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of America



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Part 1

Evaluation of Headaches in Urgent Care: Emergent Headaches

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Risk Mitigation in Urgent Care: Part 2



My previous column presented the building blocks of a risk mitigation framework for your practice. This column specifies high-risk areas of urgent care practice that create exposure for both owner and clinicians and suggests ways to mitigate that risk.

Charting / Documentation: Your best defense when there is a bad outcome is documentation. The chart should clearly communicate your decision-making. The “standard of care” is not a guarantee against harm. It only requires that the clinician use reasonable clinical judgment relative to his/her training, experience and best practice in the discipline. When the “standard of care” is applied but a bad outcome occurs, the clinician is far less likely to be sued. That is, IF the documentation clearly communicates the rationale for the care provided. Spending extra time documenting so-called “at-risk encounters” with this principle in mind will reduce your risk. Remember, the way the tort system works, the plaintiff lawyers are on the hook for all of their expenses. So they are unlikely to take a case with excellent documentation and sound decision-making, regardless of the outcome. They want the low-hanging fruit. Don’t be that fruit!

EMR risks: Most EMRs use documentation shortcuts, which offer a provider efficiency gains. Tools that allow the provider to “auto-populate” and “copy and paste” are often used. But when things go wrong, they are not your friend. They make a provider look careless and robotic (not appealing to a jury). These shortcuts should be avoided or supplemented for all high-risk encounters. A detailed explanation of medical decision-making is a more robust defense than a one-word diagnosis and auto-populated H&P.

Supervision of assistive medical personnel: The entire clinical team, front and back office, plays an important role in mitigating risk. Keys to success include:

1. Effective communication:
 - a. Eliminate verbal orders
 - b. Ensure all meds and dosages are verified by the clinician prior to administration
 - c. Ensure that only objective observations are used for the nurse note and nurse report to the clinician. Avoid subjective communications that reflect judgments, labels or assumptions.
2. Policy and procedure:
 - a. All nurse procedures and functions should have policy and procedure to guide their performance. This supports risk man-

agement, improves work flow, manages inventory more efficiently, and improves patient satisfaction. Pay particular attention to triage and med administration.

3. Training and retraining:
 - a. The value of a systematic training program with tracking and post-training assessment cannot be overstated. Most assistive clinical staff are non-licensed health care providers (most notably, medical assistants). Unlike nurses, they do not have any training standard that is monitored by the state medical boards and thus, their training is extremely variable. The urgent care nursing skill set is broad and many of these skills, including triage and emergency response, are nurse-level functions that are generally not taught in medical assistant programs.
 - b. Many urgent care centers use shadowing as a training method, which is very helpful for providing real-life perspective but inadequate for ensuring comprehensive training and highly variable.
4. Supervision:
 - a. Adequate supervision is mandatory, and to be effective without losing efficiency, the level of supervision should be determined by a review of pre-hire training and experience, scope-of-practice laws specific to each state, and a proficiency assessment at hire and post-training.

Writing about risk mitigation in urgent care has been so much fun that I’ve decided to extend it to a three-part series! In my next column, the last in this series, I will cover specific clinical policies and procedures that can effectively reduce liability risk and enhance patient safety, quality, and satisfaction. The scenarios I will present represent the rare opportunity to manage all these critical interests at once. And who can argue with the value of that? ■

Lee A. Resnick, MD
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CLINICAL

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Identifying potentially life-threatening or emergent causes of headaches can be challenging in urgent care. Emergent headaches are the focus of the first of a two-part series, aimed at aiding practitioners in appropriate evaluation and management.

Jacqueline Dancy, PA-C, MPAS

PRACTICE MANAGEMENT



18 HIPAA for Urgent Care Centers: A Primer

This article discusses potential penalties for violations of HIPAA and key steps urgent care centers should take in order to avoid such penalties.

Bart Walker and Megan Bushee

CASE REPORT

27 Acute Pericarditis

This case underscores the importance of not “anchoring” to a previous provider’s diagnosis and always remembering that medical conditions are dynamic.

John J. Koehler, MD, and Daniel Murauski, DO



IN THE NEXT ISSUE OF JUCM

Deep venous thrombosis (DVT), or formation of a clot in the deep venous system, is the subject of next month’s cover story. Every year, more than 300,000 individuals die due to DVT. Urgent care providers have a significant role to play in diagnosis of patients with acute leg pain, swelling and discoloration. This article discusses how to use the Wells criteria as a clinical predictor of DVT and how the point-of-care D-dimer test contributes to decision-making.

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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.

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This month's cover story is designed to help urgent care providers cope with the challenge of rapidly recognizing subtle and nonspecific signs and symptoms that differentiate emergent and non-emergent headaches. The focus of this article—the first of a two-part series by Jacqualine Dancy, PA-C, MPAS—is on emergent headache syndromes. Of paramount concern in identifying such cases are key components such as sudden and severe onset, exacerbation with movement, and associated vomiting, focal neurological and/or visual disturbances. Look for the second part of the series, on management of non-emergent headaches, in a future issue.

Jacqualine Dancy is Lead Physician Assistant at MedStop Urgent Care Center in San Luis Obispo, CA.



The key takeaways for urgent care providers from this month's case report—by John J. Koehler, MD, and Daniel Murauski, DO—are not to rely on a previous provider's diagnosis and to keep in mind that medical conditions are dynamic. They present the case of a 57-year-old woman with a 4-day history of "chest congestion" that had previously been treated with antibiotics by a primary care physician. Deep breathing and lying flat exacerbated her symptoms. The diagnosis? Acute pericarditis.

John J. Koehler, MD, is Chief Medical Officer at Physicians Immediate Care, Chicago, IL. Daniel Murauski, DO, is Site Director at Physicians Immediate Care, Chicago, IL.

Avoiding penalties for violations of the Health Insurance

Portability and Accountability Act (HIPAA) is the subject to this month's practice management article. The very nature of urgent care practice, with its high volume, walk-in environment and exposure to the public makes it likely that providers will face increasing scrutiny from the federal government for HIPAA compliance, say experts Bart Walker and Meggan Bushee. Their seven-step plan will help ensure that your clinic is in compliance.



Bart Walker is a partner in the Charlotte, North Carolina office of McGuireWoods LLP. Meggan Bushee is an associate in the Charlotte, North Carolina office of McGuireWoods LLP. Both attorneys are in the firm's health care group.

Also in this issue:

In Health Law this month, **John Shufeldt, MD, JD, MBA, FACEP**, discusses the potential benefit of using scribes in urgent care practice.

Sean M. McNeeley, MD, and **The Urgent Care College of Physicians** review new abstracts on literature germane to the urgent care clinician, including studies of aging and risk of heart disease, otorrhea from tympanostomy tubes, and guidelines for atopic dermatitis.

In Coding Q&A, **David Stern, MD, CPC**, discusses codes for DME and benign lesion excision.

Our Developing Data end piece this month looks at the percentage of patients transferred or directed to emergency rooms 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 backgrounds. 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.

Please send tables, graphs, sidebars (boxes) and digital or film

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FROM THE CHIEF EXECUTIVE OFFICER

Scenes from the 10th National Urgent Care Convention

■ P. JOANNE RAY

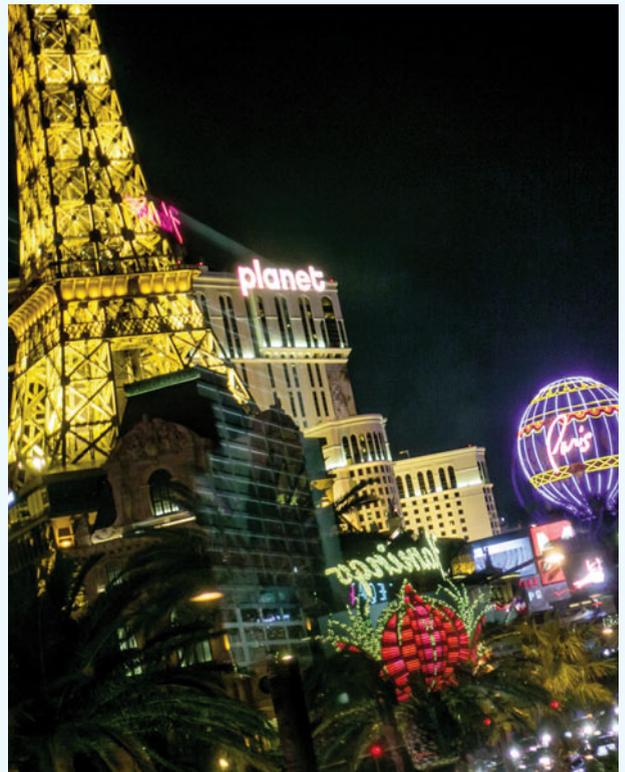
The 10th National Urgent Care Convention in Las Vegas attracted more than 1,100 attendees — one of the largest showings ever — comprising urgent care practitioners, center owners, administrators, managers, exhibitor representatives, and investors from across the United States. The sold-out exhibit hall also surpassed previous years' records with 148 exhibiting companies — of which 60 were new this year — showcasing urgent care products, services and technologies.

Most of the main convention sessions were recorded and will be made available through the UCAOA Online Education portal. To see more photos, read more about the meeting outcome, or access the recorded sessions, please visit www.ucaoa.org.

Be sure to also mark your calendars and join us when UCAOA will be continuing the celebration of its 10-year anniversary at the Urgent Care Fall Conference, October 9-11, in Denver. ■



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Clinical

Evaluation of Headaches in Urgent Care Part 1: Emergent Headaches

Urgent message: Identifying potentially life-threatening or emergent causes of headaches can be challenging in urgent care. Emergent headaches are the focus of the first of a two-part series, aimed at aiding practitioners in appropriate evaluation and management.

JACQUALINE DANCY, PA-C, MPAS

Introduction

The presentation of headaches in the urgent care setting often elicits some healthy angst. Differentiating between potentially life-threatening headaches and more benign varieties can be challenging, especially when the signs and symptoms are often subtle and nonspecific. This article will highlight features associated with the emergent headache syndromes with which patients may more commonly present in the urgent care setting.

Eliciting emergent causes of headaches can be challenging. Some of the key history questions to focus on are: onset of the headache, location, severity, associated neurological symptoms, history of similar headaches and how *this* headache differs from prior headaches.

For the purpose of this article, emergent headaches are classified as those that threaten life or pose a substantial risk of permanent disability. The majority of patients with emergent headaches present directly to the emergency department (ED), but some do present in the urgent care setting. It is likely that the latter presentations are more subtle in presentation and/or early in the disease process, although that has not been well studied. It is vital that urgent care providers be vigilant in



their assessment and include serious etiologies of headache in their differential diagnosis.

Intracranial Hemorrhage Headache

The classic presentation for an intracranial bleed (ICB) is abrupt onset of severe headache (97% of cases) with peak severity within seconds or minutes of onset (**Table 1**).^{1,2}

.....
Jacqueline Dancy is Lead Physician Assistant at MedStop Urgent Care Center in San Luis Obispo, CA.

Table 1. Pearls on Intracranial Hemorrhage-Related Headache**Symptoms**

- Sudden onset.
- Maximum intensity reached within minutes.
- Often severe (“worst headache of life”)
- Usually nausea or vomiting
- +/- neurological findings

Risk factors

- Positive family history of SAH
- Hypertension, poorly controlled
- Medications
 - Anticoagulants
 - Adrenergic (amphetamines, pseudoephedrine and phenylpropanolamine)

SAH = subarachnoid hemorrhage

Subarachnoid hemorrhage (SAH) often presents as an abrupt onset of severe pain – presenting with the classic “worst headache of my life” complaint, often with a “thunderclap” onset. The pain is usually lateralized in 30% of patients to the side of the bleed.¹ The headache may radiate into the neck and shoulders, causing meningismus.³ Patients often complain of nausea with or without vomiting and may rapidly decline with mental status change or have a seizure; however, the signs can be subtle and 25% of patients with SAH are initially misdiagnosed especially in the face of sentinel bleeds.⁴

The majority of SAH are due to an aneurysm. Risk factors for SAH include a family history of a first- or second-degree relative with SAH. The probability of a SAH is significantly higher with a positive family history.⁴

The work up for suspected ICB includes a non-contrast computed tomography (CT) scan or contrast-enhanced magnetic resonance imaging (MRI) with or without a lumbar puncture (LP). An LP is indicated when there is suspicion of an acute SAH and neuroimaging is negative.⁴ Few urgent care clinics can complete this evaluation and transfer to an ED is indicated.

The treatment for aneurysmal SAH may include various surgical interventions to stop active bleeding and decrease ICP and is considered to be the only effective treatment and it needs to be done within 24 to 72 hours; therefore, arranging prompt transfer to an ED is indicated.⁵

Sentinel headache, an unruptured intracranial aneurysm, is likely caused by leaking of blood into the subarachnoid space. Patients with these headaches often have the same presenting symptoms as with SAH, but the headache improves and may resolve within hours

to days. It is estimated that 20% to 50% of those with a SAH report a sentinel or ‘warning’ headache days to weeks prior to an aneurysm rupture.⁴

Hypertensive vasculopathy is an important cause of nontraumatic ICB. Poorly controlled hypertension is the common chronic risk factor. There are many acute factors associated with hypertensive ICB, including hemorrhagic infarction, septic emboli, brain tumor, bleeding disorders including anticoagulant therapy, central nervous system infections, and vasculitis. Drug exposures associated with hypertensive ICB are adrenergic drugs (amphetamines and phenylpropanolamine) and pseudoephedrine, which directly stimulates alpha-adrenergic receptors causing vasoconstriction, and beta-adrenergic receptors, which cause increased heart rate and contractility, often increasing vascular strain.^{6,7}

The clinical presentation differs slightly from SAH in that the neurological symptoms do not begin abruptly and are not maximal at the onset. Headache onset is often within minutes to a few hours and is frequently associated with symptoms of increased ICP and traction of the meningeal pain fibers, causing nausea with or without vomiting. Focal neurological findings are specific to the location of the bleed (that is, cerebellar bleeds present with inability to walk due to imbalance).

The etiology of the vasculopathy associated with this type of ICB is chronic hypertension leading to vessel wall damage, which in turn causes “pseudo aneurysms.” The primary risk factor is hypertension, which is thought to cause “pseudoaneurysms” by way of damage to the intimal layer of the vessel wall, causing weakened areas and increasing the risk of a massive hemorrhage. Secondary risk factors, for vascular disease, include older age, exposure to antithrombotic therapy, high alcohol intake, African-American ethnicity, lower cholesterol, lower LDL cholesterol, and low triglycerides.⁸

The diagnostic studies of choice include non-contrast CT scan or contrast-enhanced MRI.⁹

Treatments for hypertensive vasculopathy include both medical and surgical interventions tailored to the underlying etiology and severity of the ICB.¹⁰

Warfarin – associated ICB: These headaches present similarly to SAH and symptoms may include focal neurological signs such as hemiparesis, aphasia, and ataxia. These events usually occur in the older population, with a mean age of 70.¹¹ The suspicion rises with a history of head-related trauma, which may be trivial. The diagnosis of warfarin-associated ICH is met when neurological signs are present, the international normalized ratio (INR) is >1.4 and there is evidence of ICB on non-

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(moxifloxacin HCl ophthalmic solution) 0.5% as base

BRIEF SUMMARY OF PRESCRIBING INFORMATION. FOR ADDITIONAL INFORMATION REFER TO THE FULL PRESCRIBING INFORMATION.

INDICATIONS AND USAGE

MOXEZA® solution is indicated for the treatment of bacterial conjunctivitis caused by susceptible strains of the following organisms: *Aerococcus viridans**, *Corynebacterium macginleyi**, *Enterococcus faecalis**, *Micrococcus luteus**, *Staphylococcus arlettae**, *Staphylococcus aureus*, *Staphylococcus capitis*, *Staphylococcus epidermidis*, *Staphylococcus haemolyticus*, *Staphylococcus hominis*, *Staphylococcus saprophyticus**, *Staphylococcus warneri**, *Streptococcus mitis**, *Streptococcus pneumoniae*, *Streptococcus parasanguinis**, *Escherichia coli**, *Haemophilus influenzae*, *Klebsiella pneumoniae**, *Propionibacterium acnes*, *Chlamydia trachomatis**

*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.

Rx Only

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contrast CT scan or MRI. The treatment includes infusions of vitamin K and fresh frozen plasma.¹²

Warfarin is the anticoagulant most represented in the literature; however, very similar complications have been associated with all currently available Novel Oral Anticoagulants (NOAC), including dabigatran, rivaroxaban, apixaban, and edoxaba. In terms of bleeding-associated risks, these medications should be considered as warfarin-equivalent.

Brain Tumor Headache

Tumor-related headache is considered the great masquerader. It mimics common, non-emergent types of headaches including tension (77%), migraine (9%), and other types (14%).¹³ The classic “brain tumor triad” of nocturnal or early-morning headache, nausea/vomiting and severe nature is now thought to be inaccurate based on current studies.¹³ Although headache is a common symptom, it is rarely severe or the only symptom (**Table 2**). Nausea with or without vomiting is another common complaint occurring in 40% of patients.¹³ The tumor-related headache is worse with bending forward (or other Valsalva-type maneuvers) and is thought to be more sensitive and specific than the nocturnal or early morning headache. The headaches are characterized as generalized, dull, constant, and may be throbbing.¹³ Brain tumors are often associated with other neurological symptoms, such as seizure or focal weakness.¹⁴

Isolated headaches of more than 10 weeks’ duration are rarely caused by a brain tumor.¹⁵

Risk factors for brain tumor include new onset of headaches in patients older than age 50 and comorbid malignancy, particularly of the lung, breast, melanoma, and gastrointestinal cancers.

The gold standard diagnostic test is MRI with and without intravenous contrast.

Treatment is specific to the tumor location, size, type and the patient’s overall health and can include surgical interventions and palliative care when appropriate.

Idiopathic intracranial hypertension

Idiopathic Intracranial Hypertension (IIH), also known as pseudotumor cerebri, was previously known as benign intracranial hypertension but it is a serious disorder. IIH is caused by elevated ICP due to overproduction of cerebral spinal fluid (CSF) and often causes significant disability. Although this type of headache is not life-threatening, it can cause significant impairment if not identified and treated promptly. Without prompt diagnosis and treatment, patients may suffer intractable

Table 2. Pearls on Brain Tumor-Related Headache

- Headache:
- Alone is uncommon
 - Often generalized
 - Often associated with nausea/vomiting
 - Worse with Valsalva or bending forward
 - Less likely if present >10 wks

Table 3. Pearls on Idiopathic Intracranial Hypertension-Related Headache

- Headache and transient visual loss are common
 - Papilledema is common
 - Elevated opening pressure on LP
 - Female > Male
 - <50 years, obese
 - Recent use of tretinoin or doxycycline
- LP = lumbar puncture

disabling headaches and are at risk of blindness.¹⁶

The most common symptoms of IIH are headache (92%), transient visual loss (72%), pulsatile tinnitus (60%), photopsia (54%), retrobulbar pain (44%), diplopia (38%), and sustained visual loss (25%) (**Table 3**).¹⁶ The headache is often lateralized, pulsatile, and worse in the supine position. The unique quality of IIH is retrobulbar pain and pain with eye movement or globe compression. Another IIH-specific symptom is dysacusis, which are often perceived as rushing water or wind and are pulse-synchronous.¹⁷ Visual disturbances, such as transient loss, are caused by papilledema whereas diplopia is caused by sixth nerve palsy from increased ICP.¹⁸

Physical exam findings characteristic of IIH are papilledema (bilateral and symmetrical), which is the hallmark sign, visual field loss, and sixth nerve palsy.

Risk factors for IIH are being female, obese, and using tretinoin and/or doxycycline. Most cases occur in patients younger than age 50.

The diagnostics of choice for IIH are MRI: to exclude secondary cause of elevated ICP, lumbar puncture to reveal elevated opening pressure, and visual field testing to reveal an enlarged blind spot, generalized constriction, and inferonasal vision loss.

The goals of treatment for IIH are recognition and appropriate referral. Initial referral will likely be to an ED unless urgent coordinated care with a neurologist is readily available. Treatment is aimed at resolution of symptoms and preservation of vision. Options for treatment are weight loss, carbonic anhydrase inhibitors, loop diuretics, serial lumbar punctures, and surgical

Table 4. Pearls on Giant Cell Arteritis-Associated Headache

- Temporal headache: often new or different
- Scalp tenderness and jaw claudication
- Age >50 years
- Associated with PMR
- CRP and ESR elevated
- Treatment: glucocorticoids and aspirin

CRP = C-reactive protein; ESR = erythrocyte sedimentation rate; PMR = polymyalgia rheumatica

intervention.^{20,21} Carbonic anhydrase inhibitors are thought to reduce the production of CSF. First-line treatment is acetazolamide 500 mg twice daily. Caution should be used in any patient with a sulfa allergy. Furosemide (20 mg to 40 mg per day) may be helpful as an adjunct to carbonic anhydrase inhibitors. This combination has been shown to normalize CSF pressure within 6 weeks in many patients. Serial lumbar punctures are generally *not* recommended, but can be considered in patients who do not tolerate medication therapy or in pregnant women.

Surgery should be considered only in patients whose IIH has failed to respond to all other measures and who have intractable pain and loss of visual acuity loss. The procedures include ventriculoperitoneal shunt or lumboperitoneal shunt and / or optic nerve sheath fenestration.

Giant Cell (Temporal) Arteritis Headache

Giant Cell Arteritis (GCA) is a chronic vasculitis of medium and large vessels and can cause permanent vision loss, which occurs in 15% to 20% of patients.²² Although GCA rarely requires an ED evaluation, prompt assessment, treatment, and referrals are critical in reducing the risk of significant and permanent impairment, namely vision loss.

The most common symptom of GCA is new onset or new type of headache that is often temporally located, but can be more generalized (**Table 4**). Headache is the most common complaint, with the critical feature being new onset (or new type) of headache. There are often associated symptoms with GCA, including systemic complaints such as low-grade fever, anorexia, weight loss, malaise, fatigue, paresthesias, joint pain, dizziness, hoarseness and dysphagia. The most common associated symptom is jaw claudication. It occurs in more than 50% of patients with GCA and, with profound fatigue upon mastication, is the most specific symptom correlated to a confirmed diagnosis of GCA.²³ The headache is often burning with or without episodes of lancinating pain. Scalp ten-

derness is seen in about 50% of patients, who may describe pain with brushing their hair.²⁴ The headache often progressively worsens over time until treatment is initiated. Visual symptoms are not uncommon with GCA and may present as amaurosis fugax. A non-productive cough is associated with GCA in 10% of patients and is a result of vasculitis near the cough receptors.²⁵

The characteristic physical examination qualities may include tender and enlarged temporal artery and the pulse may be absent.

Risk factors for GCA include advanced age. The disorder is almost never seen in patients younger than age 50, with a mean age of 72 years at diagnosis.²⁶ Comorbid polymyalgia rheumatica is closely associated with GCA, occurring in one-half of patients.²⁷

The gold standard of diagnosis is temporal artery biopsy, which should be performed within 3 days of presentation. However, biopsy only carries an 87% sensitivity, making adjunct diagnostics studies valuable.²⁸ In addition to biopsy, erythrocyte sedimentation rate (ESR), C-reactive protein (CRP) and complete blood count (CBC) are recommended. The ESR is elevated in 85% of patients at a value >50 mm/hour.^{29,30} CRP has a sensitivity of 97.5% to 100% for active GCA and is more sensitive than biopsy with less risk. It is less influenced by factors such as age than is ESR and recognition of it as an important diagnostic test is growing.^{29,30} ESR does show age-related elevation after age 40 years, whereas CRP is also affected by age, but to a much lesser extent.³¹ The characteristic abnormality seen on CBC with GCA is thrombocytosis.^{29,30}

Treatment for GCA should not be delayed while awaiting biopsy results and should be initiated as soon as the diagnosis is entertained. The recommended treatment is glucocorticoids and the initial dose should be equivalent to 40 mg to 60 mg of prednisone as a single dose per day until symptoms improve.³² In addition to glucocorticoid therapy, low-dose aspirin (80 mg-100 mg/day) is recommended to reduce the risk of blindness.³³ Because of the increased risk of gastroduodenal complications with steroids and NSAIDs, especially when combined, and given the duration of treatment, beginning a proton pump inhibitor is highly recommended with the above therapy.

The complications of GCA include blindness. Estimates indicate that up to 50% of patients who present with unilateral visual loss or diplopia may have progression to bilateral blindness within 1 to 2 months if GCA is left untreated.³⁴

Conclusion

Rapid recognition of an emergent type of headache is essen-

Expect relief, not a follow-up visit.

Choose CIPRODEX[®] Otic the first time, every time.

For acute otitis externa (AOE) and acute otitis media (AOM) with tympanostomy tubes caused by indicated pathogens.

- The power of an anti-inflammatory and antibiotic in each drop²
- High clinical cure rates²⁻⁴
- Well-established safety profile²
- The #1 otic drop among otolaryngologists and pediatricians since 2007¹



Affordable access with 99.5% commercial lives covered⁵



New **DROPS101™** Web Tool gives your patients access to instant savings information, helpful dosing instructions, and more at drops101.com

Why choose anything else?

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

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 February 2013, USC 62320 OTIC ANTINFCT W/ GLUCOCORT. 2. CIPRODEX[®] Otic package insert. 3. Roland PS, Pien FD, Schultz CC, et al. Efficacy and safety of topical ciprofloxacin/dexamethasone versus neomycin/polymyxin B/hydrocortisone for otitis externa. *Curr Med Res Opin.* 2004;20(8):1175-1183. 4. Roland PS, Kreisler LS, Reese B, et al. Topical ciprofloxacin/dexamethasone otic suspension is superior to ofloxacin otic solution in the treatment of children with acute otitis media with otorrhea through tympanostomy tubes. *Pediatrics.* 2004;113(1):e40-e46. 5. Formulary data provided by Pinsonault Associates, LLC, PathfinderRx, March 2013.

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STERILE OTIC SUSPENSION BRIEF SUMMARY OF 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 solution should be warmed by holding the bottle in the hand for one to two minutes to avoid dizziness which may result from the instillation of a cold solution. 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. **Acute Otitis Externa:** Prior to administration of CIPRODEX® Otic in patients with acute otitis externa, the solution should be warmed by holding the bottle in the hand for one to two minutes to avoid dizziness which may result from the instillation of a cold solution. 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.

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. 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).

DOSE 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 solution. 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 solution 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 solution. 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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tial to coordinate a patient's care urgently. Identifying key components of an emergent type of headache, such as onset and severity (sudden and severe); exacerbating factors (movement), associated symptoms (vomiting, focal neurological and / or visual disturbances) is paramount. The complaint of a new or different type of headache should raise concern and warrants a detailed evaluation. For patients whose headaches have a life-threatening cause, transfer to an appropriate ED is required. Prompt recognition of a potentially disabling cause of headache is equally important to reduce the risk of permanent functional loss. ■

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HIPAA for Urgent Care Centers: A Primer

Urgent message: This article discusses potential penalties for violations of HIPAA and key steps urgent care centers should take in order to avoid such penalties.

BART WALKER and MEGGAN BUSHEE

Complying with the Health Insurance Portability and Accountability Act (HIPAA) can be a daunting challenge for smaller providers. As the urgent care industry grows, its providers will become much more visible targets for scrutiny by the federal government with respect to HIPAA compliance. In addition, the high-volume, retail-facing, walk-in nature of urgent care provides greater exposure to the public, who are increasingly learning that HIPAA exists and prone to make allegations.

In general, HIPAA governs: (1) when providers may use or disclose a patient's health information (known as "protected health information" or PHI under HIPAA); (2) to whom PHI may be disclosed; and (3) for what purpose PHI may be used or disclosed. Most states also have their own laws regulating the privacy of patient health information. HIPAA compliance is monitored and enforced by the Secretary of the Department of Health and Human Services (HHS).

Penalties for HIPAA Violations

Penalties for violations of HIPAA can be severe. For example, on February 24, 2013, Massachusetts General Hospital entered into a \$1 million settlement with HHS following a patient's complaint about the hospital's loss of documents containing the PHI of approximately 192 patients that were left on the subway by an employee. On September 17, 2012, Massachusetts Eye



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and Ear Infirmary and Massachusetts Eye and Ear Associates, Inc. entered into a 1.5 million settlement with HHS following their self-disclosure of a stolen laptop that contained the PHI of approximately 3,500 patients.

HIPAA applies to all "covered entities" and their "business associates" (and all subcontractors of business associates). Because they provide health care, urgent care centers are considered "covered entities" under HIPAA. Management and billing companies that work with urgent care providers are usually deemed to be "business associates" of the urgent care providers for purposes of HIPAA.

HIPAA violations are usually discovered due to a complaint, often by a disgruntled patient, a former

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Table 1. Four-tier Civil Penalty System for HIPAA Violations

Civil Penalties		
Tier 1	Unknowning - Covered Entity or Business Associate did not know and, by exercising reasonable diligence, would not have known that the violation occurred.	\$100-\$50,000 per violation/\$1.5M cap
Tier 2	Reasonable Cause - Covered Entity or Business Associate knew, or by exercising reasonable diligence would have known, that the violation occurred, but did not act with willful neglect.	\$1,000-\$50,000 per violation/\$1.5M cap
Tier 3	Willful Neglect - It is established that the violation was due to willful neglect and was corrected during the 30-day period beginning on the first date the Covered Entity or Business Associate liable for the penalty knew, or, by exercising reasonable diligence, would have known that the violation occurred.	\$10,000-\$50,000 per violation/\$1.5M cap
Tier 4	Uncorrected Willful Neglect - it is established that the violation was due to willful neglect and was not corrected during the 30-day period beginning on the first date the Covered Entity or Business Associate liable for the penalty knew, or, by exercising reasonable diligence, would have known that the violation occurred.	At least \$50,000 per violation/\$1.5M cap

employee, self-disclosure of a breach by the provider, or an audit, all of which can lead to an investigation by the Secretary of HHS. The Secretary can impose civil penalties ranging from \$100 to \$50,000 per violation, with a \$1.5 million cap for aggregate violations of the same HIPAA provision in a single calendar year. The amount of the civil penalty largely depends upon the level of culpability associated with the violations as established by a four-tiered civil penalty system set forth in **Table 1**, although several of the more recent settlements with HHS have been for the maximum civil penalty amount.

Both large and small providers have been subject to recent investigations by the Secretary, evidencing the importance of a thorough compliance plan regardless of the size of the provider. For example, on April 17, 2012, Phoenix Cardiac Surgery, PC, a five-physician practice, entered into a settlement with HHS for \$100,000, a significant penalty for a very small provider. The HHS investigation of the practice was triggered by an anonymous complaint that the practice was posting patient appointment information on a publicly accessible Internet-based calendar.

In addition to the civil monetary penalties outlined in **Table 2**, a provider may be required to notify local prominent media outlets after more extensive breaches, in addition to the notification of HHS and all affected individuals that is required for all breaches. Although rare, HIPAA violations can also result in criminal penal-

ties of up to \$250,000 and up to 10 years imprisonment.

Steps for Urgent Care Centers to Comply with HIPAA and Avoid Penalties

1. Implement Privacy and Security Policies and Procedures

The first step an urgent care center should take in order to comply with the often complex requirements of HIPAA is to have formal policies and procedures in place that govern the privacy and security of patient PHI and set forth a process for investigating any breach and mitigating any harm resulting from a breach. HIPAA policies and procedures generally are divided into two pieces: (1) privacy policies and procedures that comply with the HIPAA Privacy Rule, which focuses on the right of an individual to control the use and disclosure of his or her PHI; and (2) security policies and procedures that comply with the HIPAA Security Rule, which focuses on administrative, technical, and physical safeguards of electronic PHI (ePHI). In connection with creating security policies and procedures, the provider must perform a comprehensive risk assessment of its storage and transmission of ePHI. The risk assessment should assist the provider in developing safeguards for hardware and portable devices that contain ePHI. It is particularly important that the security policies strictly regulate the removal of portable devices containing PHI from the urgent care center, as well as the use of e-mail for the transmission of PHI.



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INDICATION AND DOSING

PATADAY® Solution is a mast cell stabilizer indicated for the treatment of ocular itching associated with allergic conjunctivitis. The recommended dose is one drop in each affected eye once a day.

IMPORTANT SAFETY INFORMATION

PATADAY® Solution is for topical ocular use only. It is not for injection or oral use.

To prevent contaminating the dropper tip and solution, care should be taken not to touch the eyelids or surrounding areas with the dropper tip of the bottle. Keep the bottle tightly closed when not in use.

References: 1. IMS Health, IMS National Prescription Audit™, August 2010 to November 2013, USC 61500 OPTH ANTI-ALLERGY. 2. PATADAY® Solution package insert. 3. Formulary data provided by Pinsonault Associates, LLC, PathfinderRx, November 2013.

Patients should be advised not to wear contact lenses if their eyes are red.

PATADAY® Solution should not be used to treat contact lens-related irritation. The preservative in PATADAY® Solution, benzalkonium chloride, may be absorbed by soft contact lenses. Patients who wear soft contact lenses and **whose eyes are not red** should be instructed to wait at least ten minutes after instilling PATADAY® Solution before they insert their contact lenses.

Symptoms similar to cold syndrome and pharyngitis were reported at an incidence of approximately 10%.

For additional information about PATADAY® Solution, please refer to the brief summary of prescribing information on adjacent page.

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INDICATIONS AND USAGE

PATADAY® Solution is indicated for the treatment of ocular itching associated with allergic conjunctivitis.

DOSAGE AND ADMINISTRATION

The recommended dose is one drop in each affected eye once a day.

DOSAGE FORMS AND STRENGTHS

Ophthalmic solution 0.2%: each ml contains 2.22 mg of olopatadine hydrochloride.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

For topical ocular use only.

Not for injection or oral use.

Contamination of Tip and Solution

As with any eye drop, to prevent contaminating the dropper tip and solution, care should be taken not to touch the eyelids or surrounding areas with the dropper tip of the bottle. Keep bottle tightly closed when not in use.

Contact Lens Use

Patients should be advised not to wear a contact lens if their eye is red.

PATADAY® (olopatadine hydrochloride ophthalmic solution) 0.2% should not be used to treat contact lens related irritation.

The preservative in **PATADAY®** Solution, benzalkonium chloride, may be absorbed by soft contact lenses. Patients who wear soft contact lenses **and whose eyes are not red**, should be instructed to wait at least ten minutes after instilling **PATADAY®** (olopatadine hydrochloride ophthalmic solution) 0.2% before they insert their contact lenses.

ADVERSE REACTIONS

Symptoms similar to cold syndrome and pharyngitis were reported at an incidence of approximately 10%.

The following adverse experiences have been reported in 5% or less of patients:

Ocular: blurred vision, burning or stinging, conjunctivitis, dry eye, foreign body sensation, hyperemia, hypersensitivity, keratitis, lid edema, pain and ocular pruritus.

Non-ocular: asthenia, back pain, flu syndrome, headache, increased cough, infection, nausea, rhinitis, sinusitis and taste perversion.

Some of these events were similar to the underlying disease being studied.

USE IN SPECIFIC POPULATIONS

Pregnancy

Teratogenic effects: Pregnancy Category C

Olopatadine was found not to be teratogenic in rats and rabbits. However, rats treated at 600 mg/kg/day, or 150,000 times the maximum recommended ocular human dose (MROHD) and rabbits treated at 400 mg/kg/day, or approximately 100,000 times the MROHD, during organogenesis showed a decrease in live fetuses. In addition, rats treated with 600 mg/kg/day of olopatadine during organogenesis showed a

decrease in fetal weight. Further, rats treated with 600 mg/kg/day of olopatadine during late gestation through the lactation period showed a decrease in neonatal survival and body weight. There are, however, no adequate and well-controlled studies in pregnant women. Because animal studies are not always predictive of human responses, this drug should be used in pregnant women only if the potential benefit to the mother justifies the potential risk to the embryo or fetus.

Nursing Mothers

Olopatadine has been identified in the milk of nursing rats following oral administration. It is not known whether topical ocular administration could result in sufficient systemic absorption to produce detectable quantities in the human breast milk. Nevertheless, caution should be exercised when **PATADAY®** (olopatadine hydrochloride ophthalmic solution) 0.2% is administered to a nursing mother.

Pediatric Use

Safety and effectiveness in pediatric patients below the age of 2 years have not been established.

Geriatric Use

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

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Olopatadine administered orally was not carcinogenic in mice and rats in doses up to 500 mg/kg/day and 200 mg/kg/day, respectively.

Based on a 40 µL drop size and a 50 kg person, these doses were approximately 150,000 and 50,000 times higher than the MROHD.

No mutagenic potential was observed when olopatadine was tested in an *in vitro* bacterial reverse mutation (Ames) test, an *in vitro* mammalian chromosome aberration assay or an *in vivo* mouse micronucleus test. Olopatadine administered to male and female rats at oral doses of approximately 100,000 times MROHD level resulted in a slight decrease in the fertility index and reduced implantation rate; no effects on reproductive function were observed at doses of approximately 15,000 times the MROHD level.

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Reference: 1. IMS Health, IMS National Prescription Audit, August 2010 to October 2013, USC 61500 OPHTH ANTI-ALLERGY.

[‡]This information is an estimate derived from the use of information under license from the following IMS Health information service: National Prescription Audit for the period 2004-2013. IMS expressly reserves all rights, including rights of copying, distribution and republication.

Table 2. Four Factors for Risk Assessment

1. The nature and extent of the PHI involved, including the types of identifiers and the likelihood of re-identification;
2. The unauthorized person who used the PHI or to whom the disclosure was made;
3. Whether the PHI was actually acquired or viewed; and
4. The extent to which the risk to the PHI has been mitigated.

PHI = protected health information

Providers often engage a consulting firm to perform the initial risk assessment and assist with the implementation of security policies and procedures.

While an urgent care center may have existing policies in place, significant revisions to such policies will likely need to be made to reflect the changes to HIPAA under the Omnibus Final Rule that was published January 25, 2013. Urgent care centers should have made all revisions required by the Omnibus Final Rule's compliance deadline of September 23, 2013.

2. Appoint Privacy and Security Officers

An urgent care center is required to designate a privacy officer and a security officer (which is permitted to be the same individual), who will be tasked with overseeing the implementation of the center's privacy and security policies and procedures and various other obligations.

3. Training Employees

Once an urgent care center has developed a complete set of privacy and security policies and procedures, the next step toward HIPAA compliance is to train all employees and staff members on those policies and procedures. Simply maintaining a copy of privacy and security policies will not satisfy HHS in the event of an investigation. During investigations, HHS fre-



quently requests copies of training logs evidencing employee training on the provider's HIPAA policies and procedures. All new employees must be trained on those privacy and security policies that are relevant to the employees' job duties. In addition, existing employees must receive additional training on any changes made to the policies and procedures, such as those changes resulting from the Omnibus Final Rule, if the changes will affect the employee's job duties. Training sessions do not have to be extremely formal and can be as simple as providing training at an already scheduled staff meeting.

4. Enter Into Business Associate Agreements (Where Necessary)

HIPAA requires covered entities such as urgent care centers to enter into written, signed business associate agreements (BAAs) with all entities considered "business associates" under HIPAA. Although a covered entity is not required under HIPAA to ensure that its business associates are compliant with HIPAA and it is not directly liable for a business associate's violation of HIPAA if an appropriate BAA is in place, a covered entity should still be selective with its business relationships. An urgent care center should evaluate all of its business relationships to ensure that it has a BAA in place with any entity that creates, receives, maintains, or transmits PHI on behalf of the urgent care center. This definition of business associate was recently expanded by the Omnibus Final Rule and may require urgent care centers to enter into BAAs with entities that were not previously deemed business associates under HIPAA. Existing BAAs will need to be revised or replaced to reflect certain changes under the Omnibus Final Rule. Form BAAs are generally available, although urgent care centers should ensure that the form they are using is drafted so as to favor the covered entity (and in compliance with their policies and procedures).

5. Prepare Notice of Privacy Practices

Each urgent care center must maintain a current notice of privacy practices (NPP) that it provides to every patient prior to or on the patient's first date of service at the cen-

“An urgent care center should evaluate all of its business relationships to ensure that it has a BAA in place with any entity that creates, receives, maintains, or transmits PHI on behalf of the urgent care center.”

ter. Given the nature of the urgent care business model, most centers would expect to provide the NPP to a patient at the time that he or she presents to the center. A signed acknowledgement of every patient's receipt of the center's NPP should be maintained in each patient's medical record. The NPP must be on display in a prominent location within the urgent care center, such as on a wall near the front desk where patients check in. In addition, if an urgent care center maintains a website, the NPP will also need to be

prominently located on it. Like the center's policies and procedures, the NPP also should have been revised by September 23, 2013 to reflect the changes required under the Omnibus Final Rule.

6. Understand Breach Notification Requirements

Upon learning of an unauthorized use or disclosure of patient PHI, an urgent care center must determine if there has been a breach using the new 4-factor risk assessment provided under the Omnibus Final Rule, as shown in Table 1. The use or disclosure is presumed to be a breach unless the center's analysis of the four factors demonstrates there is a low probability that the PHI has been compromised.

In the event the urgent care center determines that there has been a breach of unsecured PHI, the center must comply with the following breach notification requirements of HIPAA:

- **Notice to individual:** All affected individuals must be notified by the urgent care center without unreasonable delay, but no later than 60 calendar days after the center's discovery of the breach.
- **Notice to media:** If a breach affects more than 500 residents of a state or smaller jurisdiction (such as a county, city, or town), the urgent care center must notify a prominent media outlet.
- **Notice to HHS:** If a breach affects 500 or more individuals (regardless of location), information must be submitted to HHS at the same time notices are given to individuals. If a breach affects fewer than 500 individuals, the urgent care center need only report such breaches to HHS annually, no

later than 60 days after the start of the calendar year following the year in which the breach occurred.

7. Maintain Documentation Requirements

Finally, it is important for an urgent care center to keep up with the documentation requirements under HIPAA. HIPAA requires documentation—including business associate agreements, employee training logs, logs of unauthorized disclosures of PHI, records of any sanctions taken against employees, and documentation related to the investigation and analysis of any breach—to be maintained by the center for at least 6 years from the date of the document's creation. It is this documentation that the center will need to be able to provide to HHS to demonstrate compliance in the event of an audit or investigation.

Conclusion

Although urgent care centers tend to be smaller entity

providers, they should not disregard the importance of a thorough HIPAA compliance plan, particularly in light of HHS's recent pattern of sanctioning entities of all sizes. HHS is expected to implement an audit program within the next year that will result in covered entities of all sizes being randomly selected for an extensive audit of compliance with HIPAA. The audit pilot program was completed in December of 2012 and resulted in the audit of 115 covered entities, the majority of which were health care providers including hospitals, physician practices, dental practices, laboratories, nursing facilities and pharmacies. No urgent care centers were selected as part of the pilot program, but as covered entities, they are subject to random selection for future audits which are expected to resume in the fall of 2014. The best offense is a good defense and centers should not wait for an audit or investigation to focus efforts toward HIPAA compliance. ■

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Scribes in the Urgent Care

■ JOHN SHUFELDT, MD, JD, MBA, FACEP

For years I was subjected to corporal punishment at the hands of nuns who used to beat me when they could not read my handwriting – at least that is how I remember it. For reasons unknown, my handwriting was never legible. Even back in the day, using the T-System’s “slash and check” charting, my medical records looked like I had either DTs or Benign Essential Tremor, or both.

One can then imagine how thrilled I was to move into the world of the electronic health record (EHR). I was an early adopter of electronic medical records and survived many of the various fits and starts of the industry. The early EHRs we used in the urgent care world and in the emergency department (ED) eventually became second nature and we subsequently became very efficient whilst using them.

The EHR we used in the ED up until last April was incredibly efficient and we could really fly through the various screens when using it to document the patient’s ED course. On May 1st last year, our ED throughput, documentation, and work-related sanity all went out the window when our hospital picked a new enterprise-EHR for the entire hospital system. I can describe it in one word — horrific. Actions that used to be “1-click” now took 3. Between every click a little second hand would go around a little clock until the next click. We all wanted to quit.

In truth, it could have been much worse save for one thing — Scribes. Per the Joint Commission, a medical scribe is an unlicensed individual hired to enter information into the EHR or chart at the direction of a physician or licensed independent practitioner.¹

We learned early on that the EHR the hospital picked was near the bottom for usability, particularly in the fast-paced setting of an ED. Like urgent care medicine, emergency medicine revolves around efficiency, appropriate documentation to protect you in case of an untoward event, and generation

“Scribes are generally college age, pre-health or premedical students who are interested in learning while working.”

of the E and M code consistent with the work performed.

We started investigating the various scribe companies about a year before implementation. In a nutshell, scribes are generally college age, pre-health or premedical students who are interested in learning while working. Most of the scribes we use had just graduated or are enrolled in a local university. To a person, they are hard-working, computer-savvy (as only young adults can be), pleasant, very enthusiastic, and willing to learn. They are all, in-effect, on job interviews inasmuch as most of them at some point want letters of recommendations and connections.

Prior to a scribe being hired, the scribe company performed a background search, a thorough interview that focused on interpersonal skills, and testing to determine computer skills and a medical terminology test. Once hired, the new scribes went through both in-classroom and on-the-job training while being paired with a more seasoned scribe.

When you think about it, the economic justification for a scribe is obvious. If a provider’s cost runs \$1 to \$2 per minute, why would you want the most expensive asset sitting behind a computer banging away when they could and should be interacting with patients, i.e. taking care of people and generating revenue?

My own personal experience is that I can see on average about .5 to 1 patient more per hour or 3 to 6 more relative value units (RVUs) per hour using a scribe than my colleagues who don’t. One study evaluated 13 emergency physicians over an 18-month period. RVUs per hour increased by 0.24 units, and the number of patients seen per hour increased by 0.08 for every 10% increment of scribe usage during a shift.² Even more important, my charts are more complete and are actually all completed at the end of my shift.



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In addition, the patients seem to feel more engaged because they hear a narrative about what I am thinking and the medical direction their care is most likely to take when I relate to the scribe. Although it has not been measured in our department, I suspect that our patient satisfaction scores have improved since the advent of scribes inasmuch as the providers focus more time on the patient and less time on the computer.

Here is how I use a scribe:

1. The scribe alerts me to a patient in the triage or exam room and signs me up for it.
2. On the way to the room, the scribe tells me the patient's last visit and diagnosis if applicable.
3. When I enter the room, I introduce myself and the scribe. If my scribe is a female and the exam requires a chaperone, the scribe functions as both.
4. I start asking the patient questions, starting with the chief complaint and then going through the rest of the history. Occasionally, once I get past the HPI, I go into the physical exam and leave the scribe behind to ask ROS, PMH, FH and Social History.
5. After the history is completed, I start my physical exam by organ system. Obviously, I avoid saying anything that I wouldn't want to eventually make their way into the chart; i.e. this foul-smelling, meth-addicted patient has again disproved Darwin by finding his way into our emergency department.
6. Next I discuss my game plan with the patient as the scribe enters it into the medical decision portion of the chart. "Although the only risk factor you have for a blood clot in your lungs is a family history of protein c deficiency, you did present with shortness of breath so I think it is important to make sure you don't have a blood clot in your lungs. With your permission, here is what I would like to do..." I have left rooms where the scribe has said, "You forgot to mention that you were going to do a XXX." I am always amazed at how much medicine they learn while working with a variety of providers.
7. As I am standing in the room, I enter the orders using check boxes on my tablet computer. I will often put in discharge instructions and prescriptions at the same time.
8. Once back in the office, I review what the scribe wrote, make any changes and continue to educate the scribe on alternative phraseology; i.e. always make sure the provider asks about worst headache of the patient's life if the patient presents with a headache, etc.
9. Between patients, the scribe lets me know when labs and images are completed. During procedures, the scribe writes down what I do and during critical care events, records times, interventions, and responses.

"My own personal experience is that I can see on average about .5 to 1 patient more per hour or 3 to 6 more relative value units (RVUs) per hour using a scribe than my colleagues who don't."

Cost

From my research, the average cost of a scribe is approximately \$19 to \$24 per hour using an outsourced scribe service. Thus, if your clinic's average net collection is \$100 per patient in a 12-hour shift and the clinic has a 20% margin, your providers will need to see about 1 patient more per hour to break even. What this does not account for is the reduction in overtime because the charting will be completed at time of service as opposed to after the clinic closes, the improvement in documentation and E and M coding, and the increase in patient satisfaction.

The downside

1. Cost: Before committing to a scribe service, the practice needs to calculate the ROI. If it is break even, the benefit still outweighs the benefit cost in my mind because the use of scribes should improve patient and provider satisfaction.
2. Medical-legal: The provider is still responsible for the medical records. Thus, if the scribe writes down something incorrect and the provider misses it and still signs the chart, the provider, not the scribe or scribe service, owns any attached liability.

Conclusion

Adding scribes in our department was one of the best decisions we have made. In fact, I may start using two at once to see if I can improve my productivity. Moreover, I really like the scribes. They remind me of how we all used to be when we were in college and medical school and still should aspire to be during our day-to-day profession – enthusiastic, energetic, and thoroughly committed to the practice of medicine. ■

1. The Joint Commission. Use of unlicensed persons acting as scribes. May 18, 2011. http://www.jointcommission.org/mobile/standards_information/jcfaqdetails.aspx?StandardsFAQId=345&StandardsFAQChapterId=66 Accessed April 3, 2014.
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Case Report

Acute Pericarditis

Urgent message: This case underscores the importance of not “anchoring” to a previous provider’s diagnosis and always remembering that medical conditions are dynamic.

JOHN J. KOEHLER, MD, and DANIEL MURAUSKI, DO

Introduction

Acute pericarditis is defined as inflammation of the pericardium that surrounds the heart and the base of the great vessels. The classical presentation consists of chest pain, a pericardial friction rub, and serial changes on electrocardiogram (EKG). Although data on the incidence of pericarditis are lacking, estimates indicate that it is the cause of at least 1% of emergency room (ER) visits among patients with ST-segment elevation and up to 5% of ER visits for nonischemic chest pain.^{1,2}

Case Presentation

A 57-year-old woman presented with persistent “chest congestion” starting 4 days prior. One day after onset of symptoms, she had seen her primary care physician, who diagnosed an upper respiratory tract infection (URI) and provided a “Z pack.” The patient reported no past medical or surgical history and takes no medications other than the recently prescribed antibiotic.

On further questioning, the woman reported experiencing sharp sub-sternal chest pain that radiated into her back. It was made worse with deep breathing and lying flat. She noted mild relief after taking acetaminophen, which she took 4 hours before presentation. On review of systems, the patient reported fever, chills, malaise, and a headache. She denied sore throat, nasal congestion, body aches, cough or ear pain.

.....
John J. Koehler is Chief Medical Officer at Physicians Immediate Care, Chicago, IL. **Daniel Murauski** is Site Director at Physicians Immediate Care, Chicago, IL.



Further evaluation of the patient revealed the following vital signs:

- T 99.2°F
- BP 90/60 mmHg
- P 106 bpm
- RR 16
- O₂ Sat 97%

She did not appear toxic and her exam was normal except for trace amounts of clear nasal discharge with some mild cobble stoning in her oral pharynx. A rapid flu test was negative.

The patient’s chest x-ray (Figure 1) showed an abnormal “globular”-appearing heart with a left-sided pleural effusion. Her EKG (Figure 2) demonstrated

Figure 1.

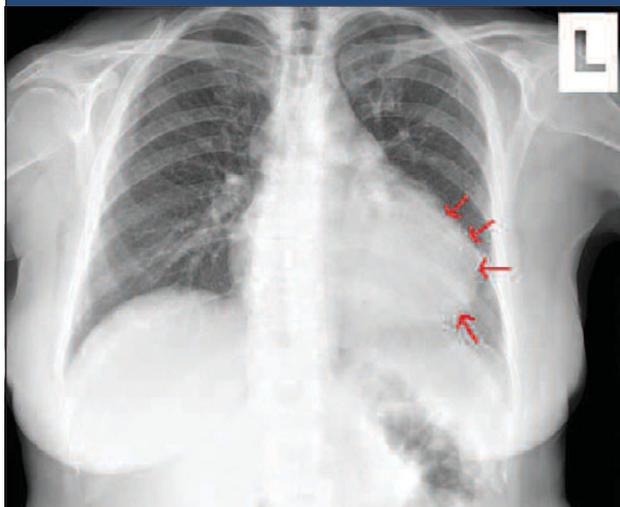


Table 1. Etiologies of Acute Pericarditis

- Inflammatory disorders: Rheumatoid arthritis, SLE, rheumatic fever
- Metabolic disturbances: Renal failure, hypothyroidism, hypercholesterolemia
- Cardiovascular disease: Acute MI, Dressler syndrome, aortic dissection
- Miscellaneous causes: Neoplasm, iatrogenic, trauma

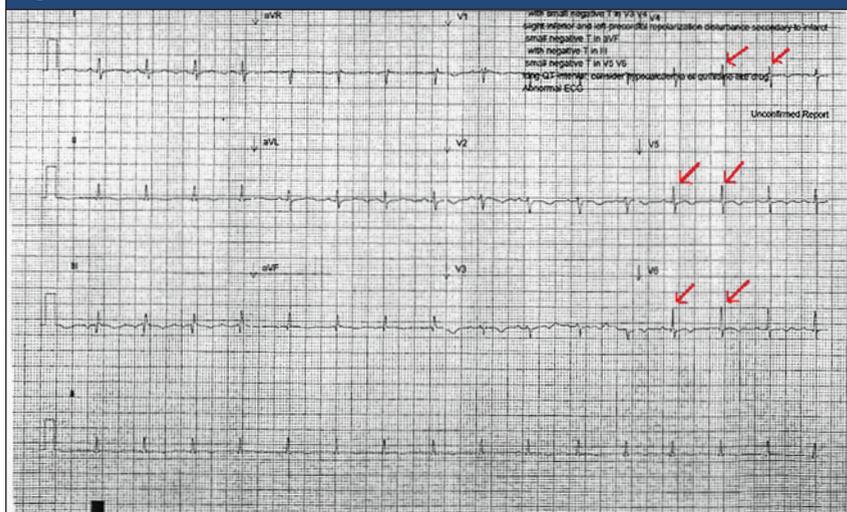
SLE – systemic lupus erythematosus

The classic history of acute pericarditis begins with prodromal symptoms of fever, myalgia, and malaise. It is followed by acute onset of pleuritic, substernal chest pain that may radiate to the scapular ridge, neck, arms or jaw. The pain is usually relieved by leaning forward and made worse with laying supine.³ Other associated symptoms include low-grade intermittent fever, dyspnea, tachypnea, cough and dysphagia.

A pericardial friction rub is the most specific physical exam finding in pericarditis (specificity approaching 100%), however, this exam finding is transient over time, has a low sensitivity, and may be present in only about 50% of cases.^{3, 4} The rub is best heard over the left sterna border, during expiration with the patient leaning forward. It is characterized by a grating or rasping sound similar to leather rubbing together.^{3,5}

A major life-threatening complication of acute pericarditis is cardiac tamponade. Pericardial effusion results from accumulation of fluid between the visceral and parietal layer of the pericardium. Tamponade occurs when the fluid pressure in the intrapericardial space alters cardiac filling. The classic signs as described by Beck’s Triad are hypotension, jugular venous distension, and muffled heart sounds. Another important physical exam finding is pulsus paradoxus, a drop of at least 10 mmHg in arterial blood pressure on inspiration.^{3,5} ECG changes include low-voltage QRS complexes in the limb leads, poor R wave progression, and electrical alternans (Figure 3). Cardiac tamponade is a medical emergency and patients should be transferred to an emergency care setting for further evaluation.

Figure 2.



poor R wave progression and T waves that had become diffusely flattened and inverted.

Disposition

Given the patient’s history and clinical findings, she was referred to the ER for suspected pericarditis with constrictive pericardial effusion. Surgical drainage of the effusion was successful without complication and she was discharged 5 days post admission.

Discussion

Although viral infection is the most common identifiable cause of acute pericarditis, there are multiple other etiologies, as listed in Table 1.^{3,4}

During acute pericarditis, ECG changes evolve through four stages as described in Table 2.^{3,5,6} The hallmark ECG findings of diffusely concave upward ST elevation (not seen in V1 and aVR) with upright T waves, and a PR interval that deviates opposite of the P wave polarity are found during Stage I (Figure 3).^{3,5} These acute findings were no longer apparent in our patient's ECG. Instead, the ST segments had normalized and the T waves had become mostly inverted. The EKG presented here is most consistent with Stage III ECG changes of pericarditis with an underlying pericardial effusion.

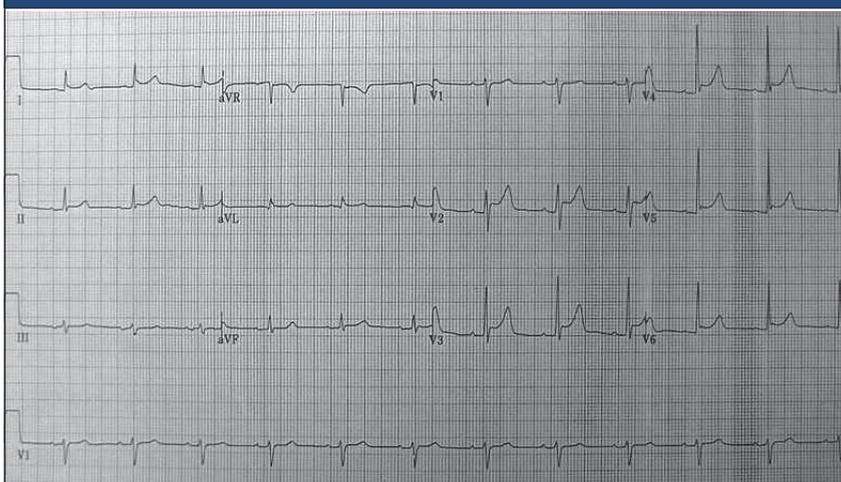
Chest x-ray is usually normal in patients with pericarditis and minimal effusion. However, when a large amount of effusion is present (200-250 mL), a chest x-ray will reveal a flask-shaped, enlarged cardiac silhouette, and a possible left-sided pleural effusion.⁶ The chest x-ray taken of our patient demonstrated an enlarged cardiac silhouette with a "globular" appearance, which is consistent with a significant pericardial effusion. In this case, an echocardiogram would be warranted to further evaluate the significance of the effusion and assess cardiac function.

Treatment for pericarditis is directed toward the underlying cause. For idiopathic and viral pericarditis, therapy should be directed toward symptom control. Non-steroidal anti-inflammatory drugs (NSAIDs) are the mainstay of therapy.²⁻⁵ Colchicine is a useful adjunct to NSAIDs and was once reserved for patient with recurrent or prolonged symptoms.⁵ Data from the Colchicine for Acute Pericarditis Trial has led to its routine use by many practitioners.⁵ Corticosteroids are not recommended for first-line treatment unless indicated for the underlying disease or because of lack of response to NSAIDs or colchicine.^{2,5} NSAIDs and steroids should not be used in pericarditis associated with acute myocardial infarction (MI). Pericardiocentesis is indicated when significant pericardial effusion is present, for both diagnostic and therapeutic purposes.

Conclusion

This case highlights several important issues for urgent care providers. First is the danger of "anchoring" to the diagnosis of a prior provider. All patients

Figure 3.



Source: Wikimedia Commons, courtesy of James Heilman, MD.

Table 2. Stages of ECG Changes During Acute Pericarditis

Stage I:

Hallmark signs. Occurs in early stages of disease. Includes diffuse concave upward ST elevation, elevation not seen in leads aVR and V1, T waves are upright in the leads with ST segment elevation, and PR segment deviates opposite of P wave polarity.

Stage II:

Occurs several days after onset of symptoms. ST segment return to baseline. and T waves flatten.

Stage III:

T waves become inverted. No Q waves should be seen.

Stage IV:

Weeks to months. EKG normalizes or if chronic pericarditis develops, T wave inversions may remain indefinitely.

Sources: Brady WJ et al¹, Tingle TE, et al⁴, and Marinella MA⁷

presenting to urgent care deserve a full investigation of their chief complaint with an open mind as to the cause. The clinical presentation of the patient in this case warranted further investigation to rule out other significant disease processes, such as MI and pulmonary embolism.

The second important issue is that medical conditions are dynamic and evolve. While it may be tempting to criticize the first provider for having "missed"

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CASE REPORT: ACUTE PERICARDITIS

*“Treatment for pericarditis
is directed toward the
underlying cause.*

*For idiopathic and viral
pericarditis, therapy
should be directed toward
symptom control.*

*Nonsteroidal
anti-inflammatory drugs
(NSAIDs) are the mainstay
of therapy.”*

the diagnosis, we do not know if the key features of sharp positional chest pain, tachycardia, and subtle hypotension were present 4 days prior. A third key issue is to make sure the clinical presentation is consistent with the patient's diagnosis. Several features make this case inconsistent with the original diagnosis of URI. The presence of positional pleuritic chest pain and subtle vital sign abnormalities and the absence of URI symptoms warranted the chest x-ray and EKG, which made the diagnosis obvious. ■

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ABSTRACTS IN URGENT CARE

- Aging and risk of heart disease
- Otorrhea from tympanostomy tubes
- Atopic dermatitis guidelines
- Antibiotics for pediatric pneumonia
- Bleach solution for staph
- Stethoscopes and infection control

■ 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.

Signs of aging and risk of heart disease

Key point: Some outward signs of aging may correlate with increased risk of heart disease including MI.

Citation: Christoffersen M, Frikke-Schmidt R, Schnohr P, et al. Visible age-related signs and risk of ischemic heart disease in the general population: A prospective cohort study. *Circulation*. 2014;41128(9):990-998.

Investigators in Denmark in this 35-year prospective trial attempted to see if outward signs of aging (frontoparietal baldness, crown top baldness, earlobe crease, xanthelasmata, grey hair and wrinkles) were able to predict ischemic heart disease (IHD) independent of age and risk factors. The investigators followed 10,855 patients aged 20 to 80 from 1976-78 to 2011. Patients received a questionnaire, exam, and blood tests and were followed for IHD, myocardial infarction (MI), and death. Risk factors including age, cholesterol and triglyceride levels, body mass index, hypertension, diabetes, and smoking were among the factors that were eliminated statistically.

The authors concluded that signs of aging including male pattern baldness, earlobe crease, and xanthelasmata increase the risk of IHD, MI, and death. The more signs of aging present the greater the risk of IHD. From an urgent care perspective, none of these factors are likely to change treatment, but they may be another piece of the puzzle. Also, the population studied in this article was exclusively Western European, so the results may not apply to all patients. ■



Sean McNeeley is an urgent care practitioner and Network Medical Director at University Hospitals of Cleveland, home of the first fellowship in urgent care medicine. Dr. McNeeley is a founding board member of UCCOP and vice chair of the Board of Certification of Urgent Care Medicine. He also sits on the JUCM editorial board.

Treating otorrhea from tympanostomy tubes

Key point: A combination of antibiotics and steroids proved best at clearing otitis media in patients with tympanostomy tubes.

Citation: van Dongen TM, van der Heijden GJ, Venekamp RP, et al. A trial of treatment for acute otorrhea in children with tympanostomy tubes. *N Engl J Med*. 2014;370(8):723-733.

Investigators in this small study attempted to find the best method to treat patients with otorrhea from tympanostomy tubes. A total of 230 children aged 1 to 10 years were treated with either hydrocortisone–bacitracin–colistin eardrops, amoxicillin–clavulanate suspension or observation. End points included presence of otorrhea at 2 weeks as well as duration of symptoms, recurrence over 6 months, quality of life, and complications. Ear drops performed best at 2 weeks with 5% still present at 2 weeks, compared with 44% for oral antibiotics and 55% for observation. Other end points were similar except duration, which was 12 days for observation and 4 and 5 days for topical and oral treatments, respectively. The authors concluded that drops were most effective. It should be noted the drops used are not FDA-approved for this purpose. A combination of ciprofloxacin and dexamethasone is available. ■

New guidelines for atopic dermatitis

Key point: Atopic dermatitis is a clinical diagnosis based on history, location, and morphology.

Citation: Eichenfield LF, Tom WL, Chamlin SL, et al. Guidelines of care for the management of atopic dermatitis: section 1. Diagnosis and assessment of atopic dermatitis. *J Am Acad Dermatol*. 2014;70(2):338-351.

The American Academy of Dermatology has released new

guidelines for the diagnosis of atopic dermatitis (AD). This disease afflicts 25% of children and 2% to 3% of adults. The current article discusses diagnosis and assessment of the disease process. This guideline replaces the previous guideline from 2004. The Strength of Recommendation

Taxonomy (SORT) was used to classify evidence in this article. The authors discuss several diagnostic criteria, which they found to be difficult to use clinically. They do create a modified criteria but it has yet to be studied prospectively. Their SORT level for the criteria is C, III. Currently available tests such as IgE and eosinophil counts are not sufficiently sensitive or specific for disease diagnosis. (SORT B,II) From an urgent care perspective, this is all that will likely apply from section 1. However, it should give acute care providers more comfort to diagnose AD without specific labs. ■

Duration of antibiotics for pediatric pneumonia

Key point: Five days of antibiotics for pediatric pneumonia may be as effective as 10 days.

Citation: Greenberg D, Givon-Lavi N, Sadaka Y, et al. Short-course antibiotic treatment for community-acquired alveolar pneumonia in ambulatory children: A double-blind, randomized, placebo-controlled trial. *Pediatr Infect Dis J*. 2014;33(2):136-142.

Most providers will treat community-acquired pneumonia with 10 days of antibiotics. Anyone who has tried to give a child an antibiotic knows that the shorter the course the better the compliance. Investigators in Israel attempted to see if a 3- or 5-day course of antibiotics was equivalent to a 10-day course.

This study was a randomized double-blind placebo-controlled trial with two arms (3 day vs. 10 day and 5 days vs. 10 days). The study included children under 5 in an area mostly served by one hospital. Investigators used amoxicillin 80 mg/kg divided into 3 doses. Of interest the pneumonia vaccine was not available in this area. Pneumonia was defined by presence on a chest x-ray, fever, and elevated white blood cell (WBC) count. The primary outcome was absence of treatment failure in 30 days. Secondary outcomes included temperature, difficulty breathing, restlessness, coughing, loss of appetite, and sleep disturbances assessed daily by the parents and laboratory tests including complete WBC counts and c-reactive protein at days 5 to 7 and 10 to 14. The 3-day arm was stopped due to failures, which also led to the second (5-day) arm. A total of 140 children were enrolled, although in a complicated manner because of the treatment failures in the first arm of the study. The only treatment failures were in the 3-day arm. This study is a good start in comparing treatment duration, but the sample size is likely too small to justify changes in current treatment. It is hoped that a larger study will be able to replicate these results. ■

Bleach solution for staph

Key point: Dilute bleach solution bath may reduce recurrence of staph infections but the difference may not be clinically significant in children.

Citation: Kaplan SL, Forbes A, Hammerman WA, et al. Randomized trial of "bleach baths" plus routine hygienic measures vs routine hygienic measures alone for prevention of recurrent infections. *Clin Infect Dis*. 2014;58(5):679-682.

Most acute care providers have seen patients frustrated with recurrence of soft tissue infections. The investigators in this article attempted to see if dilute bleach baths would work for this problem. In this randomized single-blind, controlled trial, the authors attempted to compare routine hygiene and "bleach baths" for 3 months in 987 children between 3 months and 18 years with a previously suspected community-acquired methicillin-resistant *Staphylococcus aureus* (ca-mrsa) infection. Patients were followed for a year for recurrence that needed medical care. No statistical difference was noted between the groups (bleach 17%, just hygiene 20.9%). The authors concluded that their study was limited in power due to its small size. From an acute care perspective, the small and statistically insignificant difference may not be worth the risk of error with use of bleach baths. ■

Stethoscopes and infection control

Key point: Consider cleaning your stethoscope between patients to avoid transferring infection.

Citation: Longtin Y, Schneider A, Tschopp C, et al. Contamination of stethoscopes and physicians' hands after a physical examination. *Mayo Clin Proc*. 2014;89(3):291-299.

Swiss investigators attempted to compare the total level of bacteria and the level of Methicillin-Resistant *Staphylococcus Aureus* (MRSA) on physician's dominant hands and stethoscopes after a standard physical exam of 81 patients at a teaching hospital. Fingertips, thenar eminence, hypothenar eminence, hand dorsum, stethoscope diaphragm and tube were the sites sampled. When considering total bacteria, the physician's fingertips were by far the most contaminated, followed by the stethoscope bell. Evaluating for MRSA, the stethoscope bell was similar to a physician's fingertips. Although this is a small study in a limited environment, it should provoke some thought about cleaning the stethoscope bell between patients. ■

CORRECTION

One of the abstracts in the Abstracts in Urgent Care department in the April issue contained two errors. The headline and key point for the otitis study on page 33 should have mentioned otitis externa, not otitis media. We regret the errors.



INSIGHTS IN IMAGES
CLINICAL CHALLENGE

In each issue, *JUCM* will challenge your diagnostic acumen with a glimpse of x-rays, electrocardiograms, and photographs of dermatologic 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 patient presented with an ankle injury.

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 2A

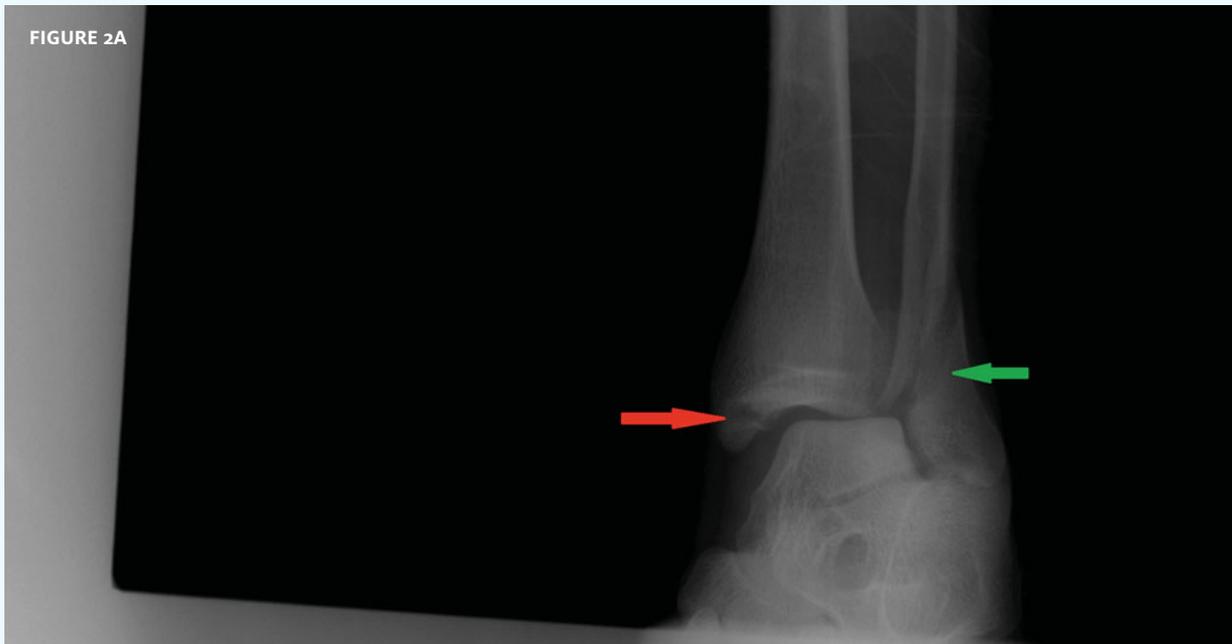


FIGURE 2B



Diagnosis: The x-ray reveals a trimalleolar fracture of the ankle (arrows).

A trimalleolar fracture of the ankle involves the lateral malleolus (green arrow), medial malleolus (red arrow) and the distal posterior aspect of the tibia (black arrow). Ligament damage and dislocation are common. This is an unstable fracture and requires emergent orthopaedic consultation and adequate immobilization and analgesia in the urgent care center.

Acknowledgement: Case presented by Teleradiology Specialists (<http://www.teleradiologyspecialists.com>)



DME, Benign Lesion Excision, Urgent Care Codes

■ DAVID STERN, MD, CPC

Q. We currently provide DME to our patients as a courtesy to them and then bill their insurance. We generally get paid by most private insurances, but not by Medicare. Our billing department claims Medicare will never pay for any DME we provide because we are not a DME provider licensed with Medicare. If our billing department is correct, would it be compliant to give DME prescriptions to all patients 65 and over?

A. I am not aware that writing a script would be non-compliant. Your policy is consistent in that you bill any payor that will pay for it.

Another option would be to have the patient sign an Advanced Beneficiary Notice (ABN) for the specific DME that is prescribed. Then you could sell the DME to the patient. The ABN would clearly state that the patient understands that Medicare does not cover the item under your arrangement with Medicare, but that it may be covered if the patient visited a store that is registered with CMS to sell DME.

This information is for educational purposes only. You are encouraged to seek legal counsel before making any decision on this issue. ■

Q. The physician removed a benign lesion from the patient's back and the cutaneous layer was closed with 3 interrupted 4-0 nylon sutures. The lesion before excision was 1.5 cm at its widest and the physician allowed margins of 1.5 cm on both sides. I billed CPT codes 11402 and 12001. Insurance only paid for the excision and not the closure. When can you bill separately for closure when excising a benign lesion?



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.

A. Excision is defined as full-thickness (through the dermis) removal of a benign lesion of skin, including margins, and includes simple (non-layered) closure when performed. Therefore, you can only bill for the closure if intermediate or complex repair is required. The excision codes are grouped by anatomy and then by size. Codes 11400-11406 are used for the excision of benign lesions of the trunk, arms, or legs. Codes 11420-11426 are used for the excision of benign lesions of the scalp, neck, hands, feet, and genitalia, whereas codes 11440-11446 are used for excision of benign lesions of the face, ears, eyelids, nose, lips, and mucous membrane.

Keep in mind that payors who follow the national correct Coding Initiative (CCI) edits may bundle intermediate and complex repairs into the excision of benign lesions of 0.5 cm or less (11400, 11420, and 11440). You can check the edits at <https://www.cms.gov/Medicare/Coding/NationalCorrectCodingInitEd/NCCI-Coding-Edits.html>.

You also need to keep in mind that when measuring lesions, you should include the margins in your calculation. In the case you presented, to get the excised diameter, you add the lesion plus the margins, which comes to 4.5 cm and changes the code to 11406.

Codes for Benign Lesion Excision of the trunk, arms, and legs are:

- 11400 – excised diameter 0.5 cm or less
- 11401 – excised diameter 0.6 to 1.0 cm
- 11402 – excised diameter 1.1 to 2.0 cm
- 11403 – excised diameter 2.1 to 3.0 cm
- 11404 – excised diameter 3.1 to 4.0 cm
- 11406 – excised diameter over 4.0 cm

Codes for Benign Lesion Excision of the scalp, neck, hands, feet, and genitalia are:

- 11420 – excised diameter 0.5 cm or less
- 11421 – excised diameter 0.6 to 1.0 cm
- 11422 – excised diameter 1.1 to 2.0 cm
- 11423 – excised diameter 2.1 to 3.0 cm
- 11424 – excised diameter 3.1 to 4.0 cm
- 11426 – excised diameter over 4.0 cm

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CODING Q & A

Codes for Benign Lesion Excision of the face, ears, eyelids, nose, lips, and mucous membrane are:

- 11440 – excised diameter 0.5 cm or less
- 11441 – excised diameter 0.6 to 1.0 cm
- 11442 – excised diameter 1.1 to 2.0 cm
- 11443 – excised diameter 2.1 to 3.0 cm
- 11444 – excised diameter 3.1 to 4.0 cm
- 11446 – excised diameter over 4.0 cm ■

Q. Are the codes 99050 and 99051 urgent care codes per se? If you bill these should you be using Place of Service (POS) 20?

A. These codes are not limited to use in urgent care settings and therefore are not restricted to POS (Place of Service) 20. Code 99050, “Services provided in the office at times other than regularly scheduled office hours, or days when the office is normally closed (e.g., holidays, Saturday, or Sunday), in addition to basic service” can be billed in addition to other services, including an E/M code, for a patient seen outside of regular office hours. Reporting code 99050 requires that your office have posted hours that clearly designate times when the office is open versus closed. For example, your posted office hours are 9:00 a.m. to 4:00 p.m. A patient calls and needs to be seen that day but cannot make it into the office until 6:00 p.m. The provider either stays in the office or leaves and comes back to see the patient. You would be justified in billing code 99050 along with an E/M code because the patient was seen after posted regular business hours. On the other hand, code 99050 does not apply if a patient is seen after normal office hours when the patient arrived during normal hours but was not seen by the provider until after the office’s normal closing time.

Code 99051, “Service(s) provided in the office during regularly scheduled evening, weekend, or holiday office hours, in addition to basic service” can be billed when the physician sees the patient in the office and provides the necessary services or care during regularly scheduled weekend, evening, or holiday hours. Again, the posted hours should clearly designate times when the office is open versus closed. Evening hours are typically considered to begin after 5:00 p.m. For example, your posted hours are 9:00 a.m. to 9:00 p.m. You can bill code 99051 with the appropriate E/M code for all patients that are seen from 5:00 p.m. to 9:00 p.m. If your posted hours include weekends, you can bill code 99051 for all patients seen on the weekend no matter what time they are seen.

Check each payor’s guidelines regarding both codes. Medicare will not reimburse for either code so it is inappropriate to bill a Medicare patient for these codes. ■

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PHS is seeking BE/BC Family Practice/ED Physicians to work in our Urgent Care Centers. There are seven Urgent Care Centers in the Albuquerque area. We currently employ over 13 MDs and over 20 midlevel providers in urgent care. Competitive pay, benefits and performance incentives.

Presbyterian Healthcare Services (PHS) is New Mexico's largest, private, non-profit health care system and named one of the "Top Ten Healthcare Systems in America". Over 600 providers are employed by PHS and represent almost every specialty. Become part of a dynamic and growing Urgent Care services group with Presbyterian Health Care. Urgent Care is part of a new and exciting Convenience Care Services with PHS, focusing on services patients are looking for, fast, friendly and high quality urgent care.

For more information contact: Laura Naaz, Physician Recruiter
 PO Box 26666, Albuquerque, NM 87125
 lnaaz@phs.org
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 Visit our website at www.phs.org or
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Urgent Care Physicians

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MedStar Health is a \$4.4 billion, not-for-profit, regional healthcare system with a network of 10 hospitals and 20 other health-related businesses across Maryland and the Washington, DC region.

MedStar is opening several new Urgent Care Centers in the Maryland and Virginia areas, and we are currently recruiting for Urgent Care Physicians for these offices. We will be opening our Belcamp, MD site in April 2014; our Federal Hill, MD site in July of 2014; and Alexandria, VA site in late summer.

The Urgent Care Centers are open from 8-8 Monday-Friday and 8-4 on Saturdays and Sundays. Our facility will be staffed with both full and part-time physicians.

MedStar Urgent Care offers a competitive salary and benefit package that includes paid malpractice insurance; 4 weeks vacation; a paid week of CME and CME allowance; sick leave, holidays and personal days; retirement plan 401 K with % match from employer; medical, dental and vision insurance and much more.

As part of the MedStar System, we strive to offer our patients personalized care in our community-based physician offices, as well as access to the latest medical advances and treatments available throughout our system.

Please contact me today for additional information:
 Ellen Gilliland, MedStar Medical Group
 ellen.s.gilliland@medstar.net, (443) 725-8709
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- Team-Oriented Workplace
- Career Advancement Opportunities

To discuss available positions please contact Eleanor Dowdy, eleanor.dowdy@patientfirst.com or (804) 822-4478. We will arrange the opportunity for you to spend time with one of our physicians to experience firsthand how Patient First offers each physician an exceptional career.





Advocate Medical Group Immediate Care in Bloomington, Illinois

THE PRACTICE:

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- Weekends and evenings shared among providers
- Lots of variety including procedures, school and sports physicals, fractures, sutures
- Experienced Nursing Staff
- Great location and beautiful facility
- Onsite X-ray and Lab
- Opportunity for growth!

THE LOCATION:

- Located in Bloomington/Normal, Illinois (pop 130,000)
- Two hours from Chicago, three hours from Indy and St. Louis
- 20,000 students attending Illinois Wesleyan and Illinois State Universities.
- Businesses such as State Farm Insurance & COUNTRY Life contribute to the thriving economy.
- You will find our community friendly, safe and clean. It is a great place to call home!

THE ORGANIZATION:

Advocate Medical Group, a physician-led, physician-governed multi-specialty group, is part of Advocate Health Care, the largest health system in Illinois and one of the largest health care providers in the Midwest.

THE SALARY AND BENEFITS:

- Competitive salary with eligibility for bonus incentive
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EDUCATION:

- MD/DO

CONTACT:

Cathy Nottoli
Ph: 309-268-2915 • Fax: 309-454-1016 • Email: cathy.nottoli@advocatehealthcare.com



Salem Clinic, P.C., 59+ physician multi-specialty group located in Salem, Oregon, has an opening for a full-time BC/BE Family Medicine Physician, Physician Assistant or Advanced Practitioner for our Urgent Care Center. Salem Clinic offers a comprehensive benefit package and competitive income guarantee. To learn more about our Clinic, please visit our website at: salemclinic.org or call Lindsay Course at 503-399-2470. You may also mail, email or fax your CV to: LindsayCourse,SalemClinic,P.C.2020CapitolSt.N.E., Salem, OR 97301, E-mail: lindsaycourse@salemclinic.org, Fax: 503-375-7429. We look forward to hearing from you soon!

Dunkirk and Solomons, Maryland

Seeking part-time BC/BE EM, IM, and FP physicians to practice urgent care medicine at Dunkirk and Solomons Urgent Care Centers in Calvert County, Maryland. Enjoy a collegial relationship with nurses, mid-level providers, and urgent care support staff, excellent work environment, a flexible schedule, and competitive compensation.

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If you are interested in Milford Hospital, please contact:

Laurie Gentile, Physician Recruiter
Call 888-766-521 or Text 215 817-4362
Laurie_Gentile@emcare.com

If you are interested in Milford Walk In & Urgent Care Center, please contact:

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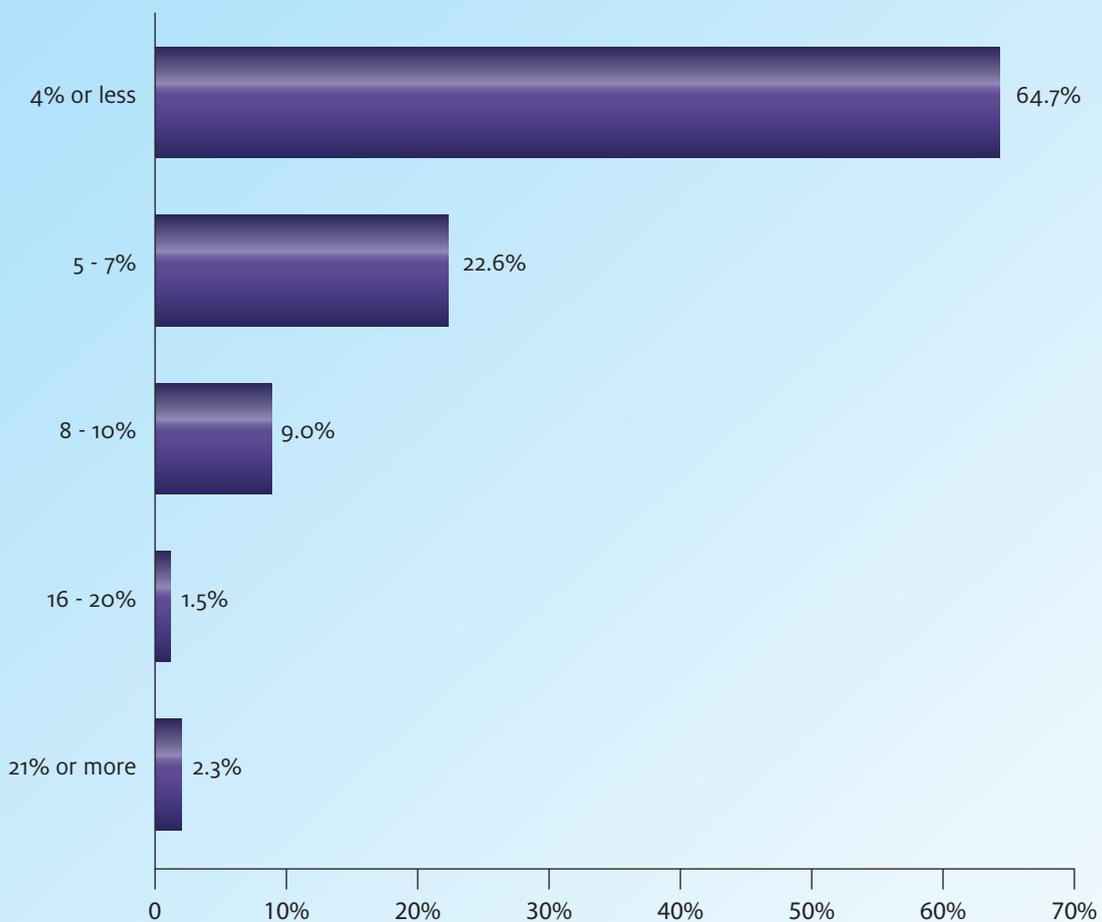


DEVELOPING DATA

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 Percentage of Patients Do Urgent Care Centers Transfer or Direct to an Emergency Room?

PERCENTAGE OF PATIENTS TRANSFERRED OR DIRECTED TO ER



An average of 3.98% of patients are either directed or transferred from an urgent care center to an emergency room, indicating that the vast majority of patients are making the appropriate choice for site of care when they visit an urgent care (n=133). Notes: Respondents include hospital-owned urgent care centers that may be near or on the same campus as the emergency room, possibly increasing the number of transfers. There were no respondents in the 11-15% range.

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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John Sanabria, MD,* thrives on his work. Owner and operator of an urgent care, a hospital chief of staff, and medical director for a Department of Defense contractor, Dr. Sanabria goes where the job takes him – even when that means military bases in Iraq.

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* Dr. Sanabria (far left) traveled to Iraq twice in 2011, leading a medical team that provided government compliant physicals to contractors deployed at forward operating bases. Dr. Sanabria's team helped save thousands of dollars in just one trip, performing 140 onsite physicals in 10 days.