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Urgent Care
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of America



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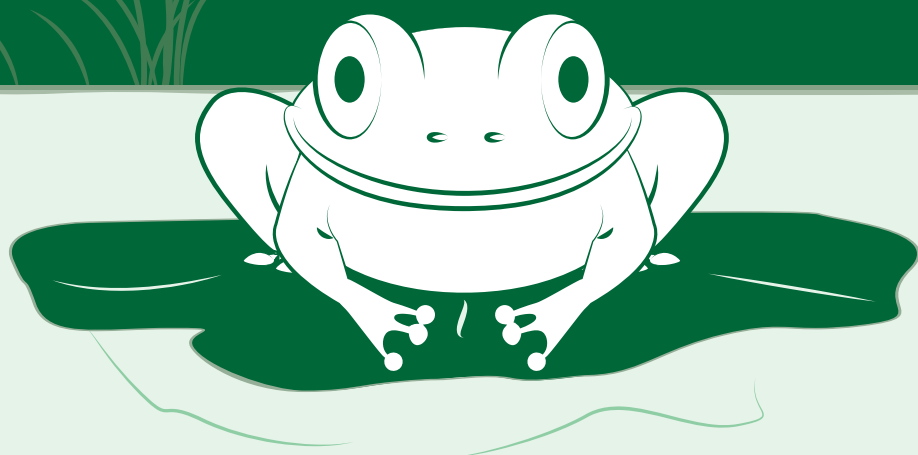


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A Rational Approach to ‘Suspected’ Ebola Virus Disease in Urgent Care



Fear and anxiety are high in the wake of the first Ebola Virus Disease (EVD) cases on American soil. As with any new, deadly, and transmissible infectious disease, confusion and missteps rule the day. The U.S. public health and disease control entities are certainly not perfect, but the reasonable clinician will see that the ability of these entities to prevent an outbreak is actually quite high.

The Disease

EVD causes a hemorrhagic fever, giving the disease characteristic features such as conjunctival hemorrhage, hematemesis, and hemoptysis. Ebola virus is not spread by breath, unlike its respiratory virus cousins. Rather, transmission is only through direct contact with contaminated fluids, making transmission more difficult, and likewise more controllable. This is precisely why most of the global pandemics are caused by respiratory viruses. Although some people have expressed skepticism after health care workers became infected despite protective gear, most experts agree that improper removal of the gear is likely to blame, not aerosolization of Ebola virus. While viral mutations are common, it is an evolutionary leap for a virus to change the type of cell it infects (e.g., from endothelial cells in blood vessels to alveolar cells in the respiratory tract). In other words, viral genetics practically eliminates the possibility of aerosolization of Ebola, and with that, a global pandemic is unlikely.

The Response

The goal of public health officials is to contain and control. With proper resources and education, countries affected by EVD should be able to adequately control the spread. This was the case in Nigeria, where a massive effort to identify and quarantine 270 cases of the disease was effective at eliminating the spread in that country. With the massive resources and modern health care system available in the United States, contain and control is expected to be equally effective at controlling spread. Sporadic cases will undoubtedly continue, but it takes more than sporadic cases to create an epidemic.

The Missteps

It is clear that our first encounters with EVD in the United States have not been managed seamlessly. But this is to be expected. With experience and education, we will get better. Although some are quick to criticize the CDC, most experts agree that a measured response with interval escalation is the right approach. We are, of course, not trying to shut down a nation in the effort to control a disease. That's simply not a good public health strategy.

The Urgent Care Response

Urgent care centers have already experienced cases of “possible” Ebola, and this is likely to recur, so preparation is key. To do so, policy and procedure is necessary, but inducing fear should certainly be avoided. The fact is that the urgent care is *not* the right place to screen and triage patients with suspected Ebola. So, our role should be “limited” and some would even argue “eliminated.” Through the course of this crisis, *JUCM* will maintain at <http://www.jucm.com/a-rational-approach-to-suspected-ebola-virus-disease-in-urgent-care/> sample policies and procedures that reflect the urgent care realities, including the up-to-date advice for screening, PPE, isolation and transfer.

This infectious disease crisis is real but a full-blown epidemic remains almost implausible in this country. Education of staff and patients is critical to the urgent care response and regular updates are important. We will continue to hear sporadic stories of suspected cases and some of these patients may present to urgent care centers. A sensible approach to preparation and response in our setting should be implemented. ■

Lee A. Resnick, MD, FAAFP
Editor-in-Chief
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Proper empiric antibiotic treatment in women with acute uncomplicated cystitis and pyelonephritis can prevent unnecessary morbidity and provide urgent relief from these common genitourinary infections.

Mozella Williams, MD

PRACTICE MANAGEMENT



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As the Affordable Care Act encourages greater integration of health insurers, hospitals, and physicians, urgent care will play an important role in increasing patient access, improving clinical outcomes and reducing health care costs.

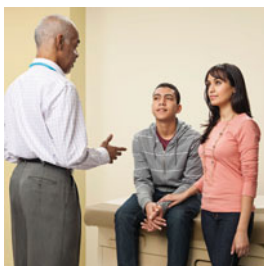
Alan A. Ayers, MBA, MAcc

CASE REPORT

24 Treating Autistic Patients in the Urgent Care Setting

As the number of patients with autism spectrum disorders continues to increase, it is important that urgent care providers proactively educate themselves about how best to provide acute care for these individuals.

Elizabeth Mangone and
John Shufeldt, MD, JD, MBA, FACEP



IN THE NEXT ISSUE OF JUCM

Scalp and face lacerations are a common presentation in urgent care and the subject of next month's cover story. The first of a two-part series underscores the importance of an appreciation for the role of anatomy in a cosmetically acceptable outcome and reviews appropriate repair preparation and technique for wounds to the scalp, forehead, eyelid, and eyebrow.

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Mission Statement

JUCM The Journal of Urgent Care Medicine supports the evolution of urgent care medicine by creating content that addresses both the clinical practice of urgent care medicine and the practice management challenges of keeping pace with an ever-changing healthcare marketplace. As the Official Publication of the Urgent Care Association of America and the Urgent Care College of Physicians, *JUCM* seeks to provide a forum for the exchange of ideas and to expand on the core competencies of urgent care medicine as they apply to physicians, physician assistants, and nurse practitioners.

Affiliations

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Half of women will experience acute, uncomplicated cystitis sometime during their lives. Such an infection can take a significant toll and warrants careful management to avoid complications such as acute, uncomplicated pyelonephritis. Timely diagnosis and appropriate antibiotic treatment of these two conditions are the subject of this month's cover story. Written by Mozella Williams, MD, it reviews the Infectious Diseases Society of America practice guidelines for treatment of uncomplicated cystitis and pyelonephritis in premenopausal, non-pregnant women who have no known underlying urogenital anatomical problems or serious comorbidities.



Mozella Williams, MD, is Assistant Professor at the University of Maryland School of Medicine, Department of Family & Community Medicine, Baltimore, Maryland.



Adults and children who are developmentally disabled present a unique set of characteristics that demand a higher quality of care. With the

prevalence of autism spectrum disorder (ASD) continuing to increase, urgent care providers are a first-line resource for treatment of acute illnesses in these patients. Adjustments to the typical urgent care protocol for this population are the subject of this month's case report, which is a departure from our typical format. In it, authors Elizabeth Mangone and John Shufeldt, MD, JD, MBA, FACEP, review key information necessary to assess and treat patients with ASD.

Elizabeth Mangone is a premed undergraduate student at Boston College. John Shufeldt, MD, JD, MBA, FACEP, is CEO of Urgent Care Integrated Network and sits on the Editorial Board of *JUCM*.

This month's practice management article is an exclusive question-and-answer session with representatives of the country's largest managed care organization, Kaiser Permanente.



Alan A. Ayers, MBA, MAcc, interviews Michael A. Neri, Jr., MD, and Peter A. King, MD, about an integrated health system that makes available higher-acuity urgent care by matching a patient's condition with the capabilities of a treating facility, thereby promoting the goals of quality and efficiency.

Alan A. Ayers, MBA, MAcc, is on the Board of Directors, Urgent Care Association of America, Associate Editor, *JUCM*, and Vice President, Concentra Urgent Care. Michael A. Neri, Jr., MD, is Regional Physician-in-Charge of Urgent Care and Riverside Area Assistant Medical Director for Kaiser Permanente Southern California. Peter A. King, MD, is Physician Director of Acute Care Services for Kaiser Permanente Georgia.

Also in this issue:

In Health Law this month, **John Shufeldt, MD, JD, MBA, FACEP**, discusses the HIPAA Privacy Rule.

Sean M. McNeeley, MD, and **The Urgent Care College of Physicians** review new abstracts on literature germane to the urgent care clinician, including the sensitivity of rapid strep tests, NSAIDs and anaphylaxis, and scalp hematomas and brain injury.

In Coding Q&A, **David Stern, MD, CPC**, discusses coding for cerumen removal and Workers' Compensation visits.

Our Developing Data end piece this month looks at what benefits are received by physicians employed by urgent care centers. ■

To Submit an Article to *JUCM*

JUCM, *The Journal of Urgent Care Medicine* encourages you to submit articles in support of our goal to provide practical, up-to-date clinical and practice management information to our readers—the nation's urgent care clinicians. Articles submitted for publication in *JUCM* should provide practical advice, dealing with clinical and practice management problems commonly encountered in day-to-day practice.

Manuscripts on clinical or practice management topics should be 2,600–3,200 words in length, plus tables, figures, pictures, and references. Articles that are longer than this will, in most cases, need to be cut during editing. The information you provide should be of practical use to our readers, who have come to practice in an urgent care setting from a variety of clinical back-

grounds. Your article should take their perspective into account by considering several key issues, such as: What immediate management is indicated? What labs or diagnostics are required? What are the next steps; with whom should the patient follow up? Who should be admitted or referred to the emergency room? Imagine yourself in the reader's shoes and ensure your article includes the answers to questions you'd be asking.

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Largest group ever attends UCAOA Urgent Care Fall Conference

■ P. JOANNE RAY

The 2014 Urgent Care Fall Conference in Denver brought together more than 400 urgent care physicians and advanced practice clinicians, center owners, administrators, managers, and investors. In addition, more than 200 representatives from 78 companies provided attendees access to the latest in urgent care products, services, and technologies.

“Most of the conference sessions were recorded and will be made available through the UCAOA Online Education portal.”

Based on previous attendee feedback, the Conference offered 60 sessions of new comprehensive content for the entire urgent care team and was centered around five themes: Comprehensive Clinic Startup, Hands-on Boot Camp, Clinical Hot Topics, Achieving Operational Excellence, and Driving Volume to Drive Profits. New this year, attendees had the flexibility of choosing courses that most appealed to them across all tracks.

A special Health & Public Policy session was added to provide updates on UCAOA activities at the federal and state levels. The UCAOA and UCCOP Boards as well as nine committees convened on site to address member business and further UCAOA and urgent care initiatives. And, KDVR Fox News (Denver) filmed on site and featured the conference and urgent care on their evening news.

Most of the conference sessions were recorded and will be made available through the UCAOA Online Education portal.

Be sure to mark your calendars for the 2015 National Urgent Care Convention (April 27-30 in Chicago) and the Urgent Care Fall Conference (September 24-26 in New Orleans). ■



P. Joanne Ray is chief executive officer of the Urgent Care Association of America. She may be contacted at jray@ucaoa.org.



Dr. Will Gluckman featured in KDVR Denver TV news coverage highlighting UCAOA and urgent care precautions for Ebola virus.



Scott Friedman, keynote speaker, engages Steve Sellars, UCAOA Board Secretary and Education Committee chair, during his presentation.



Attendees listen intently as Steve Sellars and Manny Garza focus on “Goals, Organizational Priorities, Leadership, and Performance Indicators.”

Antibiotic Management of Acute Uncomplicated Cystitis and Pyelonephritis in Women

Urgent message: Proper empiric antibiotic treatment in women with acute uncomplicated cystitis and pyelonephritis can prevent unnecessary morbidity and provide urgent relief from these common genitourinary infections.

MOZELLA WILLIAMS, MD

Introduction

Genitourinary infections in women are encountered frequently in the urgent care setting. Timely diagnosis and proper empiric antibiotic treatment will usually forestall serious complications and provide speedy relief. Over a lifetime, 50% of women will experience an acute uncomplicated cystitis, also known as a lower urinary tract infection (UTI), making acute uncomplicated cystitis the most common bacterial infection among this population. Acute uncomplicated pyelonephritis usually occurs as a consequence of ascending acute uncomplicated cystitis. Although often self-limited, acute uncomplicated cystitis takes a significant toll on women and warrants careful consideration. Pyelonephritis carries more potential for serious complications of morbidity, which makes proper empiric treatment very important.

In 2010, the Infectious Diseases Society of America (IDSA), in collaboration with the European Society of Clinical Microbiology and Infectious Diseases (ESCMID), updated their practice guidelines for the treatment of acute uncomplicated cystitis and pyelonephritis. They took into account *in vitro* resistance prevalence and the

.....
Mozella Williams, MD, is Assistant Professor at the University of Maryland School of Medicine, Department of Family & Community Medicine, Baltimore, MD.



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ecological adverse effects of antibiotic therapy.¹ These guidelines are limited to premenopausal, non-pregnant women with no known underlying urogenital anatomical problems, nor other serious comorbidity.

Acute uncomplicated cystitis

Acute uncomplicated cystitis is an infection of the lower

LET EMIT BE EMIT



Not actual patient

AGE: 4

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Dosage and Administration:

Instill 1 drop in the affected eye(s) 2 times daily for 7 days.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions:

Topical Ophthalmic Use Only - NOT FOR INJECTION.

MOXEZA[®] Solution is for topical ophthalmic use only and should not be injected subconjunctivally or introduced directly into the anterior chamber of the eye.

Hypersensitivity Reactions - In patients receiving systemically administered quinolones, including moxifloxacin, serious and occasionally fatal hypersensitivity (anaphylactic) reactions have

been reported, some following the first dose. If an allergic reaction to moxifloxacin occurs, discontinue use of the drug.

Prolonged Use - Prolonged use may result in overgrowth of non-susceptible organisms, including fungi. If superinfection occurs, discontinue use and institute alternative therapy.

Contact Lens Wear - Patients should be advised not to wear contact lenses if they have signs or symptoms of bacterial conjunctivitis.

Adverse Reactions:

The most common adverse reactions reported in 1-2% of patients were eye irritation, pyrexia, and conjunctivitis.

For additional information about MOXEZA[®] Solution please see brief summary of Prescribing Information on adjacent side.

References: 1. MOXEZA[®] Solution package insert. 2. Tauber S, Cupp G, Garber R, Bartell J, Vohra F, Stroman D. Microbiological efficacy of a new ophthalmic formulation of moxifloxacin dosed twice-daily for bacterial conjunctivitis. *Adv Ther.* 2011;28(7):566-574. 3. Tasman W, Jaeger EA, eds. *Duane's Ophthalmology*. Philadelphia, PA: Lippincott Williams & Wilkins; 2012. 4. Lindstrom R, Lane S, Cottingham A, et al. Conjunctival concentrations of a new ophthalmic solution formulation of moxifloxacin 0.5% in cataract surgery patients. *J Ocul Pharmacol Ther.* 2010;26(6):591-595. 5. Data on file, Alcon, a Novartis Company. 6. Formulary data provided by Pinsonault Associates, LLC, PathfinderRx, March 2013.

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*Efficacy for this organism was studied in fewer than 10 infections.

DOSAGE AND ADMINISTRATION

Instill 1 drop in the affected eye(s) 2 times daily for 7 days.

DOSAGE FORMS AND STRENGTHS

4 mL bottle filled with 3 mL of sterile ophthalmic solution of moxifloxacin hydrochloride, 0.5% as base.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Topical Ophthalmic Use Only
NOT FOR INJECTION. MOXEZA® solution is for topical ophthalmic use only and should not be injected subconjunctivally or introduced directly into the anterior chamber of the eye.

Hypersensitivity Reactions

In patients receiving systemically administered quinolones, including moxifloxacin, serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported, some following the first dose. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, angioedema (including laryngeal, pharyngeal or facial edema), airway obstruction, dyspnea, urticaria, and itching. If an allergic reaction to moxifloxacin occurs, discontinue use of the drug. Serious acute hypersensitivity reactions may require immediate emergency treatment. Oxygen and airway management should be administered as clinically indicated.

Growth of Resistant Organisms with Prolonged Use

As with other anti-infectives, prolonged use may result in overgrowth of non-susceptible organisms, including fungi. If superinfection occurs, discontinue use and institute alternative therapy. Whenever clinical judgment dictates, the patient should be examined with the aid of magnification, such as slit-lamp biomicroscopy, and, where appropriate, fluorescein staining.

Avoidance of Contact Lens Wear

Patients should be advised not to wear contact lenses if they have signs or symptoms of bacterial conjunctivitis.

ADVERSE REACTIONS

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to the rates in the clinical trials of another drug and may not reflect the rates observed in practice. The data described below reflect exposure to MOXEZA® solution in 1263 patients, between 4 months and 92 years of age, with signs and symptoms of bacterial conjunctivitis. The most frequently reported adverse reactions were eye irritation, pyrexia and conjunctivitis, reported in 1-2% of patients.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category C. Moxifloxacin was not teratogenic when administered to pregnant rats during organogenesis at oral doses as high as 500 mg/kg/day (approximately 25,000 times the highest recommended total daily human ophthalmic dose); however, decreased fetal body weights and slightly delayed fetal skeletal development were observed. There was no evidence of teratogenicity when pregnant Cynomolgus monkeys were given oral doses as high as 100 mg/kg/day (approximately 5,000 times the highest recommended total daily human ophthalmic dose). An increased incidence of smaller fetuses was observed at 100 mg/kg/day. Since there are no adequate and well-controlled studies in pregnant women, MOXEZA® solution should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

Moxifloxacin has not been measured in human milk, although it can be presumed to be excreted in human milk. Caution should be exercised when MOXEZA® solution is administered to a nursing mother.

Pediatric Use

The safety and effectiveness of MOXEZA® solution in infants below 4 months of age have not been established. There is no evidence that the ophthalmic administration of moxifloxacin has any effect on weight bearing joints, even though oral administration of some quinolones has been shown to cause arthropathy in immature animals.

Geriatric Use

No overall differences in safety and effectiveness have been observed between elderly and younger patients.

CLINICAL PHARMACOLOGY

Microbiology

The antibacterial action of moxifloxacin results from inhibition of the topoisomerase II (DNA gyrase) and topoisomerase IV. DNA gyrase is an essential enzyme that is involved in the replication, transcription and repair of bacterial DNA. Topoisomerase IV is an enzyme known to play a key role in the partitioning of the chromosomal DNA during bacterial cell division. The mechanism of action for quinolones, including moxifloxacin, is different from that of macrolides, aminoglycosides, or tetracyclines. Therefore, moxifloxacin may be active against pathogens that are resistant to these antibiotics and these antibiotics may be active against pathogens that are resistant to moxifloxacin. There is no cross-resistance between moxifloxacin and the aforementioned classes of antibiotics. Cross-resistance has been observed between systemic moxifloxacin and some other quinolones. In vitro resistance to moxifloxacin develops via multiple-step mutations. Resistance to moxifloxacin occurs in vitro at a general frequency of between 1.8×10^{-9} to $< 1 \times 10^{-11}$ for Gram-positive bacteria.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals to determine the carcinogenic potential of moxifloxacin have not been performed. Moxifloxacin was not mutagenic in four bacterial strains used in the Ames Salmonella reversion assay. As with other quinolones, the positive response observed with moxifloxacin in strain TA 102 using the same assay may be due to the inhibition of DNA gyrase. Moxifloxacin was not mutagenic in the CHO/HGPRT mammalian cell gene mutation assay. An equivocal result was obtained in the same assay when v79 cells were used. Moxifloxacin was clastogenic in the v79 chromosome aberration assay, but it did not induce unscheduled DNA synthesis in cultured rat hepatocytes. There was no evidence of genotoxicity in vivo in a micronucleus test or a dominant lethal test in mice. Moxifloxacin had no effect on fertility in male and female rats at oral doses as high as 500 mg/kg/day, approximately 25,000 times the highest recommended total daily human ophthalmic dose. At 500 mg/kg orally there were slight effects on sperm morphology (head-tail separation) in male rats and on the estrous cycle in female rats.

PATIENT COUNSELING INFORMATION

Avoid Contamination of the Product

Patients should be advised not to touch the dropper tip to any surface to avoid contaminating the contents.

Avoid Contact Lens Wear

Patients should be advised not to wear contact lenses if they have signs and symptoms of bacterial conjunctivitis.

Hypersensitivity Reactions

Systemically administered quinolones, including moxifloxacin, have been associated with hypersensitivity reactions, even following a single dose. Patients should be told to discontinue use immediately and contact their physician at the first sign of a rash or allergic reaction.

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Table 1. First-Line Antibiotics for Acute Uncomplicated Cystitis in Healthy, Non-pregnant, Premenopausal Women		
Drug	Dosage	Duration
Trimethoprim/sulfamethoxazole double-strength (TMP/SMX)* (i.e. <i>Bactrim DS</i> , <i>Septra DS</i>)	160/800 mg PO BID	3 days
Nitrofurantoin macrocrystals (i.e. <i>Macrobid</i>)	100 mg PO BID	5 days
Fosfomycin (i.e. <i>Monurol</i>)	3 g PO	Once
*in regions where the prevalence of <i>E. coli</i> resistance does not exceed 20%		

Table 2. Second-Line Antibiotics for Acute Uncomplicated Cystitis in Healthy, Non-pregnant, Premenopausal women		
Drug	Dosage	Duration
Ciprofloxacin (i.e. <i>Cipro</i>)	250 mg PO BID	3 days
Ciprofloxacin, extended release (i.e. <i>Cipro XR</i>)	500 mg PO qday	3 days
Levofloxacin (i.e. <i>Levaquin</i>)	250 mg PO qday	3 days
Ofloxacin	200 mg PO qday <i>or</i> 400 mg PO	3 days once

urinary tract. The classic symptoms are dysuria, urinary urgency, frequent voiding of small volumes of urine and, less commonly, suprapubic pain and gross hematuria. Risk factors for acute uncomplicated cystitis include recent sexual intercourse, diaphragm use with spermicide, and recurrent UTI.² Physical examination is often unremarkable, making history-taking crucial. Factors that reflect complicated acute cystitis, and therefore are outside the scope of these treatment guidelines, include male gender, history of childhood UTIs, immunocompromised condition, preadolescence, postmenopausal status, pregnancy, underlying metabolic disorders (including diabetes mellitus), and known renal/urological conditions (including renal stones, renal stents, indwelling urinary bladder catheters, neurogenic bladders, and polycystic kidney disease).

However, acute uncomplicated cystitis remains very common, and a healthy, premenopausal, non-pregnant woman presenting with *even one* of the classic symptoms raises the probability of the diagnosis to 50%.³ Vaginal discharge or irritation makes acute uncomplicated cystitis less likely. One study reported that a new onset of urinary frequency and dysuria in the absence of vaginal discharge or irritation has a positive predictive value of 90% for acute uncomplicated cystitis.³

Urine dipstick testing is convenient and frequently available in the urgent care setting and remains an acceptable alternative to urinalysis and urine microscopy. Discovery of urine nitrite and/or leukocyte esterase on

the strip will help confirm a suspicion of acute uncomplicated cystitis. Urine culture is not necessary for this diagnosis.

Escherichia coli is the most common pathogen found in women with acute uncomplicated cystitis, therefore, it is helpful to know the local resistance patterns to *E. coli*. Unfortunately for urgent care providers, most microbial resistance data are from inpatient labs, capturing a different (i.e., sicker, older) patient population than found in an urgent care center.

First-line empiric treatment of acute uncomplicated cystitis has shifted from fluoroquinolones due to an increase in *E. coli* resistance in the United States from

3% in 2000 to an alarming 17.3% in 2010.⁴ Three comparable first-line options—trimethoprim/sulfamethoxazole (TMP/SMX), nitrofurantoin, and fosfomycin (**Table 1**)—are recommended. As always, antibiotic selection should be tailored to each individual patient.

Fluoroquinolones can be used when drug allergy/intolerance eliminates first-line options (**Table 2**) or local *E. coli* resistance to TMP/SMX exceeds 20%. Beta-lactams such as ampicillin/clavulanate, cefdinir, cefpodoxime are less likely to be effective and not recommended as empiric first-line treatment for acute uncomplicated cystitis.

Compete resolution of symptoms should occur within 2 weeks and often begins within 36 hours of treatment. Other supportive measures have included increasing water intake and ingestion of cranberry juices and extracts, although there is no evidence that supports the latter.⁵ Analgesia with ibuprofen or acetaminophen, as well as phenazopyridine (i.e., pyridium 100-200 mg PO every 8 hours) may be helpful.

Factors that should prompt further investigation in acute uncomplicated cystitis are the development of fever (temperature greater than 100.4° F or 38° C), flank pain, hematuria and/or worsening dysuria, urinary urgency, and urinary retention. Consideration must be given to the sequelae of pyelonephritis or other serious intra-abdominal process. Any hemodynamic instability should raise suspicions of urosepsis. Stabilization efforts should be initiated in the urgent care setting with expe-

Table 3. Differentiating Uncomplicated Cystitis, Complicated Cystitis, Uncomplicated Pyelonephritis, Complicated Pyelonephritis, and Urosepsis

	Uncomplicated cystitis	Complicated Cystitis	Uncomplicated Pyelonephritis	Complicated Pyelonephritis	Urosepsis
Patient factors	<ul style="list-style-type: none"> • Female • Healthy • Reproductive age • Non-pregnant 	<ul style="list-style-type: none"> • Men • Children • Postmenopausal women • Pregnant women • Chronically ill • Immunosuppressed • Any known urogenital condition 	<ul style="list-style-type: none"> • Generally healthy • Non-pregnant • History of recurrent urinary tract infections 	<ul style="list-style-type: none"> • Chronically ill • Immunosuppressed • Congenital urethral anomalies • Congenital/acquired vesicoureteral reflux • History of pyelonephritis 	<ul style="list-style-type: none"> • History of pyelonephritis • History of urosepsis
Symptoms	<ul style="list-style-type: none"> • Dysuria • Polyuria • Urinary urgency 	<ul style="list-style-type: none"> • Dysuria • Polyuria • Urinary urgency 	<ul style="list-style-type: none"> • Fever/rigor • Flank pain • GI upset • Abdominal pain • Malaise • Myalgia 	<ul style="list-style-type: none"> • Fever/rigor • Flank pain • GI upset • Abdominal pain • Malaise • Myalgia 	<ul style="list-style-type: none"> • Fever/rigor • Confusion • Severe flank pain • GI upset/intractable vomiting
Exam findings	<ul style="list-style-type: none"> • Bacteriuria 	<ul style="list-style-type: none"> • Bacteriuria 	<ul style="list-style-type: none"> • Fever • Costovertebral angle tenderness 	<ul style="list-style-type: none"> • Fever • Costovertebral angle tenderness 	<ul style="list-style-type: none"> • Fever • Hypotension • Tachycardia • Altered mental status • Sticky/dry mucous membranes • Weak pulse • Decreased skin turgor

ditious transfer to an emergency department (ED). Empiric intravenous (IV) antibiotics, when available, can be started once blood and urine cultures are obtained. For urosepsis, the choice of antibiotics should be done in consultation with either the ED or admitting physician and is beyond the scope of this discussion. Fluid resuscitation is frequently needed and should be started immediately. IV fluid management will be discussed later.

Acute Uncomplicated Pyelonephritis

Acute uncomplicated pyelonephritis is a common serious bacterial infection in women and has the highest incidence in women ages 15 to 29. Although acute pyelonephritis can occur in men, children, and pregnant women, it is rare and outside the scope of IDSA antibiotic treatment guidelines.

As with acute cystitis, the clinical determination of uncomplicated versus complicated pyelonephritis is based upon a patient’s predisposing factors. Complicated acute pyelonephritis is diagnosed in patients who

have a known genitourinary tract abnormality (i.e., vesicourethral reflux, ectopic ureter, congenital uretero-pelvic junction obstruction) or other serious predisposing/chronic medical conditions (**Table 3**). Complicated cases require careful consideration because of the increased likelihood of non-classic presenting symptoms, broader array of causative pathogens, and progression toward intrarenal/perinephric abscess or emphysematous pyelonephritis.⁶ Urosepsis, an ascending genitourinary infection that causes hemodynamic instability, is diagnosed based on vital signs (fever, tachycardia, hypotension), physical exam findings (altered mental status, cool or clammy skin, weak pulse) and any other findings suggestive of shock.

Classic symptoms of acute pyelonephritis are sudden onset of dysuria, urinary urgency, urinary frequency, flank pain, fever, nausea, and vomiting. Flank pain is nearly always present. Gross hematuria is rare. On exam, documented fever may be noted but is often absent early in the course. Tenderness on costovertebral angle



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Table 4. First-Line Antibiotics for Acute Uncomplicated Pyelonephritis in Healthy, Non-pregnant, Premenopausal women

Drug	Dosage	Duration
Ciprofloxacin*(i.e., <i>Cipro</i>)	500 mg PO BID	7 days
Ciprofloxacin, extended release*(i.e., <i>Cipro XR</i>)	1000 mg PO qday	7 days
Levofloxacin*(i.e., <i>Levaquin</i>)	750 mg PO qday	5 days
Trimethoprim/sulfamethoxazole double-strength (TMP/SMX)*(i.e., <i>Bactrim DS</i> , <i>Septra DS</i>)	160/800 mg PO BID	14 days*

*if local *E. coli* resistance to fluoroquinolones is 10% or less, or if the isolate's fluoroquinolone susceptibility is known

Table 5. Second-Line Antibiotics for Acute Uncomplicated Pyelonephritis in Healthy, Non-pregnant, Premenopausal women

Drug	Dosage	Duration
Ceftriaxone (i.e., <i>Rocephin</i>) or Gentamicin and Second- or third-generation cephalosporin* (i.e., <i>cefaclor</i> , <i>cefuroxime</i> , <i>cefdinir</i> , <i>cefixime</i> , <i>cefpodoxime</i> , <i>ceftibuten</i>)	1 g IM/IV 5 mg/kg IM/IV Varies	once 10-14 days

*if the isolate's susceptibility is known

palpation is very common.

Unlike with acute uncomplicated cystitis, urine culture with microbial susceptibility is necessary in all cases. With the pathogen(s) identified, proper antibiotic adjustment can be made, if needed. Urine dipstick with microscopy is also frequently available and useful at the time of diagnosis in the urgent care setting. In addition to the presence of urine nitrate and leukocyte esterase, white blood cell casts, although infrequently seen, also support the diagnosis. A midstream urine collection is ideal and specific instructions should be offered to the patient before a sample is obtained. Interestingly, several studies have found no significant difference in the amount of contamination in cultures from urine of patients who used preparatory wipes to cleanse the urethral opening and those who did not.⁷⁻⁹ Urinary bladder catheterization is not necessary as long as a midstream sample is collected.⁸⁻⁹

More than 95% of women with acute pyelonephritis will have urine culture that has a single gram-negative organism of greater than 10⁵ colony-forming units. *E. coli* is the most common pathogen, and less often, other Enterobacteriaceae, *Pseudomonas aeruginosa*, group B streptococci and enterococci are seen. A baseline serum basic metabolic profile should be obtained to ascertain renal

function. Qualitative urine beta human chorionic gonadotropin testing is imperative in any woman of reproductive age. Blood cultures are not needed for uncomplicated acute pyelonephritis in the urgent care setting, and a suspicion of bacteremia warrants emergent evaluation in the ED and likely hospital admission.

Urosepsis and Rapid IV Resuscitation

Urosepsis, one of the most worrisome sequelae of acute pyelonephritis, requires rapid resuscitation to prevent hemodynamic collapse (hypovolemic shock). To prevent permanent ischemic end-organ damage, aggressive crystalloid IV fluids (isotonic 0.9% “normal” saline, lactated Ringer’s solution) should be administered at a rate appropriate for the size of the patient and with some awareness

of significant comorbidities (e.g., congestive heart failure).

In adolescents and adults, resuscitation with a 1 to 2 liter bolus of IV fluids is reasonable until transfer to a facility with more invasive monitoring is possible. In children, IV normal saline at a rate of 20 mL/kg should be initiated. Electrolyte repletion is typically not indicated until considerable fluids are given and should be done in conjunction with laboratory data (i.e., basic metabolic panel, arterial blood gas).

Although rarely needed, pelvic computed tomography with contrast media is the ideal renal imaging modality for finding a genitourinary structural problem, obstruction, or abscess. Renal ultrasonography and magnetic resonance imaging are also available. Contrast-induced nephropathy remains a concern, particularly for patients with underlying renal disease and/or who are taking potentially nephrotoxic agents, such as metformin.

According to IDSA, fluoroquinolones remain the first-line agents for acute pyelonephritis (**Table 4**). A 14-day course of TMP/SMX also is acceptable in patients who are allergic to or intolerant of fluoroquinolone, and/or if local *E. coli* resistance to fluoroquinolones is greater than 10%.¹ A second-line regimen is a one-time parenteral dose of a third-generation cephalosporin, followed by a 10- to 14-day course of a second- or third-generation

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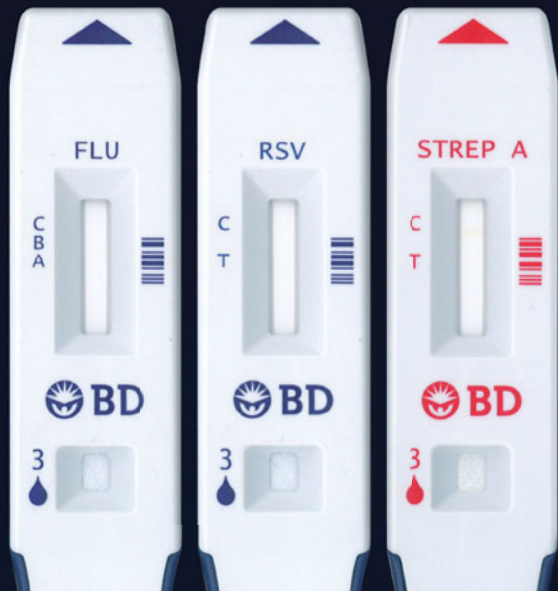
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Table 6. Ideal First-Line Antibiotics for Acute Pyelonephritis in Pregnancy

Drug	Dosage
Ceftriaxone	1 g IV every 12 hours
Cefepime	1 g IV every 12 hours
Nitrofurantoin	100 mg PO every 12 hours, 10-14 days
Amoxicillin/clavulanate (<i>i.e.</i> Augmentin)	500/125 mg PO every 12 hours, 10-14 days

cephalosporin, provided the pathogen susceptibility is known (**Table 5**).

Clinical improvement should be expected within the first 48 to 72 hours after treatment is initiated. If not, referral to an ED for consideration of hospitalization with IV antibiotics is of paramount importance.

Initial Management of Acute Pyelonephritis During Pregnancy

Although the rates of asymptomatic bacteriuria are roughly the same among pregnant and non-pregnant women, various anatomical and hormonal changes greatly increase the rates of pyelonephritis in pregnant women. During pregnancy the kidneys enlarge and are more engorged with blood, the ureters dilate, the bladder enlarges and is unable to contract as strongly, and loose vesicourethral junctions and a growing gravid uterus conspire to prevent efficient emptying of the bladder.

Acute pyelonephritis in pregnancy, in addition to maternal morbidity, carries higher rates of preterm birth, subsequent low birth weight infants, and higher infant morbidity and mortality, which compel clinicians to keep a low threshold of suspicion about pregnant women who present with urinary concerns.

Acute pyelonephritis in pregnant women warrants parenteral antibiotics initially, usually delivered IV in the inpatient setting. “Mild to moderate” pyelonephritis, in the absence of urosepsis, can be treated with 1 or 2 days of IV antibiotics and a transition to an oral 10- to 14-day regimen (based on culture sensitivity results), provided a patient is afebrile and has shown clinical improvement (**Table 6**). Ceftriaxone, cefepime, nitrofurantoin and amoxicillin/clavulanate have Class B pregnancy risk classification. The Class B status means they are reasonably safe to use, especially in the second and third trimester, because fetal harm is possible but unlikely.

For patients in whom these ideal regimens are contraindicated, others can be considered. Parenterally, ampicillin 1 to 2 g IV every 6 hours *plus* gentamicin 1.5 mg/kg IV every 8 hours can be used. Ampicillin and gen-

tamycin are pregnancy Class B and D, respectively. If the causative organism is resistant to nitrofurantoin and amoxicillin/clavulanate, trimethoprim/sulfamethoxazole double-strength (TMP/SMX), 1 tablet PO every 12 hours can be used. TMP/SMX has a Class D pregnancy, classification,

which denotes known evidence of fetal risk; however, the risk may (as is the case in acute pyelonephritis) outweigh the fetal risk in serious maternal conditions.

Conclusion

Healthy, non-pregnant, premenopausal woman frequently present to urgent care centers with acute uncomplicated cystitis and pyelonephritis. The evidence-based empiric treatment guidelines set forth by the IDSA make these conditions easily managed using basic urgent care center resources. Acute uncomplicated cystitis should be treated, unless otherwise indicated, with 3 days of double-strength TMP/SMX, 5 days of nitrofurantoin, or a one-time dose of fosfomycin. Acute uncomplicated pyelonephritis should be treated, unless otherwise indicated, with 7 days of ciprofloxacin, 5 days of levofloxacin, or 14 days of double-strength TMP/SMX. Acute pyelonephritis in pregnant women should be treated initially with parental antibiotics, followed by a 10- to 14-day course of oral treatment. Finally, if there is any hemodynamic instability in the setting of a urogenital infection, urosepsis must be considered and the patient treated with appropriate resuscitation with IV fluids and parenteral antibiotics, and transfer to an ED. ■

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- The most commonly reported treatment related adverse reactions in AOM patients with tympanostomy tubes: ear discomfort (3.0%), ear pain (2.3%), ear residue (0.5%), irritability (0.5%) and taste perversion (0.5%)²

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CIPRODEX[®] Otic is the #1 prescribed otic antibiotic drop among otolaryngologists and pediatricians since 2007¹.

INDICATIONS AND USAGE: CIPRODEX[®] Otic is indicated for the treatment of infections caused by susceptible isolates of the designated microorganisms in the specific conditions listed below: Acute Otitis Media (AOM) in pediatric patients (age 6 months and older) with tympanostomy tubes due to *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis*, and *Pseudomonas aeruginosa*. Acute Otitis Externa (AOE) in pediatric (age 6 months and older), adult and elderly patients due to *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

Dosage and Administration: The recommended dosage is four drops of CIPRODEX[®] Otic suspension into the affected ear twice daily for seven days.

IMPORTANT SAFETY INFORMATION

Contraindications: CIPRODEX[®] Otic is contraindicated in patients with a history of hypersensitivity to ciprofloxacin, to other quinolones, or to any of the components in this medication. Use of this product is contraindicated in viral infections of the external canal including herpes simplex infections.

Warnings: FOR TOPICAL OTIC USE ONLY; NOT FOR INJECTION. This product is not approved for ophthalmic use. CIPRODEX[®] Otic should be discontinued at the first appearance of a skin rash or any other sign of hypersensitivity. Serious and occasionally fatal hypersensitivity (anaphylactic) reactions, some following the first dose, have been reported in patients receiving systemic quinolones.

Precautions: Use of this product may result in overgrowth of non-susceptible organisms, including yeast and fungi. If the infection is not improved after one week of treatment, cultures should be obtained to guide further treatment. The systemic administration of quinolones, including ciprofloxacin at doses much higher than given or absorbed by the otic route, has led to lesions or erosions of the cartilage in weight-bearing joints and other signs of arthropathy in immature animals of various species.

Adverse Reactions: The most commonly reported treatment-related adverse reactions in AOM patients with tympanostomy tubes: ear discomfort (3.0%), ear pain (2.3%), ear residue (0.5%), irritability (0.5%) and taste perversion (0.5%). The most commonly reported treatment-related adverse reactions in clinical trials in AOE patients: ear pruritus (1.5%), ear debris (0.6%), superimposed ear infection (0.6%), ear congestion (0.4%), ear pain (0.4%) and erythema (0.4%).

For additional information about CIPRODEX[®] Otic, please refer to the accompanying Brief Summary of full prescribing information on adjacent page.

References: 1. IMS Health, IMS National Prescription Audit, 2007 to March 2014, USC 62320 OTIC ANTINFCT W/ GLUCOCORT. 2. CIPRODEX[®] Otic package insert. 3. Formulary data provided by Pinsonault Associates, LLC, PathfinderRx, March 2014.

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CIPRODEX[®]
(ciprofloxacin 0.3% and dexamethasone 0.1%)
STERILE OTIC SUSPENSION



STERILE OTIC SUSPENSION
BRIEF SUMMARY OF PRESCRIBING INFORMATION

For additional information refer to the full Prescribing Information

DESCRIPTION CIPRODEX® (ciprofloxacin 0.3% and dexamethasone 0.1%) Sterile Otic Suspension contains the synthetic broad-spectrum antibacterial agent, ciprofloxacin hydrochloride, combined with the anti-inflammatory corticosteroid, dexamethasone, in a sterile, preserved suspension for otic use. Each mL of CIPRODEX® Otic contains ciprofloxacin hydrochloride (equivalent to 3 mg ciprofloxacin base), 1 mg dexamethasone, and 0.1 mg benzalkonium chloride as a preservative. The inactive ingredients are boric acid, sodium chloride, hydroxyethyl cellulose, tyloxapol, acetic acid, sodium acetate, edetate disodium, and purified water. Sodium hydroxide or hydrochloric acid may be added for adjustment of pH.

CLINICAL PHARMACOLOGY

Microbiology: Cross-resistance has been observed between ciprofloxacin and other fluoroquinolones. There is generally no cross-resistance between ciprofloxacin and other classes of antibacterial agents such as beta-lactams or aminoglycosides.

INDICATIONS AND USAGE: CIPRODEX® Otic is indicated for the treatment of infections caused by susceptible isolates of the designated microorganisms in the specific conditions listed below:

Acute Otitis Media in pediatric patients (age 6 months and older) with tympanostomy tubes due to *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis*, and *Pseudomonas aeruginosa*.

Acute Otitis Externa in pediatric (age 6 months and older), adult and elderly patients due to *Staphylococcus aureus* and *Pseudomonas aeruginosa*

CONTRAINDICATIONS

CIPRODEX® Otic is contraindicated in patients with a history of hypersensitivity to ciprofloxacin, to other quinolones, or to any of the components in this medication. Use of this product is contraindicated in viral infections of the external canal including herpes simplex infections

WARNINGS

FOR OTIC USE ONLY (This product is not approved for ophthalmic use.)

NOT FOR INJECTION

HYPERSENSITIVITY: CIPRODEX® Otic should be discontinued at the first appearance of a skin rash or any other sign of hypersensitivity. Serious and occasionally fatal hypersensitivity (anaphylactic) reactions, some following the first dose, have been reported in patients receiving systemic quinolones. Serious acute hypersensitivity reactions may require immediate emergency treatment.

PRECAUTIONS

General: As with other antibacterial preparations, use of this product may result in overgrowth of nonsusceptible organisms, including yeast and fungi. If the infection is not improved after one week of treatment, cultures should be obtained to guide further treatment. If otorrhea persists after a full course of therapy, or if two or more episodes of otorrhea occur within six months, further evaluation is recommended to exclude an underlying condition such as cholesteatoma, foreign body, or a tumor.

The systemic administration of quinolones, including ciprofloxacin at doses much higher than given or absorbed by the otic route, has led to lesions or erosions of the cartilage in weight-bearing joints and other signs of arthropathy in immature animals of various species.

Guinea pigs dosed in the middle ear with CIPRODEX® Otic for one month exhibited no drug-related structural or functional changes of the cochlear hair cells and no lesions in the ossicles. CIPRODEX® Otic was also shown to lack dermal sensitizing potential in the guinea pig when tested according to the method of Buehler.

No signs of local irritation were found when CIPRODEX® Otic was applied topically in the rabbit eye.

Information for Patients: For otic use only. (This product is not approved for use in the eye.) Warm the bottle in your hand for one to two minutes prior to use and shake well immediately before using. Avoid contaminating the tip with material from the ear, fingers, or other sources. Protect from light. If rash or allergic reaction occurs, discontinue use immediately and contact your physician. It is very important to use the ear drops for as long as the doctor has instructed, **even if the symptoms improve.** Discard unused portion after therapy is completed.

Acute Otitis Media in pediatric patients with tympanostomy tubes: Prior to administration of CIPRODEX® Otic in patients (6 months and older) with acute otitis media through tympanostomy tubes, the suspension should be warmed by holding the bottle in the hand for one or two minutes to avoid dizziness which may result from the instillation of a cold suspension. The patient should lie with the affected

ear upward, and then the drops should be instilled. The tragus should then be pumped 5 times by pushing inward to facilitate penetration of the drops into the middle ear. This position should be maintained for 60 seconds. Repeat, if necessary, for the opposite ear (see dosage and administration).

Acute Otitis Externa: Prior to administration of CIPRODEX® Otic in patients with acute otitis externa, the suspension should be warmed by holding the bottle in the hand for one or two minutes to avoid dizziness which may result from the instillation of a cold suspension. The patient should lie with the affected ear upward, and then the drops should be instilled. This position should be maintained for 60 seconds to facilitate penetration of the drops into the ear canal. Repeat, if necessary, for the opposite ear (see dosage and administration).

Drug Interactions: Specific drug interaction studies have not been conducted with CIPRODEX® Otic.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term carcinogenicity studies in mice and rats have been completed for ciprofloxacin. After daily oral doses of 750 mg/kg (mice) and 250 mg/kg (rats) were administered for up to 2 years, there was no evidence that ciprofloxacin had any carcinogenic or tumorigenic effects in these species. No long term studies of CIPRODEX® Otic have been performed to evaluate carcinogenic potential.

Eight *in vitro* mutagenicity tests have been conducted with ciprofloxacin, and the test results are listed below:

Salmonella/Microsome Test (Negative),
E. coli DNA Repair Assay (Negative),
Mouse Lymphoma Cell Forward Mutation Assay (Positive),
Chinese Hamster V79 Cell HGPRT Test (Negative),
Syrian Hamster Embryo Cell Transformation Assay (Negative),
Saccharomyces cerevisiae Point Mutation Assay (Negative),
Saccharomyces cerevisiae Mitotic Crossover and Gene Conversion Assay (Negative),
Rat Hepatocyte DNA Repair Assay (Positive).
Thus, 2 of the 8 tests were positive, but results of the following 3 *in vivo* test systems gave negative results:
Rat Hepatocyte DNA Repair Assay,
Micronucleus Test (Mice),
Dominant Lethal Test (Mice).

Fertility studies performed in rats at oral doses of ciprofloxacin up to 100 mg/kg/day revealed no evidence of impairment. This would be over 100 times the maximum recommended clinical dose of otological ciprofloxacin based upon body surface area, assuming total absorption of ciprofloxacin from the ear of a patient treated with CIPRODEX® Otic twice per day according to label directions.

Long term studies have not been performed to evaluate the carcinogenic potential of topical otic dexamethasone. Dexamethasone has been tested for *in vitro* and *in vivo* genotoxic potential and shown to be positive in the following assays: chromosomal aberrations, sister-chromatid exchange in human lymphocytes and micronuclei and sister-chromatid exchanges in mouse bone marrow. However, the Ames/Salmonella assay, both with and without S9 mix, did not show any increase in His+ revertants.

The effect of dexamethasone on fertility has not been investigated following topical otic application. However, the lowest toxic dose of dexamethasone identified following topical dermal application was 1.802 mg/kg in a 26-week study in male rats and resulted in changes to the testes, epididymis, sperm duct, prostate, seminal vesicle, Cowper's gland and accessory glands. The relevance of this study for short term topical otic use is unknown.

Pregnancy: Teratogenic Effects; Pregnancy Category C.

Reproduction studies have been performed in rats and mice using oral doses of up to 100 mg/kg and IV doses up to 30 mg/kg and have revealed no evidence of harm to the fetus as a result of ciprofloxacin. In rabbits, ciprofloxacin (30 and 100 mg/kg orally) produced gastrointestinal disturbances resulting in maternal weight loss and an increased incidence of abortion, but no teratogenicity was observed at either dose. After intravenous administration of doses up to 20 mg/kg, no maternal toxicity was produced in the rabbit, and no embryotoxicity or teratogenicity was observed.

Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals.

Animal reproduction studies have not been conducted with CIPRODEX® Otic. No adequate and well controlled studies have been performed in pregnant women. Caution should be exercised when CIPRODEX® Otic is used by a pregnant woman.

Nursing Mothers: Ciprofloxacin and corticosteroids, as a class, appear in milk following oral administration. Dexamethasone in breast milk could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topical otic administration of ciprofloxacin or dexamethasone could result in sufficient systemic absorption to produce detectable quantities in human milk. Because of the potential for unwanted effects in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: The safety and efficacy of CIPRODEX® Otic have been established in pediatric patients 6 months and older (937 patients) in adequate and well-controlled clinical trials. Although no data are available on patients less than age 6 months, there are no known safety concerns or differences in the disease process in this population that would preclude use of this product (see dosage and administration). No clinically relevant changes in hearing function were observed in 69 pediatric patients (age 4 to 12 years) treated with CIPRODEX® Otic and tested for audiometric parameters.

ADVERSE REACTIONS In Phases II and III clinical trials, a total of 937 patients were treated with CIPRODEX® Otic. This included 400 patients with acute otitis media with tympanostomy tubes and 537 patients with acute otitis externa. The reported treatment-related adverse events are listed below:

Acute Otitis Media in pediatric patients with tympanostomy tubes: The following treatment-related adverse events occurred in 0.5% or more of the patients with non-intact tympanic membranes.

Adverse Event	Incidence (N=400)
Ear discomfort	3.0%
Ear pain	2.3%
Ear precipitate (residue)	0.5%
Irritability	0.5%
Taste perversion	0.5%

The following treatment-related adverse events were each reported in a single patient: tympanostomy tube blockage; ear pruritus; tinnitus; oral moniliasis; crying; dizziness; and erythema.

Acute Otitis Externa: The following treatment-related adverse events occurred in 0.4% or more of the patients with intact tympanic membranes.

Adverse Event	Incidence (N=537)
Ear pruritus	1.5%
Ear debris	0.6%
Superimposed ear infection	0.6%
Ear congestion	0.4%
Ear pain	0.4%
Erythema	0.4%

The following treatment-related adverse events were each reported in a single patient: ear discomfort; decreased hearing; and ear disorder (tingling).

DOSAGE AND ADMINISTRATION

CIPRODEX® OTIC SHOULD BE SHAKEN WELL IMMEDIATELY BEFORE USE.

Acute Otitis Media in pediatric patients with tympanostomy tubes: The recommended dosage regimen for the treatment of acute otitis media in pediatric patients (age 6 months and older) through tympanostomy tubes is: Four drops (0.14 mL, 0.42 mg ciprofloxacin, 0.14 mg dexamethasone) instilled into the affected ear twice daily for seven days. The suspension should be warmed by holding the bottle in the hand for one or two minutes to avoid dizziness, which may result from the instillation of a cold suspension. The patient should lie with the affected ear upward, and then the drops should be instilled. The tragus should then be pumped 5 times by pushing inward to facilitate penetration of the drops into the middle ear. This position should be maintained for 60 seconds. Repeat, if necessary, for the opposite ear. Discard unused portion after therapy is completed.

Acute Otitis Externa: The recommended dosage regimen for the treatment of acute otitis externa is: For patients (age 6 months and older): Four drops (0.14 mL, 0.42 mg ciprofloxacin, 0.14 mg dexamethasone) instilled into the affected ear twice daily for seven days. The suspension should be warmed by holding the bottle in the hand for one or two minutes to avoid dizziness, which may result from the instillation of a cold suspension. The patient should lie with the affected ear upward, and then the drops should be instilled. This position should be maintained for 60 seconds to facilitate penetration of the drops into the ear canal. Repeat, if necessary, for the opposite ear. Discard unused portion after therapy is completed.

U.S. Patent Nos. 4,844,902; 6,284,804; 6,359,016
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Practice Management

The Role of Urgent Care in an Integrated Care Delivery System: Insights from Kaiser Permanente

Urgent message: As the Affordable Care Act encourages greater integration of health insurers, hospitals, and physicians, urgent care will play an important role in increasing patient access, improving clinical outcomes and reducing health care costs.

ALAN A. AYERS, MBA, MAcc

Introduction

Hospitals across the country are partnering with doctors and health insurers—linked by an electronic health record (EHR)—to form accountable care organizations (ACOs) as a way to control health care expenditures by coordinating patient care. This model of care, supported by the Affordable Care Act, has been pioneered and refined by systems such as Intermountain Healthcare in Utah, Geisinger Health System in Pennsylvania, Henry Ford Health System in Michigan, and Oakland, California-based Kaiser Permanente.

In this exclusive question-and-answer session with *JUCM - The Journal of Urgent Care Medicine*, Michael A. Neri, Jr., MD, and Peter A. King, MD, detail the operating models, capabilities and connectivity of urgent care in the nation's largest managed care organization with over 9.5 million members, 17,000 physicians, 174,000 employees, and 650 hospitals, medical offices, and outpatient facilities in eight states and the District of Columbia.

Alan A. Ayers, MBA, MAcc, is Practice Management Editor of *JUCM*, serves on the Board of Directors of the Urgent Care Association of America, and is Vice President for Concentra Urgent Care.



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Dr. Neri is Regional Physician-In-Charge of Urgent Care and Riverside Area Assistant Medical Director for Kaiser Permanente Southern California and Dr. King is Physician Director of Acute Care Services for Kaiser Permanente Georgia.

Call for Articles

JUCM, the Official Publication of the Urgent Care Association of America, is looking for a few good authors.

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Submissions on clinical or practice management topics, ranging in length from 2,500 to 3,500 words are welcome. The key requirement is that the article address a topic relevant to the real-world practice of medicine in the urgent care setting.

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“The benefit of a higher-acuity urgent care center is member convenience and access, because members do not need to be transferred to the emergency department for workup.”

Dr. Michael Neri

Alan Ayers: What does urgent care look like within Kaiser Permanente today including locations, hours, clinical capabilities and staffing models?

Michael Neri: At Kaiser Permanente, our urgent care model differs depending on local needs and whether we own and operate hospitals in the area. Therefore, to provide a comprehensive overview of Kaiser Permanente’s approach to urgent care, my colleague Dr. Peter King and I will discuss how we provide urgent care in Kaiser Permanente Southern California and Kaiser Permanente Georgia. No matter where our members receive care, our urgent care centers are staffed by highly skilled Kaiser Permanente doctors and nurses. Our primary goal is to provide members with convenient access to high-quality, coordinated care.

Kaiser Permanente Southern California has 19 urgent care locations throughout the region that offer walk-in access in the morning, afternoon, and evening, 7 days a week. All of our urgent care locations operate at a higher capability than the typical community cold and flu “urgent care” model. We are able to provide care to patients with mild-to-moderate acuity ailments, including medical and surgical issues. The benefit of a higher-acuity urgent care center is member convenience and access, because members do not need to be transferred to the emergency department for workup.

Peter King: Kaiser Permanente Georgia uses a model that we call Advanced Care Center (ACC). An ACC is an outpatient facility that is physically located in a Comprehensive Medical Center (a medical office with full services including high-tech radiology, cardiac stress testing, and a gastrointestinal (GI) endoscopy suite). The ACC offers high-acuity immediate care and is staffed with board-certified emergency physicians and emergency room (ER)-trained nurses. Although the ACC is designed to provide urgent care, in the event of a higher-acuity emergency, this facility is prepared and is similar to a hospital ER. The ACC has an on-site pharmacy with intravenous (IV) medications commonly used in an ER, such as equipment for central IV lines, cardiac monitors, and respiratory support. Our ACCs are open 24 hours a

“The ACC offers high-acuity immediate care and is staffed with board-certified emergency physicians and emergency room (ER)-trained nurses.”

Dr. Peter King

day, 365 days a year.

Alan Ayers: What is the role of urgent care in increasing access to and reducing medical costs within Kaiser Permanente’s integrated model of care?

Michael Neri: Urgent care provides our members with another option when they need care quickly. It plays a key role in providing care for members who require prompt medical attention conveniently, but who do not have an emergency medical condition. This care is delivered with the same high quality and service as in our Emergency Department, but at a lower cost to our members.

Peter King: Our ACCs are a prime driver of increased access *and* decreased cost for our members with acute medical needs who do not require ER care. With ACCs, we can treat patients in the outpatient setting, which is often more convenient and effective for patients. For example, we are able to evaluate, treat, and discharge many patients with transient ischemic attack, atrial fibrillation, chest pain, GI bleeding and numerous other conditions. We routinely evaluate patients with chest pain, ruling out acute heart attack, observing overnight, and obtaining stress testing the next morning. We are able to rapidly stabilize and transfer patients who need hospitalization.

Alan Ayers: How does Kaiser Permanente ensure or coordinate follow-up with a primary care or specialist after a patient presents for urgent care with a new medical diagnosis? What is the role of Kaiser Permanente’s consolidated medical record in ensuring continuity of care?

Michael Neri: Kaiser Permanente’s comprehensive EHR, KP HealthConnect, is essential in ensuring continuity of care. Every primary care and specialty care provider has immediate access to any patient encounter in urgent care. We have standardized protocols to ensure that patients are connected to primary care or specialty care follow-up as needed.

Alan Ayers: How does Kaiser educate its members about the availability and appropriate use of urgent care services? Is there any incentive, through health plan design, communication via PCPs, or employer or indi-



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vidual marketing efforts, to steer Kaiser Permanente members away from the ER to lower-acuity settings?

Michael Neri: We have launched an education campaign that explains to members why, when, and where they can access urgent care.

Peter King: Our focus is on providing the right care, at the right time, in the right place to meet the patient's needs. We do not offer additional incentives. In many cases, a visit to an ER might not be the best option for patients. We have processes in place to guide patients to a more effective venue, based on their condition and preference, which may be an office appointment, a visit to the ACC, or telephone advice.

Alan Ayers: As we see the nation's health delivery shift from fee-for-service to more integrated models and outcomes-based payment systems, what can the urgent care industry learn from Kaiser Permanente's experience with urgent care?

Peter King: We believe that the urgent care model will play a significant role as the nation moves toward more integrated, outcomes-based care delivery models. I hope that high-acuity urgent care will become as common as the traditional low-acuity urgent care is today. This model fills a gap between the medical office and the hospital that provides patients with access to high-quality outpatient care. Our experience shows that this model is capable of improving quality, service, and patient satisfaction while making care more affordable for members.

Conclusion

Integrated health systems like Kaiser Permanente's are defined by their ownership of hospitals, physician practices, and health insurance; financial incentives that align medical cost savings, clinical outcomes, and population health; and coordination of primary and specialist care through an electronic health record. These are also the driving principles of the ACAs authorized by the March 2010 health care reform legislation. As Drs. Neri and King illustrate, when the availability of higher-acuity urgent care matches a patient's condition with the capabilities of the treating facility, unnecessary ER visits can be avoided, thus promoting the integrated system's goals of quality and efficiency. ■

Had Any Interesting Cases Lately?

Case Reports are one of *JUCM's* most popular features. They are easy to write and *JUCM* readers love them. If you've had some interesting cases lately, please write one up for us. Send it to Judy Orvos, *JUCM's* editor, at jorvos@jucm.com.

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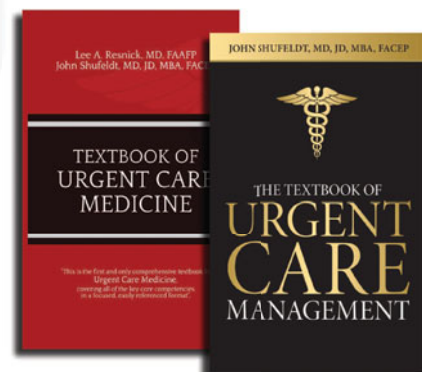
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Case Report

Treating Autistic Patients in the Urgent Care Setting

Urgent message: As the number of patients with autism spectrum disorders continues to increase, it is important that urgent care providers proactively educate themselves about how best to provide acute care for these individuals.

ELIZABETH MANGONE and JOHN SHUFELDT, MD, JD, MBA, FACEP

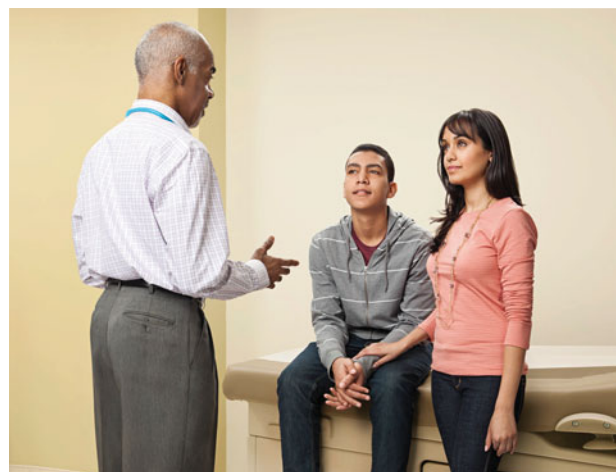
Introduction

A 14-year-old autistic male presents with both parents. The patient is non-verbal and hypersensitive to touch. The parents state that he was stung by a bee and seems to be having respiratory distress because he is drooling more than normal. As the patient is ushered through the waiting area and into an examination room, his anxiety mounts. His repetitive movements of hand flapping and rocking increase along with indistinguishable scripting that reaches an alarming pitch. The staff takes a step back to assess the situation while the parents calm their son.

Adjustments to the typical urgent care protocol are required to treat an autistic patient. Assessing the source and level of pain is delayed by the need to first determine where the patient falls on the autism spectrum. Awareness of autism signs and behaviors aids physicians and urgent care staff in diagnosing and treating a patient's acute illness, independent of the developmental disorder.

Understanding the autism spectrum

Autism Spectrum Disorder (ASD) is now the fastest growing developmental disorder in the United States.¹ A 2014 Centers for Disease Control and Prevention report estimates that about 1 in 68 children exhibit ASD.² ASD is defined as a neurodevelopmental condi-



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tion with difficulties in social interaction, verbal and non-verbal communication, and repetitive behaviors. The spectrum includes five pervasive developmental disorders with the following characteristics³:

- Classic autism: Presentation before age 4, poor eye contact, language delay, social deficits, resistance to change, prone to seizures.
- Asperger syndrome: Deficits in appropriate speech and communicative development, stereotype behaviors, expansive memories, extreme interest in a particular subject, development of normal language and cognition
- Rett syndrome (affects only females): Developmen-

Elizabeth Mangone is a premed undergraduate student at Boston College. John Shufeldt, MD, JD, MBA, FACEP, is CEO of Urgent Care Integrated Network and sits on the Editorial Board of JUCM.

tal regression after age 6 months, microcephaly, loss of motor skills

- Childhood Disintegrative Disorder: Developmental regression after age 3 years, severe functional impairment, loss of social and language skills
- Pervasive Developmental Disorder-not otherwise specified (less severe version of classic autism): Impairment in social interaction, communication, or repetitive stereotype behavior

Characteristics of ASD raise barriers to efficient, acute treatment by health care professionals in the urgent care setting. Currently, a paucity of resources are available that outline and evaluate accommodating strategies for patients with ASD in inpatient, outpatient, and emergency situations.⁴ As the number of ASD diagnoses increases, steps to provide optimal care for this challenging patient population focus on education, communication, and treatment.

Barriers to Assessment

The multidimensional nature of ASD and the non-specialist provider’s limited knowledge of the disorder

hinder the quality of care for patients with ASD who have acute medical conditions. Characteristically, ASD features deficits in communication, presence of repetitive behaviors, and hyper/hypoactive sensitivity to environmental stimuli.⁵ Each category is unique to an individual patient with ASD’s behavior and ability level. As the saying goes in the autism community, “If you’ve met one person with autism, you’ve met one person with autism.” In addition, the common absence of social reciprocity is exhibited in a variety of ways, from silence/withdrawal to excessive echolalia or violent outbursts.

Adding to these difficulties, challenges inherent to urgent care medicine create problematic stresses for patients with ASD: rushed visits, focus on a single patient complaint, and incomplete patient history. A comprehensive clinical assessment is limited due to the increased anxiety about the novel situation. Patients with autism prefer a familiar routine and environment. Varying combinations of these barriers increase the difficulty of diagnosing and treating their acute illness in the urgent care setting.

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Awareness

With the escalating growth in diagnoses and the current aging ASD population, an increased awareness of the disorder's features aids a broader range of health care professionals in appropriately accommodating these patients. Medical providers more effectively treat this population when armed with an understanding of underlying characteristics of autism as well as the medical issues that patients with ASD might present with in an urgent care center. Preliminary research points to a non-exclusive list that focuses on possible acute illnesses including gastrointestinal conditions, seizures, associated psychiatric disorders, catatonia, and self-injurious behaviors.⁵

Widespread implementation of effective training materials can increase urgent care providers' knowledge about and comfort with caring for patients with ASD. Two recently implemented resources outline protocols to help doctors treat ASD patients. The Assess Communicate Treat (ACT) plan for Autism, developed by Pennsylvania physicians, is changing patient treatment in Pennsylvania emergency rooms (ACT).⁶ The plan includes a training manual and DVD for emergency medicine clinicians that familiarizes them with common autism behaviors and recommends accommodations. Similarly, Massachusetts General Hospital's Acute Care Plan for Autism aids physicians and medical staff in assisting patients with ASD through a questionnaire completed before the emergency experience (Acute Care Plan). Both systems advise medical staff in the way to properly treat patients with ASD by first recognizing the behaviors of autism and second, diagnosing the acute illness. Providing health care professionals with the tools to understand ASD is a step towards offering better patient care and improving the urgent care experience.

Communication

Communication is the key to improving assessment and treatment of the population with ASD. Information on baseline behavior, degree of sociability, dietary habits, and communication ability is vital for medical professionals who interact with patients with ASD.⁴ The central part of this information sharing relies on communication between the caregiver and urgent care staff. Communication of preferences to the entire staff helps provide consistency of care throughout the visit.

To establish optimal treatment conditions for the patient, the following actions establish a baseline of communication²:

- Obtain patient history from caregiver.
- Avoid multipart questions.
- Use questions that require only a "yes" or "no."
- Know the individual's method of communication.
- Use a Visual Communication System.
- Develop a method to assess pain.

Patients with ASD who enter the urgent care environment present with a variety of acute illnesses and are best assessed when an effective communication method is developed. Equally important, caregiver information provides physicians with the ability to identify certain exhibited behaviors that are not maladaptive, but rather, those characterized by the spectrum.

Treatment

Treatment of patients with ASD in the urgent care setting requires adjustments to the typical protocol and level of care. Clinical standards of urgent care medical treatment change constantly. The advances in quality of care provide a new emphasis on specialized treatment for the developmentally disabled. Steps to better accommodate this population subsequently lead to a decreased incidence of hospital visits and discrepancies in care.

In offering treatment to patients with ASD, additional accommodations are required to decrease anxiety and limit overstimulation. The first step is established through offering the best environment. A quiet room equipped with familiar distractions for the pediatric or adult patient reduces overstimulation. Smaller steps and break periods between treatments keep patients on task.⁵ Modeling and allowing patients to see and touch instruments and materials used during the physical examination and treatment aids in systematic desensitization. Many of these modifications begin with communication. Though some individuals with ASD lack reciprocal communication, they process spoken language. The physician and medical staff should outline their actions to the patient before performing any exam. In doing so, physicians are advised to use a calm voice and minimize touch. Rewards can be implemented to reinforce positive behaviors. Treating a patient with ASD requires additional time and effort to compensate for the sensory processing difficulty exhibited as a component of the disorder.

Conclusion

Each patient, adult or child, labeled as developmentally disabled presents a unique set of characteristics that demand a higher quality of care. As the population of patients with ASD increases, a move to raise awareness and provide educational materials for health care professionals is required to properly treat these patients in the urgent care setting. Steps to provide quality of care for patients with ASD begin with physician awareness of the disorder's characteristics, specialized methods of communication and novel approaches to treatment. As a first-line resource to treat acute illnesses, professionals in urgent care centers are best able to help the population with ASD by learning more about the disorder and making accommodations for these patients. ■

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- Rapid strep test sensitivity
- NSAIDs and anaphylaxis
- Scalp hematomas and brain injury

■ SEAN M. McNEELEY, MD

Each month the Urgent Care College of Physicians (UCCOP) provides a handful of abstracts from or related to urgent care practices or practitioners. Sean McNeeley, MD, leads this effort.

Generic medication appearance

Key point: When providing generic prescriptions, warn patients about generic medication colors and shapes.

Citation: Kesselheim AS, Bykov K, Avorn J, et al. Burden of changes in pill appearance for patients receiving generic cardiovascular medications after myocardial infarction: Cohort and nested case-control studies. *Ann Intern Med.* 2014; 161:96-103.

Researchers in this study attempted to determine if changes in color or shape of a generic drug led to discontinuation of that drug. Patients were evaluated in a case control study after having experienced a myocardial infarction and the drugs prescribed included beta blockers, ACE inhibitors, and statins.

Changes in color increased risk of discontinuation 34% whereas a shape change increased risk of discontinuation 66%. Although this may not seem to directly apply to urgent care, if it can be generalized, it shows the importance of physicians and pharmacist warning patients, before a change occurs, that generic medications vary in both color and shape. This may even apply to a short-term medicine like an antibiotic that does not look the same as the one a patient used in the past. It is already known that a large percentage of patients

don't fill prescriptions, and an unexpected change in color or shape would likely increase that risk. ■

Sensitivity of rapid strep tests

Key point: One in 20 adults with negative rapid streptococcus tests still may have strep throat.

Citation: Dingle TC, Abbott AN, Fang FC. Reflexive culture in adolescents and adults with group A streptococcal pharyngitis. *Clin Infect Dis.* 2014;59(5):643-650.

The authors of this study note that clinical and laboratory guidelines differ as to the need for a throat culture in adults with a negative rapid test. They also note that because rheumatic fever and post-streptococcal renal involvement are rare in adults, some clinicians feel that back-up cultures are unnecessary.

In this retrospective study, researchers looked at outcomes in patients older than age 13 with a negative rapid test and subsequent positive throat culture over an 11-year period at a lab in Seattle, Washington. The policy at the referring medical centers was to send cultures on all patients who had a negative rapid test. A total of 726 patients were included who met criteria and for whom applicable visit data were available (297 did not have adequate chart data).

About 5% of the patients proved to have a positive culture after a negative rapid test, compared with 13% who were positive on rapid tests. Therefore, sensitivity was about 75% with the rapid test alone. The authors also noted that 29 of the 726 patients developed abscesses. Several other patients were noted to have other bacterial infections of the throat that improve with antibiotics but for which the rapid strep assay does not test (e.g., Group C streptococcal infections). From an urgent



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care perspective, reconsideration of back-up cultures in adults may be needed. Further prospective research, it is hoped, will help answer that question. ■

NSAIDs and anaphylaxis

Key point: Take care with nonsteroidal anti-inflammatory drugs and don't forget the epinephrine.

Citation: Aun MV, Blanca M, Garro LS, et al. Nonsteroidal anti-inflammatory drugs are major causes of drug-induced anaphylaxis. *J Allergy Clin Immunol Pract.* 2014;2(4): 414-420.

In this allergy clinic-based study of patients with previous anaphylaxis, likely causes and treatment were evaluated. A total of 806 patients with drug reactions were screened revealing 117 with anaphylaxis. About three-fourths of the patients with anaphylaxis had an identifiable cause. Non-steroidal anti-inflammatory drugs (NSAIDs) were identified as the cause in almost half of these cases, which is considered unusual because antibiotics typically are the most frequent cause of anaphylaxis.

The second important finding from this study was that epinephrine use was reported in only one-third of patients. As the authors noted, epinephrine is considered the first-line treatment for anaphylaxis and low use of epinephrine is associated with higher mortality. A final concern was that 66% of patients had already experienced an adverse drug reaction to the medication identified as the cause of their anaphylaxis.

From an acute care perspective, realizing that anaphylaxis is underdiagnosed and epinephrine is underused should keep us vigilant for its symptoms and mindful of anaphylaxis treatment. Many good reviews of the complex diagnosis of anaphylaxis are available, including one in the June 2011 edition of *JUCM*. A second take-home message is that once again, NSAIDs were shown not to be as benign as had previously been thought. ■

Scalp hematomas and brain injury

Key point: Scalp hematomas are still a significant concern for brain injury.

Citation: Dayan PS, Holmes JF, Schutzman S, et al. Risk of traumatic brain injuries in children younger than 24 months with isolated scalp hematomas. *Ann Emerg Med.* 2014(2);64:153-162.

This article reviews the previously reported data from the 2009 Pediatric Emergency Care Applied Research Network (PECARN) including only children up to age 24 months regarding scalp hematomas and significant brain injury. In a review of almost 3,000 cases of patients of younger age, non-frontal scalp hematoma, increased scalp hematoma size, and severe mechanism of injury were independently associated with traumatic brain injury. Of interest, only 50 patients had findings of traumatic brain injury. That reinforces the fact that the number of significant brain injuries is low. For urgent care providers, this report confirms previous studies on this topic. The results also underscore the low prevalence of significant findings in these patients. ■

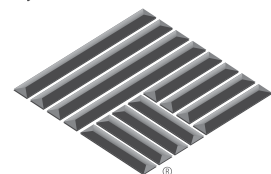
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HIPAA for Health Care Heroes

■ JOHN SHUFELDT, MD, JD, MBA, FACEP

You are working in an urgent care center when a mother shows up with her 18-year-old daughter, who is “mildly developmentally delayed,” per her mom. The daughter turned 18 yesterday and the mother is concerned that she may have gotten a little “too wild” while celebrating her birthday at a friend’s house and she would like her tested for drugs and STDs. The daughter appears to understand what is necessary to comply with her mother’s demands and reluctantly agrees. Your tech obtains the urine and runs a pregnancy test and rapid drug screen. After her exam, the patient tells you not to disclose the results to her mother under any circumstances. Her mother is adamant that you tell her the results of the testing. Now what?

I don’t have very many “pet peeves.” The only ones I can think of are hate rhetoric, flag burning, animal cruelty, broccoli in Chinese food, and when someone says “It’s against HIPAA.” I have heard “It’s against HIPAA” so many times and for such patently random things that I feel compelled to spend some time writing about it.

Candidly, what pushed me over the edge was when someone remarked that, “It was against HIPAA to tell the family members of a demented Alzheimer’s patient the result of the CT of the brain.” Really?

First, a bit of background. The Health Insurance Portability and Accountability Act of 1996 was enacted by Congress in response to the rising cost of administrative expenses due largely to complex coding taxonomy and lack of communication among providers about diagnostic and billing information (i.e., the morass that is modern medicine.) Enter the government trying to save us all!

Generally speaking, HIPAA attempts to: (1) make it easier for people to keep their health insurance; (2) protect the confidentiality and security of health care information while balancing the need to protect the public’s interest; and (3) help control administrative costs.



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“If everything is PHI then should an urgent care provider never share anything about a patient with anyone? The answer is no!”

The “portability” requirement in the Act helps avoid “job lock.” That is, it eliminated insurance companies’ ability to deny coverage to people with pre-existing conditions, which impeded people in moving to new jobs because they could not get health insurance coverage.

In many ways, HIPAA does not change the way we practice, inasmuch as privacy and confidentiality have always been a priority. It does, however, provide legal recourse when dealing with breaches. Under the Act, patients’ control of health information includes the ability to review their own medical records, request corrections to those records, and determine who is looking at them and why. It sets limits without deterring research or undermining care. And it strikes a balance between privacy and public responsibility by accounting for public uses related to public health concerns (ex., communicable diseases), health oversight (ex., provider compliance audits), research, law enforcement (offender identification), and investigations of abuse, neglect, and violence. Remedies for violations of the privacy rule include both civil and criminal penalties while acknowledging, however, that the right to privacy is not absolute (see appropriate public uses exceptions above).

HIPAA helps control administrative costs in two ways. It simplifies coding and defines standards under which health care providers can share information. That helps ensure coordination of care, eliminates repeat testing and procedures, and fosters quality of care. The Act also reduces fraud, waste, and abuse by eliminating unnecessary repeat services and tests for which providers would bill but a patient would get no benefit.

HIPAA does not cover everyone or every entity, but health care providers are among those who must comply with it. The Privacy Rule and what is considered protected health information (PHI) are what we as providers are most likely to have

“You can release PHI when the patient consents/gives authorization or one of the various exceptions applies.”

to address. PHI includes:

- Information your doctors, nurses, and other health care providers put in a patient’s medical record
- Conversations that a doctor has with nurses and others about a patient’s treatment
- Information about a patient in a health insurer’s computer system
- Billing information about a patient
- Past, present or future physical or mental health or conditions
- Services provided for health care to an individual
- Past, present, or future payment for the provision of health care
- Any other information that identifies an individual or for which there is a reasonable basis to believe it could be used to identify an individual, including name, address, birth date, and Social Security Number.

The list above raises the question: If everything is PHI then should an urgent care provider ever share anything about a patient with anyone? The answer is no!

If, in your judgment, it is in the patient’s best interest, it is completely appropriate to share information. You can release PHI when the patient consents/gives authorization or one of the various exceptions applies. Consent simply means agreeing to the use of PHI for treatment, payment, or for the smooth operation of the health care system.

Providers obtain patient consent before using or disclosing information for the purpose of providing treatment, related to payment for treatment, and for health care operations. The consent form must:

- Contain clear language that an average patient can easily understand
- Refer to the privacy notice and the right to change notice
- Advise a patient of his/her right to request restrictions on use/disclosure of PHI and a provider’s right to deny that request
- Advise of a patient’s right to revoke consent in writing
- Be signed by a patient.

The exceptions regarding the need for consent are when care is provided to an incarcerated inmate or when a reasonable attempt was made to obtain written consent after emergency treatment.

By contrast, an “authorization” is required by the Privacy

Rule for uses and disclosures of PHI not otherwise allowed by the Rule (i.e., for uses other than treatment, payment, and health care operations, such as marketing).

Where the Privacy Rule requires patient authorization, voluntary consent is not sufficient to permit use or disclosure of PHI unless it also satisfies the requirements of a valid authorization. An authorization is a detailed document that gives covered entities permission to use PHI for specified purposes, which are generally other than treatment, payment, or health care operations, or to disclose PHI to a third party specified by the individual.

An authorization must specify a number of elements, including a description of the PHI and the person authorized to use or disclose it, the person to whom the covered entity may make the disclosure, an expiration date, and, in some cases, the purpose for which the PHI may be used or disclosed. With limited exceptions, covered entities may not condition treatment or coverage on the individual providing an authorization.

An authorization form is not required for:

- Disclosures required by law
- Victims of abuse, neglect, or domestic violence
- Warrants or court orders
- Coroners, medical examiners, or funeral directors
- Organ, eye, or tissue donations
- Workers’ Compensation compliance
- Law enforcement to avert a serious threat to health or safety
- Public health purposes and health oversight activities.

The Privacy Rule gives patients the right (except with psychotherapy notes) to:

- Inspect medical information
- Make copies of medical information
- Request corrections to medical information
- Request a release of information or request restrictions on release.

There are exceptions to when you can disclose PHI:

- De-identified information – There are no restrictions on the use or disclosure of de-identified health information. Thus, removal of specified identifiers of an individual and of his/her relatives, household members, and employers is required and is adequate only if the covered entity has no actual knowledge that the remaining information could identify the individual.
- Informal permission – Informal permission may be obtained by asking the individual outright, or in circumstances that clearly give the individual the opportunity to agree, acquiesce, or object (e.g., when family or others are present and a patient asks that they stay during medical conversation).
- Emergency situations – When an individual is incapacitated, in an emergency situation, or not available, covered

entities generally may make such uses and disclosures if, in the exercise of their professional judgment, the use or disclosure is determined to be in the best interests of the individual.

Covered entities and providers generally may make use of and disclose PHI if, in the exercise of their professional judgment, the use or disclosure is determined to be in the best interests of the individual. Generally, professional judgment comes into play as an exception during emergency situations, but it is also exercised in situations in which an individual is determined to be incapacitated due to a physical or psychological condition at a time when treatment is needed. Upon restoration of capacity, a patient's privacy must again be honored unless disclosure is authorized by that patient.

The verification requirements of this paragraph are met if the covered entity relies on the exercise of professional judgment in use or disclosure in accordance with §164.510 (opportunity for individual to agree or object) or acts on a good-faith belief in making a disclosure in accordance with §164.512(j) (opportunity for individual to agree or object not required).

The HIPAA Privacy Rule at 45 CFR 164.510(b) specifically **permits** covered entities to share information that is directly relevant to the involvement of a spouse, family members, friends, or other persons identified by a patient in the patient's care or in payment for health care.

If the patient is present, or is otherwise available prior to the disclosure, and has the capacity to make health care decisions, the covered entity may discuss this information with the family and these other persons if the patient agrees or, when given the opportunity, does not object.

The covered entity may also share relevant information with the family and these other persons if it can reasonably infer, based on professional judgment, that the patient does not object. For example:

- A doctor may give information about a patient's mobility limitations to a friend driving the patient home from the hospital.
- A hospital may discuss a patient's payment options with her adult daughter.
- A doctor may instruct a patient's roommate about proper medicine dosage when she comes to pick up her friend from the hospital.
- A physician may discuss a patient's treatment with the patient in the presence of a friend when the patient brings the friend to a medical appointment and asks if the friend can come into the treatment room.

Even when the patient is not present or it is impractical because of emergency circumstances or the patient's incapacity for the covered entity to ask the patient about discussing her care or payment with a family member or other person, a

“When a person comes to a pharmacy asking to pick up a prescription on behalf of an individual he/she identifies by name, a pharmacist, based on professional judgment and experience with common practice, may allow the person to do so.”

covered entity may share this information with the person when, in exercising professional judgment, it determines that doing so would be in the best interest of the patient. [See 45 CFR 164.510(b)]. Thus, for example, a physician may, if consistent with such professional judgment, inform a patient's spouse, who accompanied her husband to the emergency room, that the patient has suffered a heart attack and provide periodic updates on the patient's progress and prognosis. Also, a provider may, if consistent with such professional judgment, discuss an incapacitated patient's condition with a family member over the phone.

In addition, the Privacy Rule expressly permits a covered entity to use professional judgment and experience with common practice to make reasonable inferences about a patient's best interests in allowing another person to act on behalf of the patient to pick up a filled prescription, medical supplies, x-rays, or other similar forms of PHI. For example, when a person comes to a pharmacy asking to pick up a prescription on behalf of an individual he/she identifies by name, a pharmacist, based on professional judgment and experience with common practice, may allow the person to do so.

So, if we have always been careful to not share PHI, what's all the hubbub? As I mentioned, HIPAA added some legal teeth to the practice of confidentiality. Fines for violating the Statute range from \$100 to \$50,000 per offense and up to \$1.5 million for identical violations occurring within a calendar year. The statute of limitations for HIPAA-related infractions is 6 years.

Returning to the scenario with the mildly developmentally delayed party girl, how should you proceed, given the HIPAA regulations? Although under HIPAA you could share information with her mother, it is clear to you that the patient does, in fact, have the capacity to object to sharing her PHI. Therefore, you should very tactfully tell the mother that unless her daughter consents or unless she has guardianship, you cannot share her daughter's results with her.

Next month, I plan to explore weird variations of HIPAA or HIPAA-like scenarios that I have experienced or can envision an urgent care provider facing. ■

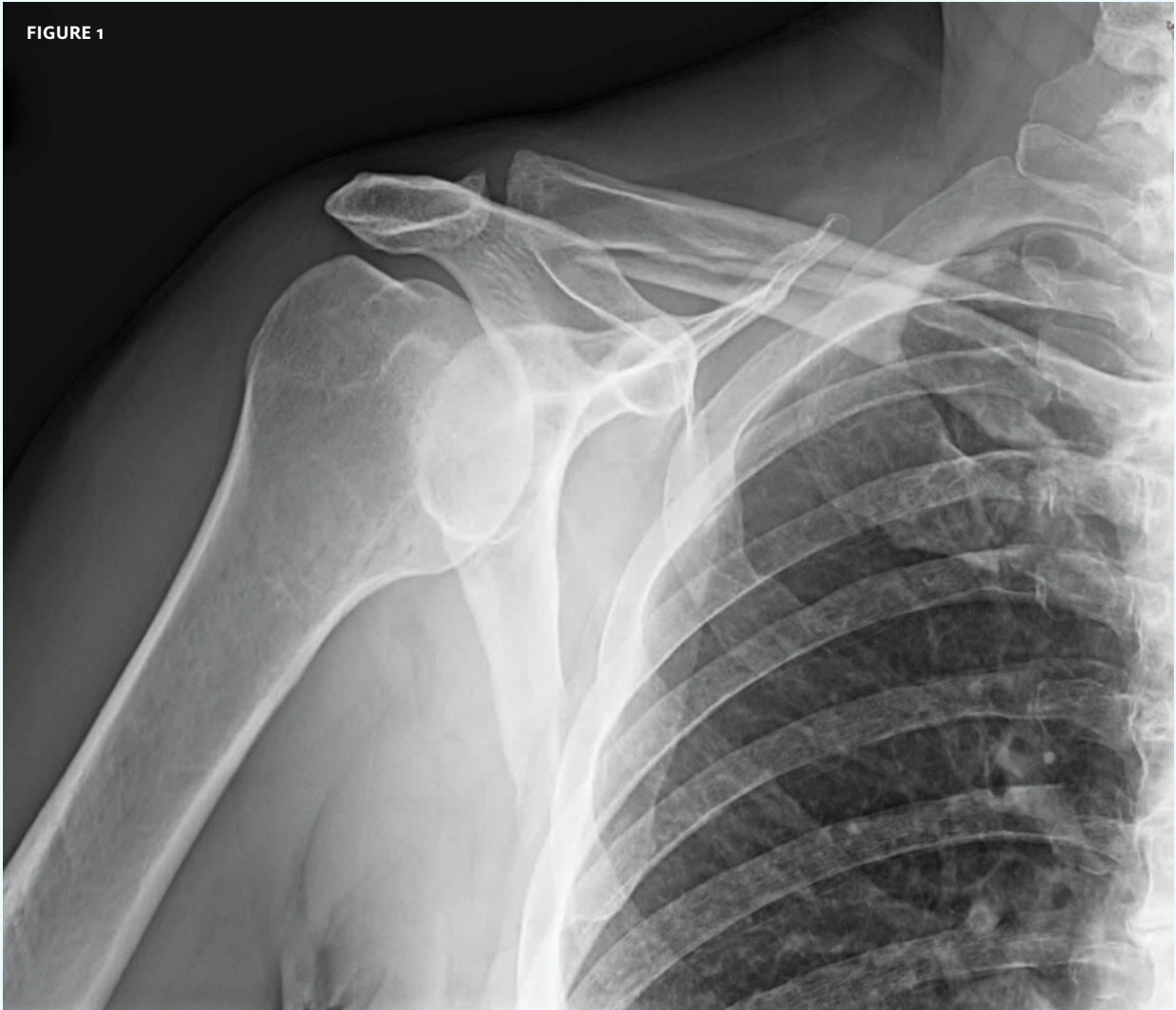


INSIGHTS IN IMAGES
CLINICAL CHALLENGE

In each issue, *JUCM* will challenge your diagnostic acumen with a glimpse of x-rays, electrocardiograms, and photographs of conditions that real urgent care patients have presented with.

If you would like to submit a case for consideration, please e-mail the relevant materials and presenting information to editor@jucm.com.

FIGURE 1



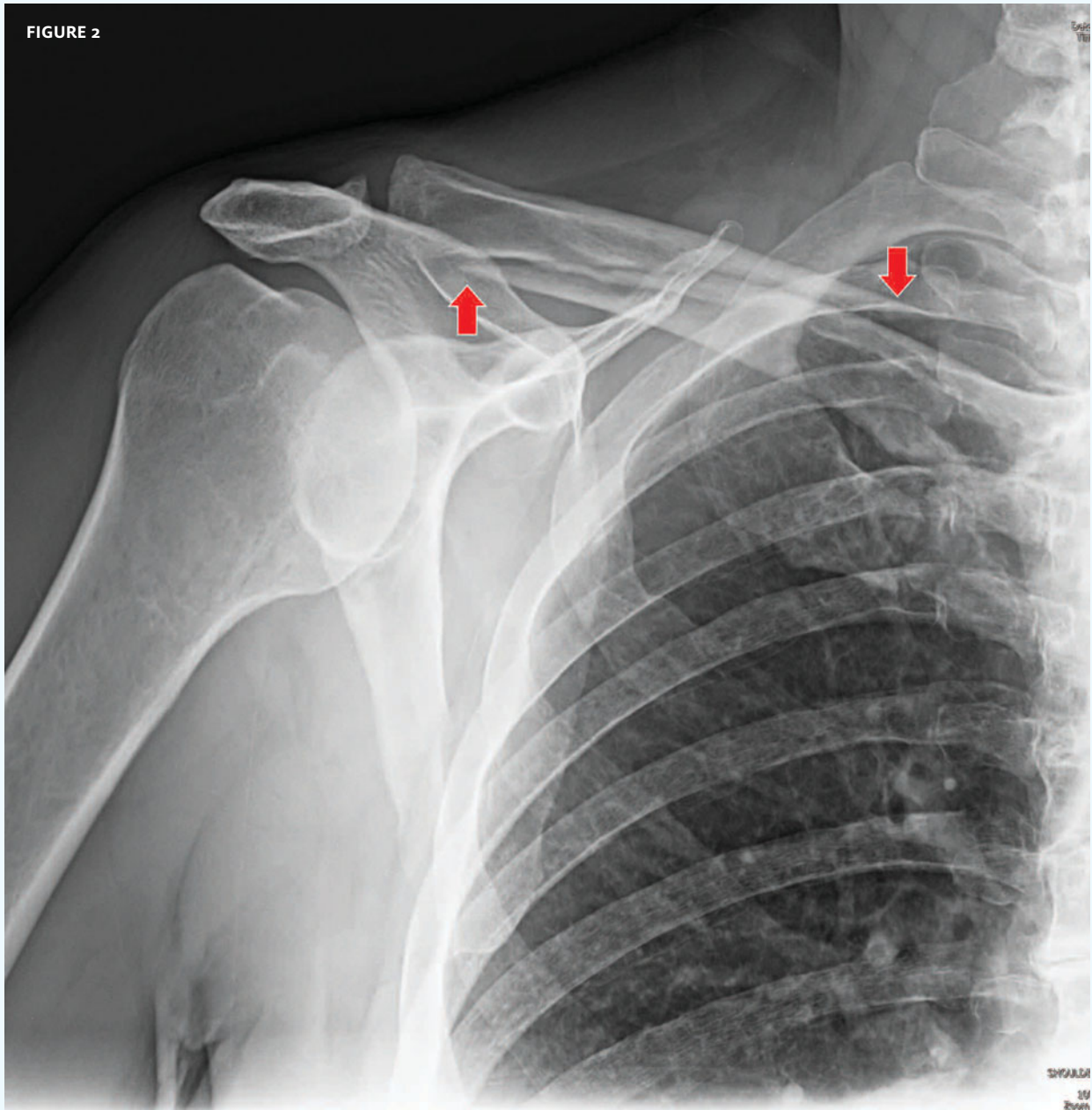
This x-ray was taken on a 72-year-old man who presented to urgent care after falling off a step stool while trimming branches. He landed directly on his left shoulder and was unable to lift his arm over his head due to severe pain. He thought his shoulder was dislocated.

View the image taken (**Figure 1**) and consider what your diagnosis would be.

Resolution of the case is described on the next page.

THE RESOLUTION

FIGURE 2



Diagnosis: The x-ray reveals a minimally displaced transverse clavicle fracture. This is an unusual clavicle fracture in that it cannot be classified into the “third system” of medial, middle, and lateral clavicle fractures. This fracture is actually lateral and middle (arrows). As there was no compromise to the skin and no severe deformity, no specific treatment was required. The patient was placed in a sling and advised to follow up with his primary care physician.

Acknowledgement: Case presented by Tracey Quail Davidoff, MD, an urgent care physician at Accelcare Medical Urgent Care and Urgent Care by Lifetime Health in Rochester, NY.



Workers' Compensation Visits, Cerumen Removal

■ DAVID STERN, MD, CPC

Q. I have a question on coding Workers' Compensation claims. I work in a hospital system and hospital coders oversee our charts. I feel they under code for the work we do. They are afraid of audits and refusal to pay. Typically, they will return the chart so that I can document my time and then they will charge for the time spent instead of the documentation.

I'm told there are no "bullet points" or increase in medical decision-making for discussing over-the-counter (OTC) medication instead of prescribing NSAIDs or narcotics, reviewing mechanism of injury or ergonomics of their job, handouts on exercises or review of stretching/exercises, discussing/making restrictions at the work site, or filling out forms for return to work/restrictions. I believe there are more layers of decision-making throughout the whole Workers' Compensation visit.

A. Although it requires more work to see a Workers' Compensation patient (for the same injury as a non-Workers' Compensation patient), more and more Workers' Compensation payors are insisting on less reimbursement for this work. In addition, the coding rules that we have from CMS do not give us extra credit for the extra work we do on these cases.

Time is unlikely to be very helpful as a coding guide because the E/M guidelines specifically preclude use of time for coding the E/M unless over half of the face-to-face time of the visit is composed of counseling or coordination of care, which is rare in urgent care. Thus time is mostly irrelevant for E/M coding in your setting.

Some modifications to the complexity of medical decision-

making have been proposed to allow for coding credit for the additional work required to see a Workers' Compensation patient. Although these modifications are in use by some occupational health providers, CMS is not likely to ever formalize these modifications as coding for Workers' Compensation has always been ignored by CMS. This is not surprising as Medicare and Medicaid do not cover Workers' Compensation injuries.

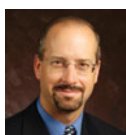
You are correct that the work involved in discussing medications, exercise handouts, and work restrictions; reviewing mechanism of injury; and filling out work forms does not increase the medical decision-making factor for the E/M level. However, CPT codes for filling out forms are listed on the Workers' Compensation fee schedule for some states. Some states will accept CPT 99080, "Special reports such as insurance forms, more than the information conveyed in the usual medical communications or standard reporting form" and others may have their own codes. For example, California has created its own set of 5-digit codes that begin with the letters "WC." ■

Q. Our claims for ear irrigation are being denied. We usually bill 69210- RT-59 and 69210-LT-59. What are we doing wrong?

A. Irrigation alone is considered part of the E/M code and is not separately payable. For 2014, CPT did change its description of code 69210, "Removal impacted cerumen requiring instrumentation, unilateral." This change clarified that the code is unilateral and that physicians must use some type of instrumentation to remove impacted cerumen.

CPT defines cerumen as impacted if any one or more of the following conditions are present:

- Cerumen impairs the examination of clinically significant portions of the external auditory canal, tympanic membrane, or middle ear condition; (Note: This is almost always the case when cerumen removal is performed.)
- Extremely hard, dry, irritative cerumen causes symptoms such as pain, itching, hearing loss, etc.;



David E. Stern, MD is a certified professional coder and board certified in Internal Medicine. He was a Director on the founding Board of UCAOA and has received the organization's Lifetime Membership Award. He is CEO of Practice Velocity, LLC (www.practicevelocity.com), PV Billing and NMN Consulting, providers of software, billing and urgent care consulting services. Dr. Stern welcomes your questions about urgent care in general and about coding issues in particular.

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C O D I N G Q & A

- Cerumen is associated with foul odor, infection, or dermatitis; or
- Obstructive, copious cerumen cannot be removed without magnification and multiple instrumentations requiring physician skills.

Instrumentation is defined as the use of an otoscope and other instrumentation such as wax curettes, wire loops, or suction plus specific ear instruments such as cup forceps or right angle hook.

Some payors will require an RT and/or LT modifier while some will require modifier -50 appended to code 69210. Others may require you to list 69210 twice and append modifier -50 to the second line. Check with individual payors for preference. If the procedure is performed alone, just bill the code and appropriate modifier. If performed with other procedures, bill the code with the appropriate RT/LT/50 modifier(s) and also append modifier -59.

Unfortunately, the Centers for Medicare and Medicaid Services (CMS) have elected to ignore the change and pay the same for cerumen removal whether you do one ear or both. CMS stated its opinion that the procedure will typically be done on both ears at the same encounter because "the processes that create cerumen impaction likely would affect both ears." Per CMS instruction, this reimbursement policy will remain in place through 2014. Due to this decision, you will likely receive a denial if you try to bill Medicare for more than one unit for code 69210 since most Medicare Administrative Contractors (MACs) are denying these claims entirely and not even paying for one unit.

In order to bill an E/M visit and cerumen removal on the same date of service, the following criteria must be met:

- The initial reason for the visit was separate from the cerumen removal.
- Otoscopic examination of the tympanic membrane is not possible due to the impaction.
- Removal of the impacted cerumen requires the expertise of the physician or non-physician practitioner and is personally performed by him or her.
- The procedure requires a significant amount of time and effort.

All of the above criteria must be clearly documented in the medical record. Modifier -25, "significant and separately identifiable evaluation and management service by the same physician on the same day of the procedure or other service" should be appended to the E/M visit code, if applicable. Clinical notes must clearly indicate that the E/M and cerumen removal are separate and medically necessary services. ■

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DEVELOPING DATA

These data from the 2012 Urgent Care Industry Benchmarking Study are based on a sample of 1,732 urgent care centers; 95.2% of the respondents were UCAOA members. Among other criteria, the study was limited to centers that have a licensed provider onsite at all times; have two or more exam rooms; typically are open 7 days/week, 4 hours/day, at least 3,000 hours/year; and treat patients of all ages (unless specifically a pediatric urgent care).

In this issue: What Benefits Do Physicians Employed By Urgent Care Centers Receive?

Benefit (in descending order)	% of Centers Providing Benefit
Malpractice insurance	95.1 (77.6 in 2010)
Including tail coverage	69.9
Without tail coverage	17.1
Varies per physician	8.1
Health Insurance	78 (72.4 in 2010)
CME Funds	70.7 (59.2 in 2010)
Paid Time Off	65.0
Combination PTO	52.0
Vacation Only	11.4
Sick Time Only	0.8
Personal Time Only	0.8
Dental Insurance	58.5 (46.9 in 2010)
401k Program	57.7
CME Time Off	54.5
Life Insurance	53.7 (48.0 in 2010)
Vision Insurance	48.8 (39.8 in 2010)
Short Term Disability	42.3 (35.7 in 2010)
Long Term Disability	37.4 (35.7 in 2010)
Profit Sharing	34.1 (22.4 in 2010)

In general, employed physician benefits have improved since 2010, with slightly greater numbers of centers providing basic benefits packages across all categories. With physicians playing such an important role in the success of a center, centers may be improving their packages in order to attract higher-quality candidates for these roles.

Note: 2010 comparisons shown where available.

Acknowledgement: The 2012 Urgent Care Industry Benchmarking Study was funded by the Urgent Care Association of America and administered by Anderson, Niebuhr and Associates, Inc. The full report can be purchased at www.ucaoa.org/benchmarking.

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