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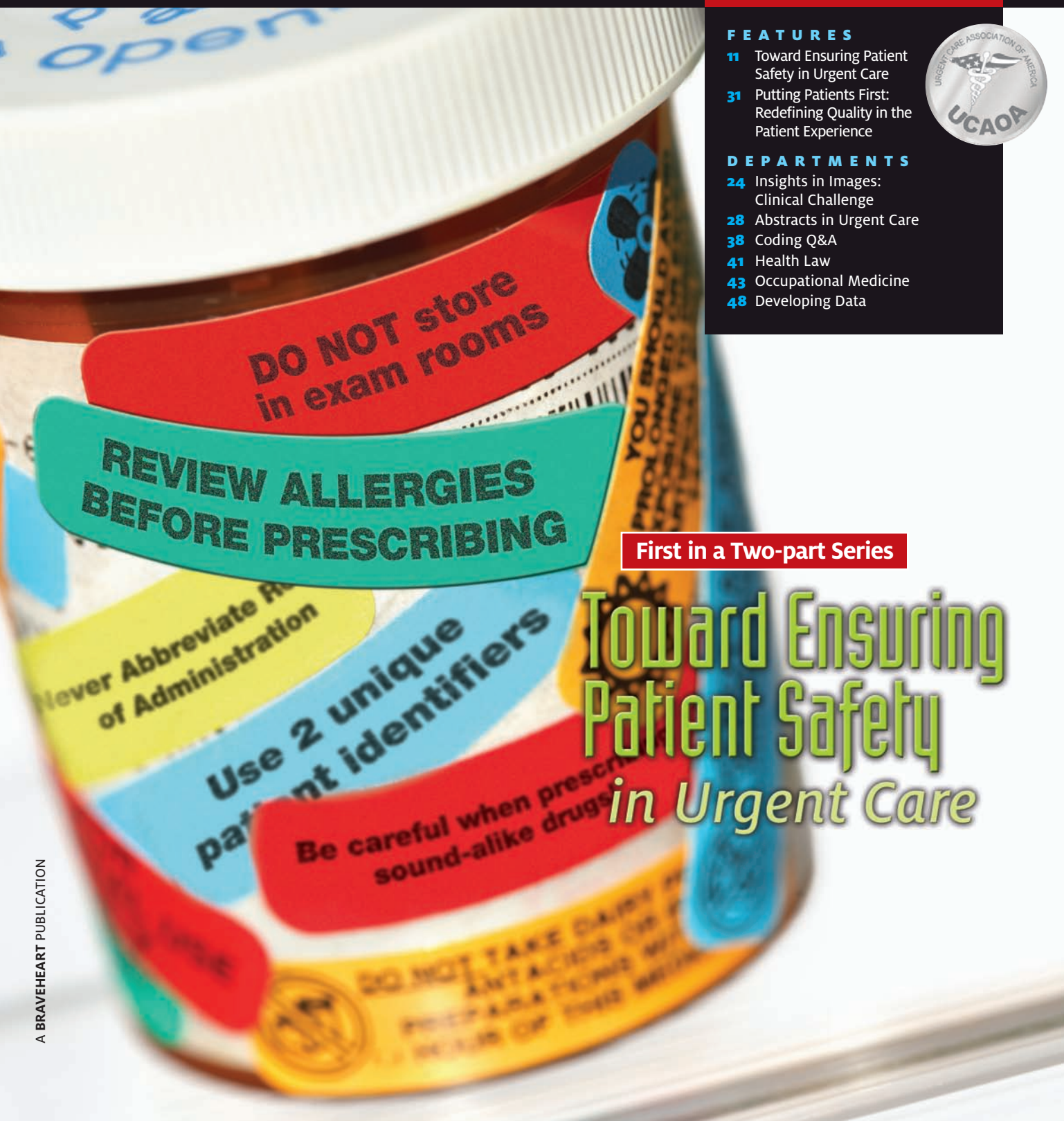
IN THIS ISSUE



First in a Two-part Series

Toward Ensuring Patient Safety in Urgent Care

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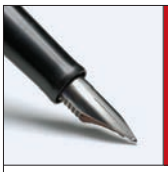


LETTER FROM THE EDITOR-IN-CHIEF

The Art of Conflict Management

Urgent cares centers are fertile ground for angry patients. Our patients are often sick and in pain, they often have long waits to be seen, and they are frustrated by an inefficient healthcare system that has landed them in urgent care in the first place.

Additionally, most of our patients are starting a new relationship with us, and they have not yet built any trust. Their prior healthcare experiences are most often lousy at best, and replete with hurdles and aggravation. They are used to being given the run-around, so they're coming in with "dukes up," ready to fight. Couple a battle-ready patient with a poorly prepared urgent care staff, and you have all the ingredients for a real scene.

The key to avoiding a full scale war in any conflict is "de-escalation." De-escalation skills are mature coping skills that most of us have never learned. The majority of us learned our coping skills on the playground at school: "I'm rubber and you're glue! Everything you say bounces off me and sticks to you!" When someone came after you with fists clenched, you got ready to punch back.

We have translated these playground lessons into our everyday lives as adults. I can freely admit to being ready for a fight every time I walk into the Department of Motor Vehicles. Unfortunately, many of our patients have the same feeling about healthcare institutions, so when they walk through our doors, they are preparing for a battle.

Understanding the root causes of hostility is the first step toward a path of de-escalation. Let's review a few others here:

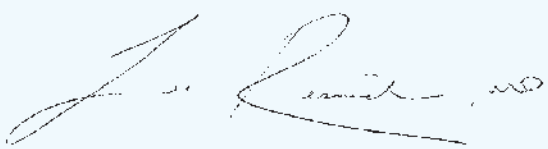
- Fear. You may not think you instill fear in your patients, but most people are, in fact, afraid of seeing doctors. In addition, they are often afraid that their condition may be something very dangerous. It may seem obvious to the practitioner that a patient's chest pain is simply reflux disease, but you can be assured that patient thinks he is having a heart attack and is scared to death about it.
- Pain. Nothing makes for better "anger food" than pain.
- Recall. A patient is coming to your office with a life's worth of bad experiences in healthcare.
- Confusion. The healthcare-and-insurance maze is one of the most challenging bureaucracies one will ever have to navigate. I have yet to see an insurance bill I understand, and I'm still trying to figure out what all my deductibles, copays and co-insurances mean. I have to laugh when I hear office staff say, "Well, it's your responsibility to understand your benefits."

Now that we know the fuel for the hostility fire, let's discuss tips on how to extinguish:

- Let them "blow off steam." During the peak of an anger reaction, there is no way you are going to be able to reason with them, so don't try. Resist the urge to react to everything they are saying. Just stop and listen. Remember, their anger is not directed at you, so don't take it personally.
- Eventually, the anger runs out of "steam" if it is not provoked.
- Once they slow down, you have an opportunity to get the train back on the tracks. This is where you say something supportive like, "I know how frustrating this must be for you." This does not mean you agree, but it shows understanding and validates. Nothing works better than validation to diffuse a situation and build trust.
- Once they have calmed down, you have the opportunity to problem solve, which is what everyone really wanted in the first place. If at any point you begin arguing with a patient, the whole process derails and escalation resumes.

Finally, if you feel unable to control a situation, get help from a colleague. Sometimes, a new face and a new pair of ears can be the difference maker. Again, don't take it personally.

In future columns, I will discuss other tips that help you provide exceptional customer service, even in the most difficult of circumstances. ■



Lee A. Resnick, MD
Editor-in-Chief
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Adapted from the "Hostility Curve" as presented by the American Hospital Association. *Teaching Patient Relations in Hospitals: The How's and Whyss, 1983.*

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May 2009

VOLUME 3, NUMBER 8

CLINICAL

11 Toward Ensuring Patient Safety in Urgent Care

Risks inherent to the practice of urgent care medicine can be mitigated by building a safety culture that embraces proper medication and lab practices. The first of two parts.

By Phillip Disraeli, MD, FAAFP

PRACTICE MANAGEMENT

31 Putting Patients First: Redefining Quality in the Patient Experience

Patients and clinicians gauge "quality" in different terms. While good care is essential to both, patients also look at themselves as customers and expect to be treated as such. Ignore their perspective at the peril of your business.

By Alan A. Ayers, MBA, MAcc

***In the next issue of* JUCM:** *Further discussion of how to foster a culture of safety, including prevention of healthcare-associated infection, proper radiation procedures, and transitioning care from one provider to another. Also, a new installment of Bouncebacks considers the case of a patient with GI symptoms—from that patient's perspective.*

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Mission Statement
JUCM *The Journal of Urgent Care Medicine* supports the evolution of urgent care medicine by creating content that addresses both the clinical practice of urgent care medicine and the practice management challenges of keeping pace with an ever-changing healthcare marketplace. As the Official Publication of the Urgent Care Association of America, *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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Preventable errors can be catastrophic for patients and have the potential to end a practitioner's career or put an urgent care center out of business. The good news is that you can be proactive and establish safeguards against patients walking out your door with a prescription for the wrong medication (or the wrong dosing regimen for the right medication, for that matter), or lab results that reflect another patient's visit.

In Toward Ensuring Patient Safety in Urgent Care (page 11), **Phillip H. Disraeli, MD, FAAFP** reviews strategies for establishing a culture of safety in your urgent care center. Part 1 of this two-part series focuses on good practices for patient identification, medication safety, and proper procedures for lab and x-ray results.

Dr. Disraeli is a partner in Metro Urgent Care in Frisco, TX, and director of clinical programs for the Urgent Care Association of America. This is the second article he has contributed to *JUCM*, the first being Managing Foot Fractures in Urgent Care (available in the Past Issues Archives at *www.jucm.com*).

Patient safety and good medical care may be the hallmarks of a "quality" experience from the clinician's perspective (and rightly so), but it is also important to recognize that patient expectations may go beyond those factors. As **Alan Ayers, MBA, MAcc** explains in Putting Patients First: Redefining Quality in the Patient Experience (page 31), patients tend to judge a visit to your urgent care center, at least partially, in the context of the level of service provided, as they might after going to a restaurant.

Mr. Ayers is assistant vice president of product development for Concentra Urgent Care.

Also in this issue:

Nahum Kovalski, BSc, MDCM reviews abstracts on the risk of occult bacteremia in children, the burden of respiratory syncytial virus in younger patients, and how age relates to the likelihood of an orthopedic injury having been caused by child abuse.

Frank Leone, MBA, MPH explains the difference between an "attribute" and a "competitive strength" in the urgent care occupational medicine marketplace and offers a formula for evaluating the strengths of your program.

John Shufeldt, MD, JD, MBA, FACEP draws parallels between safely piloting an airplane and navigating your business through economic turbulence.

David Stern, MD, CPC responds to questions about observation status codes and continues his discussion of established vs. new patients.

We would like to expand our roster of readers who contribute to *JUCM*. If you have an idea for an article on a clinical topic, a case study to share, or have found new ways to bring revenue into your urgent care center, let us know by sending an e-mail to Editor-in-Chief **Lee A. Resnick, MD**, at *editor@jucm.com*. ■

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.

We prefer submissions by e-mail, sent as Word file attachments (with tables created in Word, in multicolumn format) to *editor@jucm.com*. The first page should include the title of the article, author names in the order they are to appear, and the name, address, and contact information (mailing address, phone, fax, e-mail) for each author.

Before submitting, we recommend reading "Instructions for Authors," available at *www.jucm.com*.

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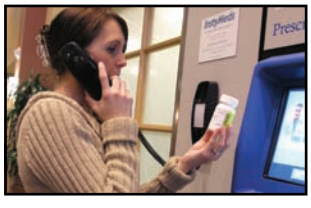

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Tweet

LOU ELLEN HORWITZ, MA

I don't have a Blackberry. I do have a cell phone; it makes calls, and can take pictures, and send text messages, but by the time I've gotten to about the third word I just get frustrated and call.

I am not a technophobe, I actually love technology—I just don't necessarily want it following me wherever I go. Which makes you wonder why I have opened a Twitter account for UCAOA.

I got dragged—kicking and screaming—into the "social networking" world about a year ago and have ended up having a marvelous time. So, when someone suggested we get a Twitter site, though it felt like one more step toward becoming a technology fashion victim, I had to look into it.

One of the biggest difficulties we have had at UCAOA is finding ways to get timely information to you in a nonintrusive, yet easy to access, but not overwhelming way. Currently, we have just a few good ways of doing that:

1. The monthly e-mail newsletter (but it only comes out once a month and we don't want to further clutter your already-full Inbox).
2. The website. We change the front page once a week at least (but you have to go there on your own to see "What's New" and we know you don't always think to do that).
3. This column (but it is written weeks in advance of your reading it, so while it's great for many things, it doesn't work for many others).

Members have long wanted the Forum e-mails to "push" to them. And they can, but not everyone wants that much content at once; again, that can be overwhelming in the middle of a busy day.

Which brings me back to Twitter. Although all the news about Twitter has been about celebrities and such, turns out it does have possibilities for us (and many other top companies who use it to communicate), so we've decided to give it a try and would like you to join us.

Lou Ellen Horwitz is executive director of the Urgent Care Association of America. She may be contacted at *lhorwitz@ucaoa.org*.

"Anytime we hear anything of interest to the urgent care world we will 'tweet' a very short, easily digestible message to you."

For those of you who haven't jumped on this bandwagon, either (or should I say bandwidth?), here's what it is and how it works:

Twitter is a service/software/company/thing that lets you "broadcast" short (there's a 140 character limit) messages to people who want to hear from you, instantly. Those people are called your "followers" in Twitter-speak.

So, if you follow UCAOA on Twitter, anytime we hear anything of interest to the urgent care world we will "tweet" (I'm not making this up) a very short, easily digestible message to you, either on your Twitter page or your cell phone or your Blackberry, to keep you up to date on what's happening.

You do need a Twitter page to make this work, but it takes literally one minute to set up at *www.twitter.com*. I know some of you already have Twitter pages (I am already following a few of you!), so tell your friends how easy it is.

Once you have a page, you just find "UCAOA" and click "follow." That's it. You don't ever have to write (sorry, "tweet") a thing, and the messages will sit on your page until you are ready to read them and catch up. You *can* get more involved than that, but you don't *have* to.

We hope you will give this a try. We don't post something every day, so don't be nervous; it should be a good way for us to share some of the "pearls" we pick up along the way and enrich your connection with the rest of urgent care.

Come on, jump on that bandwagon; you can sit by me. ■

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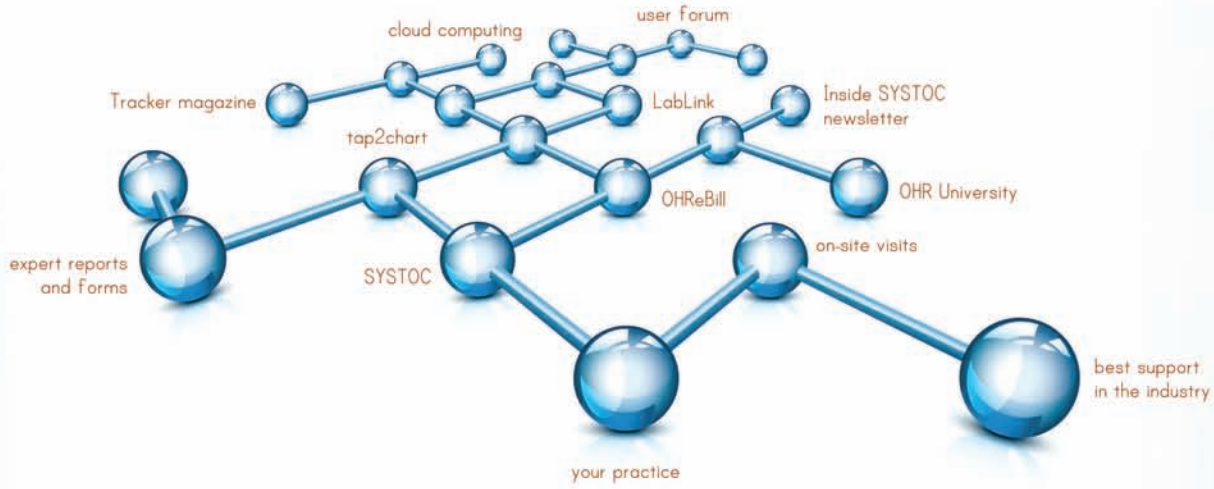

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Toward Ensuring Patient Safety in Urgent Care

Urgent message: As urgent care's role in the continuum of care continues to evolve, the practitioner must take steps to create a culture that supports proper patient identification, drug safety, and adherence to lab standards.

Phillip Disraeli MD, FAAFP

In the 1998 report *To Err is Human,* the Institute of Medicine defined patient safety as "freedom from accidental injury." The ensuing media coverage focused on the 98,000 deaths that IOM estimated occur each year due to adverse events in U.S hospitals.

Yet, the report also discussed errors that lead to injury and death across the continuum of healthcare, from medical offices, to pharmacies, home healthcare, and long-term care.

Ten years after the report, urgent care centers are an important component in the continuum of care for patients. As such, we need to evaluate our systems to ensure patient safety.

The purpose of this two-part article is to outline the common areas of risk inherent to the urgent care environment and to discuss concrete recommendations for mitigating that risk.*

Safety Culture in the Urgent Care Center

A culture that emphasizes patient safety should begin with the physicians and administration of the urgent care center.

Physicians can model behavior oriented toward intellectual curiosity, continuous quality improvement, and patient advocacy. Successful practices will use "near misses" as opportunities for learning for the entire staff, and not react by singling out individual staff for blame or ridicule.

In an approach similar to the airline industry's, sentinel events can spur the practice to perform a root-cause analysis to prevent other medical errors of the same type.

It is helpful to designate a safety officer for the practice—someone responsible for keeping the center up to date on the latest recommendations from reg-

** The majority of the recommendations were adapted from the Joint Commission, with whom the Urgent Care Association of America recently agreed on a voluntary accreditation process for urgent care centers. This article is not intended to be a legally binding guideline. Other useful resources on the topic are the Institute of Medicine, the American Board of Medical Specialties, and the Institute for Safe Medication Practices.*

ulatory and accrediting bodies, for annual assessments of potential areas of risk, and for staff and provider education. This need not be a physician, but the individual needs to have the full support and cooperation of the physicians in order to succeed. It may be helpful for the practice to assess its safety preparedness with the Physician Practice Patient Safety Assessment, available at *www.physiciansafetytool.org*.

Case Example

Mrs. Amy Jones presents to the urgent care center for treatment of cough and a fever. In the triage area, she gives the assistant her list of medications and notes that she is allergic to penicillin. The patient is evaluated by the physician in room 2, has a chest x-ray, and is diagnosed with pneumonia. Her physician decides levofloxacin would be the most appropriate treatment, and leaves to complete the chart and prescriptions.

Meanwhile, Mrs. Charlene Jones is seen by another provider for strep throat in room 3. Her physician reviews her medications and allergies and prescribes a shot of penicillin G benzathine. The order is written on the chart and handed to the nurse for the injection. The nurse sees the room number 2 in the corner of the chart—the wrong room number—and prepares the injection of penicillin and walks into room 2, where *Amy* Jones is sitting on the exam table. The nurse says, "Hi Mrs. Jones, I have an injection that the doctor ordered for you." Feeling quite ill, Amy Jones does not question the injection. She is given the penicillin intended for the other Mrs. Jones, next door, and suffers an anaphylactic reaction.

Patient Identification

Both the Joint Commission and the American Board of Medical Specialties (ABMS) recommend that healthcare providers utilize two unique patient identifiers before performing any procedure, drawing blood, or administering medications or vaccines.

The most reasonable method is to identify patients by their first *and* last names *and* their birthdates.

In the example listed above, the medication error could have been prevented in a number of ways:

- If the doctor had discussed the treatment options with the patient and mentioned that only oral medications would be prescribed, then the patient might have questioned the injection before she received it.
- The nurse could have verified that she had the correct patient by asking her for her first and last names and date of birth.
- Nurses should always verify drug allergies prior to administering an injection.
- If a practice has more than one patient with the same or similar names, they can highlight the chart and name to bring the potential confusion to light for staff.

Medication Safety

Medications are the greatest source of adverse events in ambulatory care. One systematic review by Thomsen, et al found that they occur at the rate of 14.9 events per 1,000 person months.

On review, it becomes clear that many of these are preventable. Errors may occur in the ordering, prescribing, administering, refilling, and storing of medications.

Starting with the intake of the patient, the staff should obtain a complete medication and allergy history of every patient for every encounter. This list should include prescription medications, over-the-counter meds, herbal products, and supplements.

Allergies considered should include medications, foods, latex, and contrast agents. The urgent care center should have a system in place to ensure this is done for every encounter and that the provider can rely on the medication list.

Prescription "hygiene"

When prescribing medications, the provider should indicate the full name, dose, route, frequency, duration, and indication for every medication. The prescription must be legible if handwritten, or follow a standardized method in an electronic medical records or electronic prescribing tool.

The support staff needs to be encouraged to ask for clarification for any prescription that is incomplete, illegible, or unclear.

Oral and telephone orders are an area of potential danger for patients. Whenever possible, spoken orders should be avoided within the urgent care center. However, there are occasions when spoken or telephone orders are unavoidable. In these cases, a spoken order should specify the exact medication or procedure, the dose, route, and patient identifiers.

Clinical staff who receive spoken/telephone orders should write the order in the chart or order sheet and read the order back to the prescribing person, who must verify the order.

Clinicians need to be aware of common look-alike

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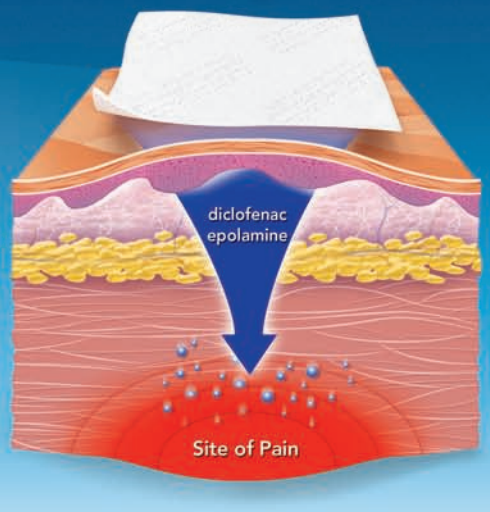

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- **FLECTOR® Patch is contraindicated for the treatment of perioperative pain in the setting of coronary artery bypass graft (CABG) surgery**

Gastrointestinal (GI) risk

- **NSAIDs cause an increased risk of serious GI adverse events at any time during use and without warning symptoms including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. Elderly patients are at greater risk for serious GI events**

FLECTOR® Patch is contraindicated in patients with known hypersensitivity to diclofenac. FLECTOR® Patch should not be given to patients who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs. Severe, rarely fatal, anaphylactic-like reactions to NSAIDs have been reported in such patients.

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NSAIDs, including FLECTOR® Patch, can lead to new onset or worsening of hypertension, contributing to increased incidence of CV events. Fluid retention and edema have been observed in some patients taking NSAIDs. Use with caution in patients with hypertension, fluid retention or heart failure.

A patient with symptoms and/or signs of liver dysfunction, or with a history of an abnormal liver test, should be monitored for a more severe hepatic reaction and therapy stopped. Anemia is sometimes seen in patients receiving NSAIDs and platelet inhibition has been shown to prolong bleeding times.

Long-term administration of NSAIDs has resulted in renal papillary necrosis and other renal injury. Renal toxicity has also been seen in patients in whom renal prostaglandins have a compensatory role in maintaining renal perfusion. FLECTOR® Patch is not recommended in patients with advanced renal disease.

NSAIDs, including FLECTOR® Patch, can cause serious skin adverse events without warning such as exfoliative dermatitis, Stevens-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. Patients should be informed about the signs and symptoms of serious skin manifestations and use of the drug should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity.

Overall, the most common adverse events associated with FLECTOR® Patch were skin reactions (pruritus, dermatitis, burning, etc.) at the site of treatment and gastrointestinal disorders (nausea, dysgeusia, dyspepsia, etc.) and nervous system disorders (headache, paresthesia, somnolence, etc.).

In late pregnancy, as with other NSAIDs, FLECTOR® Patch should be avoided because it may cause premature closure of the ductus arteriosus. FLECTOR® Patch is in Pregnancy Category C. Safety and effectiveness in pediatric patients have not been established.

Please see Brief Summary of full Prescribing Information, including boxed warning, on adjacent page.

For more information, please visit www.FlectorPatch.com or www.KingPharm.com.

References: 1. Data on file. King Pharmaceuticals®, Inc. **2.** Flector Patch [package insert]. Piscataway, NJ: Alpharma Pharmaceuticals LLC; 2008.

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Brief Summary **Rx only**

Cardiovascular Risk: • NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk (See **WARNINGS** and Full Prescribing Information, **CLINICAL TRIALS**). • Flector® Patch is contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery (see **WARNINGS**).

Gastrointestinal Risk: • NSAIDs cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious gastrointestinal events (See **WARNINGS**).

INDICATION AND USAGE: Carefully consider the potential benefits and risks of Flector® Patch and other treatment options before deciding to use Flector® Patch. Use the lowest effective dose for the shortest duration consistent with individual patient treatment goals (see **WARNINGS**).

Flector® Patch is indicated for the topical treatment of acute pain due to minor strains, sprains, and contusions.

CONTRAINDICATIONS: Flector® Patch is contraindicated in patients with known hypersensitivity to diclofenac.

Flector® Patch should not be given to patients who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs. Severe, rarely fatal, anaphylactic-like reactions to NSAIDs have been reported in such patients (see **WARNINGS - Anaphylactoid Reactions**, and **PRECAUTIONS - Preexisting Asthma**).

Flector® Patch is contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery (see **WARNINGS**).

Flector® Patch should not be applied to non-intact or damaged skin resulting from any etiology e.g. exudative dermatitis, eczema, infected lesion, burns or wounds.

WARNINGS: CARDIOVASCULAR EFFECTS: Cardiovascular Thrombotic Events: Clinical trials of several COX-2 selective and nonselective NSAIDs of up to three years duration have shown an increased risk of serious cardiovascular (CV) thrombotic events, myocardial infarction, and stroke, which can be fatal. All NSAIDs, both COX-2 selective and nonselective, may have a similar risk. Patients with known CV disease or risk factors for CV disease may be at greater risk. To minimize the potential risk for an adverse CV event in patients treated with an NSAID, the lowest effective dose should be used for the shortest duration possible. Physicians and patients should remain alert for the development of such events, even in the absence of previous CV symptoms. Patients should be informed about the signs and/or symptoms of serious CV events and the steps to take if they occur.

There is no consistent evidence that concurrent use of aspirin mitigates the increased risk of serious CV thrombotic events associated with NSAID use. The concurrent use of aspirin and an NSAID does increase the risk of serious GI events (see **GI WARNINGS**). Two large, controlled, clinical trials of a COX-2 selective NSAID for the treatment of pain in the first 10-14 days following CABG surgery found an increased incidence of myocardial infarction and stroke (see **CONTRAINDICATIONS**).

Hypertension: NSAIDs, including Flector® Patch, can lead to onset of new hypertension or worsening of preexisting hypertension, either of which may contribute to the increased incidence of CV events. Patients taking thiazides or loop diuretics may have impaired response to these therapies when taking NSAIDs. NSAIDs, including Flector® Patch, should be used with caution in patients with hypertension. Blood pressure (BP) should be monitored closely during the initiation of NSAID treatment and throughout the course of therapy.

Congestive Heart Failure and Edema: Fluid retention and edema have been observed in some patients taking NSAIDs. Flector® Patch should be used with caution in patients with fluid retention or heart failure.

Gastrointestinal Effects- Risk of Ulceration, Bleeding, and Perforation: NSAIDs, including Flector® Patch, can cause serious gastrointestinal (GI) adverse events including inflammation, bleeding, ulceration, and perforation of the stomach, small intestine, or large intestine, which can be fatal. These serious adverse events can occur at any time, with or without warning symptoms, in patients treated with NSAIDs. Only one in five patients, who develop a serious upper GI adverse event on NSAID therapy, is symptomatic. Upper GI ulcers, gross bleeding, or perforation caused by NSAIDs occur in approximately 1% of patients treated for 3-6 months, and in about 2-4% of patients treated for one year. These trends continue with longer duration of use, increasing the likelihood of developing a serious GI event at some time during the course of therapy. However, even short-term therapy is not without risk.

NSAIDs should be prescribed with extreme caution in those with a prior history of ulcer disease or gastrointestinal bleeding. Patients with a *prior history of peptic ulcer disease and/or gastrointestinal bleeding* who use NSAIDs have a greater than 10-fold increased risk for developing a GI bleed compared to patients with neither of these risk factors. Other factors that increase the risk for GI bleeding in patients treated with NSAIDs include concomitant use of oral corticosteroids or anticoagulants, longer duration of NSAID therapy, smoking, use of alcohol, older age, and poor general health status. Most spontaneous reports of fatal GI events are in elderly or debilitated patients and therefore, special care should be taken in treating this population.

To minimize the potential risk for an adverse GI event in patients treated with an NSAID, the lowest effective dose should be used for the shortest possible duration. Patients and physicians should remain alert for signs and symptoms of GI ulceration and bleeding during NSAID therapy and promptly initiate additional evaluation and treatment if a serious GI adverse event is suspected. This should include discontinuation of the NSAID until a serious GI adverse event is ruled out. For high risk patients, alternate therapies that do not involve NSAIDs should be considered.

Renal Effects: Long-term administration of NSAIDs has resulted in renal papillary necrosis and other renal injury. Renal toxicity has also been seen in patients in whom renal prostaglandins have a compensatory role in the maintenance of renal perfusion. In these patients, administration of a nonsteroidal anti-inflammatory drug may cause a dose-dependent reduction in prostaglandin formation and, secondarily, in renal blood flow, which may precipitate overt renal decompensation. Patients at greatest risk of this reaction are those with impaired renal function, heart failure, liver dysfunction, those taking diuretics and ACE inhibitors, and the elderly. Discontinuation of NSAID therapy is usually followed by recovery to the pretreatment state.

Advanced Renal Disease: No information is available from controlled clinical studies regarding the use of Flector® Patch in patients with advanced renal disease. Therefore, treatment with Flector® Patch is not recommended in these patients with advanced renal disease. If Flector® Patch therapy is initiated, close monitoring of the patient's renal function is advisable.

Anaphylactoid Reactions: As with other NSAIDs, anaphylactoid reactions may occur in patients without known prior exposure to Flector® Patch. Flector® Patch should not be given to patients with the aspirin triad. This symptom complex typically occurs in asthmatic patients who experience rhinitis with or without nasal polyps, or who exhibit severe, potentially fatal bronchospasm after taking aspirin or other NSAIDs (see **CONTRAINDICATIONS** and **PRECAUTIONS - Preexisting Asthma**). Emergency help should be sought in cases where an anaphylactoid reaction occurs.

Skin Reactions: NSAIDs, including Flector® Patch, can cause serious skin adverse events such as exfoliative dermatitis, Stevens-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. These serious events may occur without warning. Patients should be informed about the signs and symptoms of serious skin manifestations and use of the drug should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity.

Pregnancy: In late pregnancy, as with other NSAIDs, Flector® Patch should be avoided because it may cause premature closure of the ductus arteriosus.

PRECAUTIONS: General: Flector® Patch cannot be expected to substitute for corticosteroids or to treat corticosteroid insufficiency. Abrupt discontinuation of corticosteroids may lead to disease exacerbation. Patients on prolonged corticosteroid therapy should have their therapy tapered slowly if a decision is made to discontinue corticosteroids.

The pharmacological activity of Flector® Patch in reducing inflammation may diminish the utility of these diagnostic signs in detecting complications of presumed noninfectious, painful conditions.

Hepatic Effects: Borderline elevations of one or more liver tests may occur in up to 15% of patients taking NSAIDs including Flector® Patch. These laboratory abnormalities may progress, may remain unchanged, or may be transient with continuing therapy. Notable elevations of ALT or AST (approximately three or more times the upper limit of normal) have been reported in approximately 1% of patients in clinical trials with NSAIDs. In addition, rare cases of severe hepatic reactions, including jaundice and fatal fulminant hepatitis, liver necrosis and hepatic failure, some of them with fatal outcomes have been reported.

A patient with symptoms and/or signs suggesting liver dysfunction, or in whom an abnormal liver test has occurred, should be evaluated for evidence of the development of a more severe hepatic reaction while on therapy with Flector® Patch. If clinical signs and symptoms consistent with liver disease develop, or if systemic manifestations occur (e.g. eosinophilia, rash, etc.), Flector® Patch should be discontinued.

Hematological Effects: Anemia is sometimes seen in patients receiving NSAIDs. This may be due to fluid retention, occult or gross GI blood loss, or an incompletely described effect upon erythropoiesis. Patients on long-term treatment with NSAIDs, including Flector® Patch, should have their hemoglobin or hematocrit checked if they exhibit any signs or symptoms of anemia.

NSAIDs inhibit platelet aggregation and have been shown to prolong bleeding time in some patients. Unlike aspirin, their effect on platelet function is quantitatively less, of shorter duration, and reversible. Patients receiving Flector® Patch who may be adversely affected by alterations in platelet function, such as those with coagulation disorders or patients receiving anticoagulants, should be carefully monitored.

Preexisting Asthma: Patients with asthma may have aspirin-sensitive asthma. The use of aspirin in patients with aspirin-sensitive asthma has been associated with severe bronchospasm which can be fatal. Since cross reactivity, including bronchospasm, between aspirin and other nonsteroidal anti-inflammatory drugs has been reported in such aspirin-sensitive patients, Flector® Patch should not be administered to patients with this form of aspirin sensitivity and should be used with caution in patients with preexisting asthma.

Eye Exposure: Contact of Flector® Patch with eyes and mucosa, although not studied, should be avoided. If eye contact occurs, immediately wash out the eye with water or saline. Consult a physician if irritation persists for more than an hour.

Accidental Exposure in Children: Even a used Flector® Patch contains a large amount of diclofenac epolamine (as much as 170 mg). The potential therefore exists for a small child or pet to suffer serious adverse effects from chewing or ingesting a new or used Flector® Patch. It is important for patients to store and dispose of Flector® Patch out of the reach of children and pets.

Information for Patients: Patients should be informed of the following information before initiating therapy with an NSAID and periodically during the course of ongoing therapy. Patients should also be encouraged to read the NSAID Medication Guide that accompanies each prescription dispensed.

1. Flector® Patch, like other NSAIDs, may cause serious CV side effects, such as MI or stroke, which may result in hospitalization and even death. Although serious CV events can occur without warning symptoms, patients should be alert for the signs and symptoms of chest pain, shortness of breath, weakness, slurring of speech, and should ask for medical advice when observing any indicative sign or symptoms. Patients should be apprised of the importance of this follow-up (see **WARNINGS, Cardiovascular Effects**). **2.** Flector® Patch, like other NSAIDs, may cause GI discomfort and, rarely, serious GI side effects, such as ulcers and bleeding, which may result in hospitalization and even death. Although serious GI tract ulcerations and bleeding can occur without warning symptoms, patients should be alert for the signs and symptoms of ulcerations and bleeding, and should ask for medical advice when observing any indicative sign or symptoms including epigastric pain, dyspepsia, melena, and hematemesis. Patients should be apprised of the importance of this follow-up (see **WARNINGS, Gastrointestinal Effects: Risk of Ulceration, Bleeding, and Perforation**). **3.** Flector® Patch, like other NSAIDs, may cause serious skin side effects such as exfoliative dermatitis, SJS, and TEN, which may result in hospitalizations and even death. Although serious skin reactions may occur without warning, patients should be alert for the signs and symptoms of skin rash and blisters, fever, or other signs of hypersensitivity such as itching, and should ask for medical advice when observing any indicative signs or symptoms. Patients should be advised to stop the drug immediately if they develop any type of rash and contact their physicians as soon as possible. **4.** Patients should be instructed to promptly report signs or symptoms of unexplained weight gain or edema to their physicians (see **WARNINGS, Cardiovascular Effects**). **5.** Patients should be informed of the warning signs and symptoms of hepatotoxicity (e.g. nausea, fatigue, lethargy, pruritus, jaundice, right upper quadrant tenderness, and "flu-like" symptoms). If these occur, patients should be instructed to stop therapy and seek immediate medical therapy. **6.** Patients should be informed of the signs of an anaphylactoid reaction (e.g. difficulty breathing, swelling of the face or throat). If these occur, patients should be instructed to seek immediate emergency help (see **WARNINGS**). **7.** In late pregnancy, as with other NSAIDs, Flector® Patch should be avoided because it may cause premature closure of the ductus arteriosus. **8.** Patients should be advised not to use Flector® Patch if they have an aspirin-sensitive asthma. Flector® Patch, like other NSAIDs, could cause severe and even fatal bronchospasm in these patients (see **PRECAUTIONS, Preexisting asthma**). Patients should discontinue use of Flector® Patch and should immediately seek emergency help if they experience wheezing or shortness of breath. **9.** Patients should be informed that Flector® Patch should be used only on intact skin. **10.** Patients should be advised to avoid contact of Flector® Patch with eyes and mucosa. Patients should be instructed that if eye contact occurs, they should immediately wash out the eye with water or saline, and consult a physician if irritation persists for more than an hour. **11.** Patients and caregivers should be instructed to wash their hands after applying, handling or removing the patch. **12.** Patients should be informed that, if Flector® Patch begins to peel off, the edges of the patch may be taped down. **13.** Patients should be instructed not to wear Flector® Patch during bathing or showering. Bathing should take place in between scheduled patch removal and application (see Full Prescribing Information, **DOSAGE AND ADMINISTRATION**). **14.** Patients should be advised to store Flector® Patch and to discard used patches out of the reach of children and pets. If a child or pet accidentally ingests Flector® Patch, medical help should be sought immediately (see **PRECAUTIONS, Accidental Exposure in Children**).

Laboratory Tests: Because serious GI tract ulcerations and bleeding can occur without warning symptoms, physicians should monitor for signs or symptoms of GI bleeding. Patients on long-term treatment with NSAIDs, should have their CBC and a chemistry profile checked periodically. If clinical signs and symptoms consistent with liver or renal disease develop, systemic manifestations occur (e.g. eosinophilia, rash, etc.) or if abnormal liver tests persist or worsen, Flector® Patch should be discontinued.

Drug Interactions: ***ACE-inhibitors:*** Reports suggest that NSAIDs may diminish the antihypertensive effect of ACE-inhibitors. This interaction should be given consideration in patients taking NSAIDs concomitantly with ACE-inhibitors.

Aspirin: When Flector® Patch is administered with aspirin, the binding of diclofenac to protein is reduced, although the clearance of free diclofenac is not altered. The clinical significance of this interaction is not known; however, as with other NSAIDs, concomitant administration of diclofenac and aspirin is not generally recommended because of the potential of increased adverse effects.

Diuretics: Clinical studies, as well as post marketing observations, have shown that Flector® Patch may reduce the natriuretic effect-of furosemide and thiazides in some patients. This response has been attributed to inhibition of renal prostaglandin synthesis. During concomitant therapy with NSAIDs, the patient should be observed closely for signs of renal failure (see **WARNINGS, Renal Effects**), as well as to assure diuretic efficacy.

Lithium: NSAIDs have produced an elevation of plasma lithium levels and a reduction in renal lithium clearance. The mean minimum lithium concentration increased 15% and the renal clearance was decreased by approximately 20%. These effects have been attributed to inhibition of renal prostaglandin synthesis by the NSAID. Thus, when NSAIDs and lithium are administered concurrently, subjects should be observed carefully for signs of lithium toxicity.

Methotrexate: NSAIDs have been reported to competitively inhibit methotrexate accumulation in rabbit kidney slices. This may indicate that they could enhance the toxicity of methotrexate. Caution should be used when NSAIDs are administered concomitantly with methotrexate.

Warfarin: The effects of warfarin and NSAIDs on GI bleeding are synergistic, such that users of both drugs together have a risk of serious GI bleeding higher than users of either drug alone.

Carcinogenesis, Mutagenesis, Impairment of Fertility: ***Carcinogenesis:*** Long-term studies in animals have not been performed to evaluate the carcinogenic potential of either diclofenac epolamine or Flector® Patch.

Mutagenesis: Diclofenac epolamine is not mutagenic in *Salmonella Typhimurium* strains, nor does it induce an increase in metabolic aberrations in cultured human lymphocytes, or the frequency of micronucleated cells in the bone marrow micronucleus test performed in rats.

Impairment of Fertility: Male and female Sprague Dawley rats were administered 1, 3, or 6 mg/kg/day diclofenac epolamine via oral gavage (males treated for 60 days prior to conception and during mating period, females treated for 14 days prior to mating through day 19 of gestation). Diclofenac epolamine treatment with 6 mg/kg/day resulted in increased early resorptions and postimplantation losses; however, no effects on the mating and fertility indices were found. The 6 mg/kg/day dose corresponds to 3-times the maximum recommended daily exposure in humans based on a body surface area comparison.

Pregnancy: ***Teratogenic Effects. Pregnancy Category C.:*** Pregnant Sprague Dawley rats were administered 1, 3, or 6 mg/kg diclofenac epolamine via oral gavage daily from gestation days 6-15. Maternal toxicity, embryotoxicity, and increased incidence of skeletal anomalies were noted with 6 mg/kg/day diclofenac epolamine, which corresponds to 3-times the maximum recommended daily exposure in humans based on a body surface area comparison. Pregnant New Zealand White rabbits were administered 1, 3, or 6 mg/kg diclofenac epolamine via oral gavage daily from gestation days 6-18. No maternal toxicity was noted; however, embryotoxicity was evident at 6 mg/kg/day group which corresponds to 6.5-times the maximum recommended daily exposure in humans based on a body surface area comparison.

There are no adequate and well-controlled studies in pregnant women. Flector® Patch should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nonteratogenic Effects: Because of the known effects of nonsteroidal anti-inflammatory drugs on the fetal cardiovascular system (closure of ductus arteriosus), use during pregnancy (particularly late pregnancy) should be avoided.

Male rats were orally administered diclofenac epolamine (1, 3, 6 mg/kg) for 60 days prior to mating and throughout the mating period, and females were given the same doses 14 days prior to mating and through mating, gestation, and lactation. Embryotoxicity was observed at 6 mg/kg diclofenac epolamine (3-times the maximum recommended daily exposure in humans based on a body surface area comparison), and was manifested as an increase in early resorptions, post-implantation losses, and a decrease in live fetuses. The number of live born and total born were also reduced as was F1 postnatal survival, but the physical and behavioral development of surviving F1 pups in all groups was the same as the deionized water control, nor was reproductive performance adversely affected despite a slight treatment-related reduction in body weight.

Labor and Delivery: In rat studies with NSAIDs, as with other drugs known to inhibit prostaglandin synthesis, an increased incidence of dystocia, delayed parturition, and decreased pup survival occurred. The effects of Flector® Patch on labor and delivery in pregnant women are unknown.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human-milk and because of the potential for serious adverse reactions in nursing infants from Flector® Patch, 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: Safety and effectiveness in pediatric patients have not been established.

Geriatric Use: Clinical studies of Flector® Patch did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients.

Diclofenac, as with any NSAID, is known to be substantially excreted by the kidney, and the risk of toxic reactions to Flector® Patch may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken when using Flector® Patch in the elderly, and it may be useful to monitor renal function.

ADVERSE REACTIONS: In controlled trials during the premarketing development of Flector® Patch, approximately 600 patients with minor sprains, strains, and contusions have been treated with Flector® Patch for up to two weeks.

Adverse Events Leading to Discontinuation of Treatment: In the controlled trials, 3% of patients in both the Flector® Patch and placebo patch groups discontinued treatment due to an adverse event. The most common adverse events leading to discontinuation were application site reactions, occurring in 2% of both the Flector® Patch and placebo patch groups. Application site reactions leading to dropout included pruritus, dermatitis, and burning.

Common Adverse Events: Localized Reactions: Overall, the most common adverse events associated with Flector® Patch treatment were skin reactions at the site of treatment.

Table 1 lists all adverse events, regardless of causality, occurring in ≥ 1% of patients in controlled trials of Flector® Patch. A majority of patients treated with Flector® Patch had adverse events with a maximum intensity of "mild" or "moderate."

Table 1. Common Adverse Events (by body system and preferred term) in ≥1% of Patients treated with Flector® Patch or Placebo Patch[1]

	Diclofenac N=572		Placebo N=564	
	N	Percent	N	Percent
Application Site Conditions	64	11	70	12
Pruritus	31	5	44	8
Dermatitis	9	2	3	<1
Burning	2	<1	8	1
Other[2]	22	4	15	3
Gastrointestinal Disorders	49	9	33	6
Nausea	17	3	11	2
Dysgeusia	10	2	3	<1
Dyspepsia	7	1	8	1
Other[3]	15	3	11	2
Nervous System Disorders	13	2	18	3
Headache	7	1	10	2
Paresthesia	6	1	8	1
Somnolence	4	1	6	1
Other[4]	4	1	3	<1

[1] The table lists adverse events occurring in placebo-treated patients because the placebo-patch was comprised of the same ingredients as Flector® Patch except for diclofenac. Adverse events in the placebo group may therefore reflect effects of the non-active ingredients. [2] Includes: application site dryness, irritation, erythema, atrophy, discoloration, hyperhidriosis, and vesicles. [3] Includes: gastritis, vomiting, diarrhea, constipation, upper abdominal pain, and dry mouth. [4] Includes: hypoaesthesia, dizziness, and hyperkinesias.

Foreign labeling describes that dermal allergic reactions may occur with Flector® Patch treatment. Additionally, the treated area may become irritated or develop itching, erythema, edema, vesicles, or abnormal sensation.

DRUG ABUSE AND DEPENDENCE: Controlled Substance Class: Flector® Patch is not a controlled substance.

Physical and Psychological Dependence: Diclofenac, the active ingredient in Flector® Patch, is an NSAID that does not lead to physical or psychological dependence.

OVERDOSAGE: There is limited experience with overdose of Flector® Patch. In clinical studies, the maximum single dose administered was one Flector® Patch containing 180 mg of diclofenac epolamine. There were no serious adverse events.

Should systemic side effects occur due to incorrect use or accidental overdose of this product, the general measures recommended for intoxication with non-steroidal anti-inflammatory drugs should be taken.

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Manufactured for: IBSA Institut Biochimique SA, CH-6903 Lugano, Switzerland
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and sound-alike medications that have been identified as common sources of medication errors. Most of the drugs with similar-sounding names will have different medical indications, so attaching the indication for use to every prescription will help prevent confusion. **Table 1** lists such medications that are used frequently in the urgent care setting.

All clinical personnel need to be aware of these meds so they have a heightened sense of safety when prescribing or refilling them. The urgent care center may even choose to post such a list in the clinical area.

All employees need up-to-date drug references at their fingertips, including accurate pediatric dosing. An online database with a patient education component (such as Epocrates or MD Consult) would allow for clinicians to discuss side effects and provide the patient with a written summary of the information.

Table 1. Sound-alike and Look-alike Meds

Celebrex and Celexa
Clonidine and Klonopin
Hydromorphone and morphine
Lorazepam and alprazolam
Metformin and metronidazole
Topamax and Toprol XL
Zyprexa and Zyrtec
Advicor and Advair
Darvocet and Percocet
Hydrocodone and oxycodone
Prilosec and Prozac
Zantac and Xanax
Zestril and Zetia
Liquid morphine products—many concentrations available
Insulin products—numerous confusing products

Samples

Prescription samples are commonly dispensed from the urgent care center. A staff member should be responsible for maintaining the order of the sample closet and purging expired meds.

Again, particular care should be taken with medications that look alike or sound alike; these should not be stored next to each other.

Sample medications should be accepted by the practice only if they are known to be safe and effective, to be useful for common conditions seen in the urgent care center, and to be present on managed care formularies available to patients.

Providers must document the samples dispensed in the medical record in the same manner as normal prescriptions. The dosage and instructions for use need to be included. If the center has an EMR system, it may be possible to search the patient database for samples dispensed in the event of a drug recall or FDA removal.

Sound decisions based on accurate information

Physicians should prescribe medications only within the context of the urgent care center. In order to have all the necessary information for an accurate prescription, the clinician needs to have a chart with a full medication and allergy history, past medical history, and accurate demographic information. When clinicians make exceptions to this rule, they are more likely to make an error or encounter a patient who will have a preventable adverse reaction.

This is also true for personnel who are involved in the refilling of meds. They, too, must have access to the full chart. Chart access is improved in the setting of an EMR, because more than one individual may view the chart simultaneously, or even remotely.

It is most helpful when all members of the team utilize standardized protocols for refilling medications, whether electronic, by fax or, by phone. All refills must be documented in the medical record and be accessible as part of the ongoing medication history.

Jenkins, et al cite an anonymously authored article published in the *Journal of the American Medical Association* in reporting that up to one third of physician handwriting is illegible. For this reason and many others, urgent care clinicians are moving toward electronic prescribing and EMRs to enter medication orders and prescriptions. Some of these systems allow for updated drug information, interaction checking, and allergy warnings to prevent errors.

Recently, the Institute of Medicine recommended that all prescriptions be electronic by 2010. For those who have not yet made the transition, safety experts suggest that prescriptions be written carefully, while sitting in a quiet area, to improve legibility.

Abbreviations in prescriptions are especially problematic and prone to error. When writing the prescription, the name and dosing frequency should be indicated in full text, along with the indication for the prescription.

The Joint Commission recommends against using

MOXATAG is indicated for the treatment of tonsillitis and/or pharyngitis secondary to *Streptococcus pyogenes (S. pyogenes)* in adults and pediatric patients 12 years and older. MOXATAG should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. The full 10-day course of therapy should be completed for effective treatment. Patients taking MOXATAG should not chew or crush tablet.

Important Safety Information

Use caution in patients with known serious hypersensitivity to amoxicillin or to other drugs in the same class or patients who have demonstrated anaphylactic reactions to beta-lactams. Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients on penicillin therapy. If an allergic reaction occurs, MOXATAG should be discontinued and appropriate therapy instituted. *Clostridium difficile* Associated Diarrhea (CDAD) has been reported with nearly all antibacterial agents, including

Please see brief summary of Prescribing Information on next page.

References: 1. MOXATAG Prescribing Information. MiddleBrook Pharmaceuticals, Inc. 2008. **2.** Kardas P. Patient compliance with antibiotic treatment for respiratory tract infections. *J Antimicrob Chemother.* 2002;49(6):897-903. **3.** Sclar DA, Tartaglione TA, Fine MJ. Overview of issues related to medical compliance with implications for the outpatient management of infectious diseases. *Infect Agents Dis.* 1994;3(5):266-273.

New for the treatment of tonsillitis and/or pharyngitis secondary to *Streptococcus pyogenes*. . .

Once-Daily Amoxicillin Is Formed

Introducing MOXATAG™ — Refining the delivery of amoxicillin therapy with innovative proprietary technology

- Extended-release tablets efficiently deliver amoxicillin using a once-daily dose of 775 mg for 10 days[1]
- Proven efficacy for the treatment of tonsillitis/pharyngitis secondary to *S. pyogenes*[1]
- Convenient, once-daily dosing potentially leading to improved compliance[2,3]
- Favorable safety profile with observed minimal GI upset[1]

atag™

amoxicillin, and may range in severity from mild diarrhea to fatal colitis. If CDAD is suspected or confirmed, MOXATAG should be discontinued and appropriate therapy instituted. The possibility of superinfections with mycotic or bacterial pathogens should be kept in mind during therapy. If superinfections occur, MOXATAG should be discontinued and appropriate therapy instituted. The most common drug-related adverse reactions (incidence >1.0 %) are vulvovaginal mycotic infection, diarrhea, nausea, vomiting and headache.

once-daily

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moxatag™
(amoxicillin extended-release tablets)
775 mg

The following is a brief summary only; see full Prescribing Information for complete product information.

RX ONLY

INDICATIONS AND USAGE

MOXATAG is a once-daily amoxicillin product indicated for the treatment of tonsillitis and/or pharyngitis secondary to *Streptococcus pyogenes (S. pyogenes)*, more commonly referred to as 'strep throat,' in adults and pediatric patients 12 years or older.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of MOXATAG and other antibacterial drugs, MOXATAG should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

DOSAGE AND ADMINISTRATION

The recommended dose of MOXATAG is 775 mg once daily taken within 1 hour of finishing a meal for 10 days. MOXATAG should be taken approximately the same time every day. The full 10-day course of therapy should be completed for effective treatment of tonsillitis and/or pharyngitis secondary to *S. pyogenes.*

Do not chew or crush tablet.

CONTRAINDICATIONS

MOXATAG is contraindicated in patients with known serious hypersensitivity to amoxicillin or to other drugs in the same class or patients who have demonstrated anaphylactic reactions to beta-lactams.

WARNINGS AND PRECAUTIONS

Anaphylaxis and Hypersensitivity Reactions

Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients on penicillin therapy. Although anaphylaxis is more frequent following parenteral therapy, it has occurred in patients on oral penicillins. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity and/or a history of sensitivity to multiple allergens. There have been reports of individuals with a history of penicillin hypersensitivity who have experienced severe reactions when treated with cephalosporins. Before initiating therapy with MOXATAG, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, or other allergens. If an allergic reaction occurs, MOXATAG should be discontinued and appropriate therapy instituted.

***Clostridium difficile* Associated Diarrhea (CDAD)**

Clostridium difficile Associated Diarrhea (CDAD) has been reported with nearly all antibacterial agents, including amoxicillin, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile*.

CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued.

Superinfections

The possibility of superinfections with mycotic or bacterial pathogens should be kept in mind during therapy. If superinfections occur, amoxicillin should be discontinued and appropriate therapy instituted.

Mononucleosis Rash

A high percentage of patients with mononucleosis who receive ampicillin develop an erythematous skin rash. Thus, ampicillin-class antibiotics should not be administered to patients with mononucleosis.

Development of Drug-Resistant Bacteria

Prescribing amoxicillin in the absence of proven or strongly suspected bacterial infection or treating prophylactically is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

False-Positive Urinary Glucose Tests

High urine concentrations of ampicillin may result in false-positive reactions when testing for the presence of glucose in urine using Clinitest®, Benedict's Solution or Fehling's Solution. Since this effect may also occur with amoxicillin, it is recommended that glucose tests based on enzymatic glucose oxidase reactions (such as Clinistix®) be used.

ADVERSE REACTIONS

In a controlled Phase 3 trial, 302 adult and pediatric patients (≥12 years) were treated with MOXATAG 775 mg once-daily for 10 days. The most frequently reported adverse reactions (>1%) which were suspected or probably drug-related are vaginal yeast infection (2.0%), diarrhea (1.7%), nausea (1.3%) and headache (1.0%).

DRUG INTERACTIONS

Probenecid

Probenecid decreases the renal tubular secretion of amoxicillin. Concurrent use of MOXATAG and probenecid may result in increased and prolonged blood levels of amoxicillin.

Other Antibiotics

Chloramphenicol, macrolides, sulfonamides, and tetracyclines may interfere with the bacterial effects of penicillin. This has been demonstrated *in vitro*; however, the clinical significance of this interaction is not well documented.

Oral Contraceptives

As with other antibiotics, amoxicillin may affect the gut flora, leading to lower estrogen reabsorption and potentially resulting in reduced efficacy of combined oral estrogen/progesterone contraceptives.

USE IN SPECIFIC POPULATIONS

Pregnancy: Teratogenic Effects. Pregnancy Category B.

Reproduction studies have been performed in mice and rats at doses up to 2000 mg/kg (12.5 and 25 times the human dose in mg/m^2) and have revealed no evidence of impaired fertility or harm to the fetus due to amoxicillin. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Labor and Delivery

It is not known whether use of amoxicillin in humans during labor or delivery has immediate or delayed adverse effects on the fetus, prolongs the duration of labor, or increases the likelihood that forceps delivery or other obstetrical intervention or resuscitation of the newborn will be necessary.

Nursing Mothers

Penicillins have been shown to be excreted in human milk. Amoxicillin use by nursing mothers may lead to sensitization of infants. Caution should be exercised when amoxicillin is administered to a nursing woman.

Pediatric Use

The safety and effectiveness of MOXATAG in pediatric patients 12 years of age and older have been established based on results of a clinical trial that included adults and pediatric patients (12 years or older). The safety and effectiveness of MOXATAG in pediatric patients younger than 12 years has not been established.

Geriatric Use

This drug is known to be substantially excreted by the kidney, and the risk of adverse reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Renal Impairment

MOXATAG has not been studied in patients with renal impairment; however, a reduction of amoxicillin dose is generally recommended for patients with severe renal impairment. Therefore, MOXATAG is not recommended for use in patients with severe renal impairment (CrCl <30 mL/min) or patients on hemodialysis.

OVERDOSAGE

In case of overdose, discontinue medication, treat symptomatically, and institute supportive measures as required. If the overdose is very recent and there is no contraindication, an attempt at emesis or other means of removal of drug from the stomach may be performed.

Interstitial nephritis resulting in oliguric renal failure has been reported in a small number of patients after overdosage with amoxicillin.

Crystalluria, in some cases leading to renal failure, has also been reported after amoxicillin overdosage in adult and pediatric patients.

Renal impairment appears to be reversible with cessation of drug administration. High blood levels may occur more readily in patients with impaired renal function because of decreased renal clearance of amoxicillin.

For additional information about overdose treatment, call a poison control center (1-800-222-1222).

HOW SUPPLIED/STORAGE AND HANDLING

MOXATAG tablets for oral administration are provided as blue film-coated, oval-shaped tablets that contain 775 mg of amoxicillin. The tablets are printed with "MB-111" on one side in black edible ink. MOXATAG is packaged in bottles as follows:

Presentation	NDC Code
Bottles of 30	11042-142-03

Storage

Store at 25º C (77º F); excursions permitted to 15–30º C (59–86º F) [See USP Controlled Room Temperature.]

MiddleBrook PHARMACEUTICALS®
Germantown, Maryland 20876 USA

U.S. Patents 6,544,555; 6,669,948; 6,723,341

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910-0209-0075

certain abbreviations (**Table 2)** and symbols altogether. The entire list is available in PDF form at *www.jointcommission.org/PatientSafety/DoNotUseList/*.

Table 2. Abbreviations to Avoid Using

Do not use	Potential problem	Use instead
U (unit)	Mistaken for "0" (zero), the number 4, or "cc"	Write "unit"
IU (International Unit)	Mistaken for IV (intravenous) or the number "10"	Write "International Unit"
Q.D., QD, q.d., qd (daily) Q.O.D. QOD, q.o.d., qod (every other day)	Mistaken for each other Period after the Q mistaken for I and the O mistaken for I	Write "daily" Write "every other day"
Trailing zero (X.0 mg)* Lack of leading zero (.X mg)	Decimal point is missed	Write X mg Write 0.X mg
MS MSO_4 and $MgSO_4$	Can mean morphine sulfate or magnesium sulfate Confused for one another	Write "morphine sulfate" Write "magnesium sulfate"

*Exception: A "trailing zero" may be used only where required to demonstrate the level of precision of the value being reported, such as for laboratory results, imaging studies that report size of lesions, or catheter/tube sized. It may not be used in medication orders or other medication-related documentation.

Injectables

Most urgent care centers administer injectable medications and vaccines to patients. There are a number of ways one can reduce the risk of errors in these instances. For example:

- An urgent care center could choose to stock only one concentration of a medication.
- The provider must be very careful to specify the route of administration (IV, oral, SQ, IM).
- Only providers and qualified clinical personnel should administer medications.
- A member of the staff should be responsible for ongoing review of the safety and efficacy of all stocked and administered medications.
- Before administering the medication, the nurse should verify the patient with two identifiers.
- Make certain the correct patient is receiving the correct medication, correct dose, and correct route, and that the med has not expired.
- Liquid medications should be administered only in approved measuring devices. Parenteral syringes used for this purpose have accidentally resulted in aspiration of the syringe tip.
- The members of the clinical team need to be warned when a vital medication is low or out of stock.
- After administration, the center should be prepared to monitor the patient for possible adverse reactions or anaphylaxis, and be equipped to handle a complication, should one arise.

Storage

The proper storage of medications is also important. The urgent care center should follow storage instructions specified by the manufacturer.

In addition:

- Medications should not be stored in patient areas or exam rooms.
- Medications should be stocked by a standardized inventory, with a specific staff member responsible for purging expired meds at least quarterly.
- Multi-dose vials should be discarded within 30 days of opening (labeling the vial when opened with a date) or changed to single-dose vials to prevent administering expired meds.
- Emergency medications should be available as unit doses and labeled age appropriately. They should be kept separately in a crash cart in ready-to-use formulations.
- Controlled substances need to be kept in another separate locked area, and monitored daily by nursing staff.
- Medications and reagents (e.g., hemoccult developer, eye drops, glucose monitor reagents) designed for external use (i.e., podophyllin, benzoin, phenol) should be labeled "for external use only" and kept separate from other medications.

When prevention fails

Despite our best efforts, medication errors and adverse

Table 3. Sample Test Tracking Log

Test Tracking Log							
Patient name	Test ordered	Location	Ordering physician	Results received (date, time)	Action plan or no action needed	Follow-up completed (date)	Staff initials

reactions will continue to occur. In such cases, the prescribing physician should always be informed of the reaction. The urgent care center should have a process to perform a root-cause analysis of the error, so problems with the medication system can be corrected.

Lab Safety and CLIA-waived Testing

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) classifies lab testing according to four complexity levels:

1. High complexity
2. Moderate complexity
3. Provider-performed microscopy (a subset of moderate complexity)
4. Waived testing

The vast majority of urgent care centers possess a moderate complexity lab or a waived testing lab. Moderate complexity designation carries with it stringent requirements for compliance on personnel qualification, quality assurance, and controls. When followed, these guidelines help protect the patient.

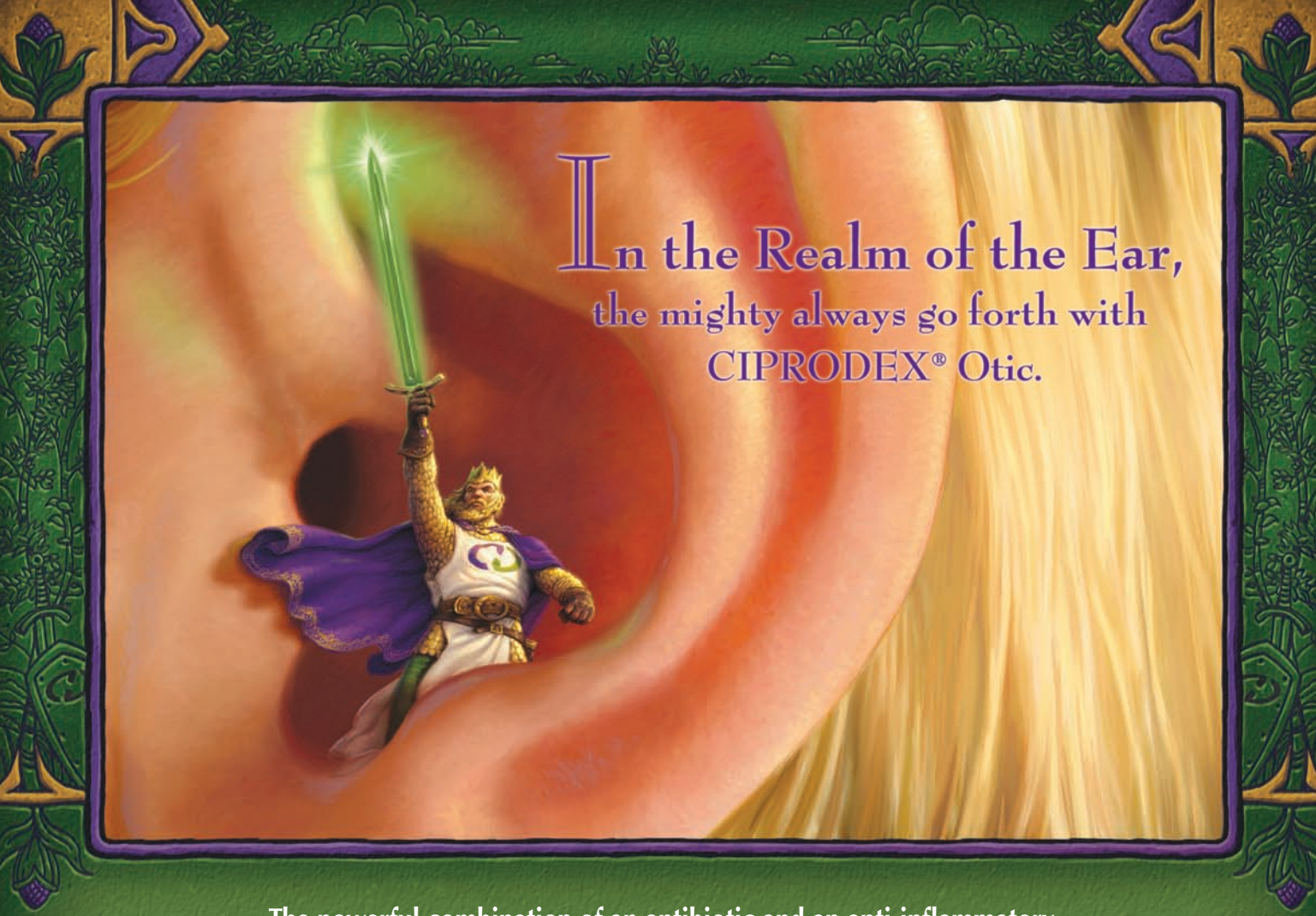
For those urgent care centers following waived testing rules, the Joint Commission requires several elements of performance.

- The urgent care center should have a designated lab director who is identified on the CLIA certificate; even CLIA-waived labs need a certificate.
- A clinical policy and procedure manual for the practice should be created.
- There should be a policy on collecting and proper labeling of specimens. Whenever possible, specimens should be labeled in the presence of the patient to reduce identification errors.
- Test reagents need to be stored and purged according to manufacturers' instructions.
- Controls on point-of-care tests should be run as indicated.
- There should be quality controls in place for the tests, with guidance for lab personnel when they have an equivocal result. Too often, lab assistants substitute their own judgment when a test is unclear. Instead, they should defer to the provider or repeat the test.
- There needs to be a clear procedure for reporting and documenting the test results, with a separate log of all in-house labs with results to be used as a back-up.
- It is important that lab personnel and the director review manufacturers' instructions when the vendor is changed or the test is updated.

The other critical component of a safe CLIA-waived lab is the lab personnel. Only designated clinical personnel should be allowed to perform lab tests. They should be identified by job title and description (e.g., certified medical assistants). Only personnel that have been properly oriented to the center's lab should perform the tests. New hires should be instructed in the proper performance of each test and their competence documented by a supervisor before they operate independently. A checklist for lab competencies would be helpful, and could be updated annually.

Tracking Lab and X-ray Results

Another area of concern for patient safety is the tracking of outside test results. This includes outside reference labs, pathology specimens, and imaging. Clinics that send blood, urine and stool tests to outside ref-



The powerful combination of an antibiotic and an anti-inflammatory to defeat acute otitis externa (AOE) or acute otitis media with tympanostomy tubes (AOMT)[1]

- In well-controlled clinical trials, CIPRODEX® Otic cured more patients with AOE than CORTISPORIN* Otic‡ and more patients with AOMT than ofloxacin[1‡]
- The anti-inflammatory agent, dexamethasone, has been added to aid in the resolution of the inflammatory response accompanying bacterial infection such as otorrhea in pediatric patients with AOMT [1]

Why trust the realm to anything less than the #1 otic drop among otolaryngologists?[2]

CIPRODEX® Otic is indicated in patients 6 months and older for acute otitis externa due to *Staphylococcus aureus* and *Pseudomonas aeruginosa* and for acute otitis media with tympanostomy tubes due to *S. aureus, Streptococcus pneumoniae, Haemophilus influenzae, Moraxella catarrhalis* and *P. aeruginosa*. 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. 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. If the infection is not improved after one week of treatment, cultures should be obtained to guide further treatment. Most commonly reported adverse reactions in clinical trials in AOE patients: pruritus (1.5%), ear debris (0.6%), superimposed ear infection (0.6%), ear congestion (0.4%), ear pain (0.4%) and erythema (0.4%). 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%).

†Clinical cures: CIPRODEX® Otic vs CORTISPORIN Otic (87%, 94% vs 84%, 89%) per protocol and (86%, 92% vs 84%, 89%) culture positive.
‡Clinical cures: CIPRODEX® Otic vs ofloxacin (86% vs 79%) per protocol and (90% vs 79%) culture positive.

Please see adjacent page for prescribing information.

Alcon®

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

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.

Ciprofloxacin, a fluoroquinolone is available as the monohydrochloride monohydrate salt of 1-cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-7-(1-piperazinyl)-3-quinolinecarboxylic acid. The empirical formula is $C_{17}H_{18}FN_3O_3{\cdot}HCl{\cdot}H_2O$. Dexamethasone, 9-fluoro-11(beta),17,21-trihydroxy-16(alpha)-methylpregna-1,4-diene-3,20-dione, is an anti-inflammatory corticosteroid. The empirical formula is $C_{22}H_{29}FO_5$.

CLINICAL PHARMACOLOGY

Pharmacokinetics: Following a single bilateral 4-drop (total dose = 0.28 mL, 0.84 mg ciprofloxacin, 0.28 mg dexamethasone) topical otic dose of CIPRODEX® Otic to pediatric patients after tympanostomy tube insertion, measurable plasma concentrations of ciprofloxacin and dexamethasone were observed at 6 hours following administration in 2 of 9 patients and 5 of 9 patients, respectively.

Mean ± SD peak plasma concentrations of ciprofloxacin were 1.39 ± 0.880 ng/mL (n=9). Peak plasma concentrations ranged from 0.543 ng/mL to 3.45 ng/mL and were on average approximately 0.1% of peak plasma concentrations achieved with an oral dose of 250-mg [3]. Peak plasma concentrations of ciprofloxacin were observed within 15 minutes to 2 hours post dose application. Mean ± SD peak plasma concentrations of dexamethasone were 1.14 ± 1.54 ng/mL (n=9). Peak plasma concentrations ranged from 0.135 ng/mL to 5.10 ng/mL and were on average approximately 14% of peak concentrations reported in the literature following an oral 0.5-mg tablet dose[4]. Peak plasma concentrations of dexamethasone were observed within 15 minutes to 2 hours post dose application. Dexamethasone has been added to aid in the resolution of the inflammatory response accompanying bacterial infection (such as otorrhea in pediatric patients with AOM with tympanostomy tubes).

Microbiology: Ciprofloxacin has *in vitro* activity against a wide range of gram-positive and gram-negative microorganisms. The bactericidal action of ciprofloxacin results from interference with the enzyme, DNA gyrase, which is needed for the synthesis of bacterial DNA. 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.

Ciprofloxacin has been shown to be active against most isolates of the following microorganisms, both *in vitro* and clinically in otic infections as described in the **INDICATIONS AND USAGE** section.

Aerobic and facultative gram-positive microorganisms: *Staphylococcus aureus, Streptococcus pneumoniae.* **Aerobic and facultative gram-negative microorganisms:** *Haemophilus influenzae, Moraxella catarrhalis, Pseudomonas aeruginosa.*

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**

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 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 (see **DOSAGE AND ADMINISTRATION**). **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 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 (see **DOSAGE AND ADMINISTRATION**).

Drug Interactions: Specific drug interaction studies have not been conducted with CIPRODEX® Otic. **Carcinogenesis, Mutagenesis, Impairment of Fertility:** Long-term carcinogenicity studies in mice and rats have been completed for ciprofloxacin. After daily oral doses of 750 mg/kg (mice) and 250 mg/kg (rats) were administered for up to 2 years, there was no evidence that ciprofloxacin had any carcinogenic or tumorigenic effects in these species. No long term studies of CIPRODEX® Otic have been performed to evaluate carcinogenic potential. Eight *in vitro* mutagenicity tests have been conducted with ciprofloxacin, and the test results are listed below: *Salmonella*/Microsome Test (Negative), *E. coli* DNA Repair Assay (Negative), Mouse Lymphoma Cell Forward Mutation Assay (Positive), Chinese Hamster V79 Cell HGPRT Test (Negative), Syrian Hamster Embryo Cell Transformation Assay (Negative), *Saccharomyces cerevisiae* Point Mutation Assay (Negative), *Saccharomyces cerevisiae* Mitotic Crossover and Gene Conversion Assay (Negative), Rat Hepatocyte DNA Repair Assay (Positive). Thus, 2 of the 8 tests were positive, but results of the following 3 *in vivo* test systems gave negative results: Rat Hepatocyte DNA Repair Assay, Micronucleus Test (Mice), Dominant Lethal Test (Mice). Fertility studies performed in rats at oral doses of ciprofloxacin up to 100 mg/kg/day revealed no evidence of impairment. This would be over 100 times the maximum recommended clinical dose of ototopical 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 vessicle, Cowper's gland and accessory glands. The relevance of this study for short term topical otic use is unknown.

Pregnancy

Teratogenic Effects. Pregnancy Category C: Reproduction studies have been performed in rats and mice using oral doses of up to 100 mg/kg and IV doses up to 30 mg/kg and have revealed no evidence of harm to the fetus as a result of ciprofloxacin. In rabbits, ciprofloxacin (30 and 100 mg/kg orally) produced gastrointestinal disturbances resulting in maternal weight loss and an increased incidence of abortion, but no teratogenicity was observed at either dose. After intravenous administration of doses up to 20 mg/kg, no maternal toxicity was produced in the rabbit, and no embryotoxicity or teratogenicity was observed. Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. Animal reproduction studies have not been conducted with CIPRODEX® Otic. No adequate and well controlled studies have been performed in pregnant women. Caution should be exercised when CIPRODEX® Otic is used by a pregnant woman.

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

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

ADVERSE REACTIONS

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

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

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

The following treatment-related adverse events were each reported in a single patient: tympanostomy tube blockage; ear pruritus; tinnitus; oral moniliasis; crying; dizziness; and erythema. **Acute Otitis Externa:** The following treatment-related adverse events occurred in 0.4% or more of the patients with intact tympanic membranes.

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

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

DOSAGE AND ADMINISTRATION

CIPRODEX® OTIC SHOULD BE SHAKEN WELL IMMEDIATELY BEFORE USE

CIPRODEX® Otic contains 3 mg/mL (3000 µg/mL) ciprofloxacin and 1 mg/mL dexamethasone.

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 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. 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.

HOW SUPPLIED

CIPRODEX® (ciprofloxacin 0.3% and dexamethasone 0.1%) Sterile Otic Suspension is supplied as follows: 5 mL fill and 7.5 mL fill in a DROP-TAINER® system. The DROP-TAINER® system consists of a natural polyethylene bottle and natural plug, with a white polypropylene closure. Tamper evidence is provided with a shrink band around the closure and neck area of the package. NDC 0065-8533-01, 5 mL fill; NDC 0065-8533-02, 7.5 mL fill. **Storage:** Store at controlled room temperature, 15°C to 30°C (59°F to 86°F). Avoid freezing. Protect from light.

Clinical Studies: In a randomized, multicenter, controlled clinical trial, CIPRODEX® Otic dosed 2 times per day for 7 days demonstrated clinical cures in the per protocol analysis in 86% of AOMT patients compared to 79% for ofloxacin solution, 0.3%, dosed 2 times per day for 10 days. Among culture positive patients, clinical cures were 90% for CIPRODEX® Otic compared to 79% for ofloxacin solution, 0.3%. Microbiological eradication rates for these patients in the same clinical trial were 91% for CIPRODEX® Otic compared to 82% for ofloxacin solution, 0.3%. In 2 randomized multicenter, controlled clinical trials, CIPRODEX® Otic dosed 2 times per day for 7 days demonstrated clinical cures in 87% and 94% of per protocol evaluable AOE patients, respectively, compared to 84% and 89%, respectively, for otic suspension containing neomycin 0.35%, polymyxin B 10,000 IU/mL, and hydrocortisone 1.0% (neo/poly/HC). Among culture positive patients clinical cures were 86% and 92% for CIPRODEX® Otic compared to 84% and 89%, respectively, for neo/poly/HC. Microbiological eradication rates for these patients in the same clinical trials were 86% and 92% for CIPRODEX® Otic compared to 85% and 85%, respectively, for neo/poly/HC.

References:

1. CIPRODEX® Otic prescribing information.
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U.S. Patent Nos. 4,844,902; 6,284,804; 6,359,016

Manufactured by Alcon Laboratories, Inc.
Rx Only
Revision date: 17 July 2003

Alcon®

erence labs must have a tracking system that is reliable for all providers and clinical employees to follow. A paper-based system should include a log of each patient, with the name of the test ordered, when the results were received, when notification was given to the patient, and what follow-up was arranged.

The ABMS recommends that patients be notified of all test results—even normal results—within a 24–48 hour timeframe, and that the communication be documented in the medical record.

Table 3 offers an example of a test tracking log.

Some EMRs allow the provider to track test results within the "To Do List" of the software. A separate log can be created for imaging tests and for referrals to specialists.

Regardless of the system chosen, the key component is the follow-up. Every test should be tracked all the way through the work-flow to the point of follow-up. Designated employees should be tasked with checking the log on a weekly basis to make certain that all tests that were ordered were, in fact, performed. They can also be charged with investigating any missing tests. Not only will this system improve patient safety, but it will also reduce an important source of malpractice liability for urgent care centers.

Physicians should *avoid* telling patients that "no news is good news" when it comes to test results. It is preferable to instruct patients to contact the practice if they have not received the results, normal or abnormal, within a specific time frame. This approach will decrease the risk that a critical result will be missed or delayed and makes patients active partners in their care, which may prevent unnecessary delay.

Critical test results

In addition to tracking routine tests, the clinic should have a process to identify and track critical test results.

According to the ABMS, failure to communicate critical test results is responsible for the majority of adverse events that lead to disability; 85% of these failures are due to a delay in receiving the results.

A critical range should be identified for lab tests so personnel can recognize results that fall outside of the range. As soon as a critical result is received by the lab or clinical personnel, they need to notify one of the providers for guidance.

It is recommended that providers take responsibility themselves for notifying patients of critical test or imaging results. Only a provider can answer the important questions a patient will have in these circumstances, and direct the follow-up or referral of the case. Leaving these conversations to others allows more uncertainty to enter the process. The patient might not understand the diagnosis or the urgency of the matter. The follow-up should be arranged by the urgent care center and tracked to ensure that it has occurred in a timely fashion.

Part 2 of this article, which will be published next month in *JUCM*, will discuss:

- healthcare-associated infection
- radiation
- transitioning care from one provider to another
- emergency preparedness
- personnel qualifications
- patient rights
- discharge considerations. ■

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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.

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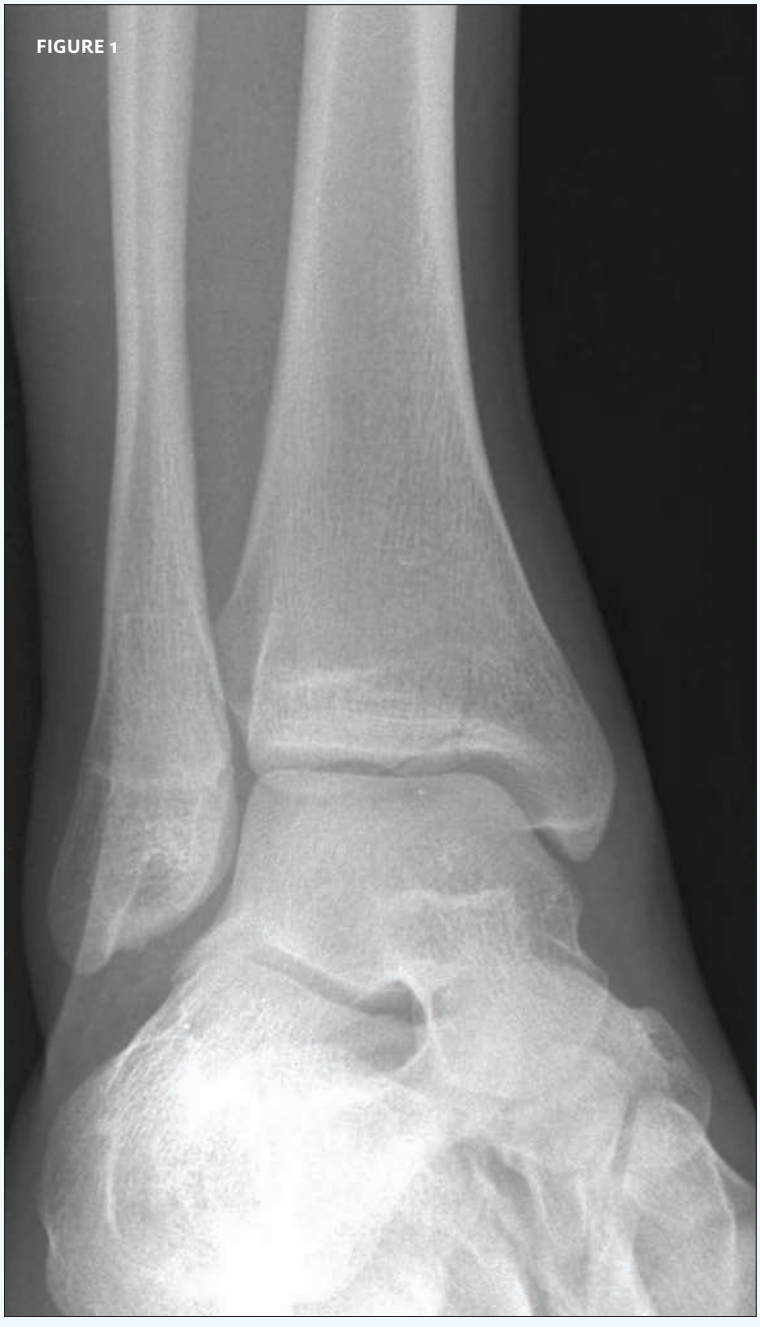

FIGURE 1

The patient is a 16-year-old male who fell from his motorcycle and received a blow to his right ankle. The motorcycle was moving at a "good pace."

On exam, he is able to weight bear, but with significant pain. You note swelling and tenderness over the medical malleolus.

View the x-ray taken (**Figure 1**) and consider what your diagnosis and next steps would be. Resolution of the case is described on the next page.

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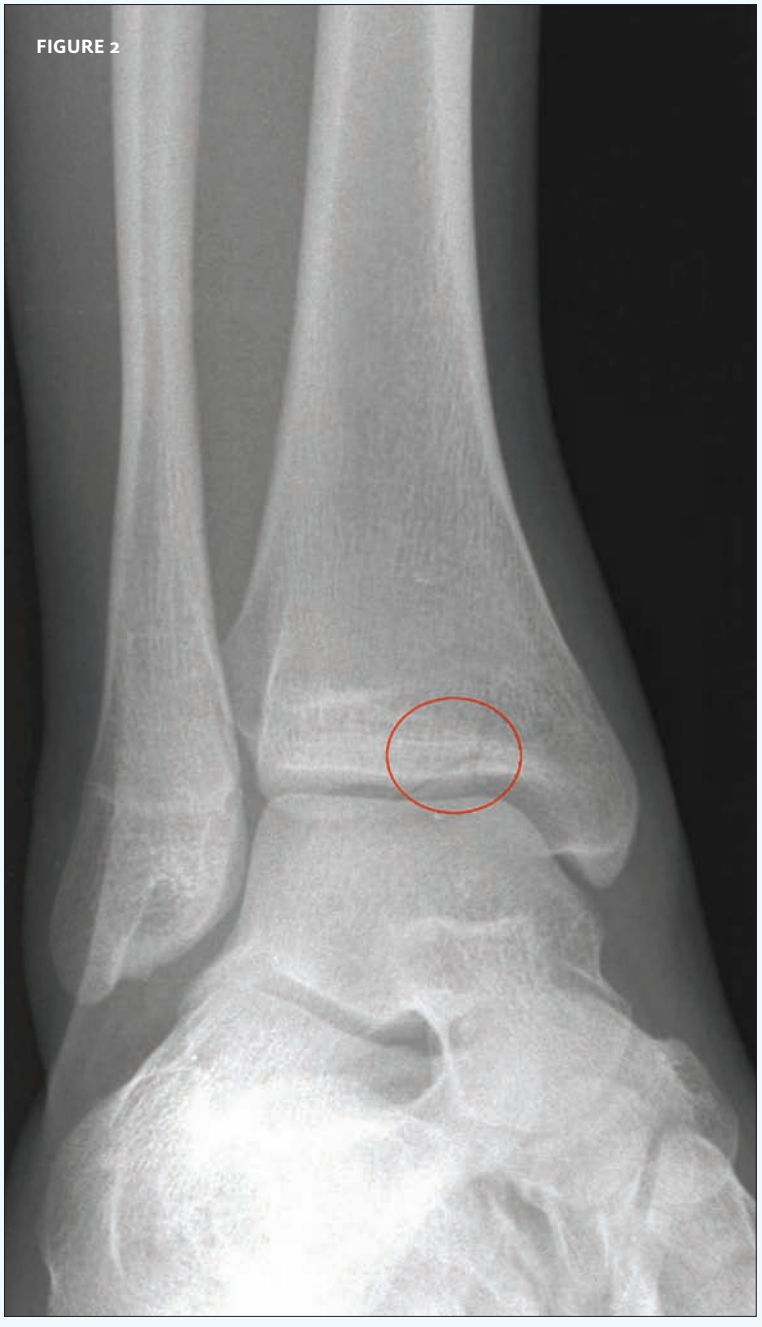

FIGURE 2

There is a suspicious line (circled) indicative of a non-displaced, intra-articular pilon fracture in the distal tibia. Further views are recommended.

Typically, such injuries are the result of axial compression forces, such as those that might occur in ski accidents and car crashes, with the distal tibia compressing against the talus.

This patient was casted in the urgent care center and referred for orthopedic follow-up.

Acknowledgment: Case presented by Nahum Kovalski, BSc, MDCM, Terem Emergency Medical Centers, Jerusalem, Israel.

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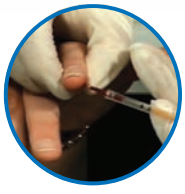

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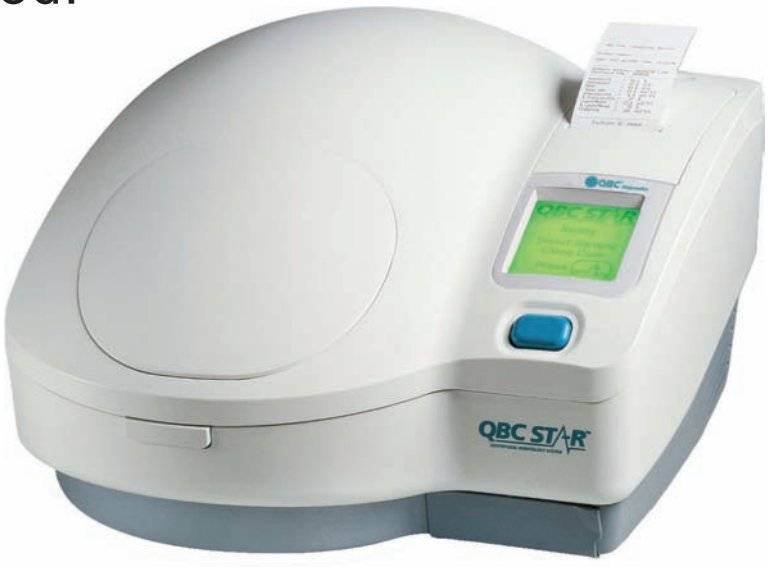

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Occult Bacteremia or RSV Infection in Young Children, and Orthopedic Injuries in Child Abuse

NAHUM KOVALSKI, BSc, MDCM

Each month, Dr. Nahum Kovalski reviews a handful of abstracts from, or relevant to, urgent care practices and practitioners. For the full reports, go to the source cited under each title.

Occult Bacteremia is Rare in Young Children with Unexplained Fever

Key point: Since introduction of the pneumococcal vaccine, urinary tract infection has become the most common bacterial infection in children who have fever without localizing signs.

Citation: Waddle E, Jhaveri R. Outcomes of febrile children without localising signs after pneumococcal conjugate vaccine. *Arch Dis Child*. 2009;94:144-147.

Occult bacteremia and invasive disease are important concerns in children with unexplained high fever. Investigators retrospectively compared the risk for serious infection in children 3 months to 36 months in age who presented to a U.K. pediatric emergency department with fever (>39°C) without localizing signs before and after introduction of the pneumococcal conjugate vaccine (1997–1999 and 2001–2004, respectively).

During the pre-PCV7 period, 17 of 148 children had positive blood cultures, with pathogens identified in 10 cases (*Streptococcus pneumococcus* in six, *Moraxella catarrhalis* in two, *Staphylococcus aureus* in one, and *Streptococcus pyogenes* in one).

In the post-PCV7 period, 13 of 275 children had positive blood cultures, and a pathogen was identified in only one case (*Enterococcus* sp). The rate of occult bacteremia among children with unexplained fever decreased from 6.8% to 0.4% in the pre- and post-vaccine periods, respectively. Rates of positive urine cultures did not change during the pre- and post-PCV7 periods (6.8% and 7.6%, respectively). About 60% of the children in each period received antibiotics; most (>90%) received antibiotics during the initial ED visit.

Successful immunization programs remove important health risks in children. Children aged 3 to 36 months who have completed *H influenzae* type B and PCV7 immunizations and who present with fever without localizing signs should be evaluated for urinary tract infections. Other cultures (including blood cultures) and treatment should be based on clinical condition and local epidemiology of non-vaccine serotypes.

[Published in *J Watch Ped Adolesc Med*, February 4, 2009—F. Bruder Stapleton, MD.] ■

Nahum Kovalski is an urgent care practitioner and assistant medical director/CIO at Terem Emergency Medical Centers in Jerusalem, Israel.

Burden of RSV Infection in Young Children

Key point: The authors estimate that, in young children, RSV infection is associated with 1 of 334 hospitalizations, 1 of 38 ED visits, and 1 of 13 primary care outpatient visits annually in the U.S.

Citation: Hall CB, Weinberg GA, Iwane MK, et al. The burden of respiratory syncytial virus infection in young children. *N Engl J Med*. 2009;360:588-598.

Respiratory syncytial virus (RSV) is associated with hospitalization in children, but the total burden of disease among young children in the U.S. is poorly understood. The CDC conducted a prospective population-based surveillance study of children younger than 5 years with diagnoses of acute respiratory disease who were hospitalized or presented to emergency departments or outpatient clinics in three U.S. cities during the RSV seasons between 2000 and 2004.

Nasal and throat swabs were obtained from 5,067 children; 919 (18%) had confirmed RSV infection. Co-infecting viruses were identified in only 6% of samples. RSV was associated with 20% of hospitalizations, 18% of ED visits, and 15% of office visits for acute respiratory infections from November through April. Average annual rates of hospitalization for RSV-associated illness were 3 per 1,000 in children younger than 5 years and 17 per 1,000 in children younger than 6 months.

[Published in *J Watch Gen Med*, February 10, 2009—Howard Bauchner, MD.] ■

Age Affects Orthopedic Injuries Seen with Child Abuse

Key point: In children under 18 months, humerus, femur, and tibia/fibula fractures were more likely to stem from abuse than from accidental trauma.

Citation: Brown AJ. Age affects orthopedic injuries seen with child abuse. Reuters Health Information. Published by Medscape, February 27, 2009. Available at *www.medscape.com/viewarticle/588883*.

Whether an orthopedic injury in a child who presents to the ED is predictive of abuse largely depends on the age of the child, according to study findings presented at the American Academy of Orthopedic Surgeons meeting in Las Vegas. The exception is rib fractures, which almost always indicate abuse.

"When examining a child in the emergency room, the clinician should pay careful attention to the age/walking status of the child, and the presence of long bone and rib fractures," lead investigator Dr. Nirav Pandya, from the University of Pennsylvania, Philadelphia, told Reuters Health.

"If clinicians can more readily identify potential cases of child abuse based on the fractures they treat, the morbidity and mortality that a child can experience from returning to an abusive household can hopefully be minimized," he added.

Although other studies have examined this topic in the past, the present investigation is one of the largest, Dr. Pandya said.

Included in the study were 500 cases of child abuse (birth to 48 months) entered in the University of Pennsylvania's Suspected Child Abuse and Neglect (SCAN) database from 1998 to 2007. The orthopedic injuries in these cases were compared with those seen in 985 accidental trauma controls.

In children under 18 months, humerus, femur, and tibia/fibula fractures were more likely to stem from abuse than from accidental trauma. The odds ratios ranged from 12.8 for tibia/fibula fractures to 1.8 for femur fractures.

By contrast, over 18 months of age, humerus and femur fractures were actually predictive of accidental trauma. Moreover, in this age group, tibia/fibula fractures can no longer differentiate abuse from accidental trauma. ■

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Alan A. Ayers, MBA, MAcc

Service industries—from retail stores to restaurants, hotels, and even banks—have embraced the customer's point of view by meshing contemporary design, cutting-edge technology, and process engineering to develop services that are increasingly affordable and convenient.

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But what about healthcare? Healthcare expenditures topped 17% of U.S. gross domestic product in 2008, according to the National Coalition for Health Care, and healthcare is one of the nation's largest service industries. But despite its prominence in the economy, healthcare is plagued with rising costs, decreased accessibility, and increased hassle for patients.

Fortunately, an urgent care center isn't any ordinary doctor's office—it's a delivery model that provides care on patients' terms. Locations in high-traffic retail or residential areas, the ability to walk in without an appointment, extended evening/weekend hours, services for the entire family, and affordable pricing make urgent care more comparable to other service industries than to conventional medical providers. Because of this, patients are likely to compare the service at an urgent care center with what they have experienced at retail stores, restaurants, and other retail establishments that have invested significantly in the customer experience.

Thus, the opportunity for urgent care operators is to redefine quality along retail standards by answering the most pressing question: Is the patient pleased? Pleasing patients depends on delivering an experience consistent with patient expectations; how well urgent care centers embrace quality from the patient's perspective will determine their future growth and profitability.

Table 1. Categories of Patient Expectations[1]

Patient expectations of service quality are categorized across five dimensions:[1]

Reliability: Ability to perform promised services dependably and accurately.

Tangibles: Appearance of physical facilities, equipment, personnel, and communication materials.

Responsiveness: Willingness to help customers and provide prompt service.

Assurance: Knowledge and courtesy of employees and their ability to convey trust and confidence.

Empathy: Caring, individualized attention provided to the customer.

It's important to note that only one attribute—reliability—concerns the service outcome. The remainder of the patient's quality evaluation focuses on the process of service delivery and factors such as the physical environment and the friendliness, competence, and caring attitude of the provider and staff.

Redefining Quality in Urgent Care

There are many ways to define quality in healthcare. Historically, standards have focused on the structure of the medical establishment (e.g., adequacy of facilities and equipment, qualification of providers, and degree of administrative oversight), clinical processes and decision making, and medical outcomes. While all of these criteria are relevant to professional practice, the recipients of care—patients—are usually unqualified to attach meaning to such measures.

By contrast, leading service companies have long understood that if consumers don't like the experience provided, they won't return and they'll tell others to do the same. That's why it's patients—not academics, accreditation agencies, or statisticians—who ultimately define "quality." And whether an urgent care center delivers "quality" depends on how closely the actual delivery of the service (i.e., the patient experience) compares with what the patient expected.

Clearly, to attain satisfaction, a patient must believe the medical reason for the visit was met—but sour employees, bumpy processes, and dowdy facilities can still undermine the best medical outcomes, resulting in patient perceptions of a very poor quality experience. (**Table 1** illustrates how medical practice is only one of five dimensions of service quality.)

If an urgent care center wants to convey quality, it must understand patient expectations of quality and manage service delivery to ensure an experience consistent with those expectations.

Understanding Patient Expectations

Given the relationship between patient expectations and experiences in defining quality, urgent care operators should consider first and foremost the implications of any business decision on patient perceptions—including people (i.e., hiring and training of providers and

staff), processes (i.e., registration, billing, and collections), and physical evidence (i.e., layout and design of the physical facility and other tangibles).

Before a patient ever crosses the threshold of an urgent care center, she has some basic expectations as to what the experience will entail. Patient expectations may be:

Explicit: What the urgent care center, through its advertising and service model, promises to deliver.

Implicit: Not directly stated, but inferred by patients from attributes such as price, location, or appearance of the facility.

Based on word of mouth: What friends, family members, and virtual communities say about their experiences frame expectations for future patients.

Based on past experience: Past experiences not only determine whether patients will return or recommend to others, but they also shape future encounters.

Once in the center, patient expectations continue to be shaped—and experiences delivered—through the interaction of people, processes, and physical evidence. For each, the urgent care operator must understand—and deliver an experience consistent with—patient expectations.

People: Putting the Patient First

Successful urgent care centers seek to hire people with a positive attitude who understand the importance of not just doing their job tasks, but anything else that will contribute to a positive patient experience. Provider and staff attitudes have a direct impact on patient attitudes towards the experience.

Figure 1. Service map.

The service map evaluates all aspects of the patient experience—from the patients' perspective—including what the patients do, where they move, and what they see, think, hear, and say.

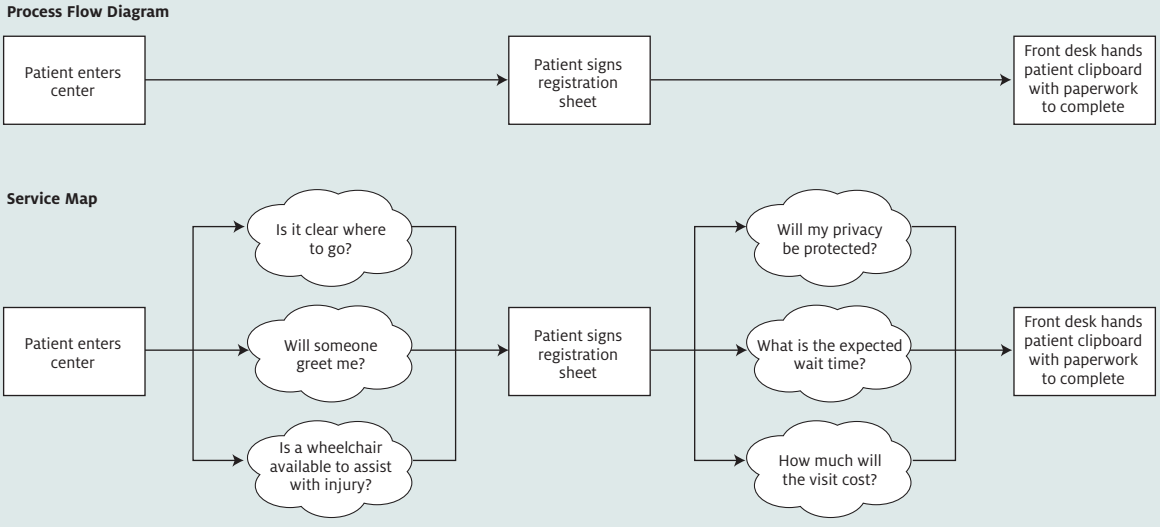

Table 2. Tangible Evidence of Urgent Care Quality

The patient's perception of the quality of urgent care services is heavily influenced by the physical environment in which they're delivered (also called the "servicescape"), as well as by other tangible aspects of the experience.

Facilities Exterior
- Signage type, size, design and visibility
- Building design and architecture
- Landscape and lighting
- Traffic accessibility and parking
- Surrounding environment
- Overall curb appeal

Other Tangibles
- Employee dress or uniforms
- Point of sale marketing materials
- Brochures, magnets, and other collateral
- Patient forms, billing statements, and receipts
- Magazines, refreshments, and other "comforts"

Facilities Interior
- Interior design and décor
- Equipment and furnishings
- Directional and informational signage
- Layout and ease of movement
- Air quality and temperature
- Lighting, music/video, and scent
- Overall ambiance

Mobilizing people to deliver a quality experience starts with understanding that patients want to be treated as individuals versus impersonally being "processed" through a system. A quality experience, therefore, entails greeting patients as they walk through the door, calling them "Mr." or "Mrs.," assisting them in filling out forms, respecting their privacy, asking if they understand the doctor's orders, and thanking them for their patronage.

Understanding patient expectations can help providers and staff anticipate patient needs before they're expressed while demonstrating the required skill to solve patient problems and showing genuine concern for the patient's well-being.

Process: Mapping the Patient Experience

While many urgent care centers conduct patient surveys that evaluate services after the fact, planning good patient experiences also involves directly observing patient behavior in the clinic environment and organizing focus groups to capture patient ideas.

As illustrated by **Figure 1**, developing a service map is similar to developing a process flow diagram in that both evaluate all activities taking place—the difference being that a service map does so only from the patient's point of view. Using observed or simulated patient experiences, the service map illustrates exactly

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what a patient sees, hears, feels, touches, tastes, and even smells in the center.

Direct observation validates a service map by demonstrating instances where patients act outside of the process—for example, interrupting registration to request a change of the television channel. When developing a service map, particular attention should be paid to patient interactions with providers, staff, and the physical environment.

In addition to improving operational processes, the data in service maps can be used to increase effectiveness of providers and staff (e.g., in writing job descriptions or developing training) and to identify enhancements to the physical facility.

Physical Evidence: The Servicescape

Service delivery is intricately coupled with the physical environment—which in marketing is referred to as the "servicescape."[2] Urgent care operators should make perfecting the servicescape a priority because it:

- influences the patient's initial reaction to the urgent care center and affects the patient's ongoing mood during the visit; what are the patient's initial cues to quality coming through the door, and is the overall environment welcoming or intimidating, calming or stressful?
- differentiates from competitors; could a patient distinguish your urgent care facility from a competitor if all signage were removed?
- facilitates a transaction; is signage visible and worded in such a way that patients readily understand, and is the facility layout intuitive such that patients move in a logical, orderly fashion and that staff can treat patients with minimal number of steps and obstacles?
- creates a social environment; does the space facilitate or hinder communication between and among patients, staff, and providers?

Physical evidence encompasses the servicescape and all other tangible aspects of the experience, as detailed in **Table 2.** The goal of creating a service environment conducive to good patient experiences, and that also differentiates an urgent care center from competitors, is why many urgent care operators invest in retail-facing locations with comfortable furnishings and a polished fit and finish.

Exceeding Patient Expectations

A frequent cliché when speaking about the patient experience is the goal of "exceeding patient expectations." The problem with this is that it sets the bar higher for future experiences. The goal shouldn't be to *exceed* patient expectations, but to meet them consistently.

For example, the first time I worked on assignment in San Francisco, the hotel upgraded my stay to a corner room with floor-to-ceiling windows providing a magnificent view of the city and bay. The room far exceeded my expectations for the corporate rate paid. On my next trip I booked the same hotel, only to be disappointed when I ended up on the fifth floor overlooking a rooftop air conditioning unit.

The hotel delivered the product it promised—the downtown location, comfortable bed, and exercise facilities—but my expectations on the total experience had been artificially raised so much on my first visit that I was disappointed when I returned.

Similar experiences occur when a new urgent care center—without an established patient base—is able to offer quick service and personalized attention. But once volume ramps up, wait times may begin to extend and the staff soon scrambles to quickly process patients. Repeat patients are likely to comment "service has really gone downhill" when in reality, the experience simply normalized after expectations had been set.

Measuring Service Quality

Because service quality is the difference between patient expectations and experiences, the only effective way to evaluate service quality is to ask patients to describe their visits to the center. Such can be accomplished by quantitative and qualitative methods.

Transactional surveys assess patient experiences immediately after their visits and utilize touch-screen kiosks, comment cards, and mail, e-mail, or telephone questionnaires. When asked to score various elements on a scale of 1 to 10, impressions can be quantified and tracked—both across centers and over time—while also providing performance-based data for employee incentives and management rewards.

While quantitative data may be directionally accurate, one shortcoming is that they don't distinguish among differing patient expectations. In addition, aggregated data cannot be used to remedy specific instances of poor service. Written patient comments provide more detail as to patient expectations and experiences.

Qualitative feedback is particularly useful in responding to specific patient issues. But in order for qualitative feedback to effect organizational change, a classification scheme must be developed to identify the most frequent types of patient feedback and trends over time. In most

cases, patient comments are used to provide anecdotal evidence for data contained in qualitative measures.

The disadvantage of all patient surveys is that they don't measure the experiences of non-patients, such as referral sources or patients who balked before being served.

In addition, dissatisfied patients often don't respond to surveys but rather, "vote with their feet."

Return on Service Quality Investment

Providing a quality patient experience does require investment—in people, processes, physical assets, and measurement systems. The link between these investments and profits is not direct, although intuition and experience indicate that it does exist.

Consider the lifetime value of a patient who returns twice a year, every year, for the next 30 years. Not only is such a patient a reliable source of revenue, but if satisfied, will pay a price premium for future services while recommending the center to others.

By contrast, when a dissatisfied patient leaves, marketing costs must be incurred to attract a new patient and to counterbalance any negative word of mouth.

Investments made to improve the patient experience contribute to top-line revenue through increased volume and prices while also reducing overhead through improved operations efficiency.

Conclusion

Urgent care is distinct from other healthcare providers—and similar to retail and other service industries—in its orientation around patient affordability, convenience, and ease of use. Therefore, patients measure the service provided against retail-oriented businesses that have invested significantly in the patient experience.

Building a quality urgent care operation involves observation and data analysis to understand patient expectations and then developing people, processes, and physical environments that will deliver an experience consistent with those expectations. ■

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CODING Q&A

Coding for Observation, and More on Established vs. New Patients

DAVID STERN, MD, CPC

Q. Is it possible for observation status codes (99217-99220) to be billed in an urgent care facility?
– Question submitted by Andrea Manfredi-Rivera, CCS-P, Staten Island Physician Practice

A. Observation codes will require the point of service (POS) to be a hospital. If your urgent care is operated by a hospital and you can legitimately use a hospital POS, then you may be able to use these codes. If you use the physician office (POS -11) or urgent care (POS -20) place-of-service codes, then you could not use these codes compliantly.

With these types of issues, however, there is always one caveat. If, for some reason, you find that your center is positioned such that you frequently provide (or would be able to provide) observation status for patients that would otherwise receive hospital admission or hospital observation, then using observation services in your urgent care (instead of the hospital) could significantly reduce costs to payors. If this is the case, you may want to consider going directly to the payors, educating them as to the value to them for patient satisfaction and cost reduction. If they are convinced, then they may be willing to sign a contract addendum that allows you to bill for observation from POS -11 or POS -20.

Q. Is there another way (in addition to the E/M code) to code for prolonged observation or treatment of a patient in the urgent care setting?

A. Yes. Prolonged observation in the urgent care setting can be coded with the following codes:

- 99354: Prolonged physician service in the office or other outpatient setting requiring direct (face-to-face) patient contact beyond the usual service (e.g., prolonged care and treatment of an acute asthmatic patient in an outpatient setting); first hour (list separately, in addition to the code for office or other outpatient Evaluation and Management service)
- 99355: Prolonged physician service in the office or other outpatient setting requiring direct (face-to-face) patient contact beyond the usual service (e.g., prolonged care and treatment of an acute asthmatic patient in an outpatient setting); each additional 30 minutes (list separately in addition to code for prolonged physician service)

It is important to note that these codes require the provider to be "face-to-face" for the entire time that is used for calculating the proper code.

For example, code 99354 can be used if the physician spends 45 minutes in the room caring for a very ill patient. Do not, however, use these codes simply to code for time that the patient ties up a room while getting nebulizer treatments or hydration therapy.

In the urgent care setting, it is very rare for the physician to spend this amount of time in "face-to-face" contact with the patient. Thus, it is very rare that these codes would be appropriate in the urgent care setting.

Q. Can an urgent care facility do away with the established patient codes and just use new patient codes all the time, since the patient will more than likely not see the same provider at the urgent care?
– Question submitted anonymously by e-mail.

A. You make an interesting suggestion, but this would not be a compliant method for coding. Instead, you would have to make sure that any physician(s) who saw the patient in the last three years in your practice was actually of a different specialty than the specific physician who is seeing the patient for today's visit. If the patient had not received services from a physician of that specific specialty, then it would be compliant to code a new patient E/M code.

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CODING Q&A

Since tracking the actual specialties of physicians performing the services for each and every visit involves so much work, most practices simply look to see if a patient has been treated by a physician (without regard to specialty) in the urgent care in the past three years. If so, then the visit is coded with an established patient E/M code.

Q. Can 99211 be used for a new patient visit that has been referred to urgent care from the emergency room only for antibiotic injections? In this situation, the patient presents with a prescription for doctor's orders and the injections are given by the nurse.

– Question submitted by Ruth J. Lawson, CCS-P, McAlester, OK

A. CPT code 99211 should not be used for a *new* patient visit to the urgent care. One possible exception to this rule would be if the emergency department was operated by the same hospital and billed under the same TIN. In that case, the patient would already be an *established* patient in the hospital. If this is not the case, however, then the patient should be seen by the physician on the first visit to establish the patient in the practice.

On follow-up visits, or visits by patients who are already established in the urgent care, you may use 99211 to code for the visit. A physician should be on site during the visit. The medical record should include more documentation than simple vital signs and "injection given."

In order to qualify for a 99211, the nurse should document pertinent history, physical, and instructions, i.e., there needs to evidence of true "evaluation and management" by the non-physician staff member. Here is an example chart note:

- S: Patient states pain from abscess is decreasing. Denies fevers and chills.
- O: Abscess in right calf with 5x5cm of redness with minimal discharge.
- A: Abscess, right calf
- P: 1. Rocephin, 500 mg, IM, right gluteus maximus, lot number...
  2. Recheck 6/5/09
  3. Patient instructed to return or go to ED if pain increases, fever >101 or any other concerns.

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Pull Up! Pull Up!

JOHN SHUFELDT, MD, JD, MBA, FACEP

I am often asked what inspired my love of flying. Although this is the first time I have admitted it in public, I am proud to say that it all began with the movie *Airplane!*

Dr. Rumack: You'd better tell the captain we've got to land as soon as we can. This woman has to be gotten to a hospital.
Elaine Dickinson: A hospital? What is it?
Dr. Rumack: It's a big building with patients, but that's not important right now.

As it happens, this was just the first of the movie's many take-home messages. The deeper meaning, along with my love of flying, grew steadily over the ensuing years. One thing I have learned is that there is always more to learn.

My most recent aviation education experience took place at Flight Safety International. It was an intensive program designed to offer students a "type-rating" in a particular aircraft.

When I first arrived, I thought, "How hard can this be?" The answer came in short order; it turned out it could be, and was, *hard*! Typical days were 12 hours long, consisting of intense classroom sessions, self study and flying realistic, full-motion simulators.

Once, when my flying partner crashed on takeoff during a simulated engine failure, the instructor offered, "Don't worry, you're fine. You are so far behind the plane that you are still in the terminal."

Looking back, I can't imagine how I learned so much in such a short period. Along with the necessary skills and knowledge related to flight, I gained some insight that is readily applicable to the business of urgent care:

1. **It is possible to make large course changes in a short amount of time with incomplete data**. The newer, glass cockpit airplanes often have an instrument called the Traffic Alert and Collision Avoidance System, or TCAS, to identify other airplanes in close proximity. Once a conflict is identified, the pilot may be required to take immediate evasive action by abruptly changing course or altitude. The pilot must be quick and decisive. "Analysis paralysis" can prove fatal.

Dr. Rumack: Can you fly this plane, and land it?
Ted Striker: Surely you can't be serious.
Dr. Rumack: I am serious...and don't call me Shirley.

Analysis paralysis is the condition caused by repeated and often unnecessary data collection and dissection down to the minutia.

In the urgent care business, this commonly manifests as an indecisive manager stalling interminably to "analyze data" in an attempt to avoid appearing ineffective. As is the case for the pilot, you must learn to analyze, decide, and take action efficiently. Too often, businesses will languish while the data are collected.

2. **When you are off course, you have a very short, finite amount of time to correct the heading before you and your passengers meet with a terrible outcome**. When a plane is on an "instrument approach" (managing the flight path based on data from instrumentation), the margin for error is minuscule, and the pilot must monitor closely to keep the plane on the glide slope. Failure to do so could be catastrophic.

Rumack: Elaine, you're a member of this crew. Can you face some unpleasant facts?
Elaine Dickinson: No.

When things are not going as planned in the urgent care center, waiting until the metrics are far off before initiating course corrections can be equally catastrophic.

If, for example, visits are down—thereby impacting revenue—you must take action *immediately*. Start by

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changing staffing levels, and focus your energies on finding other opportunities to reduce expenses. If you wait until the end of the month to preserve the bottom line, it may well be too little too late.

Multiple, constant, small course corrections not only provide a more direct route to your goal than large, intermittent changes, but they are also significantly less disruptive to the organization.

The time to be aggressive is when you are behind the curve.

3. **When you are low and slow, add power to increase your airspeed and climb**. On an approach, the worst thing a pilot can do is get slow below the glide slope. If the landing must be unexpectedly aborted, being low and slow is akin to running in waist-deep water.

Steve McCroskey: I need the best man on this. Someone who knows that plane inside and out, and won't crack under pressure.
Johnny: How about Mr. Rogers?

One of my pet peeves is the oft stated, "You know how things slow down around the holidays." It is not as if Thanksgiving, Christmas, Hanukah, Festivus, and New Year's crash down upon us out of the blue. Every year around the same time, there will be a certain amount of scheduled time off. That in mind, plan ahead to forestall avoidable delays. When the organization reaches a low and/or slow point, add power; work longer, harder, and smarter.

The time to be aggressive is when you are behind the curve. Never mind how you got there, power up and fly out while you still can.

4. **In an emergency, having too much data is a bad thing**. One cool thing about the plane I am "typed in" is that when things are going badly, the plane limits the amount of data it feeds the pilot so as not to overwhelm him or her. The last thing a pilot needs in an emergency is a cacophony of bells and alarms distracting from a rapid review of the vital check list.

Captain Oveur: You ever been in a cockpit before?
Joey: No sir, I've never been up in a plane before.
Captain Oveur: You ever seen a grown man naked?
Captain Oveur: Joey, have you ever been in a...in a Turkish prison?

Much like Captain Oveur, the urgent care operator must limit communication during an emergency to necessary data points. Do not join the "I 'cc' everyone on everything to cover my gluteus" club. No one has unlimited capacity, so determine what your team members actually need to know, and avoid sending them everything that they "might find interesting" in a calmer and more perfect world.

5. **You can keep very busy in an airplane accomplishing nothing that will save you**. Do you know people who seem really busy (and tell you they are really busy) but who, for whatever reason, don't actually accomplish anything?

Rumack: The last thing he said to me, Doc, he said, "Sometime when the crew is up against it, the breaks are beating the boys, tell them to get out there and give it all they got and win just one for the Zipper. I don't know where I'll be then doc, he said, but I won't smell too good, that's for sure.
Ted Striker: Excuse me doc, I got a plane to land.

I occasionally see this exhibited in the emergency department. Some physicians manage to look like they are moving a mile a minute, yet no patients are moving through the department.

As the old adage states, "If you are not fired with enthusiasm, you will be fired with enthusiasm." If your team is not moving, light a fire under them. If they refuse to move in the face of fire, fire them. One positive aspect of the market today is a plethora of great talent eager to work in the healthcare service industry.

At flight safety, I heard (and used) every excuse imaginable: the autopilot is f***ed up, the sun was in my eyes, the engine quit, the flight instructor went out, a flock of seagulls (not the 80s band, but the Captain Sully version) hit the plane, thunderstorms, hail, syphilis, you name it!

In running an urgent care center, you may encounter a similar spectrum of "justifications." As the leader, you must refuse to either settle or accept excuses.

This is our time. The urgent care industry is changing the face of healthcare in the United States. Losing the initiative as the result of trepidation in execution is unacceptable.

Personally, I would rather crash into a mountain at Mach 1 than stall and spin to the ground for lack of power and altitude (attitude). We must not fail during this critical juncture. If somehow we do...it appears that *"I picked the wrong week to quit sniffing glue."* ■

Evaluating Your Clinic's Competitive Strengths

FRANK H. LEONE, MBA, MPH

The ability to recognize, understand, evaluate, and articulate your clinic's competitive strengths is central to a superior sales and marketing performance. Yet even the most polished sales efforts tend to fall short in one or more of these areas.

An urgent care clinic is likely to either neglect its competitive strengths or offer a wooden recital of them. Clinics are rarely proactive in:

- assessing their strengths vis-à-vis their competition
- matching competitive strengths with sales prospect values as appropriate
- expressing their competitive strengths in a persuasive manner.

I believe that seven principles are essential if you wish to take advantage of your competitive strengths.

1. Keep "competitive" in your definition of "competitive strength."

A competitive strength is not necessarily an attribute in a pure sense (e.g., 24-hour service, multiple delivery points, certified staff). Rather, a competitive strength is simply something you do better than your competition.

For example, in one market having a board-certified occupational medicine physician on staff may not be a competitive strength because competitors also have board-certified physicians. In another market, a program may use an experienced, but non-certified, physician but still maintain a competitive edge because the competition's medical director is neither certified nor experienced.

We are talking about relative—not absolute—attributes in virtually every instance.

Frank Leone is president and CEO of RYAN Associates and executive director of the National Association of Occupational Health Professionals. Mr. Leone is the author of numerous sales and marketing texts and periodicals, and has considerable experience training medical professionals on sales and marketing techniques. E-mail him at *fleone@naohp.com*.

2. Let your market define what is important.

Assume that you cannot wait to tell your clients and prospects about a new board-certified occupational medicine physician who has joined your team. Think first before you rush out to share the good news. If your market is mired in recession, or the majority of injuries seen in the clinic are minor, some employers may perceive your board-certified occupational medicine physician as too expensive or overqualified for their needs. Accordingly, it is imperative to match your clinic's distinguishing characteristics with at-the-moment marketplace value *before* anointing the characteristic as a "competitive strength."

"If a clinic doesn't have a genuine competitive strength, it must develop one."

3. Your competitive strength is directly correlated to the difference in perceived value of that advantage between your program and your competitors.

The value of your potential competitive strengths are directly related to the strength of that advantage among your competitors.

Assume that research indicates that employers desire 24-hour access and that you are the only clinic in town with such coverage. This strength is not very strong if a competitor's clinic is open 20 hours per day or the competitor has an arrangement with a prestigious local hospital emergency department for after-hours care.

It is necessary not only to note what competitive strengths your clinic maintains but also to subjectively estimate the gap between that advantage and the status of the next best option.

To genuinely assess the power of your clinic's competitive strength portfolio, you need to answer three questions:

- Are we the best option based on these criteria?
- How much better are we than the next best competitor?
- Just how important is this attribute to our market?

4. Cite your competitive strengths selectively and only when appropriate.

What is important at the collective market level does not necessarily carry over to the individual prospect level. In a market in which employers collectively do not find the availability of a multiple clinic network to be a compelling advantage, many *other* employers are still likely to find that attribute important.

A sales professional should interview prospects to identify how much value they place on an array of potential competitive strengths. The salesperson can then refer to the clinic's competitive strengths without mentioning the "competition" directly.

5. Articulate your competitive strengths in simple, concise and persuasive terms.

The impact of your competitive strength is too important to be lost in a quagmire of information and verbiage. Competitive strength messages should be simple and easy to understand. Articulation of a competitive strength must focus on what is important to the prospect.

6. Summarize relevant competitive strengths at the conclusion of sales calls, phone calls, or written proposals.

Each sales call, important telephone call to a prospect, or written proposal should conclude with a strong summary statement. Beyond the obligatory summary of key points and action steps, a custom-crafted competitive strength summary can be quite helpful. **Table 1** presents a prototype competitive strength statement.

7. Develop competitive strengths when none seem to exist.

For every urgent care market leader, there are likely to be several market challengers. Often, market challengers are new or immature programs, or programs hampered by constraints such as poor location, fewer financial resources, or a less respected corporate name. In many instances, market challengers have fewer competitive strengths than the market leader.

If a clinic does not have a genuine competitive strength, it must develop one. This process invariably begins with the marketplace itself by identifying the primary voids that seem to exist among the market's occupational health providers. Once such voids are identified, steps can be taken to enhance your clinic's capabilities to fill the gaps. ■

Table 1. Competitive Strength Worksheet

This sample worksheet demonstrates how you can evaluate your clinic's most powerful competitive strengths. Columns 1 through 4 measure your program against the competition. Columns 5 and 6 factor in the perceived value placed on the attribute by your market. Your clinic's net score is the product of the net (dis)advantage times the market's value of that strength (your strength – competitor's strength x market value = net score).

	1	2	3	4	5	6
Strength	**Your program***	**Competitor #1***	**Competitor #2***	**Net (dis)advantage**	**Market value†**	**Net score**
Physician(s)	9	5	5	4	3	12
Availability of outcome data	9	3	3	6	1	6
Program Director	10	8	4	2	2	4
Reports	9	5	2	4	1	4
Locations	9	8	3	1	3	3
Hours of operation	10	6	10	0	2	0
Clinical staff	8	8	8	0	3	0
Linkages to rehab services	7	7	9	(2)	1	(2)
Reputation	7	8	4	(1)	3	(3)
Fees	7	8	9	(2)	2	(4)

*Your subjective opinion, on a scale of 1 to 10. †Can be based on your subjective opinion or on market research data; 3 indicates the highest score and 1 the lowest.

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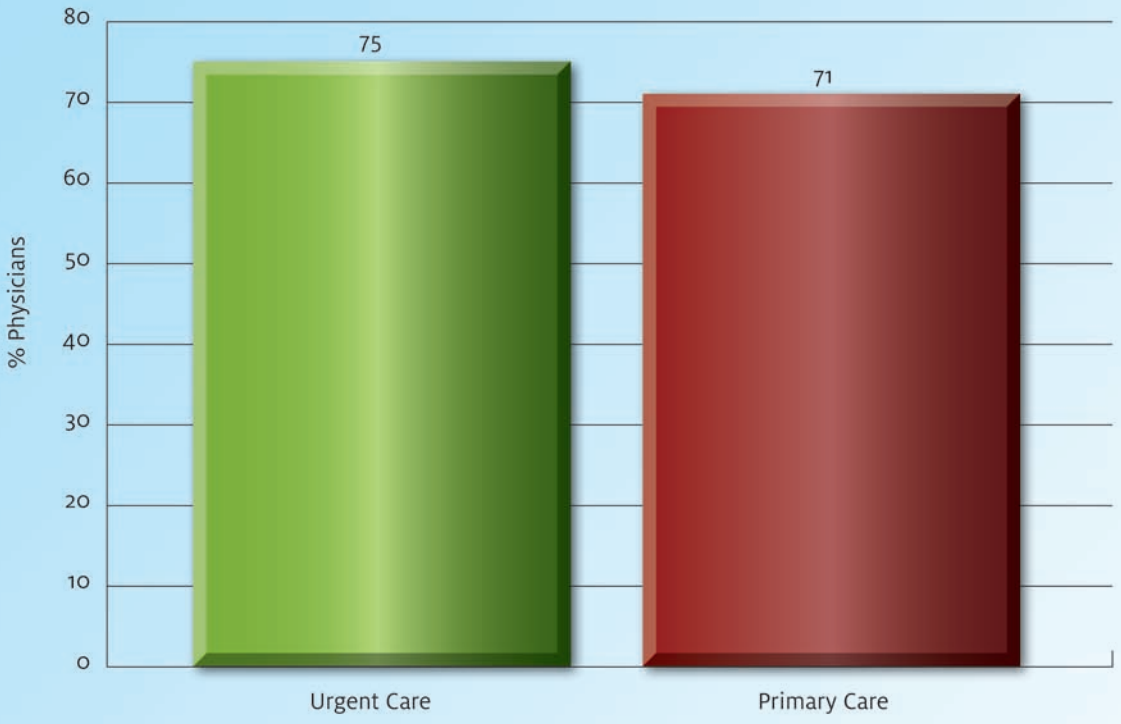
DEVELOPING DATA

In early 2008, UCAOA revamped its annual survey in conjunction with researchers at Massachusetts General Hospital and Harvard University with the goal of assuring that the UCAOA Benchmarking Committee's efforts produced a scientifically valid report.

Here we present some of the findings from this landmark survey, to which 436 urgent care centers responded.

In this issue: What percentage of physicians working in urgent care are board certified—and how does that compare with primary care?

BOARD CERTIFICATION: URGENT CARE VS. PRIMARY CARE



The survey also revealed that 85% of urgent care centers have at least one physician on site whenever the site is open.

Acknowledgment: Data submitted by Robin M. Weinick, PhD, at the time, assistant professor, Harvard Medical School and senior scientist, Institute for Health Policy, Massachusetts General Hospital and currently senior social scientist, RAND. Dr. Weinick is also a member of the *JUCM* Advisory Board. Financial support for this study was provided by UCAOA.

If you are aware of new data that you've found useful in your practice, let us know via e-mail to *editor@jucm.com*. We'll share your discovery with your colleagues in an upcoming issue of *JUCM*.

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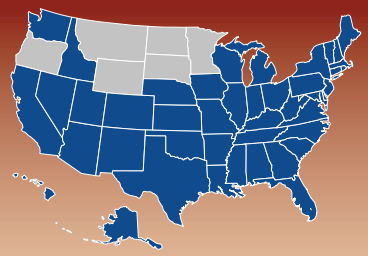

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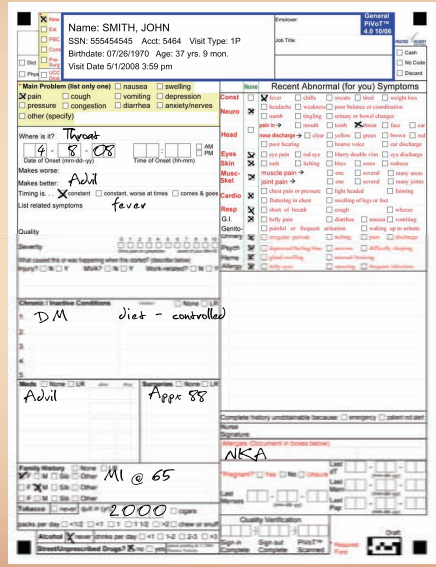

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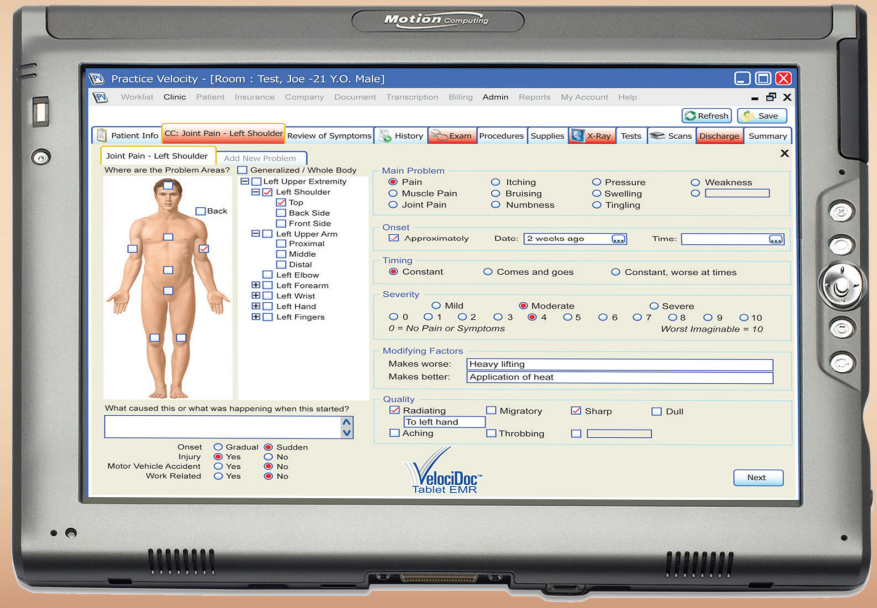

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