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In the constantly shifting landscape of drug resistance, antibiotic options, and pharmacoeconomic considerations, urinary tract infection (UTI) continues to be one of the most frequently diagnosed conditions in patients presenting to the emergency department.

It is estimated that practitioners manage 7 million new cases of cystitis in the United States each year and that, overall, UTIs account for approximately 1 million hospitalizations annually.[1,2] Moreover, UTIs are the leading cause of gram-negative bacteremia in patients of all ages, and are associated with a high risk of morbidity and mortality, especially in the elderly.[3] The total annual cost of treatment is in the billions of dollars.[4]

Among common infections managed in the outpatient setting, few conditions have treatment guidelines, antibiotic selection strategies, or diagnostic protocols that have changed or evolved as rapidly as those used for UTI. Despite a general consensus that empiric treatment of UTI in adult women requires, at the very least, mandatory coverage of Escherichia coli *and other gram-negative organisms, antibiotic selection strategies—including initial choice of therapy and duration of treatment—vary widely among practitioners and institutions.*

There are many reasons for inconsistencies in the current approach to UTI management among hospital-based physicians. Unfortunately, deciphering the strengths and weaknesses of recommendations issued by different authoritative sources can be problematic and confusing, especially since resistance patterns of infecting uropathogens may vary among geographic regions, and because outcome-effectiveness, medication compliance, failure rates, total-resource costs to achieve clinical cure, the risk of recurrent infection, and evolving bacterial resistance issues are not always entered into the drug selection equation.

Urinary Tract Infection: Risk Stratification, Clinical Evaluation, and Evidence-Based Antibiotic Therapy

Part I: Epidemiology, Emerging Resistance Patterns, and Patient-Specific Treatment Strategies

Authors: **Romolo Gaspari, MD, FACEP**, Research Director, Assistant Professor, Department of Emergency Medicine, University of Massachusetts School of Medicine, Worcester, MA; and **Gideon Bosker, MD, FACEP**, Assistant Clinical Professor, Yale University School of Medicine, New Haven, CT.

Peer Reviewers: **David S. Howes, MD, FACEP**, Program Director and Chairman, Residency Program, Department of Emergency Medicine, University of Chicago Hospitals and Clinics, Associate Professor, Pritzker School of Medicine, Chicago, IL; and **Ralph J. Riviello, MD, FACEP**, Assistant Professor, Department of Emergency Medicine, Thomas Jefferson University, Philadelphia, PA.

Because no single set of guidelines is applicable to every patient or hospital practice environment, management guidelines for UTI must be "customized" for the local practice setting and, as always, clinical judgment must prevail. This means taking into account local antibiotic resistance patterns, epidemiological and infection incidence data, and patient demographic features.

Important, new therapeutic options that have been introduced into the antimicrobial armamentarium for uncomplicated UTI offer clinicians compliance-enhancing strategies that can improve clinical outcomes. In this regard, recent introduction of extended release ciprofloxacin (Cipro XR®) has made it possible to enhance medication compliance through once-daily administration of what has been considered to be the "gold standard" antibiotic (ciprofloxacin) for uncomplicated UTI, while at the same time making available a preparation that achieves an area under the curve (AUC) that is equivalent to conventional BID ciprofloxacin and achieving a C_{max} that is 40% higher than the conventional BID formulation.

From a practical clinical perspective, because of its potentially compliance-enhancing properties (once-daily dosing and a well-tolerated side effect profile), extended release delivery system, and clinically effective urine concentrations, the extended-release formulation represents a risk-management upgrade from BID ciprofloxacin; therefore, it should replace the older formulation as the clinical standard for treatment of uncomplicated UTI when indicated. A well-designed clinical trial comparing the new and conventional formulations supports this shift to the once-daily, extended-release formulation and is described in this review.

Even when these factors are considered, a number of important questions about drug selection issues for UTI still remain: 1) What is the appropriate initial, empiric choice for uncomplicated UTI? Once-daily (QD) extended-release ciprofloxacin (Cipro XR®) or trimethoprim-sulfamethoxazole (TMP-SMX)? 2) What are the specific "intensification and treatment trigger" criteria that support amplifying initial spectrum of coverage from TMP-SMX to a fluoroquinolone such as extended release ciprofloxacin? 3) How should evolving resistance of E. coli *to TMP-SMX affect initial antimicrobial therapy? 4) What is the optimal duration of therapy for uncomplicated and complicated UTIs? 5) Which antibiotic currently provides correct spectrum coverage, safety, and reliability for outpatient treatment of uncomplicated UTI?*

Although optimizing cure rates with so-called convenient, dose- and duration-friendly branded agents that provide appropriate and predictable coverage with a low risk of antimicrobial resistance may be perceived as costly on a drug-acquisition basis, it is important to stress the following point: Antimicrobial agents with more predictable coverage against pathogens implicated in UTI can help avoid the unnecessary costs of treatment failures, disease progression, patient re-evaluations, return visits, patient dissatisfaction, and the pharmacological reservicing costs associated with initiating a second course of antibiotics.[5]

In this sense, antibiotics that lower barriers to clinical cure and provide a predictable spectrum of coverage can be seen as "productivity tools" that improve efficiency of clinical care and potentially reduce the overall costs associated with inpatient and acute outpatient management of UTI.

In light of the important advances, changes, and refinements that have occurred in the area of UTI treatment during the past year, this comprehensive, state-of-the-art review presents a revised and updated set of guidelines outlining UTI epidemiology and management in outpatient and hospital-based settings. Special emphasis has been given to both epidemiological data demonstrating the importance of correct spectrum coverage with specific fluoroquinolones, such as ciprofloxacin, and the selection of initial antibiotics for patients deemed suitable for discharge.

In addition, detailed evidence-based analysis comparing ciprofloxacin to TMP-SMX is presented to guide antibiotic selection in patients with uncomplicated UTI and pyelonephritis.[5] Cautionary notes about the overuse of extended spectrum fluoro-

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Editorial Group Head: Valerie Loner
Specialty Editor: Shelly Morrow Mark
Marketing Manager: Schandale Kornegay
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quinolones are outlined, and evidence-based studies confirming ciprofloxacin's workhorse role in hospital-based treatment of UTI is discussed. Drawing upon consensus panels, expert opinion, and clinical trials, this clinical consensus report presents antimicrobial protocols and treatment guidelines linked to, and driven by, risk-stratification criteria, evidence-based trials, and specific clinical profiles of patients presenting to the hospital with symptoms and signs suggestive of UTI.

—The Editor

Introduction

Changing resistance patterns observed with common urinary pathogens have altered the empirical approach to antibiotic selection for both upper and lower UTIs. Previously, decisions regarding antimicrobial therapy have been made based on patient characteristics and the anticipated spectrum of urinary flora. However, increasing levels of resistance to beta-lactams during the past decade has decreased the utility of this drug class for treatment of UTIs. In addition, emerging resistance among *E. coli* species to TMP-SMX also is affecting initial drug selection choices for UTI, a change characterized by the acceptance of fluoroquinolones such as extended release ciprofloxacin as the initial agent of choice for greater than 90% of uncomplicated UTIs seen in the outpatient setting.

Epidemiology

Acute UTI is one of the most common illnesses encountered in adult women, resulting in as many as 8 million office visits per year[6] and at least 100,000 hospital admissions.[7,8] Although the exact frequency of UTI is not known, based on current evidence accumulated from office and hospital surveys, it is estimated that there are approximately 7 million episodes of cystitis[9] and 250,000 episodes of pyelonephritis[10] annually in the United States. One prospective study determined the annual incidence of cystitis to be 0.5-0.7% per person-year.[11]

Although many cases of uncomplicated UTI resolve with only transient, mild symptoms, studies suggest considerable morbidity and mortality are associated with all forms of UTI. Two independent studies[12,13] found that asymptomatic bacteriuria in the elderly was associated with an increased mortality rate; however, this is not a universal finding.[14,15] Certain patient populations, in particular those with diabetes and pregnancy, have been found to have a higher level of morbidity.[16,17] Studies reviewing simple cystitis also have revealed substantial morbidity, with limited activity lasting for more than two days.[18] As many as 60% of elderly patients with pyelonephritis will develop bacteremia, and 20% of these cases will result in septic shock.[19] Life-threatening bacteremia as a complication of UTI also has been documented by a number of other investigators.[20-24]

UTIs in women vastly outnumber those in men.[25] This may be related to such factors as the length of the urethra, distance of the urogenital meatus from the anus, and the antibacterial properties of prostatic fluid.[26] Regardless of the reason, the fact that male UTIs are so uncommon has led many authors to classify them as complicated. This is supported by the high degree of virulence found in male UTI isolates, and the high prevalence of non-*E. coli* UTIs.[27]

Microbiology and Emerging Resistance Patterns

For many years, pathogens associated with uncomplicated UTIs remained constant, with *E. coli* identified as the etiologic agent in about 75-90% of infections.[25] Five to 15% of uncomplicated UTIs are caused by *Staphylococcus saprophyticus,*[28,29] with Klebsiella, Proteus, Enterococcus, and Pseudomonas species seen in much smaller percentages.[30-32]

The emergence of *E. coli* isolates demonstrating resistance to commonly used antibiotics, especially to TMP-SMX, is changing initial drug selection patterns in patients with both uncomplicated and complicated UTIs. The most common uropathogens identified in adult patients with UTI include enteric gram-negative bacteria, with *E. coli* being the most common. *(See Table 1.)* The remainder of infections are caused by coagulase-negative *Staphylococcus saprophyticus* (10-20%), while *Proteus mirabilis,* Klebsiella, and Enterococcus account for less than 5%.[3,33,34] Other aerobic gram-negative bacteria of the Enterobacteriacea family include Citrobacter, Enterobacter, Serratia, and Salmonella.[35-37] Non-enteric aerobic gram-negative rods such as Pseudomonas and aerobic gram-positive cocci such as Enterococcus are less prevalent in immunocompetent hosts. *(See Table 1).* Group B streptococci infection is observed in neonates secondary to inoculation from a colonized mother during delivery through the vaginal canal.

Anaerobic bacteria rarely are pathogenic despite their prevalence in fecal flora. The Lactobacillus species, coagulase-negative staphylococci, and Corynebacterium are not considered clinically significant isolates in the urine of healthy children between 2 months and 2 years of age.[1,38] Corynebacterium, Lactobacillus, and Streptococcus species are identified only rarely; when present in this age group, they nearly always represent contamination of the specimen rather than a true pathogen. In complicated UTI, in addition to *E. coli,* there is a higher prevalence of Pseudomonas, Enterobacter species, Serratia, Acinetobacter, Klebsiella, and enterococci.[39] There are anecdotal reports of treatment for *Gardnerella vaginalis,* lactobacilli, *Chlamydia trachomatis,* and *Ureaplasma urealyticum* in pregnant women, but it is unclear whether these organisms represent true pathogens in this population.[40,41] Candidal species now are emerging in greater numbers, especially in catheterized patients and those who received previous treatment for enterococcal UTIs.[39]

The high incidence of UTIs in the general population; the potential for complications, especially in high-risk subgroups; and the associated costs of treatment emphasize the importance of appropriate antibiotic therapy. Microbial resistance to nearly all classes of antimicrobials continues to rise despite increasing awareness and concerns worldwide. European studies have shown *E. coli* resistance rates to multiple antibiotics, specifically TMP-SMX, in as many as one-third of patients.[42,43] Similar trends in the United States have prompted a shift to fluoroquinolones such as ciprofloxacin as preferred initial agents for empiric intravenous and/or oral therapy of UTI in both hospital and emergency department settings.[44]

In a cross-sectional survey of urine cultures obtained in the emergency departments of urban tertiary care centers in the United

Table 1. Most Common Uropathogens Identified in Adult UTI Patients[§]

1) *Escherichia coli*
2) *Staphylococcus saprophyticus*
3) *Klebsiella pneumoniae*
4) *Proteus mirabilis*
5) *Enterococcus* faecalis*
6) *Pseudomonas aeruginosa*
7) *Enterobacter cloacae*
8) *Citrobacter*

§ = Listed in order of decreasing frequency
* = Gram-positive organisms

States, microbial resistance was as high as 48% to ampicillin, 25% to tetracycline, 14-28% to TMP-SMX, and 13% to nitrofurantoin.[45] Similar studies have shown that the resistance to ciprofloxacin among common uropathogens, including *E. coli,* frequently encountered in hospital-managed UTI is as low as 1-2%.[46-50]

These epidemiological data have important treatment implications, since recent studies also already are demonstrating outcome differences in clinical efficacy and patient cure rates between UTI patients managed on TMP-SMX and those managed on ciprofloxacin.[51] As would be expected, maintenance of predictable antimicrobial activity by ciprofloxacin against the anticipated spectrum of uropathogens has solidified the role of this antibiotic in treatment pathways for UTI among all institutional settings.

Surveillance and Sensitivity. Hospitals affiliated with managed care organizations also have been prompted to re-evaluate their initial approach to antibiotic selection for UTI. A cross-sectional survey of 4000 urine cultures obtained from women ages 18-50 in an HMO setting between 1992 and 1996 showed *E. coli* prevalence to be 86%, with the resistance rate to TMP-SMX increasing during this period from 9% to 18%. Recent data suggest that in some regions of the country, especially the West, Southwest, and in most major urban centers, the resistance rate to TMP-SMX has risen to as high as 35%.[5,42,43,52-55] The overall resistance to multiple groups of antimicrobials, including the penicillins, cephalosporins, and sulfa drugs, doubled from 8% to 16%.[56] In pregnant patients, *E. coli* resistance to ampicillin, which at one time was a drug of choice for UTI in this population, is now about 20-30%.[41]

Fortunately, one class of antimicrobials to which sensitivity rates have remained consistently high is the fluoroquinolone group, of which ciprofloxacin is the most frequently used in the adult population. A two-tiered study from 1989 to 1991 and 1996 to 1997 at an urban sexually transmitted disease clinic evaluated young, sexually active females diagnosed with a UTI and found *E. coli* resistance rates to ampicillin, cephalosporins, or tetracycline in as many as 25% of patients. There was very little change in the low prevalence of organisms resistant to fluoroquinolones.[57]

Additional studies at student health clinics in California during a five-year period demonstrated significant increases in the resistance of *E. coli* to ampicillin (30-45%), tetracycline (29-40%), and TMP-SMX (15-32%), with resistance to fluoroquinolones in fewer than 5% of organisms.[34] In a recent analysis of young women with uncomplicated pyelonephritis, *E. coli* was isolated in more than 90% of cultures and was resistant to TMP-SMX in 18%, compared with a 0.4% resistance to ciprofloxacin. A significant variance in resistance patterns existed in different geographic regions, with resistance to TMP-SMX as high as 35% on the West Coast of the United States as opposed to 14% in the Midwest and 7% on the East Coast.[51] One caveat regarding bacterial resistance is that in vitro sensitivity results may not correlate with clinical cure rates and in vivo sensitivity. Eradication of a uropathogen depends on the concentration of antibiotics in the urine as opposed to serum, which may be higher than the levels used in in vitro studies.[39]

Recent studies have noted a subtle shift in etiologic agents associated with UTIs. A survey of all UTI pathogens in 1997 found the top four isolates to be *E. coli* (48.6%), Enterococcus spp (13.7%), Klebsiella spp (12.0%), and *Pseudomonas aeruginosa* (6.2%).[58] More current data from 1998 support these trends.[59] This shift in pathogens may be related to factors such as bladder catheterization or antibiotic use. Another study reported a similar mix of uropathogens in catheter-associated UTIs.[60] Not surprisingly, bacterial isolates found in complicated UTIs follow a similar pattern.[61,62] *(See Table 2.)*

Although there are fewer data on patients with pyelonephritis, recently published surveys indicate a similar mix of pathogens, with about 90% of patients with pyelonephritis manifesting infection with *E. coli*.[64,65] Other isolates included those found in lower UTIs. Urethritis usually is caused by *Chlamydia trachomatis, Neisseria gonorrhoeae,* or herpes simplex virus.

***Escherichia coli (E. coli)* Resistance.** The sensitivity of a urinary tract pathogen to a specific antimicrobial agent is defined by measuring the bacteria's ability to grow in the presence of that antibiotic. In the case of *E. coli,* if the strain under evaluation can grow in media containing 2 mcg/mL or greater (mean inhibitory concentration or MIC) of the antibiotic, the strain is considered resistant to that antibiotic. Potential confusion arises when the reported resistance levels are related to the blood concentration of antibiotic and not the urine concentration. As a rule, antibiotics used for UTIs are concentrated in the urine and have higher urine levels than blood levels. Therefore, isolates that are reported resistant to an antibiotic by laboratory testing actually may be eradicated by the antibiotic in the in vivo environment. This concept is clinically relevant and has been demonstrated in a number of studies.[28,66,67]

Due to the consistent, relatively predictable spectrum of pathogens encountered in UTIs, empiric therapy represents an appropriate strategy for the majority of patients, whether they present in the outpatient, emergency department, or in-hospital setting. Historically, empiric therapy using any one of a wide range of agents has proven clinically successful for UTI. Until recently, high cure rates could be expected because a predictable group of urinary pathogens have manifested a low degree of resistance to most antibiotics selected on an empiric basis. However, a number of recent studies have highlighted evolving changes in antimicrobial resistance patterns to *E. coli.* In particu-

Table 2. Incidence of Urinary Tract Pathogens

PATHOGEN	UNCOMPLICATED CYSTITIS	COMPLICATED UTIs
Escherichia coli	70-95%	40-55%
Klebsiella spp	2-6%	10-17%
Enterobacter spp	0-2%	5-10%
Proteus mirabilis	2-4%	5-10%
Pseudomonas aeruginosa	0-1%	2-10%
Enterococcus spp	2-5%	1-20%
Staphylococcus saprophyticus	5-20%	-------

Adapted from references 25,31,63

lar, clinically and microbiologically significant changes in resistance to TMP-SMX among *E. coli* species, and in a small percentage of cases, to fluoroquinolones have been reported in Europe[68,69] and the United States.[30-32,59,70]

Resistance and Implications for Antibiotic Therapy—Fluoroquinolones Emerge as Initial Agents of Choice. Evolving changes in drug resistance dramatically have altered the approach to empiric therapy of UTI. Although beta-lactams, sulfa-based antibiotics, and fluoroquinolones each have their place in the treatment of UTI, their roles are changing, with fluoroquinolones emerging as initial agents of choice, even for uncomplicated UTI. Penicillin-based antibiotics once were a mainstay of UTI treatment, but current resistance rates among *E. coli (*approaching 40% in many regions) have limited their effectiveness.[30,71,72] Although *E. coli* resistance to fluoroquinolones in the United States has not reached the levels encountered with other antibiotics,[25,28,72] the level of resistance in other countries is alarming.[73,74] In the United States, however, increasing *E. coli* resistance to TMP-SMX has been accompanied by a paradigm shift in the initial treatment of choice for UTI (please see below).[31,75-78]

The level of *E. coli* resistance to TMP-SMX has more than doubled during the past 12 years and now exceeds 25% in some areas of the country.[79-81] One group of investigators examined a cross-section of urinary isolates from 1992 to 1996 and found an increase of TMP-SMX resistance from 9% to more than 18%.[72] Subsequent, larger studies have shown similar results.[79-81] Resistance rates in the United States vary from region to region, and knowledge of local resistance rates are important factors when determining initial antibiotic therapy.[31]

Most experts and national association panels concur that sequential selection strategies for antibiotic therapy in UTI, to a significant degree, should depend on the degree of *E. coli* resistance to TMP-SMX in a particular community. In this regard, the Infectious Disease Society of America (IDSA) recommends that alternative antibiotics (i.e., agents other than TMP-SMX) should be used as first-line therapy in areas of the country where TMP-SMX resistance is greater than 10-20%.[78] More specifically, the clinical outcome and pharmacoeconomic implications of fluoroquinolones vs. TMP-SMX therapy have been linked to a 20% *E. coli* drug resistance cut-off point.

With this antibiotic preference issue in mind, two published studies have examined the effect of *E. coli* resistance rates on patient outcomes[75] and economic parameters.[82] One study concluded that the clinical effectiveness of fluoroquinolones such as ciprofloxacin was superior to TMP-SMX when more than 10% of the *E. coli* isolates were resistant to TMP-SMX.[75] At a 20% resistance rate, nitrofurantoin also was superior to TMP-SMX. Another study, using a cost-analytical model, approached the issue of antimicrobial selection from a different angle. Performing a cost analysis of first-line UTI antibiotic options—examining the desirability of one agent vs. another through the prism of increasing antibiotic resistance rates—these investigators found progressive cost savings to the community when a fluoroquinolone was substituted for TMP-SMX as initial agents of choice in areas characterized by a 20% or greater resistance rate among *E. coli* to TMP-SMX.[82] Although authorities identify different resistance rate breakpoints that would favor a shift to a fluoroquinolone as first-line therapy, there is general agreement that the greater the resistance rate, the greater the clinical and pharmacoeconomic benefits to fluoroquinolone use.

It should be stressed that the fluoroquinolones are not immune to the selective pressures causing antibiotic resistance in UTI isolates. Studies in some foreign countries, where there has been heavy use of this class of antibiotics, have shown increasing rates of resistance. A multi-center study found *E. coli* resistance to ciprofloxacin in 36% and 20% of urinary isolates from Portugal and Spain, respectively.[30] However, most studies of urinary isolates in the United States show only a 1-4% resistance rate to fluoroquinolones.[31,59]

Multi-drug resistant uropathogens are becoming increasingly common across the United States. One retrospective study found that 37% of UTI isolates from emergency department patients were multi-drug resistant.[32] A larger national study of inpatients as well as outpatients looked at almost 39,000 urinary isolates from patients with UTIs and found the number of multi-drug resistant isolates to be 7.1%. Among the resistant strains, 98% were resistant to ampicillin and 93% were resistant to TMP-SMX. The resistance to ciprofloxacin and nitrofurantoin was 39% and 8%, respectively.[79]

Urinary Tract Infections in Women—Principles of Management

Asymptomatic Bacteriuria. Asymptomatic bacteriuria is a well-documented entity that affects women of all ages. A number of large-scale population studies have shown the prevalence of asymptomatic bacteriuria to be directly related to age, with a 1-2% rate in young women, 6-10% in women older than age 60,[83] and 15-20% in women ages 65 and older.[15,84,85] These rates only represent a "snapshot in time," inasmuch as studies have demonstrated a "turnover" of bacteriuria from positive to negative and back again during sequential six-month urine cultures.[86,87]

As a rule, asymptomatic bacteriuria (ASB) should not treated in most patients, since multiple studies have shown that antibiotic therapy does not make a significant impact on long-term outcomes in an otherwise healthy adult population.[88] A recent prospective study of asymptomatic bacteriuria in sexually active

Table 3. Patient Subgroups Associated with Complicated Lower Urinary Tract Infections

STRUCTURAL ABNORMALITIES (SURGICAL, CONGENITAL, OR ACQUIRED)
Renal tumors
Urethral or ureteral strictures
Renal cysts
Congenital abnormalities of the urogenital system
Urogenital surgery
FUNCTIONAL ABNORMALITIES
Neurogenic bladder
Vesicoureteral reflux
MECHANICAL OBSTRUCTION TO URINE FLOW
Indwelling bladder catheterization
Nephrolithiasis
Ureteral stents and nephrostomy tubes
Urogenital instrumentation
HIGH RISK
Diabetes mellitus
Pregnancy
Immunosuppressed
Sickle cell anemia and trait
Renal failure

Adapted from references 7, 63

young women found prevalence rates of approximately 5%, with 8% of those women developing symptomatic UTI within one week.[89] Specific groups benefiting from antibiotic treatment include pregnant women, neutropenic patients, patients with abnormal renal function, renal transplant recipients in the early post-transplantation period, and men and women planning to undergo urologic procedures.[3,89]

Infants with ASB represent a low-risk population for the development of UTIs, with a tendency toward spontaneous abacteriuria within a few months, and do not generally require antibiotic treatment.[90] School-age children usually are left untreated; however, patients with underlying voiding disorders should be referred appropriately for further evaluation and treatment.

Pregnant women with ASB should be treated with a three- to seven-day course of antibiotics, followed by a subsequent culture to ensure sterilization of urine. Despite increasing resistance rates to ampicillin, amoxicillin and cephalosporins remain a first-line choice in these patients. Ceftriaxone is the preferred agent in pregnant women. Nitrofurantoin is becoming a first-line drug, because it is efficacious, inexpensive, and well-tolerated. The only contraindication to using this drug is in patients with G6PD deficiency, in whom hemolysis can occur. TMP-SMX remains a first-line agent in areas of low resistance, but should be avoided in the first and third trimesters secondary to possible teratogenic effects and the risk of kernicterus from competitive binding of TMP-SMX to bilirubin binding sites. At this time there is no clear evidence to support a single-dose regimen over a typical three- to seven-day course.[40,91] A properly sized, randomly controlled trial is recommended for comparison of these regimens, as a single dose has lower cost, fewer adverse effects, and increased compliance compared with longer treatment regimens.[91]

Initial evidence in the elderly population had suggested an increased risk of morbidity and mortality in patients with ASB. More recent studies have challenged these reports, but have failed to identify a connection between ASB and an increase in long-term sequelae such as hypertension or end-stage renal disease. Up to 40% of the elderly will have ASB at some time. Aggressive screening and treatment have little effect on decreasing symptomatic or clinically significant infection and associated complications.[3] Catheterized patients, including those with neurologic disorders or spinal cord injuries, rarely require aggressive work-up and treatment unless symptoms intervene.[93] Interestingly, a recent study of catheterized patients found that catheter-associated UTIs are rarely symptomatic and infrequently cause bacteremia (< 1%). No significant differences were noted between symptomatic and asymptomatic bacteriuria groups with regard to signs and symptoms commonly associated with infection (i.e., fever, dysuria, urgency, or flank pain) or leukocytosis.[94] Investigations have noted that both groups are a major reservoir for antibiotic resistant organisms in the hospital setting.

The long-term consequences of asymptomatic bacteriuria have not been fully elucidated, but this condition may have the potential to cause symptomatic UTIs and/or sepsis in a small minority of patients, although such sequelae have not been uniformly substantiated. In addition, the potential for persistent bacteriuria and recurrent UTI to decrease survival continues to be debated, with some investigators finding an association[12,13] while others have not.[14,15] A recent, well-conducted analysis of patients with asymptomatic bacteriuria failed to show an increase in mortality when comorbid factors were accounted for.[95] In summary, most experts currently do not recommend treatment for asymptomatic bacteriuria, except in the high-risk patient populations identified above.[83,96]

Uncomplicated Lower Urinary Tract Infection. The majority of uncomplicated lower UTIs occur in patients who have no functional or anatomical abnormality of their urinary system. Lower UTIs can be categorized into two distinct categories: cystitis and urethritis. In the emergency department, it may be difficult to distinguish between uncomplicated and complicated cystitis. As a rule, however, the clinician will be able to distinguish between cystitis and urethritis on the basis of history and physical exam. Symptoms of urethritis overlap with cystitis, but urethritis usually has a more gradual onset with milder symptoms and little to no urgency or frequency. Associated vaginal discharge or lesions may make the diagnosis more apparent. It usually is reasonable to assume that a young, non-pregnant female with acute onset of dysuria and frequency has a simple cystitis if she has not had any instrumentation or recent antibiotic therapy.

Certain patient populations are at an increased risk for developing a UTI. One group has determined that recent sexual intercourse, diaphragm use, and a history of previous UTIs are independent risk factors for developing a UTI.[11] Although the study population was limited to college age women, other studies that included older women have demonstrated similar risk factors.[97]

Table 4. Ciprofloxacin Extended Release (Cipro XR®) vs. Ciprofloxacin BID in Patients with Uncomplicated UTI

SIDE EFFECT, SAFETY, AND TOLERABILITY PROFILES	CIP EXT-REL (N = 444)	CIP BID (N = 447)
Drug-related Adverse Events (AEs)	46 (10%)	41 (9%)
Headache	7 (2%)	3 (< 1%)
Nausea	12 (3%)	4 (< 1%)
Vaginal moniliasis	4 (< 1%)	10 (2%)
Vaginitis	4 (< 1%)	7 (2%)
Serious drug-related AEs	0 (0%)	0 (0%)
Drug-related AEs leading to premature discontinuation	1 (< 1%)	0 (0%)

Adapted from reference 131

However, these risk factors are not universally agreed upon and many patients with a confirmed diagnosis of UTI will cite no risk factors.

Complicated Lower Urinary Tract Infections and High Risk Patients. Complicated UTIs typically occur in patients who have an underlying urinary tract abnormality causing obstruction. The abnormality may be a physical obstruction (i.e., kidney stone or bladder catheter), or it may be a functional abnormality (i.e., neurogenic bladder or vesicoureteral reflux). Infections in patients with such disease states as diabetes or renal failure, as well as renal transplantation, also fall into the category of so-called complicated UTI. *(See Table 3.)* Complicated UTIs encompass patients with a wide variety of syndromes and risk factors that increase the likelihood of poor outcomes. Moreover, studies aimed toward evaluating etiological agents in complicated infections demonstrate a broad range of microbial pathogens, of which *E. coli* is the most common.[63]

An associated concept is the high-risk patient with UTI, which would include individuals who are pregnant, immunosuppressed, or those who have an indwelling catheter. High-risk patients may or may not have a urogenital abnormality, but the potential sequelae of UTI in these subgroups may overlap with those encountered in patients with complicated infections; as a result, some authors use the terms interchangeably. From a clinical perspective, the important concept is that both patients who have a complicated UTI and those deemed at high risk require more prudent management, which includes a longer duration of therapy and closer follow up.

Upper Urinary Tract Infection. Upper UTI generally refers to pyelonephritis and its potential complications, including perinephric abscess. Many studies have confirmed that pyelonephritis occurs through ascending infection from the bladder.[98,99] It is thought that fecal organisms inoculate the urethra, spread into the bladder, and subsequently ascend the ureters to the kidney parenchyma. The incidence of pyelonephritis is much lower then that of cystitis, although the morbidity and mortality are much greater.[25] Acute pyelonephritis can progress to chronic pyelonephritis or perinephric abscess depending on host factors such as immune status and obstruction.[100]

Symptoms of pyelonephritis can vary from dysuria to fulminant urosepsis. Only 20-30% of patients with isolated dysuria actually will have subclinical pyelonephritis.[101-103] Patients with subclinical pyelonephritis present with symptoms characteristic of cystitis, but infection is located in the kidney. Subclinical pyelonephritis is impossible to differentiate from cystitis without complicated localization techniques that mostly are used in research studies. Most patients with symptomatic pyelonephritis will present with flank pain, nausea, vomiting, fever, and costovertebral angle tenderness.[104]

Diagnostic Strategies in Urinary Tract Infection: Urinalysis, Culture, and Imaging Studies

The majority of patients with UTI present with unambiguous symptoms and signs suggestive of this disease process, and therefore, present few diagnostic challenges for the astute clinician. However, a minority of infections, especially those encountered in the elderly or immunocompromised individual, may be more clinically challenging. For example, most clinicians would have little difficulty making the diagnosis of UTI in a young woman presenting with one day of dysuria and frequency, whereas diagnostic challenges are likely to surface when UTI causes obtundation in an elderly male. Because a number of modalities are available for diagnostic evaluation, the practitioner must determine which laboratory tests and/or imaging modalities are appropriate and cost-effective in individuals presenting with symptoms suggestive of UTI.

Diagnostic Approach. Clinical experience suggests that most uncomplicated lower UTIs encountered in the outpatient setting can be diagnosed (and cured) without the use of urine cultures.[75] Accordingly, patients who present with symptoms consistent with cystitis or urethritis should undergo a history, physical exam, and urinalysis. The use of dipstick urinalysis and/or microscopic urinalysis provides a diagnostic yield that is sufficiently specific and sensitive to establish the diagnosis of uncomplicated UTI.[105] Due to the increased morbidity and mortality associated with pyelonephritis and UTI in high-risk patients, a urine culture still is recommended for the work-up in this patient subgroup.

Urinalysis. A urinalysis continues to be the "workhorse" laboratory evaluation for establishing the diagnosis of UTI in a broad range of patients; therefore, it is the principal modality employed for the work-up of UTI. The primary utility of a urinalysis is to examine for and document the presence of pyuria, hematuria, nitrates, leukocyte esterase, and bacteria. Although semi-quantitative dipstick and microscopic urinalysis are widely used and have been extensively reviewed in the literature, studies are conflicting as to their accuracy.[105-110]

The presence of red or white cells in the urine can help differentiate the location of the infection. Pyuria is present in almost all patients with urethritis, cystitis, and pyelonephritis. The laborato-

Table 5. Antibiotic Therapy for Acute Uncomplicated UTI in Adults

CYSTITIS (3-DAY REGIMEN)

AGENT OF CHOICE:

Fluoroquinolone (initial agent of choice)

Ciprofloxacin extended release (Cipro® XR) 500 mg po QD x 3 days

ALTERNATIVE FIRST-LINE AGENTS:

Fluoroquinolones (alternative)

Levofloxacin 250 mg po QD x 3 days

Ofloxacin 200 mg po BID x 3 days

Norfloxacin 400 mg po BID x 3 days

Trimethoprim/sulfamethoxazole* 160/800 mg po BID x 3 days

SECONDARY ALTERNATIVES:

Amoxicillin 500 mg po TID x 7-10 days (known enterococcus infection only)

Nitrofurantoin 100 mg po BID x 7 days

Amoxicillin-clavulanic acid 250 mg po QID x 7 days

Fosfomycin One 3-g sachet orally

*Only if *E. coli* resistance is < 10-20% in patient population (based on regional resistance surveillance data).

ry/clinical definition of pyuria (number of white cells per high-powered field [hpf]) will affect its sensitivity and specificity for establishing the diagnosis of UTI. One group found that the presence of greater than 5 WBCs per hpf was 85% sensitive for UTI, whereas other authors[111] have reported that greater than 10 WBCs/hpf was a more reliable breakpoint for making the diagnosis.[107] The presence or absence of pyuria should be interpreted within the context of other findings in the urinalysis. Hematuria can be present with cystitis and pyelonephritis but rarely is seen in urethritis.[25] It can be diagnosed semi-quantitatively with a urine dipstick or quantitatively on a microscopic urinalysis. Studies looking at dipstick hematuria have found a sensitivity and specificity of 44% and 88%, respectively.[112] Microscopic analysis of the urine also may demonstrate red cell casts that are indicative of upper tract disease.

Several unique esterases produced by neutrophils in the urine form the basis of one of the screening tests for UTI. The leukocyte esterase can be detected rapidly using a urine dipstick, which appears to provide a reliable method for detecting pyuria. Studies have shown that the leukocyte esterase has a sensitivity in the range of 74-96% and a specificity of about 94-98%,[108,113,114] although this may not distinguish the presence of pyuria with this degree of accuracy in clinical practice.[112,115]

The nitrite test on a dipstick urinalysis is a rapid screening test for bacteriuria. It has been found to be 39% sensitive and 93% specific for bacteria in the urine in both prospective and retrospective studies.[105,107,112] One investigation combined nitrate results with the presence of microscopic bacteriuria and/or pyuria (> 10 WBCs per hpf) and found a sensitivity and specificity in the range of 71-95% and 54-86%, respectively.[107] Other studies have found that the accuracy of this test can be affected by a low level of infection[20] or the type of infecting microorganism.[116]

Urine Culture. Bacteriuria is considered by most clinicians to be the definitive marker of UTI. Studies conducted in the 1950s found that 10^5 colony forming units (cfu) per milliliter was indicative of a UTI.[117,118] However, more recent studies suggest that this level of bacteriuria may miss a large group of UTIs, and support the concept that lower levels (10^2-10^4 cfu) should be considered positive.[7,119] In one provocative study, patients provided urine samples when a diagnosis of UTI was suspected, but they were not treated for two days after onset of symptoms. A repeat urine culture was obtained two days later at which time empiric treatment was started. Interestingly, urine cultures cleared spontaneously in only 5% of the patients who had a low colony count initially, while 48% now had a colony count of 10^5 or more.[120]

It should be emphasized that lower levels of bacteriuria have been shown to predict UTIs in a variety of settings. Levels greater than 10^2 have shown a sensitivity of 95% and a specificity of 85% for the diagnosis of cystitis in women.[121] Male patients with urine samples growing greater than 10^3 cfu/mL are considered positive for UTI.[26] All patients with pyelonephritis have been found to have a higher level of bacteriuria, with cultures almost uniformly growing at levels greater than 10^4 cfu/mL.[117,122] In summary, studies suggest that antibiotic therapy should be considered for any patient with symptoms of a UTI and a culture positive for 10^3 cfu/mL or greater of a urinary tract pathogen.

Urine Collection. The method by which urine is collected has received little attention in the scientific literature. The most commonly recommended collection technique for women is either a mid-stream clean-catch urine sample, or an in-and-out catheterized specimen. Despite the effort that goes into instruction for a mid-stream clean-catch urine sample, contamination is a frequent problem.[123] There is little rigorous scientific research that supports a mid-stream clean-catch urine sample as the standard for urine collection. In one study, urine samples randomly were collected by one of two techniques. One group received instructions on cleaning and technique for obtaining a mid-stream clean-catch urine specimen. The other group did not clean, and no other instructions were given. There was no difference in contamination between the groups. Studies in men revealed similar results.[124,125]

In-and-out sterile catheterization is the most reliable method to obtain a urine sample from women. This procedure has the lowest chance of contamination from vaginal or perineal flora and has a low risk of complications. There is a risk of inducing infection in 1-3% of patients.[126] Catheterizing a male to get a urine sample is not recommended, as any urine sample usually is clean. If the situation demands obtaining a urine sample from a male who cannot cooperate, a catheterized specimen is recommended, but a clean "condom" catheter may as useful as bladder catheterization.[127]

Imaging Techniques. Radiographic imaging has no role in the initial work up of most UTIs. Some specific imaging modalities may have utility in identifying upper UTIs or their complications. Ultrasound is relatively poor at identifying infectious conditions of the kidney other than perinephric abscess, infected hydronephrosis, or emphysematous pyelonephritis; fortunately,

Table 6. Antibiotic Treatment of Pyelonephritis (10-14 Day Treatment Duration)

FIRST-LINE AGENTS	
Fluoroquinolones	10-14 day course
Ciprofloxacin	(preferred) 500 mg Q 12 hours PO, IV
ALTERNATIVE FIRST-LINE AGENTS	
Levofloxacin	250 mg Q 24 hours PO, IV
Ceftriaxone	1-2 g Q 24 hours IV
Ofloxacin	200-300 mg Q 12 hours PO, IV
Norfloxacin	400 mg Q 12 hours PO
SECOND-LINE AGENTS	
TMP-SMX	160/800 mg Q 12 hours PO, IV
Ampicillin/sulbactam	3 g Q 6 hours IV
Amoxicillin/clavulanate	875/125 mg Q 12 hours PO
Piperacillin/Tazobactam	4.5 g Q 8 hours IV
Gentamicin	3-5 mg/kg/day divided q 6 hours IV

Adapted from references 25, 78

the conditions are rare.[128] CAT scan has been found to be better for visualizing all infectious conditions of the kidney and has the advantage of identifying alternative, non-infectious conditions.[129,130] The few categories of patients with UTI who should be considered for imaging are patients with recurrent illness or patients who are not improving despite therapy.

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Correction

A table in the October 7, 2002, issue listed an incorrect dosage for fentanyl. The correct dosage should be 0.1 mcg/kg.

Emergency Medicine Reports
CME Objectives

To help physicians:

- quickly recognize or increase index of suspicion for specific conditions;
- understand the epidemiology, etiology, pathophysiology, and clinical features of the entity discussed;
- be educated about how to correctly perform necessary diagnostic tests;
- take a meaningful patient history that will reveal the most important details about the particular medical problem discussed;
- apply state-of-the-art therapeutic techniques (including the implications of pharmaceutical therapy discussed) to patients with the particular medical problems discussed;
- understand the differential diagnosis of the entity discussed;
- understand both likely and rare complications that may occur;
- and provide patients with any necessary discharge instructions.

release ciprofloxacin vs. conventional twice-daily ciprofloxacin for the treatment of uncomplicated urinary tract infections. 42nd Interscience Conference on Antimicrobial Agents and Chemotherapy, Sept. 27-30, 2002; San Diego, CA. Abstract L-1800 (oral presentation, E. Riffer, Sept. 30, 2002).

Physician CME Questions

61. The most common uropathogen in urinary tract infections in all age groups is:
    A. *Proteus mirabilis.*
    B. *E. coli.*
    C. Klebsiella.
    D. Enterococci.

62. In acute cystitis, which of the following antibiotics is now recommended as a first-line agent in most adult populations with resistance rates to TMP-SMX in excess of 10-20%?
    A. TMP-SMX
    B. Amoxicillin/clavulanic acid
    C. Nitrofurantoin
    D. Fluoroquinolone (extended release ciprofloxacin, Cipro XR®)

63. Acute urinary tract infection results in as many as 8 million office visits per year and at least 100,000 hospital admissions.
    A. True
    B. False

64. The majority of uncomplicated lower urinary tract infections occur in patients who have a functional or anatomical abnormality of their urinary system.
    A. True
    B. False

65. The level of *E. coli* resistance to TMP-SMX has more than doubled during the past 12 years and now exceeds 25% in some areas of the country.
    A. True
    B. False

66. As a rule, asymptomatic bacteriuria (ASB) should be treated in most patients, since multiple studies have shown that antibiotic therapy makes a significant impact on long-term outcomes in an otherwise healthy adult population.
    A. True
    B. False

67. The advantages of extended release (once-daily) ciprofloxacin compared to ciprofloxacin BID potentially include which of the following?
    A. Extended release ciprofloxacin is potentially compliance-enhancing because of its once-daily dosing and a well-tolerated side effect profile.
    B. The extended release delivery system delivers clinically effective urine concentrations.
    C. The extended release formulation represents a risk-management upgrade as compared to BID ciprofloxacin, and should replace the older formulation as the clinical standard for treatment of uncomplicated UTI when indicated.
    D. A well-designed clinical trial supports this shift to the once-daily, extended release formulation based on features cited above.
    E. All of the above

68. Recent data suggest that the resistance rate to TMP-SMX has risen as high as 35% in which region(s) of the country?
    A. East
    B. Southeast and Central
    C. Midwest and rural areas
    D. West, Southwest, and most major urban centers

69. Specific groups that would benefit from antibiotic treatment for ASB include which of the following?
    A. Renal transplant recipients in the early post-transplantation period
    B. Neutropenic patients
    C. Patients with abnormal renal function
    D. Patients planning to undergo urologic procedures
    E. All of the above

70. What is the preferred drug for treating pregnant women with ASB?
    A. Ampicillin
    B. Nitrofurantoin
    C. Ceftriaxone
    D. TMP-SMX

In Future Issues:

Urinary Tract Infection, Part II

CME Instructions

Physicians participate in this continuing medical education program by reading the article, using the provided references for further research, and studying the questions at the end of the article. Participants should select what they believe to be the correct answers, then refer to the list of correct answers to evaluate their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. *After completing this activity, you must complete the evaluation form that will be provided at the end of the semester and return it in the reply envelope provided to receive a certificate of completion.* When your evaluation is received, a certificate will be mailed to you.

CME Answers

61. B; 62. D; 63. A; 64. B; 65. A
66. B; 67. E; 68. D; 69. E; 70. C

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EMTALA Update: Current Practice and Future Impact

Author: **Jay C. Weaver, JD, EMT-P**, Boston Public Health Commission Emergency Medical Services; Adjunct Faculty, Northeastern University, Boston.

Peer Reviewer: **James Hubler, MD, JD, FCLM, FAAEM, FACEP**, Clinical Assistant Professor of Surgery, Department of Emergency Medicine, University of Illinois College of Medicine at Peoria; EMS Medical Director, Central Illinois Center for Emergency Medicine, OSF Saint Francis Hospital, Peoria, IL.

In 1986, when the federal government proposed the first "anti-dumping" legislation in the form of the Emergency Medical Treatment and Labor Act (EMTALA), the practice of emergency medicine changed forever. The law originally was designed to prevent hospitals from refusing to treat patients or transferring patients to other hospitals for financial reasons. Since the legislation has been enacted, much confusion has occurred regarding how best to comply with the constantly evolving mandates. During the past four years, the U.S. Department of Health and Human Services (HHS) has instituted an aggressive enforcement campaign with millions in fines levied against individual physicians and hospitals. Some reports indicate that the law actually has impaired rather than promoted patient access to care.[1]

Recently, the Centers for Medicare and Medicaid Services (CMS) proposed several changes to EMTALA that attempt to clarify hospital and physician duties. While these changes have yet to be instituted, many experts anticipate that regulatory amendments will be adopted this year. Undoubtedly, this new legislation will have an impact upon the care of emergency patients and the emergency physicians caring for them. In this issue, the current requirements of the law as well as the proposed future direction of EMTALA will be discussed.

This article will focus on emergency department (ED) liability under EMTALA. The first section will describe the background of this legislation. The second section will examine the obligations of hospitals and ED personnel under EMTALA. The article will conclude with practical suggestions for avoiding EMTALA liability in the ED.

—The Editor

The History of EMTALA

American common law traditionally imposed no duty on physicians to initiate care. Doctors had an obligation not to abandon their patients once treatment had begun,[2] but in general, they could refuse to enter a physician-patient relationship for any reason.[3] This right existed even when the individual seeking care suffered from a potentially life-threatening condition.[4] Nineteen states eventually imposed statutory obligations on hospitals to provide emergency care to all who needed it, but these statutes rarely were enforced.[5]

Well into the 1980s, then, individuals could not be certain that they would receive treatment upon entering an ED. Efforts by the federal government to compel emergency treatment through antidiscrimination statutes[6] and the Internal Revenue Code[7] succeeded only in creating a patchwork of obligations not applicable to all patients. Thousands of hospitals agreed to provide a "reasonable volume" of uncompensated care in exchange for federal funding under the Hill-Burton Act,[8] but even this did not ensure consistent access to emergency services.[9] "Deplorably lax" compliance by the hospitals,[10] coupled with virtually nonexistent enforcement by the HHS,[5,11] continually undermined Hill-Burton's intent.[5] Furthermore, the vague language of the statute caused disagreement among the courts over the extent to which it created a private right of action.[12]

Concern over the availability of emergency health care to the poor grew during the 1980s as a result of highly publicized incidents of "patient dumping."[13,14] Pressured to contain costs, while at the same time confronted by growing numbers of indigent patients,[15] hospitals routinely transferred uninsured patients to

other facilities, often without first providing medical stabilizing care. Meanwhile, some EDs went even further, flatly refusing to provide treatment to such patients.[13]

Intent on closing the gaps in protection left open by the Hill-Burton Act and other federal statutes,[5,13] Congress enacted EMTALA as part of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1986.[16] This statute imposed on Medicare-provider hospitals "a duty to afford medical screening and stabilizing treatment to any patient who seeks care in a hospital emergency room."[14] Unlike federal antidiscrimination statutes, which protect only certain classes of individuals, EMTALA confers a right to emergency treatment upon everyone who enters a qualified hospital.[17-20] And unlike the Hill-Burton Act, it expressly creates a private right of action against hospitals that fail to comply.[21]

EMTALA occupies just five pages of the United States Code. Despite its brevity, this statute has generated a steady flow of litigation in the 17 years since it took effect. The Health Care Financing Administration (HCFA) and its successor, CMS, have adopted several sets of regulations intended to clarify the obligations of hospitals under EMTALA. CMS last amended these regulations in April 2000.[22] Health care experts have expressed optimism that the regulations now under consideration will lessen the burden of compliance by hospitals overall, in addition to providing badly needed clarification.[23]

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Editorial Group Head: Valerie Loner
Managing Editor: Allison Mechem
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Customer Service: 1-800-688-2421

Customer Service E-Mail: customerservice@ahcpub.com
Editorial E-Mail: allison.mechem@ahcpub.com

World Wide Web page: http://www.ahcpub.com

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Hospital Obligations Under EMTALA

Congress has not preempted state law regarding the provision of health care.[24] Each state, therefore, retains the right to regulate care provided to individuals within its jurisdiction.[25] Accordingly, the federal government lacks the authority to compel all hospitals to open their doors to all patients. Instead, Congress has circumvented this problem—as it did in 1946, when crafting the Hill-Burton Act—by linking obligations under EMTALA to the receipt of federal funding. Only hospitals that voluntarily execute Medicare provider agreements must comply with the statute's provisions.[26] Conversely, qualified hospitals that fail to comply may lose the right to participate in the Medicare program.[27-31]

The first step in analyzing potential EMTALA liability, then, is to ascertain whether the hospital accepts Medicare funding. The vast majority of hospitals with EDs fall within this category, but a few do not. Hospitals need not concern themselves with liability under EMTALA if they have not executed a Medicare provider agreement.

Coming to the Emergency Department

A hospital's obligation under EMTALA begins when an individual comes to the ED and requests examination or treatment for a medical condition.[32] It logically follows, then, that a hospital can incur obligations under EMTALA only when it actually operates an emergency department. Rehabilitation hospitals and other facilities that do not categorize hold themselves as emergency care providers fall outside the scope of EMTALA, regardless of whether they participate in the Medicare program or not. These facilities must take care not to erect signage or conduct activities that might be construed as offering "emergency care" to the public, lest they unwittingly subject themselves to EMTALA's requirements.[33]

EMTALA does not define the term "emergency department." Remarkably, this oversight has not produced significant litigation.

Determining whether an individual has "come to the emergency department," on the other hand, has proven quite problematic. In *Baber v. Hospital Corporation of America*, the plaintiffs alleged that a hospital had violated EMTALA by failing to provide a screening examination to a patient transferred from another hospital's ED. Rather then receiving an examination in the ED at the receiving facility, the patient was admitted directly to the psychiatric ward, where she soon lapsed into a coma and died of an intracerebral hemorrhage. Finding that the patient "did not present herself to [the defendant's] emergency department for treatment," the Fourth Circuit Court of Appeals held that the hospital had committed no EMTALA violation.[34,35] Likewise, the courts in *Miller v. Medical Center of Southwest Florida,* have held that contacting an ED by telephone does not, by itself, constitute "coming to the emergency department."[36]

Communications between emergency medical services (EMS) personnel and ED personnel raise a more complicated issue. In *Johnson v. University of Chicago Hospitals*, a nurse at the University of Chicago Hospitals (UCH) instructed paramedics by radio to transport a pulseless infant to St. Bernard's Hospital, rather than to the UCH ED, which was located just five blocks from the scene of the 911 call. The nurse issued this instruction because UCH had gone on "partial bypass" status due to a lack of avail-

able beds in its pediatric intensive care unit. In the subsequent wrongful death lawsuit against UCH, the infant's mother alleged that UCH had violated EMTALA by ordering an unstable patient transferred away. Finding that UCH had ordered the diversion in its capacity as an EMS resource hospital, not as a receiving facility, the Seventh Circuit dismissed the EMTALA claim. However, the court suggested that communications between ambulance personnel and an ED might, under the right circumstances, trigger EMTALA protection. "Although the Act refers to individuals who come to the hospital," the court wrote, "we agree with [plaintiff's] assertion that an individual can seek medical assistance from a hospital through telemetry communications and paramedic services without coming to the hospital's emergency room."[37]

In the years since Johnson, HHS has issued regulations that comport at least to some extent with the Seventh Circuit's reasoning. These regulations define "comes to the emergency room" as meaning "on the hospital property." "Hospital property," in turn, includes ambulances owned and operated by the hospital, regardless of their location, as well as non-hospital-owned ambulances that have arrived on hospital grounds. The regulations further specify that communication between ambulance personnel and ED personnel does not constitute "coming to the emergency department." At the same time, however, the regulations allow an ED to deny access in such cases only when it has entered "diversionary status" due to insufficient emergency staff or facilities.[38]

These regulations figured prominently in a 2001 Ninth Circuit decision, *Arrington v. Wong*.[39] There, paramedics announced by radio that they intended to transport a patient suffering from severe respiratory distress to the defendant hospital. A physician in the ED replied that he thought it would be OK to bring the patient to a different facility at which the patient normally received care. Interpreting this as a directive, the paramedics proceeded to the more distant hospital, and the patient died shortly after arrival. In the trial that followed, the district court held that radio contact alone does not constitute "coming to the emergency room."[40] Relying more heavily on the "diversionary status" language in the regulations, the Ninth Circuit reversed on grounds that "[a] hospital may not prevent a non-hospital-owned ambulance from coming to the hospital, unless it has a valid treatment-related reason for doing so."[39]

CMS has endeavored to resolve some of these issues by incorporating into its proposed regulations a new designation: the "dedicated emergency department." A designated ED would be a "specially equipped and staffed area of the hospital that is used for a significant portion of the time for the initial evaluation and treatment of outpatients for emergency medical conditions."[41] This would encompass not only the traditional "emergency room," but also labor and delivery departments, psychiatric units, and other components of the hospital—whether located on the main campus or outside of it—"held out to the public as an appropriate place to come for medical services on an urgent, nonappointment basis."[42] An individual who seeks emergency care in any of these areas, therefore, would be entitled to EMTALA's protection. CMS has not yet decided whether to quantify the phrase "significant portion of the time" for the purpose of identifying designated EDs. Thus, under the final rule, a location within a hospital might be deemed a "designated emergency department" only if a specified percentage of the patients treated in that area go there for the purpose of obtaining emergency care.[42]

HHS recognized long ago that individuals who come to a hospital for the purpose of obtaining emergency care may require treatment even before they enter the ED.[42] An individual may collapse after walking through the main entrance, for example, or a clerk in the registration area outside of the ED may observe that a patient's condition suddenly has worsened. To ensure that these individuals fall within the scope of protection afforded by EMTALA, the existing regulations utilize arrival on the "hospital property" as the defining moment, rather than physical presence in the ED.[38] "Hospital property," in turn, currently includes not only the main hospital buildings, but also structures and outdoor areas of the hospital within 250 yards of those buildings,[38,43] and outpatient departments of the hospital located in separate facilities away from the main campus.[44] Utilization of the term "emergency department" or "emergency room" does not automatically place a hospital within the scope of EMTALA. Nor does the absence of such terminology obviate EMTALA duties. CMS has indicated, however, that a facility will be treated as a "designated emergency department" where it would be "perceived by a prudent layperson as [an] appropriate place to go for emergency care."[44] CMS regulations presently require personnel in off-campus departments routinely staffed by doctors or nurses to possess training in emergency care. Personnel in other off-campus departments must receive protocols directing them to contact emergency personnel at the main campus in appropriate situations.[45]

CMS has proposed one crucial change to these definitions: Excluded from EMTALA coverage would be "areas or structures that are located within 250 yards of the hospital's main building but are not a part of the hospital."[41] Thus, under the new regulations, a hospital no longer will incur EMTALA obligation for emergencies occurring in doctor's offices, skilled nursing facilities, or other non-medical facilities, such as shops or restaurants—even when these facilities are located on hospital grounds.[41] EMTALA liability will exist at facilities located off the main hospital campus only where that facility qualifies as a "designated emergency department" under CMS regulations.[33,41] These changes significantly will reduce the scope of obligations for many hospitals.

Under the new CMS regulations, hospital-owned ambulances will continue to be treated as an extension of the dedicated ED. CMS has crafted an exception to this rule, however, applicable to hospital-owned ambulance operating under a community-wide protocol. These protocols often dictate the destination of all ambulances operating within a specified geographical region. They may require, for example, that all 911 ambulances transport patients to the nearest hospital. Under the new regulation, transporting a patient to a hospital other than the one that owns the ambulance will not result in an EMTALA violation as long as the ambulance transports the patient in accordance with an applicable community-wide protocol. In these instances, patients will be treated as having "come to the emergency department" of the hospital to which they actually are delivered.[46,47]

Inpatients will have no rights under the proposed EMTALA regulations, except to the extent that they may have accrued EMTALA rights prior to admission.[48] The proposed regulations do not specifically address the issue of scheduled outpatient visits, but CMS has indicated in the preamble to its proposed regulations that it will not treat individuals who arrive for appointments as "coming to the emergency department" for EMTALA purposes.[49] Both inpatients and outpatients who arrive for scheduled appointments are entitled to receive care in accordance with Medicare regulations governing participation agreements, however.[49]

Screening Examinations

Once an individual has come to an ED and requested assistance with a medical condition, the hospital must provide "an appropriate medical screening examination within the capability of the hospital's emergency department" to determine whether an emergency condition exists. In so doing, the ED must make use of the hospital's ancillary services. EMTALA refers to this process as a "medical screening examination."[31]

The screening examination required by EMTALA differs significantly from traditional diagnosis. EMTALA screenings are conducted for a very limited purpose—to determine whether the subject of the screening requires emergency care.[32]

Recognizing that an EMTALA screening is not meant to take the place of a comprehensive physical examination, the courts have refrained from applying a malpractice standard of care. Plaintiffs have introduced misdiagnosis as evidence of EMTALA violations with remarkable frequency, but the courts universally have dismissed such evidence as indeterminative.[50-52] In other words, misdiagnosis does not, by itself, give rise to an EMTALA claim.[53-55]

Having decided that the traditional rules of malpractice do not apply, the courts have struggled to determine what constitutes an "appropriate" screening examination. "Appropriate," as the Sixth Circuit Court of Appeals observed in one EMTALA case, "is one of the most wonderful weasel words in the dictionary, and a great aid to the resolution of disputed issues in the drafting of legislation."[20] By including this term in the statutory language of EMTALA, Congress has left the sufficiency of each screening examination open to judicial analysis.

For the most part, courts have responded to this dilemma by adopting a differential treatment standard. As long as a hospital provides similar screening examinations to all patients presenting with the same complaint, the examinations generally will be deemed "appropriate" under EMTALA.[17,20,56-58] Hospital policies often serve as evidence of consistency in this regard.[59,60] As the District of Columbia Circuit Court of Appeals noted in *Gatewood v. Washington Healthcare Corporation*: "[A] hospital fulfills the 'appropriate medical screening' requirement when it conforms its treatment of a particular patient to its standard screening procedures. By the same token, any departure from standard screening procedures constitutes inappropriate screening in violation of [EMTALA]."[14] A number of courts have held that *de minimus* deviations from standard procedures do not, by themselves, prove the existence of an EMTALA violation.[59]

A screening examination need not be performed by a physician. Rather, this task may be completed by any employee who meets certain criteria under Medicare regulations[61] and is deemed qualified by the rules and regulations or bylaws of the hospital.[62] Triage alone does not suffice in this regard. The extent of the required examination will vary with the nature of the individual's complaint. CMS has indicated that in situations where the request for medical care is unlikely to involve an emergency, an individual's statement that he is not seeking medical care, coupled with brief questioning by the ED personnel, would be sufficient to establish that no emergency condition exists.[53] However, a hospital, therefore, may incur liability in failing to conduct a screening examination even when no emergency actually exists.[63]

Stabilizing Treatment for Emergency Medical Conditions and Labor

Once hospital personnel discover that an individual has an emergency medical condition, the hospital becomes obligated to provide stabilizing care.[64,65] The hospital may not transfer or discharge that individual until the condition has been stabilized.[66,67]

An "emergency medical condition" for EMTALA purposes is one that might reasonably result in "serious impairment to bodily functions" or "serious dysfunction of any organ or body part." An emergency medical condition also exists where the health of the individual or an unborn child is jeopardized, or where a pregnant woman experiencing contractions cannot be transferred safely before delivery.[68] The hospital must have actual knowledge of the emergency medical condition before an obligation to provide stabilizing treatment arises.[17,20,51,52,69-72] Where the hospital does not learn of the emergency medical condition because of an inadequate screening examination, liability will arise under the act's examination provision.[73]

Hospitals obligated to provide stabilizing care under EMTALA must do so within the capabilities of their staff and facilities.[32,65,74] Unlike screening examinations, which generally must conform only to the ordinary practices of the hospital, the adequacy of stabilizing treatment is analyzed in terms of professional standards. A patient is considered stable when, within reasonable medical probability, "no material deterioration" is likely to occur.[38] Once this state has been achieved, the obligation to provide treatment ends—at least with regard to EMTALA—and the hospital becomes free to discharge or transfer the patient.

A medical condition need not be alleviated entirely for the patient to be considered stable. In *Brooker v. Desert Hospital*, for example, a woman who entered the defendant hospital's ED complaining of chest pain was found to have 99% occlusion of her left anterior descending artery and 70% occlusion of her right posterior descending artery. The hospital's cardiac surgeon was not available, so the patient's cardiologist inserted an intraaortic balloon pump and transferred the patient to another hospital for surgery. His progress note described the patient's condition at that time as "clinically stable" but overall "critical." The patient brought action against the hospital, claiming that she had suffered myocardial infarction during the transfer, and that the hospital had violated EMTALA by transferring her without stabilizing her condition. The district court dismissed the

claim. Noting that the patient's condition had been "stabilized" as defined by EMTALA, the Ninth Circuit Court of Appeals affirmed.[75]

Some courts have interpreted EMTALA to mean that a hospital's duty to provide stabilizing treatment ends with the patient's admission to the hospital.[69] In *Bryant v. Redbud Community Hospital*, a 17-year-old who had been treated and discharged from the defendant hospital's ED was summoned back after x-rays revealed a lung abscess. He was admitted, transferred to the intensive care unit (ICU) at another hospital, and eventually discharged, but died shortly thereafter. In the ensuing wrongful death action, the plaintiffs conceded that the patient had received an appropriate medical screening, and that an obligation to stabilize did not arise during the initial ED visit, because the emergency condition went undetected. They also conceded that the transfer did not violate EMTALA. The plaintiffs alleged, however, that the hospital had incurred a duty to stabilize the patient once the lung abscess had been discovered, and that the hospital had breached that duty when it failed to stabilize the patient after admission. Finding that "EMTALA generally ceases to apply once a hospital admits an individual for patient care," the Ninth Circuit upheld summary judgment for the hospital.[69]

Other courts have taken an even more restrictive view of the stabilization requirement, holding that it applies only when the patient will be transferred. In *Harry v. Marchant*, a woman suffering from respiratory distress arrived by ambulance in the defendant hospital's ED. She was admitted to the ICU after a lengthy delay and eventually died. The plaintiffs brought an action against the hospital, a nurse, and several doctors, alleging that the hospital's negligent treatment had violated EMTALA's stabilization requirement. The 11th Circuit held that this requirement applies only to patients who are transferred, and that the plaintiffs, therefore, had failed to state a claim.[76]

The Sixth Circuit has interpreted the stabilization requirement quite differently. In *Thornton v. Southwest Detroit Hospital*, a woman who had received emergency care for a stroke was discharged home after 21 days as an inpatient. Her condition deteriorated from a lack of rehabilitative care, and she brought action against the hospital, alleging that she had been discharged in an unstable condition. The court found that the hospital had, in fact, stabilized her condition, and therefore had complied with EMTALA, but it stressed that the patient's status as an inpatient had not determined the outcome of the case. To the contrary, the court suggested that a violation of EMTALA can be established long after a patient had been admitted to the hospital, since "emergency care does not always stop when a patient is wheeled from the emergency room into the main hospital."[77]

The language of EMTALA and regulations promulgated thus far by CMS seem to track the 11th Circuit's reasoning in *Harry*, imposing an obligation to provide stabilizing care only until an "appropriate transfer" occurs.[78] At the same time, CMS has announced that it views the EMTALA stabilization requirement as continuing after admission. "Once a hospital has incurred an EMTALA obligation with respect to an individual," CMS has stated in the preamble to its proposed regulations, "that obligation continues while the individual remains at the hospital."[79] In fact, CMS proposes to modify existing EMTALA regulation with the addition of a new subsection entitled "Application to inpatients—admitted emergency medical patients."[80] This subsection specifically provides that "[a]dmitting an individual whose emergency medical condition has not been stabilized does not relieve the hospital of further responsibility to the individual under this section."[81] CMS believes this change is justified as a means of preventing hospitals from admitting patients merely to circumvent stabilization liability.[79]

The proposed regulations further specify that a hospital will not be relieved of liability where an inpatient rapidly or frequently "goes in and out of stability."[79] For the first time, hospitals will be required to document relevant clinical data establishing a "period of stability" to satisfy its stabilization responsibilities.[82] CMS has not wavered from its position that EMTALA obligations cannot arise after a patient has been admitted for elective, "non-emergency" diagnosis or treatment, though,[79,83] and the courts have embraced this position.[53]

Transfer

Beyond obligations to provide screening examinations and stabilizing treatment, EMTALA imposes several obligations on EDs that seek to transfer patients.

First, the patient or someone acting on the patient's behalf, must make a written request for transfer after being informed of the hospital's obligations.[84] CMS requires the patient to include in this writing the reason for the request, as well an indication that the patient recognizes the risks and benefits of the transfer.[85]

Second, a physician must sign a certificate indicating that the benefits anticipated from treatment at the receiving facility outweigh the risk of the transfer. This certification must contain a summary of the risks and benefits upon which this decision is based.[86,87] When a physician is not physically present in the ED, any other "qualified medical person" may sign the certificate.[88,89]

Third, the transfer must be "appropriate."[90] To effectuate an appropriate transfer, the transferring hospital must provide stabilizing treatment that minimizes the risk of the transfer to the patient and any unborn child of that patient. The hospital must send with the patient copies of all available medical records relating to the patient's emergency medical condition, as well as copies of the required consent and certification forms and the names of any on-call physician who refused or failed to appear within a reasonable time to provide stabilizing care. The receiving facility must possess adequate space and qualified personnel to treat the transferred patient, and the transfer must be conducted by qualified personnel utilizing adequate equipment.[91]

The courts have had little occasion to determine what constitutes an "appropriate" transfer. In *Burditt v. United States Department of Health and Human Services*, the Fifth Circuit held that a hospital had not conformed to EMTALA requirements when it transferred a severely hypertensive woman in active labor 170 miles for further care. The court found that the emergency medical technicians and obstetrical nurse who had accompanied the patient possessed the necessary qualifications to assist with an uncomplicated delivery, but that they could not have performed a caesarian section—a procedure that might well

have become necessary, given the woman's condition.[31] A federal court held in *Owens v. Nacogdoches County Hospital* that an inappropriate transfer had occurred when the defendant hospital directed a patient to drive to another facility.[92] The court in *Wey v. Evangelical Community Hospital*, on the other hand, held that the transfer of a patient with a fractured leg by private automobile did not violate EMTALA. This decision turned primarily on the fact that the plaintiff produced no expert testimony that this mode of transport was medically inappropriate, however.[93]

A hospital that refuses to accept an appropriate transfer can incur EMTALA liability for "reverse dumping." In *St. Anthony Hospital v. United States Department of Health and Human Services*, a physician at a rural ED attempted to transfer a patient who had sustained a traumatic aorta rupture, but the teaching hospital that was to receive the patient appropriately declined because it already had two emergency surgeries to perform. The ED physician then contacted a vascular surgeon at another hospital who also refused the transfer, saying that "the case was [the teaching hospital's] problem." Finding that the patient had suffered from an unstabilized emergency medical condition, and that the transferring hospital lacked the ability to perform the complex surgical procedure needed, the 10th Circuit upheld a $50,000 fine levied against the hospital that had inappropriately refused to accept the transfer.[30]

CMS already has issued a regulation that prohibits reverse dumping. Section 489.24(e) of the EMTALA regulations require Medicare-provider hospitals possessing specialized capabilities to accept appropriate transfers from anywhere within the United States, except where the receiving hospital lacks the capacity to provide adequate care. Specialized capabilities include such facilities as burn units, trauma units, and neonatal ICUs.[94] The proposed regulations do not affect this requirement.

Patients Who Refuse to Consent

Patients who possess the mental capacity to make rational treatment-related decisions need not consent to examination, stabilizing treatment, or transfer.[95] A hospital meets the requirements of EMTALA as long as a hospital representative informs the individual of the risks and benefits associated with the proposed course of action, and as long as the encounter is properly documented. The medical record must contain a description of the activities that the patient refused. Additionally, the hospital must take "all reasonable steps" to obtain a written statement of refusal from the patient. This statement must include the reasons for the refusal and should reflect the fact that the risks and benefits were explained.[96,97]

On-Call Requirements

As a requirement of participation in the Medicare program, hospitals must maintain a list of on-call physicians who will examine and treat patients with emergency medical conditions.[98-101] The responsibilities of these physicians must be defined within the hospital's by-laws or policies.[114] Failure of an on-call physician to respond within a reasonable time may constitute an EMTALA violation.[103] Each hospital must adopt procedures that will ensure adequate coverage when an on-call physician cannot respond because of unanticipated circumstances.[104]

Recognizing that some hospitals possess limited staffing resources—particularly with regard to specialists—CMS has proposed a liberal on-call regulation that will leave decisions about staffing procedures largely to the hospitals. The new regulation expressly states that physicians need not remain "on call at all times." It also permits great latitude with respect to physician on-call lists, requiring only that they reflect the "best needs of the hospital's patients."[103] However, hospital administrators should not interpret this language to mean that they enjoy total freedom when making on-call staffing arrangements. CMS has indicated that it will review the adequacy of each on-call arrangement on a case-by-case basis, taking into account all relevant factors, including the number of available physicians, the frequency with which a particular specialty is utilized, and the sufficiency of any existing back-up plans.[105]

In June 2002, CMS revised its position on simultaneous on-call duties. Physicians now may serve on call at more than one hospital at a time, as long as each hospital involved is aware of the physician's scheduling conflict.[47]

Prior Authorization

With so many Americans now covered by health maintenance organizations and other managed-care plans, ED personnel often contact the insurer before rendering care. This practice may be undertaken for the financial benefit of the hospital, or it may be done as an accommodation to the patient, who may require authorization to be indemnified. But ED personnel should not delay emergency medical screenings or stabilizing treatment to inquire about insurance or ability to pay. EMTALA expressly prohibits this practice.[103]

Notification

Medicare-provider hospitals must post—conspicuously in their EDs and in places likely to be noticed by individuals waiting to receive care—signs that describe the rights of individuals under EMTALA.[106]

Enforcement

Failure to comply with EMTALA can have dire consequences. One section of the statute creates a private right of action that allows individuals to claim "those damages available for personal injury under the law of the state in which the hospital is located."[21] Another section confers a right of action upon "any medical facility that suffers a financial loss as a result of a participating hospital's violation."[107] The courts universally have held that plaintiffs may bring these actions only against hospitals, however, and not against individual physicians.[57,108]

EMTALA also provides for enforcement by the government. Hospitals and responsible physicians may be assessed fines of up to $50,000 per violation.[109] Violations need not be intentional. To the contrary, the statute specifically creates penalties for negligent violations.[109]

Because EMTALA preempts state laws pertaining to the provision of emergency medical services, hospitals may not invoke any Good Samaritan immunity that may be conferred under state law.[107] Public hospitals may be able to claim sovereign immunity under the 11th Amendment, however.[110-112] The majority of courts

have upheld state-imposed statutory damage caps.[113,114]

Avoiding EMTALA Liability

EMTALA imposes complex obligations on Medicare-provider hospitals. Hospitals can increase the likelihood of compliance by regularly educating their personnel about EMTALA's requirements.

Hospitals continually should reinforce to their ED personnel the importance of providing equal treatment to all patients. The adoption of broad policies pertaining to screening examinations and stabilizing care will accomplish this goal without imposing rigid standards on ED staff—the deviation from which may, by itself, serve as evidence of an EMTALA violation. Screening examinations and stabilizing care should be documented thoroughly. Documentation becomes especially crucial any time ED personnel deviate from hospital policy.

Personnel in the ED and elsewhere in the hospital should be reminded that the obligation to provide stabilizing treatment continues even after admission. When admitting a patient, ED personnel must communicate adequately with nursing and medical personnel elsewhere in the hospital to ensure continuity of care.

When transferring a patient, ED personnel must ensure that the mode of transportation is appropriate. Personnel who will accompany the patient must possess adequate training, and proper equipment must be available. Allow patients to transport themselves only when there is virtually no chance of deterioration between facilities. Remember, too, that a copy of the medical record must accompany the patient.

Above all else, err on the side of caution when making discharge, admission, and transfer decisions.

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Physician CME Questions

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1. Under regulations proposed by CMS, which of the following locations would fall outside the scope of EMTALA?
   A. A gift shop located within the main hospital building
   B. An obstetrical unit
   C. An ED waiting area
   D. The sidewalk immediately outside of the ED entrance

2. Which of the following is an example of reverse dumping?
   A. An inpatient unit transports an unstable patient downstairs to the ED.
   B. A hospital refuses to accept a transfer because the patient lacks insurance.
   C. A hospital transfers a patient to a rehabilitation facility unnecessarily.
   D. A hospital refuses to accept a transfer because it lacks sufficient personnel.

3. Which of the following describes CMS's view on stabilizing treatment?
   A. The duty to stabilize ends with admission.
   B. A duty to stabilize exists only when the patient later will be transferred.
   C. The duty to stabilize continues even after the patient has been admitted.
   D. The duty to stabilize ends only when the patient is discharged from an inpatient unit.

4. Which of the following best describes a screening examination?
   A. An effort to determine whether an individual has an emergency medical condition
   B. An effort to determine whether a patient has insurance coverage
   C. An effort to determine whether a patient may be transferred safely
   D. An effort to determine whether a patient requires admission

5. Which of the following constitutes a violation of EMTALA?
   A. A hospital lacking surgical capability transfers a patient who has been shot in the chest.
   B. A hospital admits a patient who may be discharged safely.
   C. A hospital refuses to accept a transfer from a hospital in Canada.
   D. A hospital transfers a patient to a specialized facility without explaining the reason.

6. Under EMTALA, when is a patient considered stable?
   A. When the patient's condition is unlikely to materially deteriorate
   B. When the patient has been admitted to an inpatient unit
   C. When the patient's complaint has been alleviated completely
   D. When the patient no longer requires constant observation

CME Answers

1. A; 2. B; 3. C; 4. A; 5. D; 6. A

In Future Issues: **Update on Child Abuse**

Emergency Medicine Reports
The Practical Journal for Emergency Physicians

Urinary Tract Infection, Part I

Most Common Uropathogens Identified in Adult Patients§

1) *Escherichia coli*
2) *Staphylococcus saprophyticus*
3) *Klebsiella pneumoniae*
4) *Proteus mirabilis*
5) *Enterococcus* faecalis*
6) *Pseudomonas aeruginosa*
7) *Enterobacter cloacae*
8) *Citrobacter*

§ = Listed in order of decreasing frequency

* = Gram-positive organisms

Incidence of Urinary Tract Pathogens

PATHOGEN	UNCOMPLICATED CYSTITIS	COMPLICATED UTIs
Escherichia coli	70-95%	40-55%
Klebsiella spp	2-6%	10-17%
Enterobacter spp	0-2%	5-10%
Proteus mirabilis	2-4%	5-10%
Pseudomonas aeruginosa	0-1%	2-10%
Enterococcus spp	2-5%	1-20%
Staphylococcus saprophyticus	5-20%	-------

Patient Subgroups Associated with Complicated Lower Urinary Tract Infections

STRUCTURAL ABNORMALITIES (SURGICAL, CONGENITAL, OR ACQUIRED)

Renal tumors
Urethral or ureteral strictures
Renal cysts
Congenital abnormalities of the urogenital system
Urogenital surgery

FUNCTIONAL ABNORMALITIES

Neurogenic bladder
Vesicoureteral reflux

MECHANICAL OBSTRUCTION TO URINE FLOW

Indwelling bladder catheterization
Nephrolithiasis
Ureteral stents and nephrostomy tubes
Urogenital instrumentation

HIGH RISK

Diabetes mellitus
Pregnancy
Immunosuppressed
Sickle cell anemia and trait
Renal failure

Ciprofloxacin Extended Release (Cipro XR) vs. Ciprofloxacin BID in Patients with Uncomplicated UTI

SIDE EFFECT, SAFETY, AND TOLERABILITY PROFILES

	CIP EXT-REL (N = 444)	CIP BID (N = 447)
Drug-related Adverse Events (AEs)	46 (10%)	41 (9%)
Headache	7 (2%)	3 (< 1%)
Nausea	12 (3%)	4 (< 1%)
Vaginal moniliasis	4 (< 1%)	10 (2%)
Vaginitis	4 (< 1%)	7 (2%)
Serious drug-related AEs	0 (0%)	0 (0%)
Drug-related AEs leading to premature discontinuation	1 (< 1%)	0 (0%)

Antibiotic Therapy for Acute Uncomplicated UTI in Adults

CYSTITIS (3-DAY REGIMEN)

AGENT OF CHOICE:

Fluoroquinolone (initial agent of choice)
Ciprofloxacin extended release (Cipro® XR) 500 mg po QD x 3 days

ALTERNATIVE FIRST-LINE AGENTS:

Fluoroquinolones (alternative)
Levofloxacin 250 mg po QD x 3 days
Ofloxacin 200 mg po BID x 3 days
Norfloxacin 400 mg po BID x 3 days

Trimethoprim/sulfamethoxazole* 160/800 mg po BID x 3 days

SECONDARY ALTERNATIVES:

Amoxicillin 500 mg po TID x 7-10 days (known enterococcus infection only)
Nitrofurantoin 100 mg po BID x 7 days
Amoxicillin-clavulanic acid 250 mg po QID x 7 days
Fosfomycin One 3-g sachet orally

*Only if *E. coli* resistance is < 10-20% in patient population (based on regional resistance surveillance data).

Antibiotic Treatment of Pyelonephritis (10-14 Day Treatment Duration)

FIRST-LINE AGENTS	
Fluoroquinolones	10-14 day course
Ciprofloxacin	(preferred) 500 mg Q 12 hours PO, IV
ALTERNATIVE FIRST-LINE AGENTS	
Levofloxacin	250 mg Q 24 hours PO, IV
Ceftriaxone	1-2 g Q 24 hours IV
Ofloxacin	200-300 mg Q 12 hours PO, IV
Norfloxacin	400 mg Q 12 hours PO
SECOND-LINE AGENTS	
TMP-SMX	160/800 mg Q 12 hours PO, IV
Ampicillin/sulbactam	3 g Q 6 hours IV
Amoxicillin/clavulanate	875/125 mg Q 12 hours PO
Piperacillin/Tazobactam	4.5 g Q 8 hours IV
Gentamicin	3-5 mg/kg/day divided q 6 hours IV

Supplement to *Emergency Medicine Reports*, March 24, 2003: "Urinary Tract Infection: Risk Stratification, Clinical Evaluation, and Evidence-Based Antibiotic Therapy. Part I: Epidemiology, Emerging Resistance Patterns, and Patient-Specific Treatment Strategies."
Authors: **Romolo Gaspari, MD, FACEP,** Research Director, Assistant Professor, Department of Emergency Medicine, University of Massachusetts School of Medicine, Worcester, MA; **Gideon Bosker, MD, FACEP,** Assistant Clinical Professor, Yale University School of Medicine, New Haven, CT.