			
Eradication	121 (65.8)	100 (56.2)	9.6 (-1.0, 20.1)
Persistence	50 (27.20)	69 (38.8)	
Indeterminate	13 (7.1)	9 (5.1)	

Results – Resistance Outcomes

	Fosfomycin (n = 184)	PIP/TAZ (n = 178)
ESBL, % (n/N)		
Cure	93 (52/56)	93 (51/55)
Eradication	55 (32/58)	47 (27/57)
Amino-R, % (n/N)		
Cure	97 (29/30)	94 (29/31)
Eradication	67 (20/30)	38 (12/32)
CRE, % (n/N)		
Cure	100 (9/9)	85 (11/13)
Eradication	56 (5/9)	31 (4/13)
MDR, % (n/N)		
Cure	92 (34/37)	90 (28/31)
Eradication	54 (20/37)	36 (12/33)

Safety Analysis

	Fosfomycin (n = 233), %	PIP/TAZ (n = 231), %
Treatment-emergent AE		
Mild	84 (36.1)	49 (21.2)
Moderate	35 (15.0)	38 (16.5)
Severe	5 (2.1)	4 (1.7)
Alanine aminotransferase increase	20 (8.6)	6 (2.6)
Aspartate aminotransferase increase	17 (7.3)	6 (2.6)
Hypokalemia	15 (6.4)	3 (1.3)
QTc >450 msec (with baseline <450)	17 (7.3)	6 (2.6)
AE leading to discontinuation	7 (3.0)	6 (2.6)

Conclusion

- IV fosfomycin was noninferior to piperacillin/tazobactam in overall success as well as clinical and microbiological success
- IV fosfomycin led to more non-serious adverse events compared to piperacillin/tazobactam
- Adverse effects noted were mild and transient, such as hypokalemia, elevated serum aminotransferases, and QTc prolongation
- Sodium content may attribute to the observed electrolyte imbalances (330 mg/g of fosfomycin vs 65 mg/g of piperacillin/tazobactam)

FOREST: Effectiveness of Fosfomycin for the Treatment of Multidrug-Resistant *Escherichia coli* Bacteremic Urinary Tract Infections

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Methods

- Multicenter, randomized, pragmatic, open clinical trial from June 2014 to December 2018
- Assessed noninferiority of IV fosfomycin to comparator in the treatment of bacteremic UTIs due to multidrug-resistant *E. coli*
- Primary endpoint: clinical and microbiological cure at 5 to 7 days after finalization of treatment (-7% margin for noninferiority)
- 1:1 randomization of fosfomycin 4 g IV q6h or ceftriaxone 1 g IV q24h
 - If resistant to ceftriaxone, switch to meropenem 1 g q8h
 - Allowed switch to PO fosfomycin or IV ertapenem after 4 days
 - Fosfomycin was renally dose adjusted to 4 g q12h, q24h, or q48h for CrCl: 2-40 mL/min, 10-20 mL/min, or ≤ 10 mL/min, respectively

Baseline Characteristics

	Fosfomycin (n = 70)	Comparator (n = 73)
Age, median, (IQR), y	69 (62-81)	73 (62-84)
Women	34 (48.6)	39 (53.4)
Charlson Comorbidity Index score, median (IQR) ≥3, n (%)	1 (0-3) 22 (31.4)	2 (1-3) 22 (30.1)
Comorbidities		
Congestive heart failure	8 (11.4)	11 (15.1)
Chronic kidney disease	9 (12.9)	14 (19.2)
Diabetes	19 (27.1)	19 (26.0)
Present Infection		
Community-acquired	33 (47.1)	39 (53.4)
Healthcare-associated	25 (35.7)	23 (31.5)
Nosocomial	12 (17.1)	11 (15.1)
Low urinary tract	39 (55.7)	45 (61.6)
Flank pain or tenderness	27 (38.6)	26 (35.6)
Severe sepsis	15 (21.4)	22 (30.1)

Baseline Characteristics, cont'd

	Fosfomycin (n = 70)	Comparator (n = 73)
Susceptibility of baseline <i>E. coli</i>		
Amoxicillin	7 (10)	5 (6.8)
Amoxicillin-clavulanate	38 (54.3)	29 (39.7)
Piperacillin-tazobactam	55 (78.6)	54 (74.0)
Cefotaxime	32 (45.7)	33 (45.2)
Cefepime	43 (48.6)	32 (48.6)
Meropenem	70 (100)	73 (100)
Ciprofloxacin	14 (20.0)	11 (15.1)
Trimethoprim-sulfamethoxazole	33 (47.1)	21 (28.8)
Amikacin	59 (84.3)	66 (90.4)
Fosfomycin	70 (100)	73 (100)

Results

	Fosfomycin (n = 70)	Comparator (n = 73)
Length of IV therapy, mean (SD), d	5.4 (0.9)	5.5 (1.8)
Total length of therapy, mean (SD), d	11.5 (3.9)	11.9 (2.0)
Oral antibiotic therapy after IV transition, n (%)	60 (85.7)	48 (65.7)
Fosfomycin trometamol	60 (85.7)	1 (1.4)
Cefuroxime axetil		28 (38.3)
Amoxicillin-clavulanate		7 (9.6)
Trimethoprim-sulfamethoxazole		7 (9.6)
Ciprofloxacin		5 (6.8)
Parenteral ertapenem after transition, n (%)		13 (17.8)

Results

	Fosfomycin (n = 70)	Comparator (n = 73)	Risk Difference (1-sided 95% CI)	P value, 1- sided
CMC at TOC, n (%)				
All patients	48/70 (68.6)	57/73 (78.0)	-9.4 (-21.5 to ∞)	.10
CTX-susceptible	25/31 (80.6)	27/31 (87.0)	-6.4 (-21.7 to ∞)	.24
CTX-resistant	23/39 (59.0)	30/42 (71.4)	-12.4 (-29.8 to ∞)	.12
Withdrawn due to AE, n (%)	6/70 (8.5)	0/73	8.5 (-∞ to 13.9)	.006
Heart failure	4			
Rash	1			
Cholecystitis	1			
Persistence of fever	1			

50 | CMC: clinical and microbiological cure
 TOC: test of cure
 CTX: ceftriaxone

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Conclusion

- Fosfomycin did not demonstrate noninferiority to comparators
- Margin for noninferiority was -7%
 - Secondary and subgroup analysis did show potential for noninferiority
- Broader inclusion of patient population may attribute to differences in results when compared to the ZEUS 2/3 trial
 - Patients in which fosfomycin was discontinued were all over the age of 80
 - All but 1 had pre-existing heart failure or kidney insufficiency
- IV fosfomycin may be considered in select patient populations

Summary of IV Fosfomycin for cUTI

IDSA recommendation: not first line due to lack of susceptibility testing, concern of adverse events, and limitations to specific populations

ZEUS Trial: noninferior to piperacillin/tazobactam with higher rates of adverse events

FOREST Trial: failed to demonstrate noninferiority, may still have potential efficacy in select populations

Currently under HCA formulary status review

Future investigation for use in cUTI and other sites of infection is warranted

In Conclusion...

Uncomplicated and complicated UTIs have been redefined per the IDSA cUTI Guidelines

Morbidity and mortality-associated values have been reassessed when considering treatment options

Updates were made regarding empiric therapy, transitions and duration of therapy

IV fosfomycin is currently under class review

Assessment Question 5

In the FOREST trial, IV fosfomycin did NOT demonstrate noninferiority to comparator based on a predetermined margin of 7%?

- a. True
- b. False

Assessment Question 5

In the FOREST trial, IV fosfomycin did NOT demonstrate noninferiority to comparator based on a predetermined margin of 7%?

- a. True
- b. False

Assessment Question 6

What are some factors to consider when selecting empiric antibiotic therapy?

- a. Prior exposure to a fluoroquinolone in the past 12 months
- b. Recent resistant pathogen isolated in the urine
- c. Patient-specific factors such as allergies, contraindications, and drug-drug interactions
- d. All of the above

Assessment Question 6: Correct Response

What are some factors to consider when selecting empiric antibiotic therapy?

- a. Prior exposure to a fluoroquinolone in the past 12 months
- b. Recent resistant pathogen isolated in the urine
- c. Patient-specific factors such as allergies, contraindications, and drug-drug interactions
- d. All of the above

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Thank you!!

Alex Hodge, PharmD – PGY2 Resident, Infectious Diseases
Alexander.Hodge@HealthTrustPG.com

Isabelle Price, PharmD – PGY1 Resident, Managed Care
Isabelle.Price@HCAHealthcare.com