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IN THIS ISSUE

Second in a Two-part Series

Toward Ensuring Patient Safety in Urgent Care

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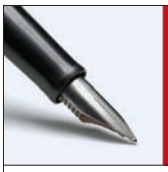

LETTER FROM THE EDITOR-IN-CHIEF

Of Swine Flu, 'Chicken Little,' and the Great Depression

History teaches us so many lessons, most of which we quickly forget until the next history-making crisis. Nothing in history is a more predictable crisis producer than "fear." Fear sows panic, panic sows irrational behavior, and irrational behavior sows wars, economic disasters, bigotry, and protectionism.

When the dust settles, we analyze our missteps and, often, recognize most of the fallout could have been avoided had we learned from history.

The Great Depression was a real economic crisis rooted in overinvestment and the crash of 1929, but fear and lack of confidence added many more years of pain as armchair economists around the country fled the markets and froze consumption in fear of what *could* happen. "Better safe than sorry" turned into a crisis of confidence that further brutalized the markets.

And then, Franklin D. Roosevelt would famously say, "The only thing we have to fear is fear itself." One sentence, saying absolutely nothing concrete, changed the way we perceived the crisis, and led to a slow, but steady, rise in confidence that ultimately led us out of perpetual economic doom. Every economic depression since, regardless of cause (oil scares, savings and loan failures, dot com busts, real estate busts) follows a similar pattern of recovery. Public confidence, ultimately, determines when the depression ends.

So what does all this have to do with swine flu (now known as the far less threatening-sounding H1N1)? Only six short years ago, SARS taught us several lessons in public health, most of which we quickly forgot. Perhaps the most notable: The fear of the disease often has a far greater impact than the disease itself.

Though 1,000 people died from SARS worldwide, we all know this pales in comparison to the deaths from seasonal flu every year. Yet, people canceled flights, donned the familiar surgical masks, and created an economic impact far greater than the reality of the outbreak. Much of this was fueled by the same "fear of what could happen", and the "better safe than sorry" approach that prolongs must economic depressions.

In the end, the surgical mask was deemed of little value, and in the end, the public health message was honed down to "wash your hands" and "stay home if you're sick."

So, here we go again, with swine flu—doomed from the start by its name alone. Panic, fear, protectionism, face masks, and an economic impact far greater than the reality of the public health threat. The CDC stumbled in the first week of the scare, changing their recommendations sometimes twice daily and often out of step with local health departments. This, despite the fact that the plan of test-and-treat should have been for the sickest patients and those at risk for complication from the very beginning.

Closing schools turned out not to be the answer, and the face masks, once again, proved of little worth. All lessons we should have learned from SARS. Businesses suffered at a time they could ill afford to. An entire country (Mexico) and all of its citizens were hung out to dry, leaving an already precarious neighbor on the brink.

Don't get me wrong, a real pandemic is nothing to sniff at, and is still possible with H1N1. Even if it remains a mild illness, a pandemic could sicken a full one-third of the world's population and lead to thousands of deaths. But you are still more likely to die of the seasonal flu in your lifetime, and you don't shutter the doors every winter, or cancel your trip to Mexico.

The lessons are simple, and have not changed:

- Wash your hands frequently.
- If you do get sick, stay at home, and stay away from those most vulnerable.
- Seek treatment if you are at high risk for complication or are very ill.
- Do not seek treatment "just in case."

And one more thing: Nothing turns a "scare" into a "crisis" more quickly than when someone yells, "The sky is falling! The sky is falling!" ■

Lee A. Resnick, MD
Editor-in-Chief
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CLINICAL

IN THE NEXT ISSUE OF *JUCM*

Head lacerations are a common presentation in urgent care. In addition to treating the wound itself, what other steps should the clinician take to assure a positive outcome?

WEB EXCLUSIVE

Outpatient Management of Opioid Dependence in Urgent Care

Opioid dependence is a significant problem in the U.S. You may be able to help patients in need while also adding a new facet to your business. Exclusively on *www.jucm.com.*

By Paolo T. Coppola, MD, FACEP and Matthew I. Salzberg

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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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LETTERS TO THE EDITOR

Regarding Our March and May Issues

Lower Extremity Edema

To the Editor:

While I generally found Evaluation and Management of Lower Extremity Edema (by Michael S. Miller, DO, *JUCM* March 2009) interesting and informative, I was disappointed there is no mention of using a D-dimer as a screen.

It seems to me studies such as Evaluation of D-Dimer in the Diagnosis of Suspected Deep-Vein Thrombosis (Wells PS, et al, *N Engl J Med* 2003;349(13):1227-1235) show that D-dimer is useful at differentiating which urgent care patients need referral for further testing such as Doppler US or CT angio.

David Hoyer, MD FAAEM
Clinical Assistant Professor of Emergency Medicine (Vol.)
The University of Texas Health Science Center at Houston
Attending Emergency Physician
Clear Lake Regional Medical Center, Houston, TX

Dr. Miller responds: I agree with Dr. Hoyer and thank him for his response. Clearly, D-dimer has a place in screening for DVT. However, as with all tests, appropriate indications should be identified.

Despite good evidence that D-dimer is a valid screening test, there is still a tendency by many to go right to the deep venous Doppler as the "screening" test. However, it is unrealistic to use this in all patients due to the cost.

With respect to DVT, stratifying patients as having high, moderate, or low probability of DVT/PE can help identify which are most at risk. The D-dimer then can be used to identify which patients need additional evaluations.

Nonetheless, the cost of even this test needs to be considered, as at one of my facilities the cost of a D-dimer is $198.50; it then takes 1 1/2 hours to get the results.

My goal in the article was to encourage clinicians to use common sense in establishing a diagnosis and initiating treatment for the plethora of venous-related disorders.

Pulmonary Embolism

To the Editor:

The brief report on the diagnosis of pulmonary embolism (A Patient with Suspected Pulmonary Embolism, by John Shufeldt, MD, JD, MBA, FACEP and Kelli Hickle, *JUCM* March 2009) is a good overview. The best way to avoid missing a pulmonary embolism is to have a high index of suspicion. It is imperative, as noted in the article, to know the risk factors for PE and to document those risk factors or their absence on the patient's chart.

I must take issue, however, with the author's reference to the use of the D-dimer to rule out PE.

The author states that a normal D-dimer can almost always rule out a PE in the outpatient setting. This statement should be qualified.

The fact is that the D-dimer test is only useful to rule out a PE in those patients with a lack of risk factors and in whom one has a low index of suspicion. In all other patients, it is completely useless and I would not recommend its routine use.

In any patient who presents with any risk factors for PE, or in whom a PE is clinically suspected for whatever reason, the appropriate thing to do would be to arrange for a STAT outpatient CT angiogram or VQ scan. Alternatively, the patient should be sent to the ED for imaging.

Still, even if imaging is nondiagnostic, a PE is not ruled out if there is a high index of suspician. Those patients should be admitted and treated with anticoagulation. Remember that the diagnostic gold standard is still the pulmonary angiogram.

Joseph A. LiMarzi, MD
Newton Memorial Hospital, Newton, NJ
Milford Urgent Care Center, Milford, PA

Continued on page 8.

JUCM CONTRIBUTORS

Ideally, patients leave the urgent care center on their way to recovering from whatever complaint led them there in the first place. Sometimes that's not possible due to the nature of their condition or other factors beyond the clinician's control. Other times, however, patients come in with one illness and walk out with two due to infection they picked up in the facility.

The conclusion of Toward Ensuring Patient Safety in Urgent Care (page 11) addresses prevention of healthcare-related infections as well as radiation safety, preparation for everyday emergencies like a fire on the premises, and other topics germane to keeping patients and staff safe within the confines of the urgent care center.

Part 1 of the article (*JUCM*, May 2009, available at *www.jucm.com*) by **Phillip H. Disraeli, MD, FAAFP** focused 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.

Failing to identify the cause of a patient's symptoms is an entirely different issue, of course, but clearly one that is of at least equal importance. The consequences of missing key factors can be deadly for the patient, devastating for his family, and ruinous for the practitioner. The Story of Jonathan—One Week in January (page 25), the latest installment of Bouncebacks by **Michael B. Weinstock, MD** and **Jill C. Miller, MD**, is the tale of an artist who was on the brink of his big break when he was misdiagnosed by numerous practitioners at two different institutions.

Sometimes, it's not the diagnosis that proves elusive, but the etiology. Such is the message of a case report contributed by **Rajan B. Masih, MD, FACA, FICA** and **Anil Makani, MD, FACS, FRCS**. Appendicitis Due to Squirrel Dinner (page 32) also illustrates the importance of considering a patient's lifestyle and regional customs when trying to get to the bottom of a case. Dr. Masih is medical director of Hardy County Medical Urgent Care in Moorefield, WV and clinical assistant professor of emergency medicine at West Virginia University School of Medicine. Dr. Makani is attending surgeon at Grant Memorial Hospital in Petersburg, WV.

Finally, we are launching a new initiative with our June issue. Each month, in addition to the original content published in *JUCM*, we will debut an additional article exclusively on our website (*www.jucm.com*).

For the first web bonus, we've selected an article that furthers our efforts to shed light on clinical services that serve the dual purpose of treating more patients and introducing new facets to your practice.

Outpatient Management of Opioid Dependence in Urgent Care, by **Paolo T. Coppola, MD, FACEP** and **Matthew I. Salzberg**, makes a case for becoming certified to prescribe buprenorphine-naloxone for opioid dependence. In addition to explaining the certification process, the authors discuss the withdrawal experience, how to identify potential patients, and staff and business concerns when introducing this new service into your practice.

Dr. Coppola is a founding partner of Stat Health Immediate Medical Care, PC, in Smithtown, NY. Mr. Salzberg is entering his senior year at Tufts University, where he is a Biology and Pre-Med major.

Also in this issue:

Nahum Kovalski, BSc, **MDCM** reviews abstracts on acute myocardial infarction in patients presenting with syncope, crying babies, exacerbations of chronic obstructive pulmonary disorder, and pediatric fatalities associated with use of over-the-counter cough and cold medications.

Frank Leone, MBA, MPH suggests methods of identifying—and forging a relationship with—the "right" contact person at a prospective occupational medicine client company.

John Shufeldt, MD, JD, MBA, FACEP offers a short course in torts pertinent to urgent care medicine. Congratulations are in order for Dr. Shufeldt; for the second year in a row, the Health Law column he contributes to *JUCM* has been awarded a Bronze Award by the American Society of Healthcare Publication Editors in the category of Best Regular Column: Contributed.

David Stern, MD, CPC answers questions about coding for particular supplies, new patient E/M codes, and how to decide whether a procedure is better considered as "lesion removal by shaving" or as a biopsy, for coding purposes.

If you have an idea for an article—an interesting case, a business idea that's working out well for your urgent care center, or a more academic clinical topic—please let us know. Send an e-mail to Editor-in-Chief **Lee A. Resnick, MD** at *editor@jucm.com*. ■

LETTERS TO THE EDITOR

Dr. Shufeldt responds: Dr. LiMarzi is correct; using a D-dimer in a patient without significant risk factors is appropriate. For those patients with significant risk factors, imaging (particularly a CT angiogram) is the best way to rule out a pulmonary embolus.

Insights in Images: Motorcycle Injury

To the Editor:

I agree with the diagnosis (non-displaced, intra-articular pilon fracture of the distal tibia, contributed by Nahum Kovalski, BSc, MDCM; Insights in Images, *JUCM*, May 2009) but disagree with the management. It recommends additional views of the fracture site. This is one reason to not cast the ankle. Now the cast would have to be removed. The other reason is that the person who puts the cast on should do the follow-up care.

We would use an ankle splint and refer to orthopedist. The orthopedist then can charge for the closed reduction and/or casting. They then assume the follow-up care.

Our urgent care attempts to be an extension of the primary care office and we do not routinely do procedures that should be done by specialist. This has worked out well because PCPs and other specialist refer patients they cannot see at the time to us. We then do the necessary exam, testing, and diagnosing. We then take care of the patient for the short term and refer to the specialist or PCP for the long-term follow-up.

Jim Bean, MD
Home Town Urgent Care,
Springboro, OH

Dr. Kovalski responds: Physicians at Terem Emergency Medical Centers in Jerusalem never apply full casts. Perhaps I should have specified that a "cast splint"—what might be called a plaster splint, fiberglass splint, or custom splint in the U.S.—was applied. This allows the follow-up physician to remove the cast splint in seconds and continue evaluation as needed.

I agree wholeheartedly that our urgent care approach is to assist PCPs and specialists. From our experience in Israel, the application of cast splints at Terem is welcomed by all that provide the continuing care. ■

Hearing Voices

LOU ELLEN HORWITZ, MA

Talk of healthcare woes and healthcare reform is everywhere. The system is broken, the costs are out of control, the providers are scarce and getting scarcer, and on and on and on.

Every now and then, urgent care is mentioned as an area that is actually working and serving the need it was created to serve. What's curious to me is why it's not more ubiquitous in the conversations.

While we are seeing more and more coverage in the media, and patients are certainly filling up your centers nationwide, I can recall urgent care being referred to only once in the context of policy making. Why is that, and what can we, as an industry, do about it?

Though we as an association are perhaps comparatively young and small, as an industry urgent care is well populated—and growing. As a group we provide at least a partial solution to America's healthcare woes, but we may be so focused on getting the job done (seeing patients!) that we are not paying enough attention to getting our voices heard.

If you recall from that wonderful Dr. Seuss book, *Horton Hears a Who!*, the Whos didn't elect a representative to "Yawp!" on their behalf; it took every single one of their voices for them to be heard at last. Now, we are not all living on a speck on a flower and about to be boiled in oil (at least I don't think we are)—but I do think we are all in agreement that there is a lack of awareness about urgent care at many important levels.

The first place your voices need to be heard is actually the easiest for you—at your local level. Do your local mayor, alderman, congressperson, representative, school systems, media (print, radio, TV, Internet), sports teams, state clinical societies, every physician in town, retail clinics, hospitals, chambers of commerce, fire department, police station....know you exist? Better yet, do you have a *relationship* with these people?

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

Everyone knows someone else that you probably don't know. Everyone is in a circle of influence that you may not be a part of yet. Whether it's a children's play group or a healthcare reform task group, you never, never, never know who may put your name or your clinic's name in the right place at the right time. I can guarantee, however, that if they've never heard of you, the likelihood of that goes down considerably!

"Your support will determine how fast and how far we go in the many projects you want us to undertake."

So, while you are working on your "grassroots" areas, what is UCAOA doing? There are two main initiatives to help move this concept forward:

1. Legislative and Regulatory Committee: This group is looking at ways we can be more involved and/or accessible for participation in the legislative and regulatory processes in our states and at the national level.
2. Foundation Development Committee: This group is working to create a foundation where industry resources can be pooled to support a variety of activities for furthering urgent care, including research and surveys, training programs, community benefit analysis, and other projects not yet conceived.

Your support of these efforts will determine how fast and how far we are able to go in accomplishing the many projects you want us to undertake. In the coming months, we'll share more about the specific plans for spending those resources so you can determine how you and your center(s) want to contribute.

In the meantime, we encourage you all to reach out to your communities.

Let's see, if the average urgent care center has 16.9 employees (11.8 clinical, 5.1 administrative), and there are about 8,000 centers...that, my friends, is a lot of "Yawps"! ■

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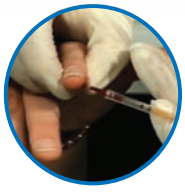

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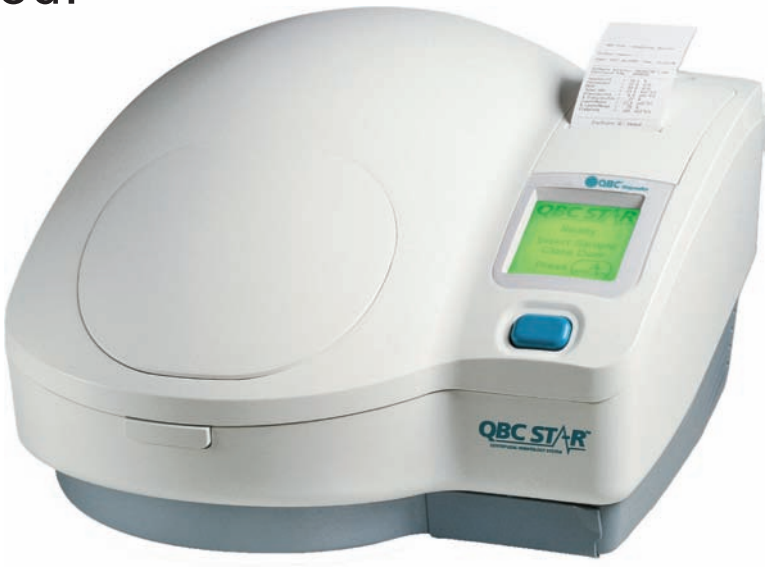

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Toward Ensuring Patient Safety in Urgent Care

Urgent message: Creating a safety culture in the urgent care clinic starts with proper hand washing before even seeing a patient and ends with transitioning care out of the practice—and includes close attention to every detail in between. The second of two parts.

Phillip Disraeli MD, FAAFP

The Institute of Medicine's 1998 *Report to Err is Human* grabbed media attention by estimating that 98,000 deaths each year can be attributed to adverse events in U.S. hospitals. More than 10 years later, the importance of keeping patients safe in public facilities, including healthcare institutions, continues to make headlines—witness the recent panic over reported cases of swine flu.

© iStockPhoto; Composite: Tom DePrenda

With urgent care continuing to grow in prominence along the continuum of care, the time is right to review some of the more common risks inherent to treating patients in any acute care setting.

Part 1 of this two-part series (*JUCM*, May 2009) focused on patient identification and medication and lab safety. This article continues the discussion of creating a "safety culture" and minimizing risk with regard to:

- healthcare-associated infections
- radiation safety
- transitioning care
- emergency preparedness
- personnel qualifications and competency
- patient rights and informed consent
- verifying the correct patient/site/procedure
- patient discharge instructions.

Case Example

Dr. Smith noticed a troubling pattern of methicillin-resistant *Staphylococcus aureus* (MRSA) infections in his urgent care center. In a two-week span, seven patients from different families presented to his center with MRSA skin infections on the trunk and extremities.

He decided to investigate the pattern and found that the only common denominator for these infections was a previous visit to his UCC in the two weeks prior to the onset of infection.

A root cause analysis by the staff of the center revealed that clinical personnel practiced proper hand washing or use of alcohol rubs before and after patient contact

Table 1. Suggested Immunizations for Staff

1. **MMR:** If born after 1956, personnel should receive two doses of vaccine, unless confirmed immunity to all three components.
2. **Hepatitis B:** Series of three vaccines or confirmed immunity, required by OSHA for personnel with blood contact.
3. **Varicella:** Two doses of vaccine unless confirmed immunity or documented illness.
4. **Influenza vaccine:** Should be offered free of charge to all employees.
5. **Adolescent–adult Tdap:** Recommended once for all personnel with direct patient contact.

Source: Centers for Disease Control and Prevention. *MMWR* Recomm. Rep. 2004, volume 43.

in only 20% of patient visits.

Reducing Healthcare-associated Infections

Reducing the risk of healthcare-associated infections is one of The Joint Commission's major National Patient Safety Goals for 2009. Urgent care centers have an important role to perform in preventing transmission of infections from patient to patient, and between patients and staff.

We also must keep abreast of emerging infections within the community, as urgent care may be the entry point for these infections in our patients. Local health departments and the Centers for Disease Control and Prevention are the best sources for up-to-date information on emerging infections.

There are four possible routes of transmission of infectious agents:

1. Fecal–oral
2. Contact
3. Droplet
4. Airborne

Fecal-oral transmission can be prevented with scrupulous hand hygiene after using the toilet.

Contact transmission requires human-to-human touching; typically, this occurs between patients and staff. The vast majority of cold viruses are transmitted by means of direct contact. Viruses are spread from hands and fomites within the building, such as toys, stethoscopes, medical equipment, door handles and countertops.

Keep It Clean

Bearing in mind the prevalence of cold viruses in the urgent care center, a comprehensive approach to disinfection of the clinic is important.

Exam rooms should be kept visibly clean. Counters, exam tables, and handles should be disinfected after every patient, using wipes or sprays designated for such use and approved by the Environmental Protection Agency.

Providers should avoid wearing white coats unless they are laundered daily; studies by Kerr and Dancer, published in the *Canadian Medical Journal* and *The Lancet Infectious Disease*, respectively, have shown pathogens are present on the sleeves of white coats, neckties and stethoscopes. In fact, white coats are banned in the United Kingdom.

Numerous studies have documented the presence of pathogens on waiting room toys. Unless an urgent care center is prepared to disinfect toys after each child plays with them, it is suggested that toys not be offered to children. Parents can be encouraged to bring their own toys to the clinic and take them home after the visit.

Hand hygiene with an alcohol-based rub or soap and water is the single most important method of prevention of contact transmission. Alcohol-based rubs should be available for patients to use in the reception area and all patient contact rooms. Care providers need to use alcohol-based rubs before and after each patient contact, and after removing gloves. (Gloves can contaminate hands on removal, or they may have microscopic breaks.)

Alcohol rubs contain 60% to 95% isopropyl alcohol and decontaminate hands more effectively than soap and water. Urgent care centers should select rubs with 1% to 3% glycerol or other skin conditioners to prevent excessive dryness, or compliance with their use will be low.

Soap and water washing is recommended whenever the hands are visibly soiled, after using the bathroom, and before and after eating. The CDC has created an interactive training website for healthcare personnel on hand hygiene, available at *www.cdc.gov/ handhygiene*.

Droplets

Infectious pathogens in the respiratory tract of patients and personnel can be transmitted a few feet through the air via droplets.

Examples of droplet transmission include influenza virus, *Bordetella* pertussis, adenovirus, and SARS-related coronavirus. To prevent droplet transmission within the urgent car center, patients with suspected influenza or one of these other agents should be of-

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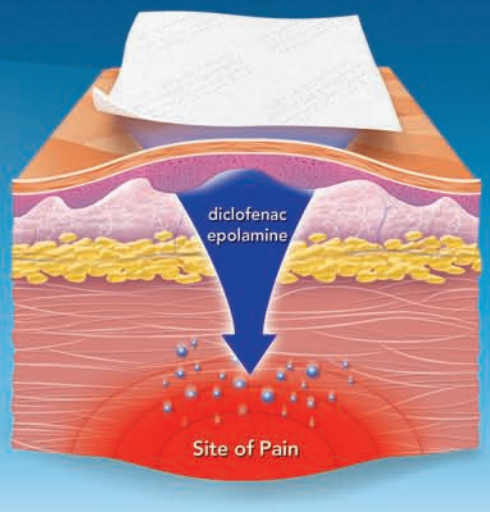

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Important Safety Information

Cardiovascular (CV) risk

- **NSAIDs may cause an increased risk of serious CV thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with CV disease or risk factors for CV disease may be at greater risk**
- **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.

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.

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.

King Pharmaceuticals

FLE5904 01/2009

Flector® patch
(diclofenac epolamine topical patch) 1.3%
Targeted NSAID Power

Flector® Patch (diclofenac epolamine topical patch) 1.3%

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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(Telephone: 1-888-840-8884) • www.FlectorPatch.com
Manufactured for: IBSA Institut Biochimique SA, CH-6903 Lugano, Switzerland
Manufactured by: Teikoku Seiyaku Co., Ltd., Sanbonmatsu, Kagawa 769-2695 Japan
Version June 2008 FI/161 1086 Ed. II/06.08

fered a mask and triaged to an exam room as soon as feasible. Employees should be immunized against influenza and pertussis.

The CDC recommends that we educate our patients in proper cough etiquette: covering the mouth and nose with the bend of the elbow when coughing or sneezing. There are posters available for waiting areas. Keep contagious patients with URI symptoms at least three feet away from other patients and staff.

Airborne

A few infectious agents are capable of suspension in the air and transmission several feet to other patients and employees.

Examples include measles, varicella and *Mycobacterium* tuberculosis. These infections will be very difficult to prevent within the urgent care center. Therefore, it is best to keep them out altogether.

For measles, we must ensure that our employees and patients are properly immunized and be aware of any community outbreaks. For varicella, immunization is also recommended. If a patient arrives with suspected varicella or measles, they should be seen in the car or brought in and out of the center through a back entrance, utilizing a remote exam room.

Active tuberculosis cases (patients with pulmonary infection, cough, fever, night sweats and weight loss) need to be identified immediately. If possible, these patients should be referred to the health department or a facility with reverse airflow capabilities for treatment, and not seen in the urgent care center.

According to the CDC, personnel need to be tested before employment and annually for tuberculosis with a tuberculin skin test to ensure early detection.

Urgent care centers should follow standard precautions as directed by the CDC. In addition to proper hand hygiene, clinical personnel should wear personal protective equipment if there is anticipated exposure to bodily fluids.

- Gloves should be used if there will be hand contamination or mucous membrane contact.
- Masks and eye protection should be worn if there could be splashes of fluids.
- Gowns should be worn if there could be soiling of the clothes.

In addition, patients need to be protected from bloodborne pathogens through use of only approved medical waste containers for blood-soaked sponges and drapes. Use only OSHA acceptable sharps containers, best mounted on the wall, away from children.

Table 2. Standard Precautions Modified for Urgent Care

1. Hands should be disinfected with alcohol-based hand rubs before and after patient contact. Have alcohol rubs in every patient room and waiting area.
2. Soap and water should be used when hands are soiled, and before and after using restroom or eating.
3. Gloves should be worn when contacting mucous membranes, open wounds, or body fluids.
4. Masks and protective eyewear should be worn during procedures that might generate droplets of blood or body fluids.
5. Gowns should be worn if splashes of blood or body fluids are possible.
6. Respiratory hygiene: Cover mouth and nose with arm when coughing, keep ill patients 3 feet apart; patients with suspected influenza should be given a mask.

Source: Infection Prevention and Control in Pediatric Ambulatory Setting. American Academy of Pediatrics, Committee on Infectious Diseases. *Pediatrics*. Vol. 120 No. 3 September 2007, pp. 650-665.

Surgical site infection

Urgent care centers need to prevent surgical site infections to the best of their ability. Physicians should follow the evidence-based guidelines for asepsis and antibiotic prophylaxis.

The Joint Commission recommends that hair be clipped instead of shaved when prepping a surgical site or laceration because shaving leaves microscopic wounds that have been shown to increase the rate of infections.

Sick employees

In some cases, employees will need to be restricted from direct patient care to prevent transmission of infections.

- Employees with conjunctivitis or URIs should stay home until active discharge (runny nose, runny eyes, sneezing,) resolves, and use scrupulous hand hygiene until all symptoms are gone.
- Employees suffering from gastroenteritis should be excluded from work until they no longer experience vomiting and diarrhea.
- Gastroenteritis is difficult to contain until suffers are no longer vomiting or have diarrhea.
- Employees with hepatitis A should be restricted one

Table 3. 2009 National Patient Safety Goals for Urgent Care

1. Improving accuracy of patient identification—use two unique identifiers.
2. Improve the effectiveness of communication among caregivers.
3. Improve the safety of using medications.
4. Reduce the risk of healthcare-associated infections.
5. Accurately and completely reconcile medications across the continuum of care.
6. Reduce the risk of surgical fires.
7. Encourage patients' active involvement in their own care.

Adapted from The Joint Commission.

week after onset of jaundice.
- Herpetic whitlow is contagious until lesions are crusted.
- Measles is contagious until seven days after the onset of the rash.
- Mumps is contagious for five days after onset of parotitis.
- Employees with pertussis should be restricted until treated for five days with antibiotics.
- Personnel infected with MRSA (or who have any *Staph* infection) need to stay home until all wounds can be kept covered and the patient has been on appropriate antibiotics for 24 hours.
- Group A strep infections are contagious until at least 24 hours has elapsed on antibiotic treatment.
- Employees with varicella need to stay home until all lesions have crusted over.
- As mentioned above, tuberculosis-infected employees need to be excluded from work until their treating physician states they are no longer contagious.

Radiation Safety

Most urgent care practices have on-site radiology services for patients. In general, these services are regulated by the state health department. All centers need to be aware of their pertinent state regulations and guidelines for safe equipment operation and maintenance, as well as the competencies for x-ray personnel.

In addition, the practice should have written policies and procedures for the x-ray department. Women of childbearing age should be queried about possible pregnancy and offered a pregnancy test if necessary. Lead shields should be used to protect the fetus and the genitals of patients.

Providers also need to be aware of the level of radiation exposure associated with their common x-rays. In general, plain films have very little radiation exposure.

However, CT scans have exponentially higher levels of exposure, and this is where we really need to pay attention. Lee, et al, estimate in *Radiology* that one abdominal CT exposes a patient to the equivalent radiation of 100 to 250 chest x-rays. This is particularly important when considering a CT scan on a child or young adult because these scans have been associated with a higher rate of cancer in later years. For instance, Brenner reports that a head CT on a child confers a 0.35% lifetime risk for eventual cancer.

Handoffs and Transitions

Another of The Joint Commission's National Patient Safety Goals for 2009 is improving communication among care providers. In the urgent care setting, this will impact several areas.

As discussed in part 1 of this series (*JUCM*, May 2009), providers should try to avoid ordering prescriptions or other treatment orally. In addition, moving toward electronic records will eliminate handwriting as a possible source of errors.

When the practice transfers responsibility of a patient to an ED, hospital or another physician, the urgent care clinician needs to identify the receiving physician and confirm that the new physician accepts responsibility. Necessary clinical information has to be transmitted to the ED charge nurse or receiving physician and the conversation documented in the medical record.

This handoff must include an accurate medication list, allergies, and treatments received at the urgent care center. If orders are given, they should be read back. If the patient is being transferred to the ED/hospital, the urgent care should provide EMTs or family members with written documentation of the visit whenever possible.

Our centers are often staffed by people working shifts, so there may be times when patient transitions occur within the practice, at the end of the shift. Providers and nurses should focus on accurate handoffs, in a quiet area. It is helpful to provide written notes concerning the future plan of care for the new provider to follow. The first clinician must document their contribution to the care and make clean on the medical record where the transition occurred.

Emergency Preparedness

Urgent care centers need to be prepared for emergencies—medical and non-medical—that could affect their patients. It is most helpful to designate a safety officer who can oversee the program for the center.

In the area of life safety, practices should be prepared for natural disasters and have a plan for evacuating and closing their office if necessary. Other potential emergencies must be considered, as well, however.

Fire

Urgent care owners need to consider fire safety and compliance in the construction and finish-out of the building.

The National Fire Protection Agency's Life Safety Code pertains to all urgent care centers that care for "four or more patients at the same time, if the patients receive treatment that renders them incapable of saving themselves in the event of an emergency." Regulations govern everything from the width of doors and hallways to the presence of firewalls and fire doors.

On the local level, the fire marshal may mandate that your site have rails, ramps, or illuminations, so it is important to have a fire inspection early in the build-out of a clinic, especially if the space is being converted from non-medical use.

Fire extinguishers should be installed at regular intervals in the building, as directed by the fire marshal, and be tested or inspected annually.

In the event of a fire, safe egress has to be anticipated for several patients at once. Therefore, the hallways and exits need to be well illuminated and clear. Anticipate that some patients will be incapacitated by illness or the emergency itself.

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

moxatag™

(amoxicillin extended-release tablets)

For more information, visit moxatag.com or call 1-877-MYMOXATAG

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

Issue Date 02/2009
910-0209-0075

Quarterly fire drills are recommended, though actual evacuation of live patients is not necessary. Smoke detectors should also be tested quarterly. Fire alarms should be tested annually. Care should be taken to prevent combustibles materials being stored around oxygen.

Medical emergencies

The practice will need to identify possible medical emergencies that could present to the urgent care, and decide on a process for handling these. Anticipating actual emergent diagnoses that could present will help to create a process to triage and treat each condition.

There should be a written policy or guideline for each such condition or chief complaint (e.g., chest pain, dyspnea, seizures, and loss of consciousness). There should also be policies in place regarding the advanced cardiac life support (ACLS) training of providers and basic life support (BLS) for other staff.

The urgent care center will need to have emergency medical equipment available and the staff properly trained in its use. The exact content of the crash cart will depend on the location of the center and its proximity to emergency services. However, most urgent cares will possess, at a minimum, an automatic defibrillator, airway and suction equipment for bag and mask ventilation of children and adults, oxygen, and a few basic emergency medications.

Personnel Qualifications and Competency

Patients receiving care in any urgent care center will be expecting that only qualified and competent individuals are part of the clinical team. Improperly trained physicians, nurses, or medical assistants can be a source of preventable adverse events.

Every new physician or employee should receive a structured orientation that covers the policies, procedures, and administrative guidelines of the clinic, as well as the use of all medical equipment where applicable.

Nurses and medical assistants can be provided with a checklist of all procedures and skills required in the clinic, and a supervisor can check off each competency as it is demonstrated. The checklist can be a part of the employee file.

Providers should be encouraged to partake in urgent care-specific continuing education. The practice should not rely on pharmaceutical representatives to provide accurate prescribing information, but instead should use evidence-based materials to make clinical decisions. The materials need to be available at the clinical workstation to ensure their use.

Patient Rights and Informed Consent

As healthcare providers, we are encouraged to involve our patients in their own care. This means communicating clearly and providing quality patient education.

The Joint Commission states that practices should have written policies on patient rights. All care providers need to introduce themselves in person to each patient, and wear a nametag or embroidery that indicates their professional credentials.

Patients have the right to participate in discussions about their care and to make treatment decisions in conjunction with the provider.

The provider should review the common side effects of medications, and explain how to proceed in the event of an adverse reaction. Printed handouts on medications can be obtained from numerous online sources and databases.

Other patient education materials should be available for common conditions seen in the urgent care, as should after-care sheets on head injury, lacerations, splints, etc.

Prior to initiating an invasive procedure, the provider should obtain written informed consent from the patient and document it in the medical record.

The clinic should have a policy on treatment of minors that conforms to state law.

There needs to be a standard process for review of all patient complaints to address systematic problems that could impact quality and safety for patients.

Correct Person/Site/Procedure

In its report, *Crossing the Quality Chasm,* The Institute of Medicine recognized the extent of the problem of wrong person/wrong site/wrong procedures in the United States.

The Joint Commission developed a Universal Protocol to be followed for invasive procedures. Many of their recommendations do not apply to urgent care, where procedures are only performed on conscious patients (e.g. the requirements for pre-admission testing and surgical site marking). However, the issue is still important, as these errors do occur in urgent care, usually due to miscommunication.

To avoid treating the wrong patient, procedures need to be ordered carefully. Each patient should be identified and verified prior to initiating venipuncture, x-rays, injections, and treatments. Patients should not be identified by their room number or location, as these could be in error.

Procedures ordered for a side of the body or extremity must be designated in writing as to the side, and the patient queried prior to the procedure.

This is particularly important for x-rays. For example, a technician may believe an ankle film will be ordered,

Table 4. Structured Time-out Before Procedures

1. Is this the correct patient?
2. Is this the correct side and site for the procedure?
3. Written informed consent documented?
4. Does patient agree to the procedure?
5. Correct patient position?
6. Proper equipment and assistance available?
7. Medication and allergies verified?

but the physician actually desires a foot x-ray. The order should be written in the chart "left foot film, 3 views."

To avoid performing the wrong procedure on a patient, the patient must be involved in the decision to treat and the treatment verified prior to initiating (i.e., "Ms. Jones, Dr. Smith has asked that I give you a Rocephin shot for your pneumonia. Does that sound correct to you?").

As suggested in the Universal Protocol, a "time-out" is recommended prior to any invasive procedure. This allows the physician and assistants to verify that everything is correct before proceeding. A structured time-out for urgent care is provided in **Table 4**.

Patient Discharge Instructions

Effective communication at discharge will prevent many adverse events for urgent care patients. At the end of the patient visit, all patients should be provided with written discharge instructions that include the diagnosis given, procedures and treatments performed, medications prescribed, patient education material provided, and follow-up instructions.

The patients must understand how to take their medications and what side effects or adverse reactions are important. Patients should be encouraged to report significant side effects or adverse reactions; this will enable the provider to make modifications as necessary.

The clinician also needs to be very clear about additional instructions given to the patient regarding dietary and activity restrictions, expected course of the illness, what to do if the patient thinks he or she is getting worse, and when to return or call the office.

Most urgent care clinics provide acute care services only, and will desire the patient to follow up with a primary care provider or specialist. This follow-up needs to be documented in the medical record and on the written discharge instructions.

If the patient does not have a primary care physician, then the practice will want to have a database of local clinics from which to choose to refer the patient. Patients with established relationships with a primary care can have their discharge instructions faxed to the office to facilitate follow-up. Other urgent care centers will offer varying degrees of primary care and follow up themselves. In these circumstances, specific follow-up at the practice should be arranged at discharge and documented.

Conclusion

This two-part article was created to highlight some of the important opportunities to improve the safety for our patients in urgent care. The author used The Joint Commission ambulatory standards as a guide to develop recommendations, as their experience and focus is directed at patient safety.

In 2008, the Urgent Care Association of America established a partnership for voluntary accreditation with The Joint Commission. Practices that correct deficiencies highlighted by this discussion can make useful strides to prepare for this accreditation in the future. ■

Resources

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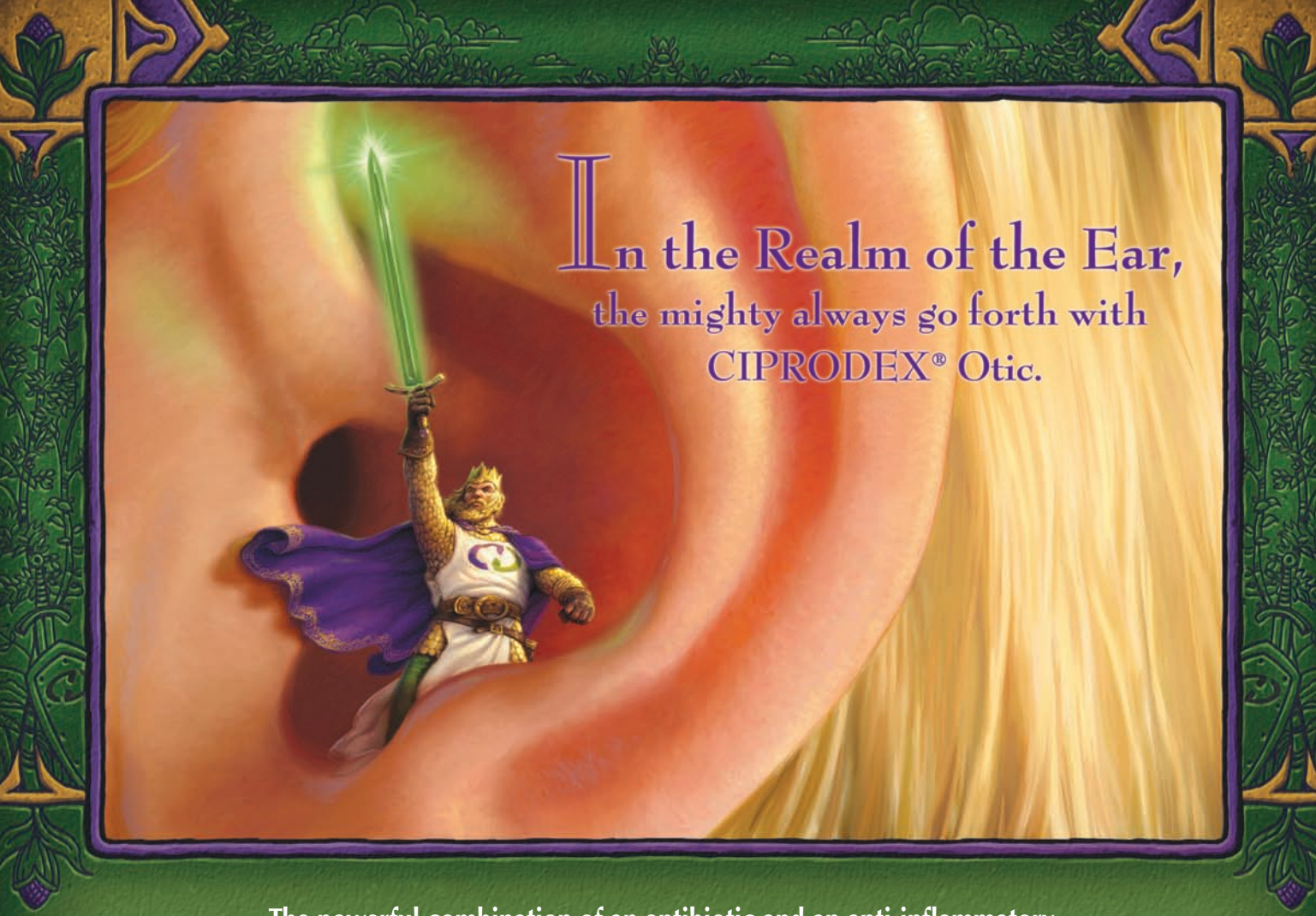

The powerful combination of an antibiotic and an anti-inflammatory to defeat acute otitis externa (AOE) or acute otitis media with tympanostomy tubes (AOMT)[1]

- 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.

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

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The Story of Jonathan—One Week in January

In Bouncebacks, *which appears semimonthly in* JUCM, *we provide the documentation of an actual patient encounter, discuss patient safety and risk management principles, and then reveal the patient's "bounceback" diagnosis.*

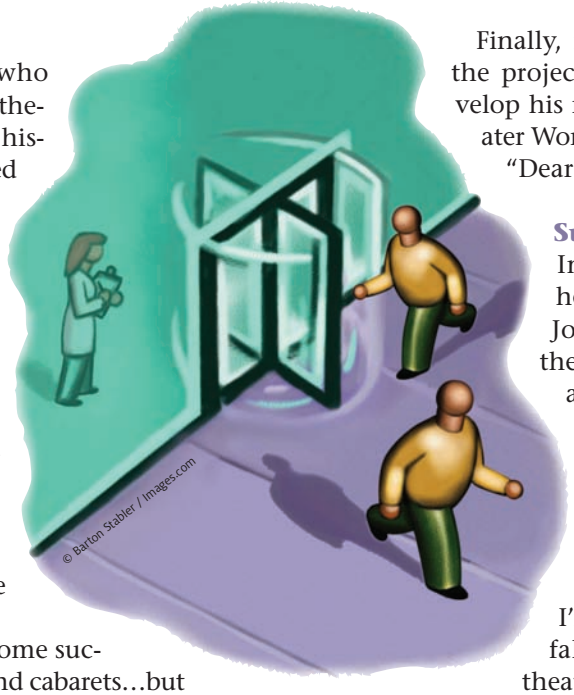
Cases are adapted from the book Bouncebacks! Emergency Department Cases: ED Returns *(2006, Anadem Publishing,* www.anadem.com*; also available at* www.amazon.com *and* www.acep.org*) by Michael B. Weinstock and Ryan Longstreth. The book includes 30 case presentations with risk management commentary by Gregory L. Henry, past president of The American College of Emergency Physicians, and discussions by other nationally recognized experts.*

Michael B. Weinstock, MD and Jill C. Miller, MD

The Patient's Perspective

Jonathan is a young man who changed the course of musical theatre and would still be making history today if things had turned out differently.

Jonathan was born in Mount Vernon, NY in 1960. When he was 22, he moved to New York City to pursue his dream of writing a musical. Like most struggling artists, life wasn't easy. He spent weekends waiting tables at the Moondance Diner in Soho. He spent weekdays at his keyboard writing songs. His tattered four-story walkup was so tiny, he had a bathtub in the kitchen.



Through the years, he had some success writing for Sesame Street and cabarets…but not the big break he was hoping for.

In the late 80s, he began work on a new project; he had a vision to create a modern version of "La Boheme." He didn't merely want to update the opera, but to transform the American musical tradition, appealing to a younger audience raised on MTV and changing social values.

Finally, in1994, years after he began the project, he received a grant to develop his musical at the New York Theater Workshop. He sent his dad a note: "Dear Dad, I quit work. Love, Jon."

Sunday, January 21, 1996

In December 1995, dress rehearsals begin. A month later, Jonathan is in the theater for the final week of rehearsals, visualizing the last seven years of hard work.

After dinner, he is suddenly struck by intense chest pains. He is short of breath and dizzy. He tells a friend, "You'd better call 911. I think I'm having a heart attack," then falls to the floor between the theaters's last two rows. An ambulance rushes him to Cabrini Medical Center.

On the way, the paramedics record their diagnosis: pleuritic chest pain.

The Doctor's Perspective

Sunday, January 21, 1996

- **6:45 p.m.:** The patient is triaged at Cabrini and

"Sometimes, patients will tell approachable staff members information they will not share with you."

vital signs are recorded as normal. Triage nurse records a chief complaint of "Inspiratory chest pain."

- **7:00 p.m.:** He is seen by the doctor, who records a different chief complaint, "Epigastric pain."

  The physician records that the patient had "eaten a turkey sandwich which didn't taste right. Had dinner and smoked marijuana prior to developing Sx. Hx of ulcers but no hx cardiac disease, no smoking or cardiac risk factors… just finished producing a play…increased stress." ROS negative for n/v/d.
  - **PE:** Normal except for minimal epigastric tenderness with palpation.
  - **Testing:** EKG and CXR performed, but results not recorded on the chart.
- **8:35 p.m.:** The patient experiences a dizzy spell while in the radiology department. The nurse documents Jonathan saying, "I can't take a breath." It is unclear from records whether the doctor was informed of this episode
- Jonathan's friend asks the doctor for an update and is told, "I can't find anything wrong. You'll be out of here in one hour."
- **10:15 p.m.:** Diagnosis: Food poisoning.
- Vital signs are not repeated.
- **Disposition:** Patient is instructed to take a bland diet for 24 hours and return to the ED if necessary. The next morning, a radiologist over-reads the chest x-ray as normal.

DISCUSSION OF PATIENT SAFETY/RISK MANAGEMENT—VISIT 1

1. The six life-threatening causes of chest pain include:
   a. myocardial ischemia/infarction
   b. pulmonary embolism
   c. aortic dissection
   d. tension pneumothorax
   e. pericardial tamponade
   f. Boerhaave syndrome (esophageal rupture)

   This list can rapidly be narrowed to the first three with history and physical exam alone, assuming no history of vomiting in a patient with equal breath sounds who has normal heart sounds and is not tachycardic, tachypnic, or hypotensive.

2. A discrepancy in the records represents a significant medical–legal risk. The paramedics and nurse both recorded chief complaint of "pleuritic chest pain," whereas the doctor recorded "epigastric pain." There is no indication the physician was aware of the discrepancy. Some ways to address differences in documentation include:
   a. Confirm with triage/nursing that the history recorded was the actual history related by the patient. If not, ask them to change their documentation to accurately reflect the encounter.
   b. Specifically ask the patient about the discrepancy and record their answer in the chart. Sometimes the patient will confirm both versions, sometimes they will clarify the inconsistency.
   c. If unresolved, record "nursing note appreciated" and detail that you have asked the patient the question several times and they have confirmed that your history is the accurate one.

3. Though a patient has symptoms out of your eyesight, he is still under your care while still in the urgent care facility. Foster an atmosphere of approachability so that ancillary staff will understand they are partners in the care of patients; sometimes, patients will tell approachable staff members information they will not share with you.

4. Avoid specific unsupported diagnoses. Our patient was diagnosed with "food poisoning" without nausea, vomiting, or diarrhea. A better diagnosis remains "chest pain" or "epigastric pain." This also lets the patient know that there remains *diagnostic uncertainty* and if their symptoms persist or worsen they need to return.

The Patient's Perspective

Monday, January 22, 1996—Jonathan returns home

Jonathan wakes up and calls the hospital to see if tests showed evidence of food poisoning. He is told, "If there was something wrong you would have been notified."

That night, his roommate Brian returns to their apartment to find Jonathan in bed, short of breath

and mumbling. He described Jonathan's color as, "pale and off-greenish." Jonathan is able to eat only Jell-O and tapioca pudding. Jonathan asks Brian to sleep on the living room floor, so Brian sets an alarm and wakes every couple of hours.

Tuesday, January 23, 1996
Waking Tuesday morning, Jonathan finds that his symptoms have improved, but come evening the chest pains again become so intense that he takes a cab to the closest ED, St. Vincent's Hospital and Medical Center.

The Doctor's Perspective

Tuesday, January 23, 1996

- **23:00:** The nurse triages patient as "urgent" and records chief complaint of right-sided "inspiratory chest pain" for four hours. Notation is made that the patient thinks his pain may be from heartburn. There is no conversation between nurse and doctor.
  - **Vital signs:** temperature 100.4°, pulse 100, respiratory rate 22, normotensive.
- **00:40:** Seen by doctor. History is brief, but confirms fever and right-sided inspiratory chest pain which patient rates as 7/10. Patient complains of "not feeling right." Denies malaise, cough, diaphoresis, myalgia, n/v/d.
  - PE is normal.
  - Testing: CXR and EKG both read as normal by ED physician.
  - ED course, Vital signs not repeated.

Later, a friend describes Jonathan's appearance. "He was slumped over in a chair with his head in his hands, just completely out of it, white as a ghost, sweating and pissed off." He remembers Jonathan saying; "I just don't know what it is. I feel like shit, but they can't find anything and I just don't feel right."

- **Diagnosis:** Viral syndrome.
- **Disposition:** "Follow up with your physician." Condition: improved.

DISCUSSION OF PATIENT SAFETY/RISK MANAGEMENT—VISIT 2

1. Differential diagnosis now has pulmonary embolism near the top of the list. Our patient has pleuritic chest pain and is tachycardic. Neither a chest x-ray nor EKG has sufficient sensitivity to exclude this diagnosis.

Other considerations still include myocardial ischemia/infarction and aortic dissection. With a fever, myocarditis has now entered the differential.

2. A red flag is the severity of his pain. Though the physician was not able to localize an exact etiology, a patient with severe pain should prompt a "second look," similar to a parent crossing a busy street with kids in tow who looks both ways twice.
3. A "bounceback" patient is a high-risk encounter, by definition. These patients require extra vigilance and care; confirm that the history and exam are accurate, recheck abnormal vital signs, speak with family and friends, arrange for timely and action-specific follow-up care.

This should not be an annoyance, but a "second chance" for the doctor to exclude life-threatening etiologies of the symptoms.

The patient's perspective—Who is Jonathan?

The writer we have been discussing is Jonathan Larson, author of the musical *Rent*, which went on to change the direction of musical theatre. *Rent* became one of the longest running shows on Broadway, closing 12 years later in the fall of 2008.

Wednesday, January 24, 1996—Jonathan returns home
During the cab ride home from St. Vincent's, Jonathan complains of continued pain and tightness in his chest, saying, "Nothing has changed."

- **Morning:** the radiologist over-reads the CXR as showing "Heart size upper limit of normal." Cardiologist reads EKG and writes "question lateral MI."

  There is no follow-up with the patient.
- **7:30 p.m.:** Jonathan arrives at the theater for a performance of *Rent* before 200 invited guests. His musical receives a standing ovation. The director describes Jonathan that night: "He was moving slowly and didn't speak loudly. Jonathan was usually an exuberant guy, and he was behaving gently."
- **Midnight:** Jonathan meets with a *New York Times* reporter and is told that the music is tremendous and will change the direction of musical theatre. Jonathan replies that he needs to respond in some way to celebrate the lives of his friends who have died young.

  Jonathan prophetically explains the message of his play to the reporter, "It's not how many years you live, but how you fulfill the time you spend here." He leaves the theatre in a cab planning to meet with the director in the morning.

Thursday, January 25, 1996
3:40 a.m.: Jonathan's roommate Brian returns home to find a gas flame burning under a scorched tea kettle and Jonathan lying on the floor. Brian opens Jonathan's shirt and begins chest compressions, yelling, "Wake up! Wake up, Jon!"

Police arrived shortly after and pronounce him dead, the day before opening night.

Friday, January 26, 1996—Autopsy is performed
Findings

1. Cystic medial degeneration of the aorta, likely from undiagnosed Marfan's syndrome.
2. Twelve-inch aortic dissection from base of aorta to the bifurcation of the common iliac arteries.
3. Hemopericardium and cardiac tamponade with 700 cc blood found in pericardial sac.

That night, the curtain rises on the first preview. The rock opera's opening night ends with no applause. The audience, cast, and crew sit completely silent until an unidentified voice says, "Thank you, Jonathan Larson."

Within a few months *Rent* moves to Broadway, where it wins the Pulitzer Prize, four Tony awards, six Drama Desk awards, and three Obie awards.

The Family's Perspective

Family files a negligence lawsuit for $250 million against both hospitals, based on estimates of revenues from *Rent*. The suit is settled for undisclosed amount. Part of the money is used to fund educational efforts by the National Marfan Foundation.

The New York State Health Commissioner's Perspective

A report on ABC New's *Primetime* raises serious questions about the quality of care administered and results in an investigation by the New York State Health Commissioner. The investigative process includes an extensive review of the ED visits and 29 interviews, plus the advice of eight physicians, including three with expertise in emergency medicine and five board-certified radiologists.

The commissioner summarized their findings: "While we believe the diagnosis of aortic dissection would pose a diagnostic challenge to the best clinician, we do have concerns about the appropriateness and medical soundness of the treatment Mr. Larson received. That is why we feel it is incumbent upon the state to impose fines and require corrective action to ensure these deficiencies do not occur in the future."

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Cabrini Medical Center

- ED doctor did not fully evaluate the complaint of chest pain. No information was presented that considered or eliminated the possible causes of chest pain.
- There is no evidence the physician interpreted the chest x-ray r EKG prior to ED discharge, contrary to established procedures.
- The diagnosis of food poisoning was not supported by the patient's symptoms or complaints, except for possible epigastric tenderness and description of eating a turkey sandwich with a bad taste.
- There were no documented repeat vital signs despite nursing documentation of breathing problems and dizziness.
- *Summary:* The patient was not correctly diagnosed and was incorrectly treated. The Commission issued a statement of deficiency and fined Cabrini $10,000.

St. Vincent's Hospital

- Vital signs, including pulse, were abnormal and were not repeated, as required by the hospital's own protocol.
- With the exception of fever, diagnosis of viral syndrome was not supported by Mr. Larson's condition or presenting symptoms. There was no malaise, cough, diaphoresis, myalgia, nausea, vomiting, nor diarrhea.
- *Summary:* The patient was not correctly diagnosed and was incorrectly treated. The Commission issued a statement of deficiency and fined St. Vincent's $6,000.

Discussion

Mr. Larson had pain described by friends as severe, with associated shortness of breath and two near syncopal episodes.

In retrospect, these symptoms fit neatly into a picture of aortic dissection in a patient with probable Marfan's syndrome. It is easy to see how this unusual problem could have been missed, especially if it was not in the physician's differential diagnosis.

Like many of our patients, Jonathan Larson did not want to have a serious diagnosis, telling the first physician about a bad turkey sandwich and the second that he thought he had heartburn. Both physicians were led astray. But both missed opportunities to make the diagnosis, including reading the nurses' and paramedics' notes, getting additional history from the patient's friends in the ED, reassessing him after he had a near syncopal episode in radiology, and having time- and action-specific follow-up in a patient who is discharged with diagnostic uncertainty.

The second visit was more troubling, as he was now a bounceback patient; this puts him at higher risk of having serious underlying problem.

At that point, Jonathan also had another serious risk for misdiagnosis: a previous diagnosis. His doctor fell into the trap. His tachycardia was not recognized or repeated; his chest x-ray was possibly misread. Over-reliance was placed on testing above clinical findings. The ECG was abnormal and not discussed in a progress note by the physician, and was not repeated.

The findings of the New York State health commissioner speak for themselves, but more telling are the grievous words issued by Jonathan's father, Alan Larson, who summed up the feelings of any parent who survives their child. "You wake up and it's the same nightmare," he said. "Parents should never have to cry for their lost children." ■

The authors wish to thank Allan Larson, Jonathan's father, for his support and clarification of details; Jonathan Martin, director of education at the National Marfan Foundation; Sora Newman, from National Public Radio; and the State of New York Department of Health for allowing access to the commission's findings.

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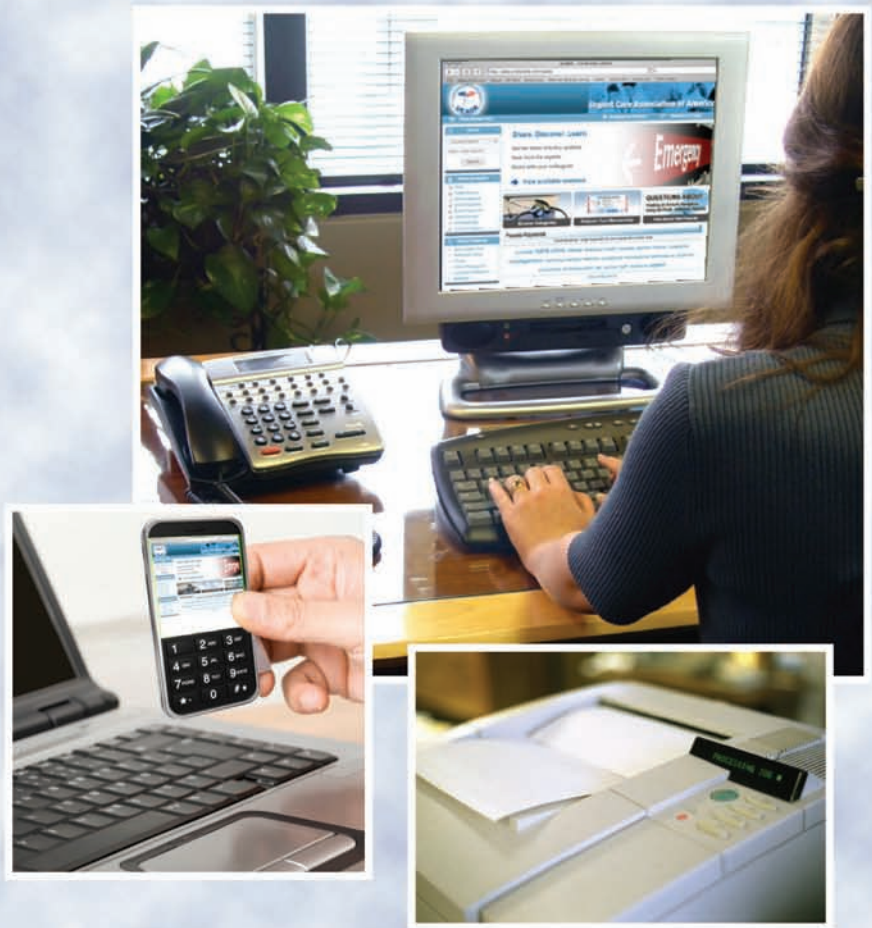

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Case Report

Appendicitis Due to Squirrel Dinner

Urgent message: History of ingested foods—as well as regional customs and lifestyle—should be elicited and considered when considering pain suggestive of appendicitis.

Rajan B. Masih, MD, FACA, FICA and Anil Makani, MD, FACS, FRCS

Introduction

Appendicitis due to foreign bodies is a rare occurrence; most cases reported in the literature have occurred due to sharp objects such as pins, needles, toothpicks, and small nails.

Solid foreign bodies—such as a bullet—rarely cause appendicitis. Appendicitis due to traumatic gunshot wounds has been described before, as have appendicitis cases due to ingested birdshot.

Here, we describe an interesting case that demonstrates the importance of eliciting a history of ingested food—including wild game—in a patient presenting with symptoms suggestive of appendicitis, particularly in areas of the country where hunting may be an important part of the patient's lifestyle.

Case Study

A 55-year-old white male presented to our urgent care center with a complaint of progressively worsening right lower quadrant pain, nausea, and a two-day history of anorexia. His most recent meal was squirrel stew, which he prepared for himself, 48 hours before our examination. He reports that he had also shot the squirrel himself two days prior.

The patient denied any diarrhea, constipation, fever, chills, dysuria, or melena. He had taken over-the-counter antacids without relief of his symptoms. His past medical history, surgical history, family history, and social history were otherwise unremarkable and noncontributory.

Findings

On examination, we found this thin male in moderate distress, with:

- BP 140/110 mmHg
- heart rate 120 beats per minute
- T 98.4°F
- respiration 20 per minute.

In addition:

- A CBC revealed a white blood cell count of 11,200, with 82% segs and 2% bands.
- Hemoglobin was 16.4.

Figure 1

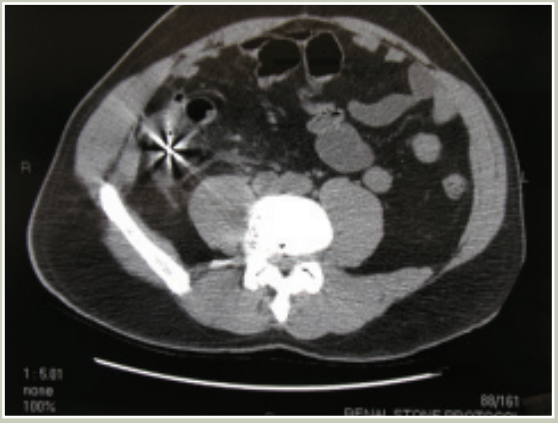
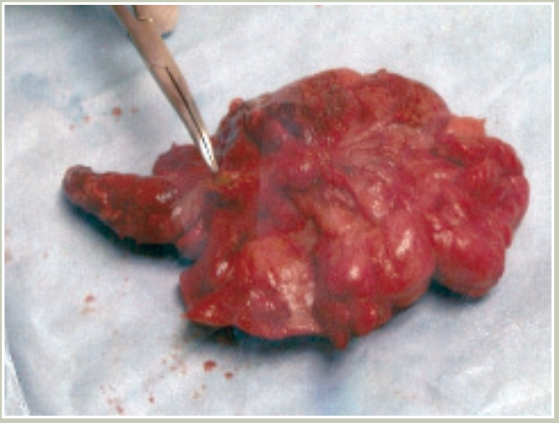


Figure 2



- Hematocrit was 38%.
- Platelet count was 450,000.
- Comprehensive metabolic profile (CMP) was normal, except for blood urea nitrogen of 31 mg/dL, creatinine of 1.0 mg/dL, and bicarbonate of 22.
- Urinalysis was unremarkable.

The patient had no jaundice, no oral mucosal lesions, no neck lymphadenopathy, and a normal cardiac examination except for sinus tachycardia. His lungs were clear to auscultation, and he had no thoracic wall tenderness.

The abdomen was not distended, and he had no visible or palpable herniae, and hyperactive bowel sounds in the epigastria area. He was tender to palpation in the periumbilical area and in the right lower quadrant, with point tenderness over McBurney's area. The psoas sign and obturator sign were negative. He had no involuntary guarding, and no rebound tenderness. Rectal examination revealed no rectal tenderness, no mass, and hemoccult-negative stool. Genitourinary examination was unremarkable.

A flat and upright film of the abdomen revealed no free air, no air-fluid levels, and no signs of obstruction. There was, however, a radiopaque density in the right lower quadrant.

A CT scan of the abdomen and pelvis with thin slices through the appendix revealed a metallic foreign body in the vicinity of the appendix (**Figure 1**). Bowel gas pattern demonstrated inflammatory changes in the region of the appendix, consistent with acute appendicitis.

An attending surgeon was consulted, and the patient was emergently transferred, ultimately to be taken to the operating room. Intra-operatively, the surgeon found a .22 caliber rifle slug causing luminal obstruction of the proximal appendix, as well as evidence of early necrosis (**Figure 2**).

The patient was discharged from the hospital two days later, with an uneventful postoperative course.

Discussion

West Virginia is a true sportsman's paradise and has numerous seasons for hunting wild game, fishing, and an abundance of outdoor activities.

Typically, squirrels are shot with a small caliber rifle such as a .22 caliber or a 16- or 20-gauge shotgun.

Our patient reported using a .22 caliber rifle to shoot squirrels on the first day of squirrel hunting season. He slaughtered the animals himself, and prepared and cooked the meat, although he did not find a bullet or bullet fragment in the meat. He assumed that the .22 caliber bullet had passed through the animal.

Foreign bodies can cause acute appendicitis by appendiceal lumen obstruction.[1,2] Studies have shown that foreign bodies cause appendicitis in 0.0005% of all cases.[3] A large number of foreign bodies have been described in the lumen of the appendix; most commonly, these are fruit seed, bone fragments, chewing gum, and gallstones.[4] Occasionally, extremely unlikely foreign objects such as fishhooks, dental drill bits, and even a portion of a condom have caused appendiceal lumen obstruction.[5]

Rare as they may be, most cases of appendicitis caused by a foreign object are found to occur due to sharp for-

eign objects like the aforementioned pins, needles, toothpicks, and nails.[6] Birdshot and similar smooth, round objects have been found in cases of appendicitis, and as many as 500 small shotgun BBs have been reported in the appendix of Inuit Indians who eat wild game as a major part of their diet.[7]

Most foreign objects pass through the GI tract without any incident, but heavy objects such as a bullet or lead shot from shotguns may have a long transit time—up to two weeks—to traverse the GI tract.[8]

The position of the appendix is an important risk factor for foreign body obstruction of the lumen, resulting in appendicitis. The anterior position of the appendix rarely is implicated in foreign body-induced appendicitis; however; a retrocecal appendix by virtue of gravity and its dependent position is more likely to become occluded by foreign body resulting in appendicitis.

The ingestion of a foreign body and the development of appendicitis do not go hand in hand. Most of the time, there is a delay (sometimes years) of the onset of symptoms of an ingested foreign body.[9]

Conclusion

Although most foreign bodies pass through the GI tract without incident, luminal obstruction of the appendix can occur, leading to acute appendicitis. Clinicians are cautioned to be vigilant to this possibility, particularly, in patients presenting with abdominal pain in geographic regions where hunting plays a large part of their lifestyle and diet. ■

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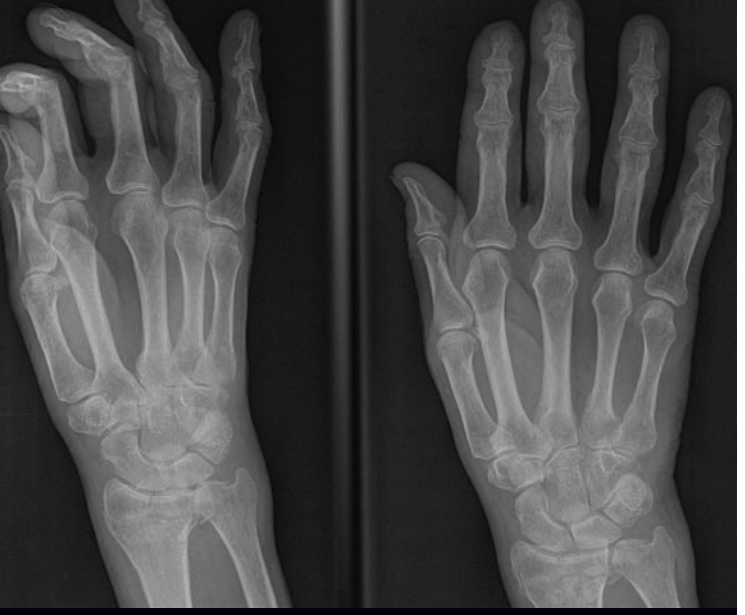


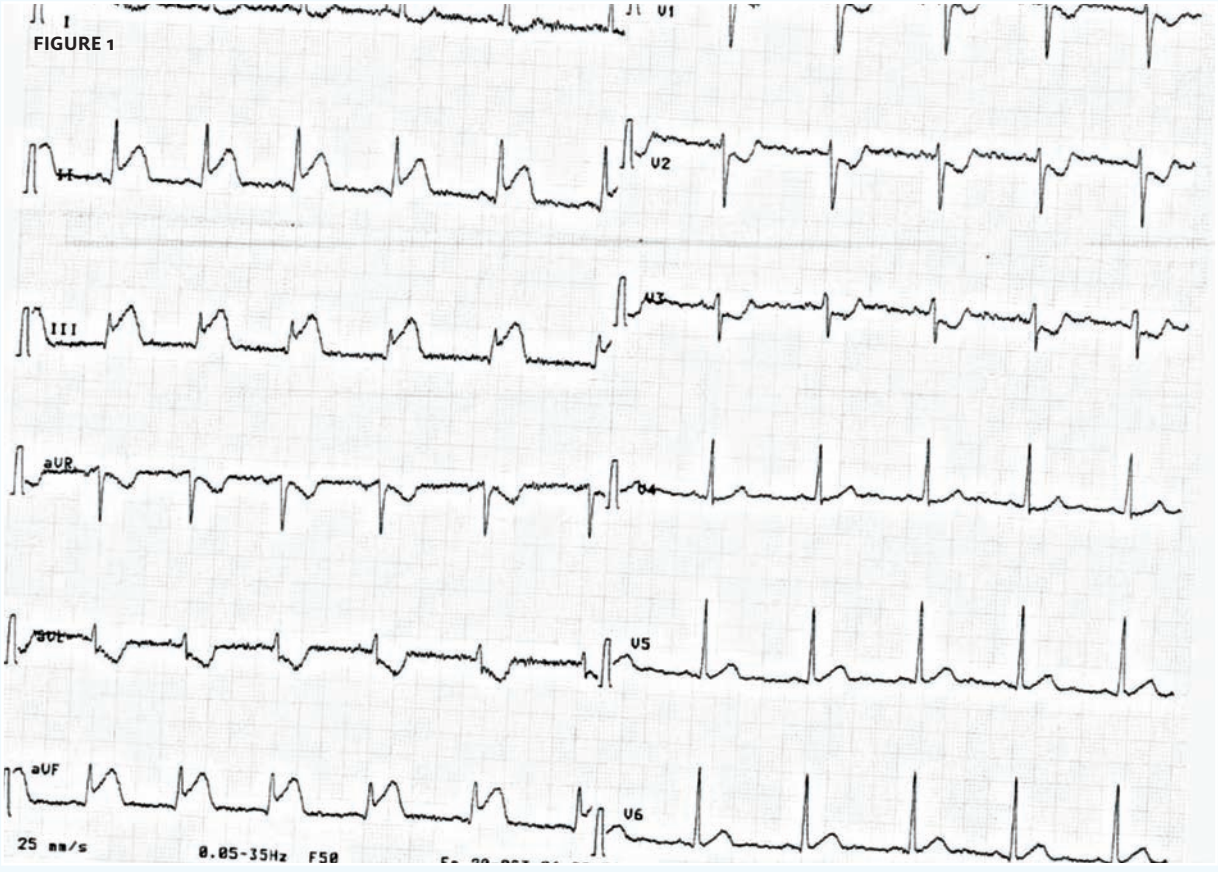
INSIGHTS IN IMAGES

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.

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

FIGURE 1



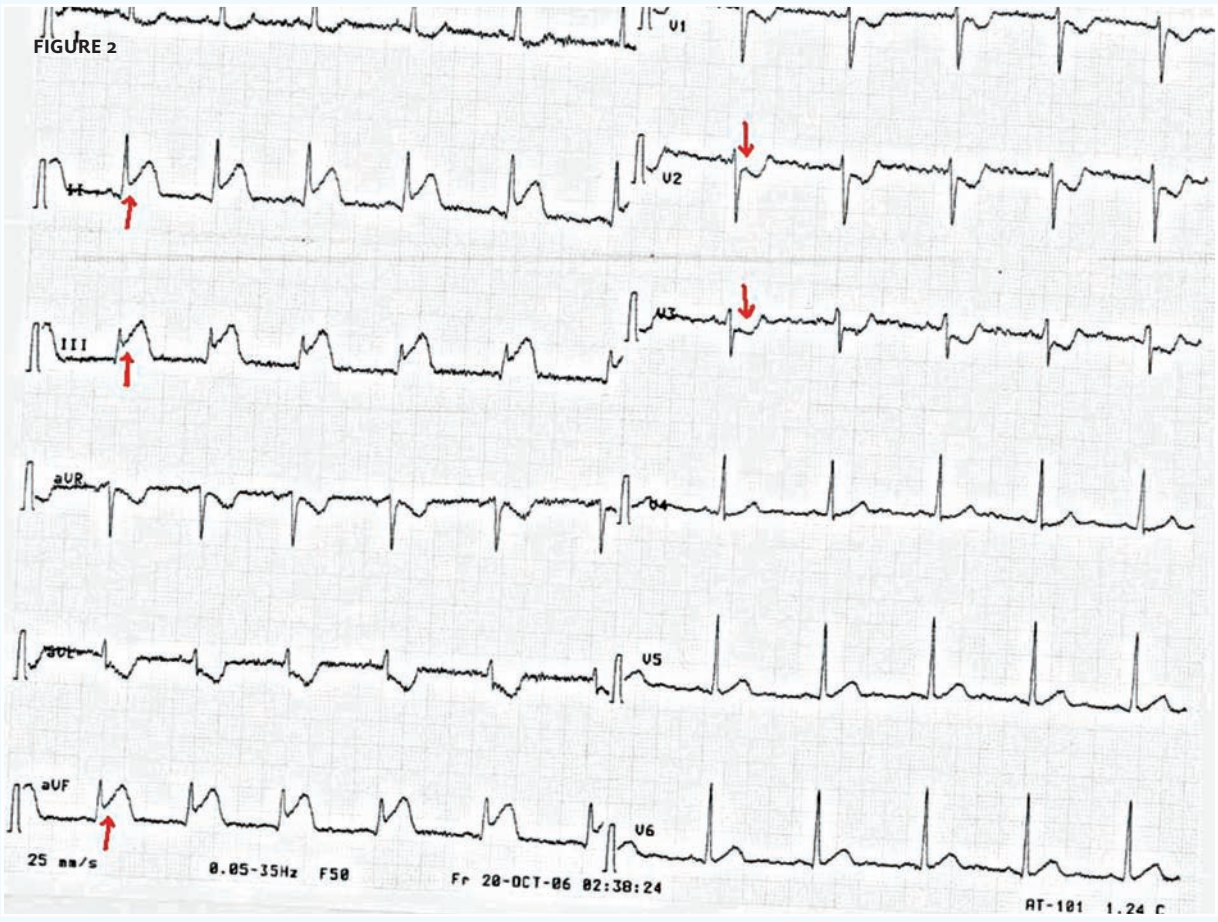
The patient is a 32-yar-old male who woke up at 1 a.m. with a burning sensation in the mid-chest (a first-time event, he reports).

The patient is not diaphoretic, and has no dyspnea. He is generally healthy and has no known risk factors for heart disease. His physical exam is unremarkable. In addition, you find:

- BP: 154/102
- Pulse: 68
- Sat: 99%
- Temperature: 97.3°F

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

THE RESOLUTION



The ECG is consistent with an inferior MI. The patient was transferred to the ED by ambulance after receiving ASA, nitroglycerin SL, and oxygen.

While MI is rare in patients under age 35, it should be considered when presentation is otherwise typical.

The most common causes of MI in young adults are hypercoagulable states and substance abuse (cocaine, primarily).

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

On AMI in Syncopal Patients, Crying Babies, PE in COPD, Pediatric Fatalities with OTC Cough and Cold Medications, and More

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.

Incidence of AMI in Patients with Syncope

Key point: In a cohort study of nearly 1,500 patients, the incidence of AMI was 3%, and most patients presented without ST-segment elevation.

Citation: McDermott D, Quinn JV, Murphy CE. Acute myocardial infarction in patients with syncope. *CJEM*. 2009;11:156-160.

Which patients with syncope require hospital admission? To answer this question, researchers studied the incidence of acute myocardial infarction within 30 days of presentation in a cohort of 1,474 consecutive emergency department patients who presented with syncope or near-syncope (mean age, 62) in California.

Emergency physicians used a structured data form during patient evaluation to classify electrocardiograms as normal or abnormal. ECGs were considered abnormal if they showed rhythm changes or new abnormalities compared with prior ECGs or any abnormalities when no prior study was available. Diagnosis of AMI during 30-day follow-up was assessed by chart review or by contacting the primary physician and the patient.

Of the 95% of patients available for follow-up, nearly all (1,393, or 93%) underwent an ECG as part of their initial evaluation. AMI was diagnosed in 46 patients (3%), of whom 42 (91%) had no ST-segment elevation and nine (20%) had normal initial ECGs. An abnormal initial ECG had a sensitivity of 80% and a specificity of 64% for predicting AMI, with a negative predictive value of 99% and a positive predictive value of 7%.

AMI was rare in this cohort of patients who presented with syncope. Most patients who ultimately were diagnosed with AMI had nondiagnostic ECGs without ST-segment elevation, and some had normal initial ECGs. Until we have better methods to risk-stratify patients with syncope, we should continue to admit patients with new-onset syncope based on our clinical judgment, unless a cardiac cause has been ruled out.

Published in *J Watch Emerg Med*, March 27, 2009—Kristi L. Koenig, MD, FACEP. ■

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

The Crying Baby: What to Do?

Key point: History and physical exam remain the basis for evaluating infants who present with acute, excessive, unexplained crying and for determining which infants require diagnostic testing.

Citation: Freedman SB, Al-Harthy N, Thull-Freedman J. The crying infant: Diagnostic testing and frequency of serious underlying disease. *Pediatrics*. 2009;123(3):841-848.

Crying is normal in infancy and varies by age, time of day, and from child to child. However, because excessive crying can be a symptom of serious disease, an evidence-based approach to diagnostic evaluation of crying infants would be helpful.

In this study, researchers retrospectively reviewed the charts of 238 consecutive afebrile infants <12 months old (median age,

2.4 months) who presented to a pediatric emergency department (ED) in Toronto with a chief complaint of crying.

Diagnoses that would constitute potentially serious underlying etiologies for crying were determined a priori. The general appearance of 95% of the infants was described as "well."

Two infants <4 months with UTIs had no suggestive history or physical examination findings but were diagnosed by tests obtained in the ED. Only one fluorescein eye examination and eight fecal occult blood tests were conducted; all were negative.

Final diagnoses included crying (27%), viral illness (21%), reflux (13%), colic (6%), and atypical colic (5%). Telephone follow-up performed nine to 18 months after the ED visit in 61% of the study group revealed no subsequently diagnosed serious conditions.

In this large group of generally well-appearing crying infants, history and physical examination findings, either alone or as the driver for diagnostic testing, led to the identification of serious underlying etiologies in 10 of 12 infants. In the remaining two infants, the diagnosis (UTI) was made by testing alone without suggestive history or physical examination findings. The authors recommend that infants who present with a chief complaint of crying during the first few months of life should undergo a urine test, although it might have a very low yield.

Published in *J Watch Ped Adolesc Med*. April 15, 2009—Cornelius W. Van Niel, MD. ■

Consider Pulmonary Embolism in Acute Exacerbations of COPD

Key point: One of four COPD patients who require hospitalization for an acute exacerbation may have PE.

Citation: Rizkallah J, Man SFP, Sin DD. Prevalence of pulmonary embolism in acute exacerbations of COPD: A systemic review and meta-analysis. *Chest*. 2009;135(3):786-793.

There is no clear etiology for nearly 30% of all exacerbations of chronic obstructive pulmonary disease. Although pulmonary embolism (PE) can exacerbate respiratory symptoms such as dyspnea and chest pain, and COPD patients are at a high risk for PE due to a variety of factors, including limited mobility, inflammation, and comorbidities, the prevalence of PE during exacerbations is uncertain.

A systematic review of the literature was performed to determine the reported prevalence of PE in acute exacerbations of COPD in patients who did and did not require hospitalization. Of the 2,407 articles identified, five met the inclusion criteria (n=550 patients).

Overall, the prevalence of PE was 19.9%. Prevalence was higher in patients who were hospitalized than in those who were evaluated in the emergency department (24.7% vs. 3.3%, respectively). Presenting symptoms and signs were similar between patients who did and did not have PE.

One of four COPD patients who require hospitalization for an acute exacerbation may have PE. A diagnosis of PE should be considered in patients with exacerbation severe enough to warrant hospitalization. ■

Pediatric Fatalities Associated with Over-the-Counter (Nonprescription) Cough and Cold Medications

Key point: Pediatric fatalities caused by nonprescription cough and cold medications were uncommon, involved overdose, and primarily affected children younger than 2 years.

Citation: Dart RC, Paul IM, Bond GR, et al. *Ann Emerg Med*. 2009;53(4):411-417.

Fatalities that involved a child <12 years of age and mentioned a cough and cold ingredient were obtained from five sources. An independent panel of eight experts (pediatrics, pediatric critical care, pediatric toxicology, clinical toxicology, forensic toxicology, forensic pathology) used explicit definitions to assess the causal relationship between medication ingestion and death.

Of 189 cases included, 118 were judged possibly, likely, or definitely related to a cough and cold ingredient. Of these 118 cases, 103 involved a nonprescription drug, whereas 15 cases involved a prescription medication alone.

Of the 103 cases associated with nonprescription drugs, the evidence indicated that 88 involved an overdosage. Dosage could not be assessed in the remaining 15 cases.

Several contributing factors were identified: age <2 years, use of the medication for sedation, use in a daycare setting, use of two medicines with the same ingredient, failure to use a measuring device, product misidentification, and use of a nonprescription product intended for adult use. All cases that occurred in a daycare setting involved a child <2 years.

Occult Bacteremia in the Postpneumococcal Vaccine Era: No More Blood Cultures

Key point: In a study of some 8,000 previously healthy, young febrile children with no apparent source of infection, the rate of true-positive blood cultures was only 0.25%.

Citation: Wilkinson M, Bulloch B, Smith M. Prevalence of occult bacteremia in children aged 3 to 36 months presenting to the emergency department with fever in the postpneumococcal conjugate vaccine era. *Acad Emerg Med*. 2009: Mar; 16:220-225.

For decades, the work-up of febrile young children included blood cultures to rule out occult bacteremia. This study assessed the usefulness of this practice in the era of routine childhood immunization with pneumococcal vaccine.

Researchers retrospectively reviewed the charts of 8,408 previously healthy children (age range, 3 months to 36 months)

who presented to a pediatric emergency department in Phoenix between 2004 and 2007 with fever ≥39°C, no apparent source of infection, blood cultures drawn, and who were discharged from the ED.

A pediatric infectious disease specialist determined that 21 blood cultures were true positives (0.25%); of these, 14 grew *Streptococcus pneumoniae*. Another 159 positive cultures (1.89%) were determined to be contaminants, yielding a ratio of 7.6 contaminants for every one true positive culture.

Routine vaccination for *Haemophilus influenzae* and pneumococcus has virtually eradicated occult bacteremia in well-appearing febrile children, and the results of this study suggest that blood cultures should no longer be performed in such patients. The complete blood count also is of questionable usefulness in this patient cohort and should not be ordered. Ill-appearing children, whether febrile or not, still warrant an appropriately directed work-up, which might include blood cultures.

Published in *J Watch Emerg Med,* April 17, 2009—Diane M. Birnbaumer, MD, FACEP. ■

The Management of Children with Gastroenteritis and Dehydration in the Emergency Department

Key point: The most useful predictors of >5% dehydration are abnormal capillary refill, abnormal skin turgor, and abnormal respiratory pattern.

Citation: Colletti JE, Brown KM, Sharieff GQ, et al. *J Emerg Med*. 2009;Apr 2 [e-pub ahead of print].

No single laboratory value has been found to be accurate in predicting the degree of dehydration and this is not routinely recommended. However, evidence suggests that the three most useful predictors of ≥5% dehydration are abnormal capillary refill, abnormal skin turgor, and abnormal respiratory pattern.

Several studies found that low serum bicarbonate combined with certain clinical parameters predicts dehydration.

In most studies, oral or nasogastric rehydration with an oral rehydration solution was equally efficacious as intravenous rehydration.

Many experts discourage the routine use of antiemetics in young children. However, children receiving ondensetron are less likely to vomit, have greater oral intake, and are less likely to be treated by IV rehydration. Mean length of emergency department stay is also less, and very few serious side effects have been reported.

Treatment for Children with Viral-Induced Wheeze

Key point: For children with no history of atopy and no family history of asthma, treatment with oral steroids or inhaled corticosteroids is not warranted.

Citation: Bauchner H. *Medscape Today*. March 20, 2009. Available at: *www.medscape.com/viewarticle/587826*.

Children with viral-induced wheeze often receive oral or inhaled corticosteroids or a leukotriene inhibitor despite a lack of good evidence that they work. Three studies shed light on this condition.

In a double-blind, randomized trial, 220 children (age range, 1–5 years) who had histories of intermittent wheeze associated with respiratory tract infection received albuterol plus a seven-day course of inhaled budesonide (1000 mcg twice daily), montelukast (4000 mcg daily), or placebo at the onset of each RTI. The three groups had similar proportions of episode-free days during 12 months of treatment (the primary outcome, about 75%), oral steroid use, and healthcare utilization.

However, during the 14 days after initiation of the study drug, children who received inhaled budesonide or montelukast had significant reductions in total symptom scores (reflecting wheeze, cough, and activity level). Children who were considered at high risk for asthma at baseline received the greatest benefit from the study medications.

In another double-blind, randomized, 12-month trial, 127 children (age range, 1-6 years) with histories suggestive of viral-induced wheeze received high-dose fluticasone (750 mcg twice daily) or placebo at the onset of each RTI and continued until 48 hours after they were symptom free.

If symptoms worsened, parents administered two to four inhalations of albuterol (100 mcg). Children whose symptoms lasted more than 10 days received medical consultation. Rescue oral steroids were required in significantly more episodes of RTI in the placebo group than in the fluticasone group (18% vs. 8%), and fluticasone-treated children had significantly shorter symptom duration (about one to two days). However, fluticasone recipients gained significantly less weight (mean, 1.53 kg vs. 2.17 kg) and height (mean, 6.23 cm vs. 6.56 cm) than placebo recipients.

In a third randomized trial, 687 children (age range, 10 months–5 years) who were hospitalized in three U.K. hospitals with viral infection-associated wheezing and did not respond to albuterol received a five-day course of once-daily oral prednisolone or placebo. No differences between groups emerged for the primary outcome of time to discharge from the hospital or for the secondary outcomes of number of albuterol administrations during hospitalization and respiratory scores at four, 12, and 24 hours.

Where does this leave us for treatment of children with viral-induced wheezing? For children who have no history of atopy and no family history of asthma, treatment with oral steroids or inhaled corticosteroids is not warranted. However, for children who seem to be at risk for asthma (by virtue of positive family history or atopy), either medium-dose inhaled corticosteroids or a leukotriene inhibitor might be warranted during an RTI. ■

A Short Course in Tort

JOHN SHUFELDT, MD, JD, MBA, FACEP

I just completed teaching a semester of Health Law and Ethics at the W.P. Carey School of Business at Arizona State University. Over the next few months in this column, my goal is to distill the 40-hour course down to a few pages chock full of practical legal information.

Hopefully, as a result of this overview, you will garner enough practical knowledge to keep out of overt danger!

Lesson 1: Torts

A *tort* is a civil wrong committed against a person or property interest for which the court provides a remedy in the form of damages.

Malpractice

We're all familiar with the tort known as *malpractice*. Breaking it down to its essence, malpractice occurs when a professional performs in a careless or negligent manner within the context of that profession, compared with a reasonable person with similar background and training in a similar situation. This definition assumes there is proof of actual injury, without which a defendant cannot be found liable.

A "negligent manner" is characterized by the unintentional commission or omission of an act that a reasonably prudent person would or would not commit under given circumstances. The right vs. wrong standard is, what would a person of average intelligence and common sense do in the similar circumstance?

To prove malpractice, a plaintiff must show that the practitioner did not live up to his "duty to care," which exists when there is a legal obligation of care. Generally speaking, in privately held urgent care centers, there is no duty to care for the unestablished patient who presents demanding treatment. If you or your center has already been treating the patient during the course of illness, however, you are required to continue the treatment through completion.

Breach of that duty is the failure to meet a prevailing standard of care, which is defined nationally, not locally. Expert witnesses often are used to help determine what a reasonably prudent person would or would not have done in such a case.

Some other terms and concepts that it may behoove you to understand:

- *Causation* refers to the idea that the defendant's negligence (or other action) must be a substantial and foreseeable factor in having caused an injury for which damages are being assessed.

  In this context, "foreseeable" means a reasonable person should be able to anticipate that the action or inaction in question could reasonably lead to the injury.
- The legal doctrine of *respondeat superior*, loosely translated as "let the master respond," holds employers liable for the wrongful acts of their employees. This doctrine is also referred to as *vicarious liability*, whereby employers are accountable for the negligent acts of their employees while the employees are carrying out their job-related duties or any activities while "on the clock."
- *Res ipsa loquitur* means the "thing speaks for itself." The broader concept is that a negligent act can be inferred merely from the occurrence of an injury (for example, leaving a clamp in the abdomen after surgery or amputating the wrong appendage).

  Three elements are necessary to prove *res ipsa*; if they are present, the burden of proof is shifted from the plaintiff to the defendant:
  - The event would not have occurred in the absence of negligence.
  - The defendant must have exclusive control over the cause of the injury.
  - The plaintiff cannot have contributed to the injury.

Of course, not every bad outcome is the result of negligence on the part of the provider. And just because you've been accused of negligence does not mean that you actually were negligent, or that you will be found culpable.

John Shufeldt is the founder of the Shufeldt Law Firm, as well as the chief executive officer of NextCare, Inc., and sits on the Editorial Board of *JUCM*. He may be contacted at *JJS@shufeldtlaw.com*.

There a number of viable defenses to such charges.

Patients bear a certain degree of inherent risk every time they seek treatment in any practice setting. They know some degree of danger exists and voluntarily expose themselves to it in order to get medical care. This is known as *assumption of the risk*.

Similarly, the *borrowed servant* and *captain of the ship* doctrines hold that the employer is not liable for injury negligently caused by the servant (i.e., her employee) while that servant is being directed by another individual. Operating rooms are a good example of how the captain of the ship doctrine is applied, with the surgeon being the one in command and the hospital's staff filling the roles of "borrowed servants."

There are other situations in which, as they say, "there's plenty of blame to go around."

Comparative negligence simply means that each defendant is responsible for his or her proportional share of any damages awarded, while *contributory negligence* can be defined as any lack of ordinary care on the part of the person injured that, when combined with the negligent act of another, caused the injury and without which the injury would not have occurred.

A person is contributorily negligent when that person does not exercise reasonable care for his or her own safety. For example, a drunk person wanders across a busy highway outside of the cross walk and is struck by a speeding car. The drunk has contributed to his own injuries and without his negligent act, the injury would not have occurred.

There are also situations in which physicians and other healthcare professionals may be relieved of liability altogether. "Good Samaritan" laws fall under this category, unless the provider had a pre-existing duty to care.

Intervening cause means that the act of a third party, independent of the defendant's original negligent act, is the actual and proximate cause of the injury.

The terms i*gnorance of fact* and *unintentional wrongs* are the legal equivalent of "the sun was in my eyes" and will not work as a defense.

Finally, while not a defense, the term *statute of limitations* may bring some degree of relief to clinicians who otherwise might find themselves on the wrong end of a judgment; this refers to the legislatively enacted constraints that limit the period of time after an incident during which a legal action must be commenced.

Defamation

In our profession, malpractice is likely to be the tort we fear most, and the one with the potential to inflict the most damage on our ability to practice medicine. It is not the only route to incurring damages by virtue of our actions, however.

The Constitution may guarantees us freedom of speech, but that doesn't speech is always "free." Ill-advised words can come with a price tag if you are guilty of *defamation of character*—a false oral or written communication that subjects a person's reputation to scorn and ridicule in the eyes of a substantial number of people in the community. Speaking negatively about someone to that person's face without anyone else present, on the other hand, is not defamation.

There are two ways to defame someone:

- *Libel* is the written expression of defamation. It can be presented in the form of signs, photographs, letters, and cartoons. To be actionable, defamation must be communicated to a third person.
- *Slander* is oral expression of defamation. It is presumed that any slanderous reference to someone's professional capacity is damaging. However, there are very few slander lawsuits because of the difficulty in proving defamation, the small awards, and high legal fees associated with recovery.

Damages

If you are found guilty of a tort, there are a number of different types of damage awards you may face:

- *Nominal* damages are simply a token in recognition that a wrong has been committed.
- *Compensatory* damages are intended as compensation for the damage or injury sustained.
- *Hedonic* damages are awarded to compensate the plaintiff for the loss of enjoyment of life. This is in addition to the compensation offered by compensatory damages.
- *Punitive* damages are additional recompense when an injury is caused by gross negligence or wanton indifference.

Until next month, keep your torts to yourself and get geared up for an overview of contract law! ■

Editor's note

JUCM would like to again congratulate Dr. Shufeldt for receiving a Bronze Award in the American Society of Healthcare Publication Editors 2009 Annual Awards Competition. This is the second year in a row the Health Law column has been recognized in the category of Regular Column: Contributed, which is open to non-staff authors who regularly contribute columns to healthcare-related magazines and journals in the U.S. We appreciate Dr. Shufeldt's ongoing support of JUCM*, as well as that demonstrated by all our contributors.*

Identifying, Contacting, and Cultivating the 'Best' Contact Person

FRANK H. LEONE, MBA, MPH

Identifying the right contact person at a prospective client company begins with a sound, well-conceptualized, and up-to-date mailing list. Central to the list is the name of the individual responsible for the health and safety of the workforce.

This information needs to be verified or updated regularly, something that could be accomplished by having a clerical staff member or high school student call every employer in your database each summer.

Even when working from a list that is updated annually, you or a sales professional in your organization should place a preliminary call to a prospect company moments before the actual sales call to confirm that the information you have is correct.

A 30-second call to a company before a sales call ("Could you verify that Luc Richard is still with your company and is responsible for the health and safety of your workforce?") saves time and trouble later. This brief interview can be as important as the sales call to follow.

Note, however, that *perfection is not attainable*. A 100% "right contact person" score is simply not in the cards. For one thing, there often is more than one individual who is "the right person"—there may be many, in fact—or that individual may change by the day. Or the gatekeeper may err and provide your clinic with an inappropriate contact name. Thus, you have to frequently adjust on the fly; always be asking who is who and whether it would be more appropriate to deal with someone else.

Contacting the Right Individual

In occupational health sales, there are cold calls, cool calls, and hot calls.

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*.

A classic cold call: just showing up at someone's office and hoping for the best is a poor idea. Not only is it invariably a waste of precious sales time, but it is also an easy way to alienate a prospective buyer.

A cool call involves a professional and customized letter and/or phone call as an entrée for a face-to-face meeting. Not bad, except the author or caller is likely to be viewed as just another salesperson and quickly forgotten.

A hot call is a cool call with some sizzle. A hot call is one in which the groundwork has been done via an astute name recognition/marketing campaign so that the recipient is more likely to be aware of who you are and what you represent.

This process begins with fundamental marketing, which has everything to do with ensuring that as many prospects as possible know who you are, what you do, and what sets your clinic and its services apart from any other option. If your clinic has done a good job in this regard, there is a greater likelihood that the prospect will know who you are going in and offer you the time that you need.

Cultivating the Right Individual

Cultivation involves discipline and patience.

- Clearly articulate who you are, what your program does, and the objective of the interchange, whether it is by letter, phone, or in person.

  A brief entrée might be something like "My name is Mike Roll and it is my responsibility to speak with employers such as yourself to learn more about your challenges and see how our clinic can help you address those challenges." The "cut to the chase" proviso is alive and well in the world of occupational health sales.
- Never shut the door when you can leave it open a crack. Always look at defeats at the sales counter as temporary. It is best to pick up your marbles and set the stage to come back and play the game another day.

Continued on page 44

CODING Q&A

Medication Supplies, New Patient E/M, and Skin Shaving Vs. Skin Biopsy

■ DAVID STERN, MD, CPC

Q. On our new superbill, there is a spot to code for Phenergan (generic is promethazine HCl) 50 mg when administered intramuscularly. How would we code for Phenergan when the physician orders Phenergan 25 mg IM? Do we mark the code x ½?

– Anonymous, Illinois

A. If you administer 50 mg of promethazine or any portion of 50 mg, then you use code J2550 (Injection, promethazine HCl, up to 50 mg).

For example:

- 25 mg = J2550
- 50 mg = J2550
- 70 mg = J2550 x 2
- 100 mg = J2550 x 2

This is a general rule for HCPCS medication codes, i.e., you use the code for the amount listed or for any fraction of the amount listed.

Of course, you should also code for the administration code for Therapeutic IM Injection (96372).

Note: For 2009, all therapeutic, prophylactic, and diagnostic injection and infusion codes have been changed to place them in a new code range (96360-96379). In the example noted above, the CPT code 90772 for Therapeutic IM Injection has been eliminated and replaced with the new code 96372. ■

Q. I understand that you can code a new patient E/M every three years. Do you know of a system that will track when the last new patient visit was coded, so that we can make sure that we code a new patient E/M when it has been three years since the last new patient E/M code?

– Anonymous, Florida

A. This is another confusion that persists about new vs. established patient E/M codes.

No, you do not code a new patient visit every three years. Rather, you should code a new patient E/M (99201-99205) if and when the patient is being seen in your urgent care, and the patient has not received face-to-face provider services from a provider (of the same specialty) in your urgent care at any time during the past three years.

If the patient has received face-to-face services from a provider in your urgent care at any time during the past three years, then you should use an established patient E/M code (99212-99215).

Visits where the patient does not receive face-to-face services from a provider may include influenza vaccinations, drug screens, and blood pressure checks.

These visits do not count as face-to-face encounters, and should not be considered when applying the three-year rule. **Figure 1** (page 44) should help to illustrate this principle. ■

Q. The doctor obtained a biopsy specimen of a suspicious nevus by shaving the lesion. Should I use a code for lesion removal by shaving or should I use a biopsy code?

– Anonymous, California

A. The question to ask first is this, "*Why* did the doctor remove the lesion?" Was it to obtain a biopsy specimen for microscopic evaluation by a pathologist, or was it to simply excise the lesion from the patient's skin?

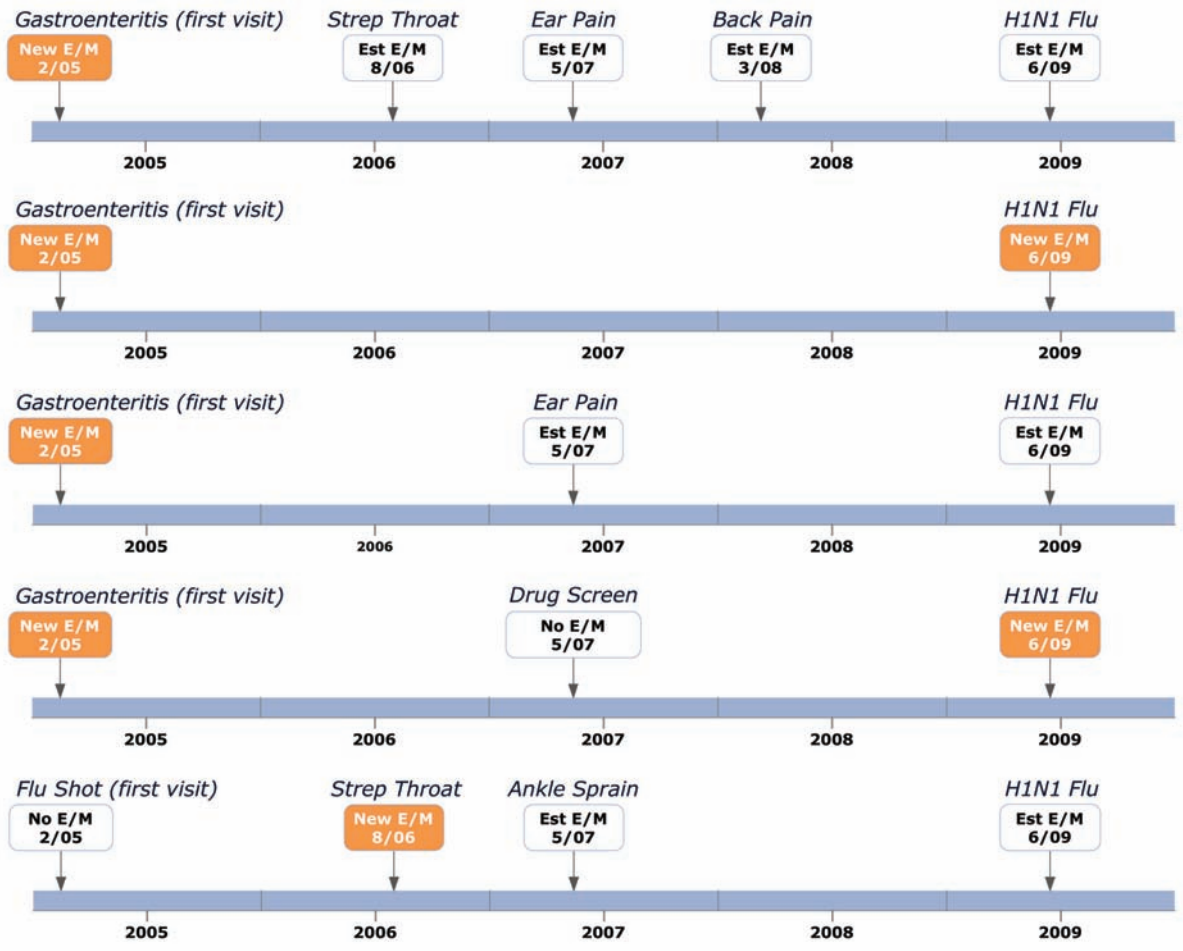
In the case you mention, the lesion was "suspicious" for malignancy, so the biopsy code (11100-11101) should be used.

On the other hand, if the lesion was removed via shaving for cosmetic or comfort reasons, then you should code with a code for removal of a lesion by shaving (11300-11313). ■

David E. Stern, MD, CPC is a certified professional coder. He is a partner in Physicians Immediate Care, operating 12 urgent care centers in Oklahoma and Illinois. Stern serves on the Board of Directors of the Urgent Care Association of America and speaks frequently at urgent care conferences. He is CEO of Practice Velocity (*www.practicevelocity.com*), providing urgent care software solutions to more than 500 urgent care centers. He welcomes your questions about coding in urgent care.

CODING Q & A

Figure 1. Established vs. New E/M *(Real Life Examples)*



OCCUPATIONAL MEDICINE

It is always useful to have a "freebie" tucked in your portfolio. It may be a complimentary subscription to your low cost e-mail advisor (a good reason to create such an advisor), an invitation to a conference or a meeting, or a free password to valuable password-protected areas of your website. Prospects are often impressed by such tenacity and fair play.

- Stay in touch and use multiple modalities. Strike a balance between being sufficiently visible and being a nuisance. Call the prospect every few months and take the high road; ask them what you (or your clinic) could do for them and check in to see how things are going.
- Keep your prospect pipeline "just right." Occupational health sales professionals tend to err on both sides of this equation; often, the pipeline is insufficiently full, meaning that you are counting on a small number of prospects to come through soon. Or the pipeline is too full; that is, you simply have too many prospects in various stages of development to manage each of them as well as you should.

The axiom "time is money" rules the roost in occupational health sales. Nothing seems to take more time than pursuing dead-end leads. There will, of course, be many dead ends; the secret is to minimize them by developing and executing a proactive plan to identify, contact, and cultivate the right person. ■

Career Opportunities

NORTHERN VIRGINIA/D.C. SUBURBAN – Full- and part-time positions available at hospital affiliated urgent care centers. Send CV to: securemedical@gmail.com.

FAMILY PHYSICIAN OPPORTUNITY – Aurora Illinois' award-winning ED's urgent care section desires additional physician. Highly competitive compensation; flexible scheduling. Contact Mary Deans-O'Claire: (847) 697-8868; or tylercreek tvl@sbcglobal.net.

LAWRENCE, KANSAS - PHYSICIAN OPPORTUNITY available in established, free-standing, physician owned, urgent care and occupational health clinic with onsite physical therapy. Lawrence is home of the University of Kansas and is less than one hour from Kansas City. Excellent housing and schools. Send CV to: Mike Geist M.D., PromptCare, 3511 Clinton Place, Lawrence, KS 66047; or call: (785) 838-1500; or email: promptcare@sunflower.com.

PART-TIME PHYSICIAN for urgent care in Shenandoah Valley. Flexible hours, maximum 20 hours/week. No Sundays. Malpractice insurance provided. Mail CV to: Ana Mata, 3590 Traveler Road, Harrisonburg, VA 22801.

INDEPENDENT, democratic emergency physician group has need for part-time (6 hour/day) PA in our Immediate Care Facility in Chicago's western suburbs. Competitive salary, benefits and malpractice insurance included. Interested parties should contact: Sonia Mininni, M.D. Medical Director, Du Page Convenient Care, LLC, 6840 Main Street, Downers Grove, IL 60516. Email: smmvalentine@yahoo.com.

LOS ANGELES, CALIFORNIA – SmartClinic, is seeking BC/BE emergency or family medicine physicians to staff a new urgent care opening September 2009. Competitive compensation, flexible scheduling and great work environment. Must be ACLS certified. Submit inquiries and CV to: mysmartclinic@gmail.com.

TEXAS URGENT CARE OPPORTUNITIES: Seeking BC/BP primary care physicians for hospital based urgent care in Palestine (near Tyler) and Byran/College Station. We are a stable group offering flexible scheduling, competitive compensation, paid malpractice and tail insurance, plus opportunity for partnership! For more information contact Gretchen Moen at: (888) 800-8237; or Gretchen@eddocs. com.

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URGENT CARE OPPORTUNITY – STOCKTON, CALIFORNIA

Gould Medical Group, Inc., California's premier multispecialty group, is currently seeking two BC/BE emergency, family medicine, or internist physicians to staff their new urgent care department, which will be housed in a brand new 130,000 square foot office building scheduled to open in November of 2009. Candidates should have a full range of urgent care skills, be ACLS certified, and have an interest in working with an innovative group.

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For additional information visit our Web site at www.suttergould.org/doctors
Email your CV to gmgrecruiting@sutterhealth.org, or fax to: (209) 550-4892.

Harjit Singh, Director ~ Sutter Gould Medical Foundation
(866) 45-Gould or (866) 454-6853

West Virginia University School of Medicine ~ Department of Emergency Medicine is seeking a new faculty member at WVU Urgent Care. Training in emergency medicine, urgent care or a primary care specialty is preferred. Board certification/eligibility in emergency medicine, family medicine or internal medicine is advantageous. Experience in an urgent care setting is preferred, but not required. Responsibilities include teaching of residents and mid-level providers and patient care.

WVU Urgent Care opened in September 2007 and is on pace to see 19-20K patient visits this year. The clinic currently operates from 8am to 8pm, seven days a week. Hours may expand in the future. Staffing includes one physician and one mid-level provider at all times.

Morgantown, WV offers culturally diverse, large-city amenities in a safe, family-like setting. There are excellent school systems and an abundance of recreational opportunities. The community has been ranked by several publications as one of the best small metro areas in the country.

WVU offers a highly competitive and comprehensive recruitment package.
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Laura Blake, Director, Physician Recruitment
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FOR SALE – Urgent care practice in Virginia. Free standing center in an excellent, high-traffic location. This well-established business is in a growing area. Owner is retiring. Contact MT Consulting, (610) 527-8400.

Practice Sales

Services

BUSINESS BROKER SERVICES – Own a busy, clinically excellent urgent care practice? Call for a free consultation from experienced urgent care business brokers. Contact Tony Lynch or Steve Mountain at MT Consulting, (610) 527-8400; or tony@mtbizbrokers.com; www.mtbizbrokers.com.

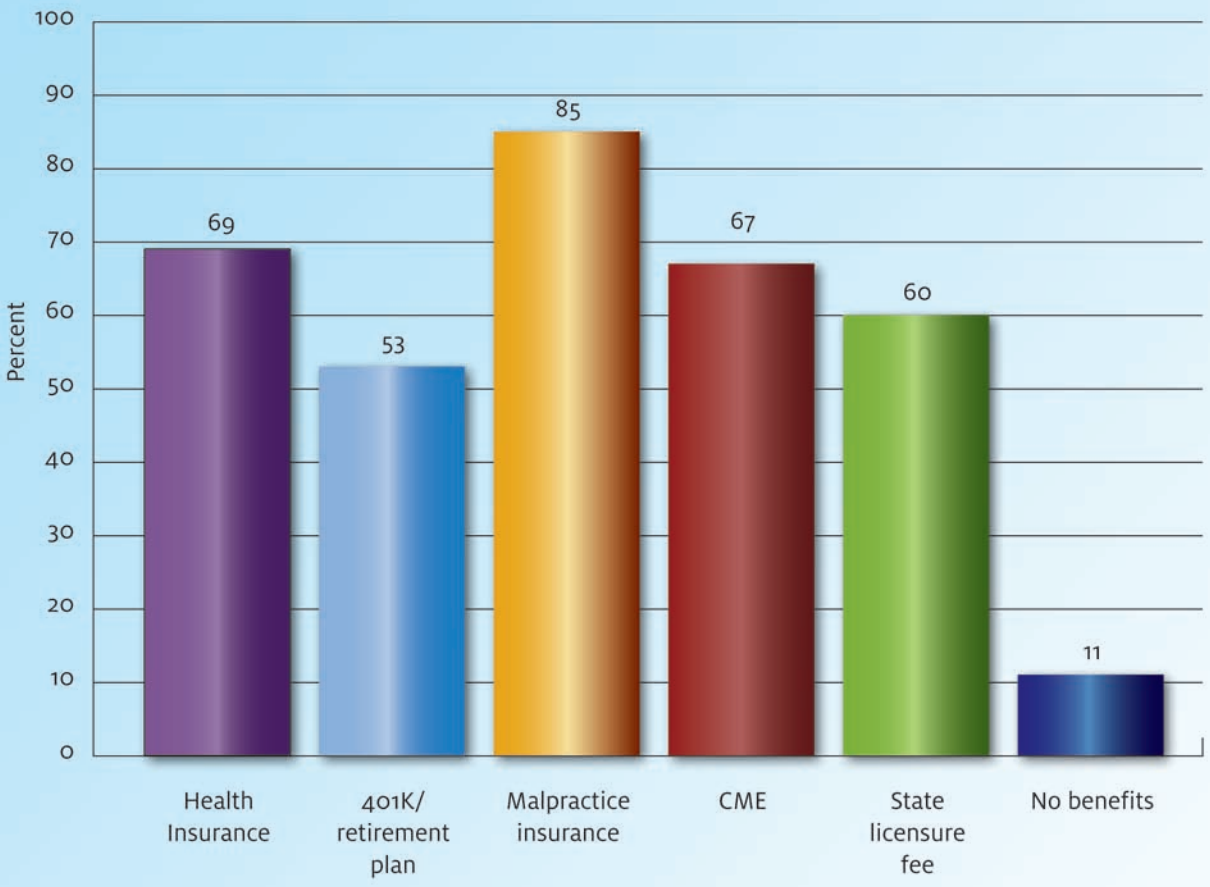
DEVELOPING DATA

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 benefits do urgent care centers provide for their physician employees?

PHYSICIAN BENEFITS COVERED BY URGENT CARE CENTER



Acknowledgment: Adapted from Urgent Care Centers in the U.S.: Findings from a National Survey. Weinick RM, Bristol SJ, DesRoches CM. 2009. *BMC Health Services Research*.

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*.

UCAOA

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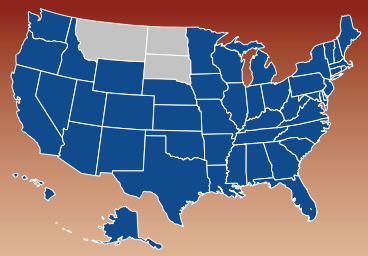

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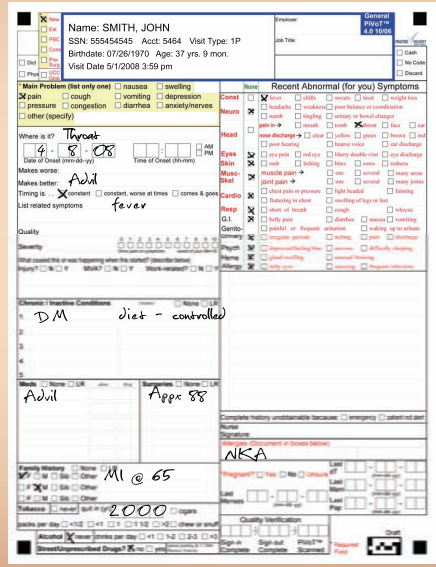

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