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CLINICAL FOCUS

Epididymitis

The Optimal Urologic Evaluation Management Approach in the Urgent Care Setting

ORIGINAL RESEARCH

Emergencies in the Office:

Why Are 911 Calls Placed From Family Medicine and Urgent Care Offices?

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Keeping the Joy of Practice



Many physicians in urgent care face burnout. While the numbers are probably far less than our emergency medicine colleagues, the burdens of productivity, quality, patient satisfaction, employee satisfaction, and risk management can weigh heavily on urgent care physicians, and with time, take the joy out of practicing. This is the first in a series of editorials providing practical tips for reducing “urgent care fatigue syndrome.”

Let’s start with an approach to managing patients who are antibiotic and narcotic seekers: make a dent in the armor / you can’t win the war in one visit / live to fight another day. Attempting to right all the wrongs in the world is a surefire way to burn out or lose your job to poor productivity.

Case 1: ‘Recurrent Sinusitis’

This patient arrives in the urgent care for “recurrent sinusitis,” but it becomes clear during the history that this patient is undoubtedly receiving multiple courses of antibiotics inappropriately, has never had an appropriate work-up, and has never been given an evidence-based treatment plan. She has been conditioned to pursue antibiotics when she feels this way.

You could do “battle” with this patient on inappropriate antibiotics, but I can guarantee you she will reject your theory and go to other caregivers who will make you look bad by giving her the antibiotics anyway. You will have accomplished nothing by way of reducing antibiotic use this way. Here’s an alternative that will save you the speech, and maybe recruit her onto the side of sensible antibiotic use:

“You seem frustrated that you keep getting ‘sinus infections’ requiring multiple courses of antibiotics. I think we need to recruit a specialist to help find out why, and to develop a treatment plan for whenever you get ‘sinus symptoms’ so you don’t develop resistance, but still get appropriate treatment when you need it. Ask the specialist exactly when you should start antibiotics and when you should just treat symptomatically. We need to give you more clear guidance, so that you can feel sure you are getting the most appropriate treatment.”

Even if you give this patient an antibiotic this time, you have made a dent in her psyche without offending her. Referring this

patient to an ENT whom you trust will provide her with a long-term management plan that is consistent with established guidelines.

Case 2: Migraine Headache, ‘Needs Demerol’

Everyone dreads this encounter, but this is an opportunity to impact this patient’s care for the future.

I have found that the majority of these patients are victims of poor medical care, and are *not* drug seekers. They have been conditioned by providers who have never explained migraine management or the importance of a treatment plan from a migraine specialist. Most of these patients are indeed out of the window for effective triptan use anyway.

After thorough neurologic evaluation for alternative causes, I say this: “The use of narcotics for migraines is a last resort for most patients. I am concerned that you have not been given an effective prevention and treatment plan for your migraines, which may be contributing to your frequent, debilitating attacks. Because narcotics are rarely used for migraine management, we have a policy requiring an order from a headache specialist highlighting your treatment plan, should they be necessary on an ongoing basis.”

This avoids the battle, presumes innocence, and protects against the real drug seekers. At our clinics, we have no return offenders with this policy and never meet any resistance from patients. Most are simply grateful that we took a genuine interest in their well-being. The same approach can be taken for the other common narcotic requestor: the “back pain” patient.

In future editorials, I will address the following important contributors to career durability and satisfaction:

- Understanding patient agendas
- Communication tools for more effective patient encounters
- Filling your “emotional tank”

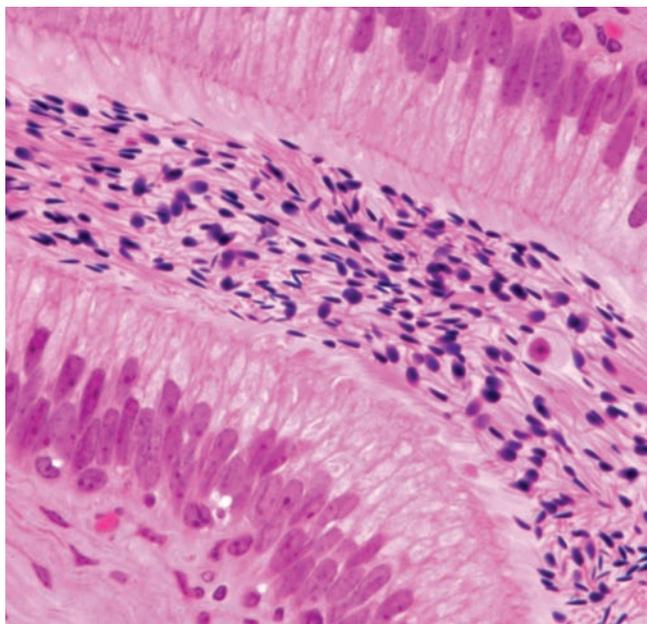
Sincerely,

Lee A. Resnick, MD
Editor-in-Chief

JUCM, The Journal of Urgent Care Medicine

January 2007

VOLUME 1, NUMBER 3



CLINICAL FOCUS

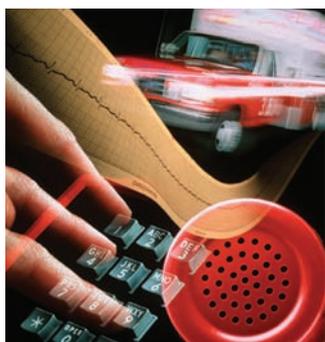
10 Epididymitis: The Optimal Urologic Evaluation Management Approach in the Urgent Care Setting

Distress over bothersome symptoms is driving increasing numbers of men to urgent care for evaluation and treatment of epididymitis, making it imperative that providers understand the proper approach to management.

By Richard A. Schoor, MD, FACS

ORIGINAL RESEARCH

19 Emergencies in the Office: Why Are 911 Calls Placed From Family Medicine and Urgent Care Offices?



The decision to call—or not call—911 for a patient in the urgent care clinic is a crucial one for all providers. Exclusive new data indicate that clinicians make the call based on a wide range of criteria.

*By Robert J. Dachs, MD, FAAFP,
Ephraim Back, MD, FAAFP, and
Brian Glick, PA-C, FAAPA, NREMT-P*

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From the Executive
Director

DEPARTMENTS

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- 40 Developing Data



When cough shows up in
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TUSSIONEX® is indicated for relief of cough and upper respiratory symptoms associated with allergy or a cold. Each teaspoonful (5 mL) of TUSSIONEX® contains hydrocodone polistirex equivalent to 10 mg hydrocodone bitartrate and chlorpheniramine polistirex equivalent to 8 mg chlorpheniramine maleate.

TUSSIONEX® is contraindicated in the presence of known allergy to hydrocodone or chlorpheniramine. The most common adverse reactions associated with TUSSIONEX® are sedation, drowsiness, and mental clouding, which may impair the mental and/or physical abilities required for potentially hazardous tasks.

As with other drugs in this class, the possibility of tolerance and/or dependence, particularly in patients with a history of drug dependence, should be considered.

*Based on pharmacokinetic data.¹

Reference: 1. Data on file, UCB, Inc.

Please see adjacent page for full Prescribing Information.

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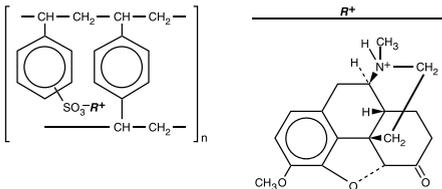
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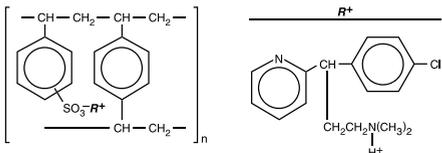


DESCRIPTION: Each teaspoonful (5 mL) of TUSSIONEX Pennkinetic Extended-Release Suspension contains hydrocodone polistirex equivalent to 10 mg of hydrocodone bitartrate and chlorpheniramine polistirex equivalent to 8 mg of chlorpheniramine maleate. TUSSIONEX Pennkinetic Extended-Release Suspension provides up to 12-hour relief per dose. Hydrocodone is a centrally-acting narcotic antitussive. Chlorpheniramine is an antihistamine. TUSSIONEX Pennkinetic Extended-Release Suspension is for oral use only.

Hydrocodone Polistirex: sulfonated styrene-divinylbenzene copolymer complex with 4,5 α -epoxy-3-methoxy-17-methylmorphinan-6-one.



Chlorpheniramine Polistirex: sulfonated styrene-divinylbenzene copolymer complex with 2-[p-chloro- α -[2-(dimethylamino)ethyl]-benzyl]pyridine.



Inactive Ingredients: Ascorbic acid, D&C Yellow No. 10, ethylcellulose, FD&C Yellow No. 6, flavor, high fructose corn syrup, methylparaben, polyethylene glycol 3350, polysorbate 80, pregelatinized starch, propylene glycol, propylparaben, purified water, sucrose, vegetable oil, xanthan gum.

CLINICAL PHARMACOLOGY: Hydrocodone is a semisynthetic narcotic antitussive and analgesic with multiple actions qualitatively similar to those of codeine. The precise mechanism of action of hydrocodone and other opiates is not known; however, hydrocodone is believed to act directly on the cough center. In excessive doses, hydrocodone, like other opium derivatives, will depress respiration. The effects of hydrocodone in therapeutic doses on the cardiovascular system are insignificant. Hydrocodone can produce miosis, euphoria, physical and psychological dependence.

Chlorpheniramine is an antihistamine drug (H₁ receptor antagonist) that also possesses anticholinergic and sedative activity. It prevents released histamine from dilating capillaries and causing edema of the respiratory mucosa.

Hydrocodone release from TUSSIONEX Pennkinetic Extended-Release Suspension is controlled by the Pennkinetic System, an extended-release drug delivery system which combines an ion-exchange polymer matrix with a diffusion rate-limiting permeable coating. Chlorpheniramine release is prolonged by use of an ion-exchange polymer system.

Following multiple dosing with TUSSIONEX Pennkinetic Extended-Release Suspension, hydrocodone mean (S.D.) peak plasma concentrations of 22.8 (5.9) ng/mL occurred at 3.4 hours. Chlorpheniramine mean (S.D.) peak plasma concentrations of 58.4 (14.7) ng/mL occurred at 6.3 hours following multiple dosing. Peak plasma levels obtained with an immediate-release syrup occurred at approximately 1.5 hours for hydrocodone and 2.8 hours for chlorpheniramine. The plasma half-lives of hydrocodone and chlorpheniramine have been reported to be approximately 4 and 16 hours, respectively.

INDICATIONS AND USAGE: TUSSIONEX Pennkinetic Extended-Release Suspension is indicated for relief of cough and upper respiratory symptoms associated with allergy or a cold.

CONTRAINDICATIONS: Known allergy or sensitivity to hydrocodone or chlorpheniramine.

WARNINGS: Respiratory Depression: As with all narcotics, TUSSIONEX Pennkinetic Extended-Release Suspension produces dose-related respiratory depression by directly acting on brain stem respiratory centers. Hydrocodone affects the center that controls respiratory rhythm, and may produce irregular and periodic breathing. Caution should be exercised when TUSSIONEX Pennkinetic Extended-Release Suspension is used postoperatively and in patients with pulmonary disease or whenever ventilatory function is depressed. If respiratory depression occurs, it may be antagonized by the use of naloxone hydrochloride and other supportive measures when indicated (see OVERDOSAGE).

Head Injury and Increased Intracranial Pressure: The respiratory depressant effects of narcotics and their capacity to elevate cerebrospinal fluid pressure may be markedly exaggerated in the presence of head injury, other intracranial lesions or a pre-existing increase in intracranial pressure. Furthermore, narcotics produce adverse reactions which may obscure the clinical course of patients with head injuries.

Acute Abdominal Conditions: The administration of narcotics may obscure the diagnosis or clinical course of patients with acute abdominal conditions.

Obstructive Bowel Disease: Chronic use of narcotics may result in obstructive bowel disease especially in patients with underlying intestinal motility disorder.

Pediatric Use: In pediatric patients, as well as adults, the respiratory center is sensitive to the depressant action of narcotic cough suppressants in a dose-dependent manner. Benefit to risk ratio should be carefully considered especially in pediatric patients with respiratory embarrassment (e.g., croup) (see PRECAUTIONS).

PRECAUTIONS: General: Caution is advised when prescribing this drug to patients with narrow-angle glaucoma, asthma or prostatic hypertrophy.

Special Risk Patients: As with any narcotic agent, TUSSIONEX Pennkinetic Extended-Release Suspension should be used with caution in elderly or debilitated patients and those with severe impairment of hepatic or renal function, hypothyroidism, Addison's disease, prostatic hypertrophy or urethral stricture. The usual precautions should be observed and the possibility of respiratory depression should be kept in mind.

Information for Patients: As with all narcotics, TUSSIONEX Pennkinetic Extended-Release Suspension may produce marked drowsiness and impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery; patients should be cautioned accordingly. TUSSIONEX Pennkinetic Extended-Release Suspension must not be diluted with fluids or mixed with other drugs as this may alter the resin-binding and change the absorption rate, possibly increasing the toxicity. Keep out of the reach of children.

Cough Reflex: Hydrocodone suppresses the cough reflex; as with all narcotics, caution should be exercised when TUSSIONEX Pennkinetic Extended-Release Suspension is used postoperatively, and in patients with pulmonary disease.

Drug Interactions: Patients receiving narcotics, antihistaminics, antipsychotics, anti-anxiety agents or other CNS depressants (including alcohol) concomitantly with TUSSIONEX Pennkinetic Extended-Release Suspension may exhibit an additive CNS depression. When combined therapy is contemplated, the dose of one or both agents should be reduced.

The use of MAO inhibitors or tricyclic antidepressants with hydrocodone preparations may increase the effect of either the antidepressant or hydrocodone.

The concurrent use of other anticholinergics with hydrocodone may produce paralytic ileus.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Carcinogenicity, mutagenicity and reproductive studies have not been conducted with TUSSIONEX® Pennkinetic® (hydrocodone polistirex and chlorpheniramine polistirex) Extended-Release Suspension.

Pregnancy: Teratogenic Effects – Pregnancy Category C. Hydrocodone has been shown to be teratogenic in hamsters when given in doses 700 times the human dose. There are no adequate and well-controlled studies in pregnant women. TUSSIONEX Pennkinetic Extended-Release Suspension should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nonteratogenic Effects: Babies born to mothers who have been taking opioids regularly prior to delivery will be physically dependent. The withdrawal signs include irritability and excessive crying, tremors, hyperactive reflexes, increased respiratory rate, increased stools, sneezing, yawning, vomiting and fever. The intensity of the syndrome does not always correlate with the duration of maternal opioid use or dose.

Labor and Delivery: As with all narcotics, administration of TUSSIONEX Pennkinetic Extended-Release Suspension to the mother shortly before delivery may result in some degree of respiratory depression in the newborn, especially if higher doses are used.

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 TUSSIONEX Pennkinetic Extended-Release Suspension, 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 of TUSSIONEX Pennkinetic Extended-Release Suspension in pediatric patients under six have not been established (see WARNINGS).

Geriatric Use: Clinical studies of TUSSIONEX 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. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

This drug is known to be substantially excreted by the kidney, and the risk of toxic 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.

ADVERSE REACTIONS: Central Nervous System: Sedation, drowsiness, mental clouding, lethargy, impairment of mental and physical performance, anxiety, fear, dysphoria, euphoria, dizziness, psychic dependence, mood changes.

Dermatologic System: Rash, pruritus.

Gastrointestinal System: Nausea and vomiting may occur; they are more frequent in ambulatory than in recumbent patients. Prolonged administration of TUSSIONEX Pennkinetic Extended-Release Suspension may produce constipation.

Genitourinary System: Ureteral spasm, spasm of vesicle sphincters and urinary retention have been reported with opiates.

Respiratory Depression: TUSSIONEX Pennkinetic Extended-Release Suspension may produce dose-related respiratory depression by acting directly on brain stem respiratory centers (see OVERDOSAGE).

Respiratory System: Dryness of the pharynx, occasional tightness of the chest.

DRUG ABUSE AND DEPENDENCE: TUSSIONEX Pennkinetic Extended-Release Suspension is a Schedule III narcotic. Psychic dependence, physical dependence and tolerance may develop upon repeated administration of narcotics; therefore, TUSSIONEX Pennkinetic Extended-Release Suspension should be prescribed and administered with caution. However, psychic dependence is unlikely to develop when TUSSIONEX Pennkinetic Extended-Release Suspension is used for a short time for the treatment of cough. Physical dependence, the condition in which continued administration of the drug is required to prevent the appearance of a withdrawal syndrome, assumes clinically significant proportions only after several weeks of continued oral narcotic use, although some mild degree of physical dependence may develop after a few days of narcotic therapy.

OVERDOSAGE: Signs and Symptoms: Serious overdosage with hydrocodone is characterized by respiratory depression (a decrease in respiratory rate and/or tidal volume, Cheyne-Stokes respiration, cyanosis), extreme somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, and sometimes bradycardia and hypotension. Although miosis is characteristic of narcotic overdose, mydriasis may occur in terminal narcosis or severe hypoxia. In severe overdosage apnea, circulatory collapse, cardiac arrest and death may occur. The manifestations of chlorpheniramine overdosage may vary from central nervous system depression to stimulation.

Treatment: Primary attention should be given to the reestablishment of adequate respiratory exchange through provision of a patent airway and the institution of assisted or controlled ventilation. The narcotic antagonist naloxone hydrochloride is a specific antidote for respiratory depression which may result from overdosage or unusual sensitivity to narcotics including hydrocodone. Therefore, an appropriate dose of naloxone hydrochloride should be administered, preferably by the intravenous route, simultaneously with efforts at respiratory resuscitation. Since the duration of action of hydrocodone in this formulation may exceed that of the antagonist, the patient should be kept under continued surveillance and repeated doses of the antagonist should be administered as needed to maintain adequate respiration. For further information, see full prescribing information for naloxone hydrochloride. An antagonist should not be administered in the absence of clinically significant respiratory depression. Oxygen, intravenous fluids, vasopressors and other supportive measures should be employed as indicated. Gastric emptying may be useful in removing unabsorbed drug.

DOSAGE AND ADMINISTRATION: Shake well before using.

Adults: 1 teaspoonful (5 mL) every 12 hours;
do not exceed 2 teaspoonfuls in 24 hours.

Children 6-12: 1/2 teaspoonful every 12 hours;
do not exceed 1 teaspoonful in 24 hours.

Not recommended for children under 6 years of age (see PRECAUTIONS).

HOW SUPPLIED: TUSSIONEX Pennkinetic (hydrocodone polistirex and chlorpheniramine polistirex) Extended-Release Suspension is a gold-colored suspension.

NDC 53014-548-67 473 mL bottle

Shake well. Dispense in a well-closed container. Store at 59°-86°F (15°-30°C).

CELLTECH

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Rochester, NY 14623 USA

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Tussionex® Pennkinetic® Extended-Release Suspension: US Patent No. 4,762,709.2.

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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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JUCM CONTRIBUTORS



Richard A. Schoor, MD, FACS, who penned our lead clinical article this month, is widely published as the author of scientific papers on topics concerning male infertility, urinary tract infections, and computational neural network modeling, as well as numerous textbook chapters on urologic subjects. In private practice in Smithtown, NY, Dr. Schoor is certified by the American Board of Urology and is an active member of the American Urologic Association, The American Society of Andrology, The American Society of Reproductive Medicine, and The American College of Surgeons. His first contribution to *JUCM*, Epididymitis: The Optimal Urologic Evaluation Management Approach in the Urgent Care Setting begins on page 10.

We're also indebted to **Robert J. Dachs, MD, FAAFP, Ephraim E. Back, MD, MPH, FAAFP, and Brian H. Glick, PA-C, FAAPA, NREMT-P** for contributing the first piece of original research we've had the privilege of publishing. Their article on what cases move urgent care centers to call 911 on behalf of patients in their care begins on page 19; it compares data from urgent care centers with that gleaned from family practice offices. To our knowledge, this represents the first such research specific to urgent care. All three of the authors practice at St. Clare's Hospital in Schenectady, NY; Dr. Dachs is assistant director of the Department of Emergency Medicine, as well as clinical assistant professor of St. Clare's Family Medicine Residency Program, Albany Medical College, Dr. Back is



chief of the Department of Family Medicine and associate director of the Family Practice Residency Program, while also serving as clinical associate professor of family and community medicine at Albany Medical College, and Mr. Glick is a PA in emergency medicine and volunteers as a paramedic with the Clifton Park & Halfmoon Emergency Corps, of which he has been chairman of the board for the past five years.

Of course, we continue to appreciate the contributions of **Nahum Kovalski, BSc, MDCM** of Terem Immediate Medical Care in Jerusalem, Israel; **John Shufeldt, MD, MD, MBA, FACEP**, CEO of NextCare, Inc.; **Frank Leone, MBA, MPH**, president and CEO of RYAN Associates as well as founder and executive director of the National Association of Occupational Health Professionals; and **David Stern, MD, CPC**, a partner in Physicians Immediate Care and chief executive officer of Practice Velocity, who have contributed their time and expertise to each of the first three issues of *JUCM*.

The Clinical Challenges for this issue (pages 29-32) were contributed by **Drs. Scott Fields, Aryeh Poms, Rafold Livshin, and Uri Frankl**.

As always, all this transpires under the watchful eye of our editor-in-chief, **Lee Resnick, MD**, who is medical director of University Hospitals Urgent Care (University Hospitals Medical Practice, Inc.), and assistant clinical professor in the Department of Family Medicine at University Hospitals Case Medical Center in Cleveland, as well as a member of the Board of Directors and the chair of academics for UCAOA.

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

Manuscripts on clinical or practice management topics should be 2,600–3,200 words in length, plus tables, figures, pictures, and references. Articles that are longer than this will, in most cases, need to be cut during editing.

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

the name, address, and contact information (mailing address, phone, fax, e-mail) for each author.

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

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Shooting for Great or Trying to Survive?

■ LOU ELLEN HORWITZ

“We have met the enemy, and he is us.”

Walt Kelly, Pogo

If you have read Jim Collins’ book, *Good to Great*, then you have learned why the true enemy of being a great organization may be trying to be “good” at too many things. Our efforts to be competitive with all comers can sometimes blind us to the unique qualities we have that make us great.¹ Let me give you an example.

Let’s say Main Street Urgent Care has been open for about 18 months when the big-box retailer down the street opens a walk-in clinic in the space where the video rental department used to be. The physician/owner of Main Street is concerned that the low-cost visits offered by the new clinic will lure patients away.

What would you do? Would you scale back on your physician caregivers and add more nurse practitioners so you can offer some of the same low-cost visits without losing your shirt? Would you run a negative ad campaign depicting the retail clinic as providing “inferior medical care” and run by an uncaring corporation? Would you close down Main Street and buy into one of the retail clinics? Would you think, “How can we get good at what they are good at so we can compete with them?”

While all of these are options, what Collins argues is that these kinds of “threats” are an opportunity to reanalyze (or discover) what he calls your “Hedgehog Concept”—what it is that Main Street Urgent Care can be *the best in the world* at doing.

If right now you are not the best in the world (or at least in your community) at anything, then the new retail clinic may indeed be a threat to you and you need to make some

adjustments. If you are the very best in your community at delivering the care that your patients need when they want it, in the way that they want it, then you will probably weather the retail clinic’s arrival just fine (anecdotal evidence indicates that many have done just that).

If you don’t know if you are the best at anything, then it’s time to get your team together and have some vigorous discussions about what you can be the best at, and get to work on whatever that turns out to be (and then market it!). It’s not a fast process, nor generally an easy one, so even if you are still the only urgent care center in your market, the time to think about your “hedgehog concept” is now, before competition starts to hone in on your patients. At UCAOA, we get at least one e-mail a week from owners who are about to open a new clinic; it’s only a matter of time before one of them opens in your territory.

A Whole New Mind

The second enemy of *great* may be our natural tendency to continue thinking about our business the way we always have. We focus on how we can improve our turnaround times, better predict staffing needs, increase collection rates, etc. Meanwhile, patients are self-diagnosing using criteria gleaned from the Internet, more and more treatments are becoming available over the counter, new models for who can prescribe treatment are emerging, radiology films are being read by practitioners in India, and consumers are demanding different levels of service than in the past.

With these rapid evolutions in the delivery of health-care, medicine is well on its way to becoming a commodity, and while urgent care providers may not be influenced as quickly as a solo practitioner, we are not immune.

At the same time, the medical community is struggling to keep pace with pharmacological advances, new technologies, and the limited hours available in the day to see patients. With so many day-to-day issues, how do you, as a clinic leader, focus your efforts and your resources?



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

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FROM THE EXECUTIVE DIRECTOR

As we have learned from watching the ramifications of the Institute of Medicine's reports on medical errors, quality medical care is the price of entry in our field—it's the bare minimum requirement for even opening your doors. It just makes sense that is where your focus must be.

After quality care (which we hope was already your focus) you need to look at what will make you stand out in your community (with patients, employers and other "customers"). More and more research is indicating that what Daniel Pink, best-selling author of *A Whole New Mind*, calls "high concept, high touch" is influencing both consumer choice and even medical training. Students at institutions like Columbia University Medical School, Yale School of Medicine, and UCLA Medical School are all being trained not only in traditional clinical skills but also in empathy, observation, and spirituality. Jefferson Medical School even measures its physicians' "empathy index."² (Is that part of your compensation formula?)

So, what is the patient experience like in a typical visit to your clinic? Is your front desk staff busy pushing paper, primarily, or are they able to use higher-level discretionary skills to make patients feel welcome, calm, attended to, and generally in good hands? Are your clinicians trained in conversing effectively with patients to avoid overlooking an underlying concern beyond the presenting problem? If many of your patients are from a different cultural background than your own, have you done any research or training about sensitivities you and your staff should be aware of?

In short, are your patients walking out the door (and into the community) feeling pleasantly surprised at how fantastic the care was at your center, or are they thinking that it "wasn't too bad" for a walk-in place?

As technology replaces the human touch in more and more activities, we will all need to capitalize on the skills that only humans can deliver: the simple act of being human to one another. While most of us are delighted to bypass the human element while checking in for our airline flight, when it comes to our health we want another thing entirely—to have a qualified group of people who care for our well-being helping us to get better.

If your clinic isn't getting that message across, then you are not going to be a great urgent care center, no matter how exemplary your clinical care is. Find a way to give that message to your patients, and let your next big worry be how to invest your profits. ■

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1. *Good to Great: Why Some Companies Make the Leap...and Others Don't*. Collins, J. (2001) Harper Business, New York.
2. *A Whole New Mind: Moving from the Information Age to the Conceptual Age*. Pink, D. (2005) Riverhead Books, New York.



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Epididymitis

The Optimal Urologic Evaluation Management Approach in the Urgent Care Setting

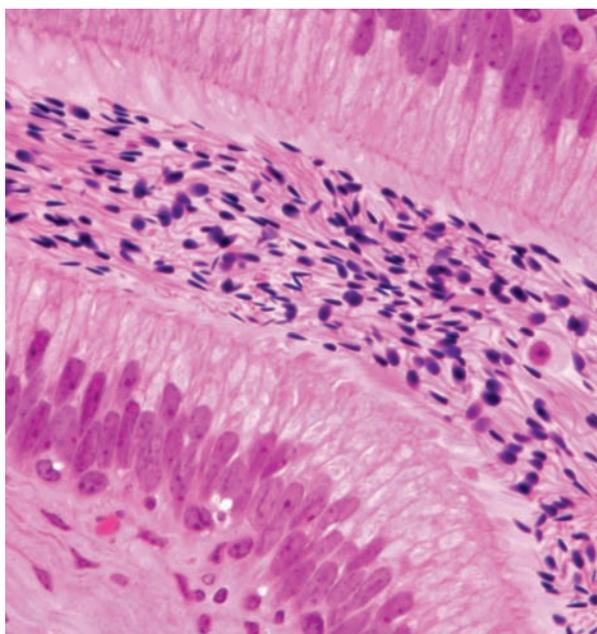
Urgent message: Though epididymitis is clinically non-urgent, its symptoms are driving more and more men to urgent care, making it imperative that providers are familiar with its epidemiology, etiology, evaluation, and treatment.

Richard A. Schoor, MD, FACS, Private Practitioner, Smithtown, NY

Introduction

Epididymitis is among the most frequently diagnosed and treated conditions in men. Typically, men present to, and are diagnosed and treated by, their primary care physicians or their urologist. Treatment is with antibiotics on an outpatient basis. Epididymitis is, in general, non-life threatening and non-urgent. However, afflicted patients experience significant distress from the symptoms and tend to seek treatment early.

Urgent care medicine is emerging as a distinct specialty, separate from both emergency medicine and primary care. From a patient's perspective, an urgent care office visit would be an attractive alternative to an emergency room visit for a variety of reasons, especially if the patient perceives his symptoms to be non-life threatening, but is concerned nonetheless to the point of wanting immediate medical attention without long waits and other unpleasanties



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associated with an emergency department visit.

Epididymitis, for the most part, fits this description well and has become commonplace in urgent care centers. Therefore, it is imperative that urgent care physicians understand the epidemiology, etiology, evaluation, and therapy of epididymitis.

Etiology and Epidemiology

Sperm is produced in the testicle and matures in the epididymis, a long convoluted tube that sits adjacent to the testicle. From the epididymis, the sperm is transported via the vas

deferens to the ejaculatory duct, in the prostatic urethra. It is at this location that infected urethral urine may access the male reproductive tract, ascend to the epididymis, and cause epididymitis. Sterile urine can also reflux up these ducts and cause a reactive, chemical epididymitis.

Epididymitis connotes inflammation of the epi-

didymis, an accessory gland in the male reproductive tract. Classically, the inflammatory process is the result of bacterial infection, but it can be caused by viruses or reflux of sterile urine up the reproductive tract.

In men less than 35-years-old, *Chlamydia* is the likely agent, thus making epididymitis in this group a sexually transmitted disease.^{1,2} In men greater than 35-years-old, *E coli* is the most commonly isolated pathogen.³

Hematogenous spread of bacteria is rare, but can occur with tuberculosis. True bacterial epididymitis in older men or children is typically associated with an anatomic abnormality, such as bladder outlet obstruction or a congenital urologic anomaly, such as an ectopic ureter.

Viral infection (e.g., mumps) may also cause epididymitis. Mumps epididymal orchitis is more common in the post-pubertal, pediatric population but has become uncommon due to the routine use of the mumps vaccine.

Fungal infections may also cause epididymitis, most notably in the immunocompromised.⁴⁻⁶ Other causes of epididymitis include medications (amiodarone), vasculitis ulititis (Henoch-Schönlein purpura), and parasites.⁷⁻⁹

Epididymitis affects one in 350 U.S. men annually and has no race predilection.¹⁰

Diagnosis

History and Physical Examination

Men with epididymitis present with scrotal or testicular pain that can range from a mild, achy discomfort to severe pain with associated high fever and a leukocytosis. Men with the latter will most commonly present to an emergency department due to the severity of their symptoms and will occasionally require admission for intravenous antibiotics.

In an ambulatory setting, men more commonly present with milder complaints of testicular or scrotal pain. Occasionally, they will have dysuria or urinary frequency suggestive of a urinary tract infection (UTI), though often voiding symptoms will be absent.

A comprehensive medical history should be performed and specifically include a urologic history. The physician needs to inquire about any history of urinary tract surgery or instrumentation, voiding complaints, prior infections, and prior episodes of scrotal pain in the patient.

Finally, a sexual history, including prior sexually transmitted diseases, should be elicited and needs to include

the patient's use of safe sex practices, or lack thereof.

A physical examination of the scrotum, testicles, and epididymis is to be done and will likely demonstrate tenderness over the involved epididymis. In severe cases, fluctulance is present. Occasionally, epididymitis will cause a reactive hydrocele to form and when large enough, the hydrocele will impair physical examination and prevent accurate diagnosis.

In this case, a scrotal sonogram is indicated. It is important to exam the testicles, as well, and to determine whether or not the acute scrotal pain is caused by testicular torsion or tumors, the two most serious diagnoses in the differential. The involved testicle in men with torsion will be very tender and have an abnormal transverse lie within the scrotum and the ipsilateral cremaster reflex will be absent, in general.

When testis torsion is suspected, the patient should be sent to an emergency department for immediate urologic consultation and, if need be, surgical detorsion.

Adjunctive Tests

Readily available adjunctive tests, when added to a comprehensive history and physical, can suggest or rule out the more serious conditions in the differential diagnosis. The urine analysis should be the first adjunctive test performed, and in severe cases of epididymitis will show pyuria. While the presence of pyuria suggests the diagnosis of epididymitis, it is not diagnostic and its absence does not rule out the diagnosis since patients can have fairly severe cases of epididymitis without urinary findings.

A urine culture should be performed, as well. The clean-catch method is the preferred technique, especially in the uncircumcised male, in whom preputial microbes can contaminate a urine specimen. The clean-catch technique involves instructing the man to retract his foreskin (if present) and clean the glans penis with an aseptic towelette, and then void mid-stream into the sterile collection cup. This technique should be used routinely in the urgent care setting and provides accurate urine culture results in men with minimal specimen contamination risk.

Alternatively, the three-glass cycle collection technique is optimal (**Figure 1**).¹¹ In the three-glass cycle, the patient is asked to clean as above, and then to void the first 10 cc of urine into cup A, and the rest into cup B. The third specimen is collected into a sterile cup after the physician performs a prostate examination. This method can enable the physician to localize the source of the infection to the urethra (glass A),

the bladder, (glass B), or the prostate (glass C). While the three-glass cycle is optimal, it is somewhat cumbersome to perform and is not routinely used nor mandatory in the urgent care setting.

A relatively new urine test that can detect *Neisseria gonorrhoea* (GC) and *Chlamydia* in the urine via DNA amplification, the BD ProbeTec™ (Quest Diagnostics), is also available. It uses polymerase chain reaction (PCR) technology to detect GC and chlamydial DNA fragments in the urine of patients with suspected STDs.¹²⁻¹⁴

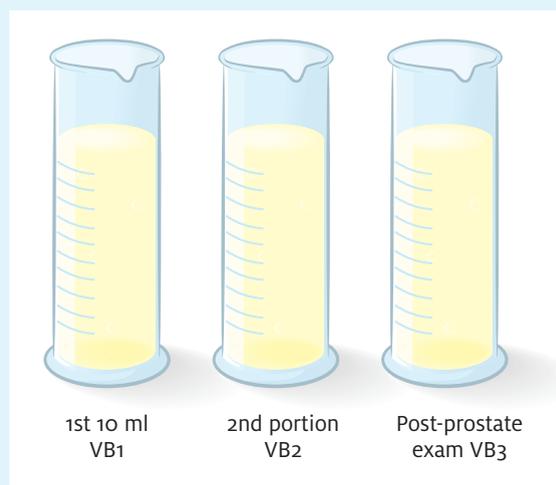
Other highly sensitive and specific PCR-based tests are also available. Men are simply asked to void into a sterile collection cup, and the urine is transferred to the preservative-containing transport tube with a pipette. No urethral swab is needed. Since epididymitis in young men is considered an STD and most commonly caused by chlamydial infection, the DNA urine probe has become a useful adjunct in the diagnosis and treatment of epididymitis.

Scrotal Sonogram

Perhaps the single most important adjunctive test is the scrotal sonogram.¹⁵⁻¹⁷ The scrotal sonogram is abundantly available, safe, painless to perform, and inexpensive and provides the most accurate diagnostic information relating to scrotal pathology. Sonograms will readily detect testicular tumors, even small, non-palpable ones, can visualize the testicle within a hydrocele, and has echo-features that are characteristic for epididymitis and orchitis. Most sonogram units today, even portable office-based units, have Doppler flow capabilities and are useful in ruling out the presence of testicular torsion.

However, if testicular torsion is even suspected, it is prudent for the evaluating physician to obtain a prompt urology consult or to send the patient imme-

Figure 1. Three-glass cycle collection technique.



The three-glass cycle is used for localization of urine cultures. The VB1 represents the urethral component, the VB2 samples bladder urine, and the VB3—the portion after a prostate massage—can indicate whether the bacteria are localized to the prostate.

diately to the emergency room at a hospital that is equipped to handle this type of emergency.

Sonographically, epididymitis has findings that are suggestive, though not diagnostic, of the condition. These findings include hyperemia of the epididymes and surrounding testicle or epididymal engorgement. Often, a reactive hydrocele is present and can be seen on the sonogram. However, the most important sonographic findings are the absence of a testis mass and the presence of testicular blood flow on Doppler.¹⁶⁻¹⁷

Cautionary Notes

The clinician should bear the following cautions in mind at all times:

- The presence of Doppler flow in the testicle does not completely rule out testis torsion. In cases of suspected torsion, urologic consultation is mandatory.
- Epididymitis is uncommon in prepubertal boys. Acute scrotal pain in this population should be considered torsion until proven otherwise.
- Bacterial epididymitis in the pediatric population represents a urinary tract infection and needs to be evaluated appropriately.

Therapy

The treatment of epididymitis depends on a variety of factors that include the age of the patient, the severity of the presentation, and the patient's medical history.

In young adults or in patients at risk for an STD, ceftriaxone sodium and doxycycline are the preferred agents due to their efficacy against *Neisseria gonorrhoea* and *Chlamydia*. Ceftriaxone is given as a one-time dose, but doxycycline must be given for seven to 14 days, which can adversely affect compliance.

Alternatively, the treating physician may prescribe azithromycin, which is advantageous over ceftriaxone sodium and doxycycline with regard to both its



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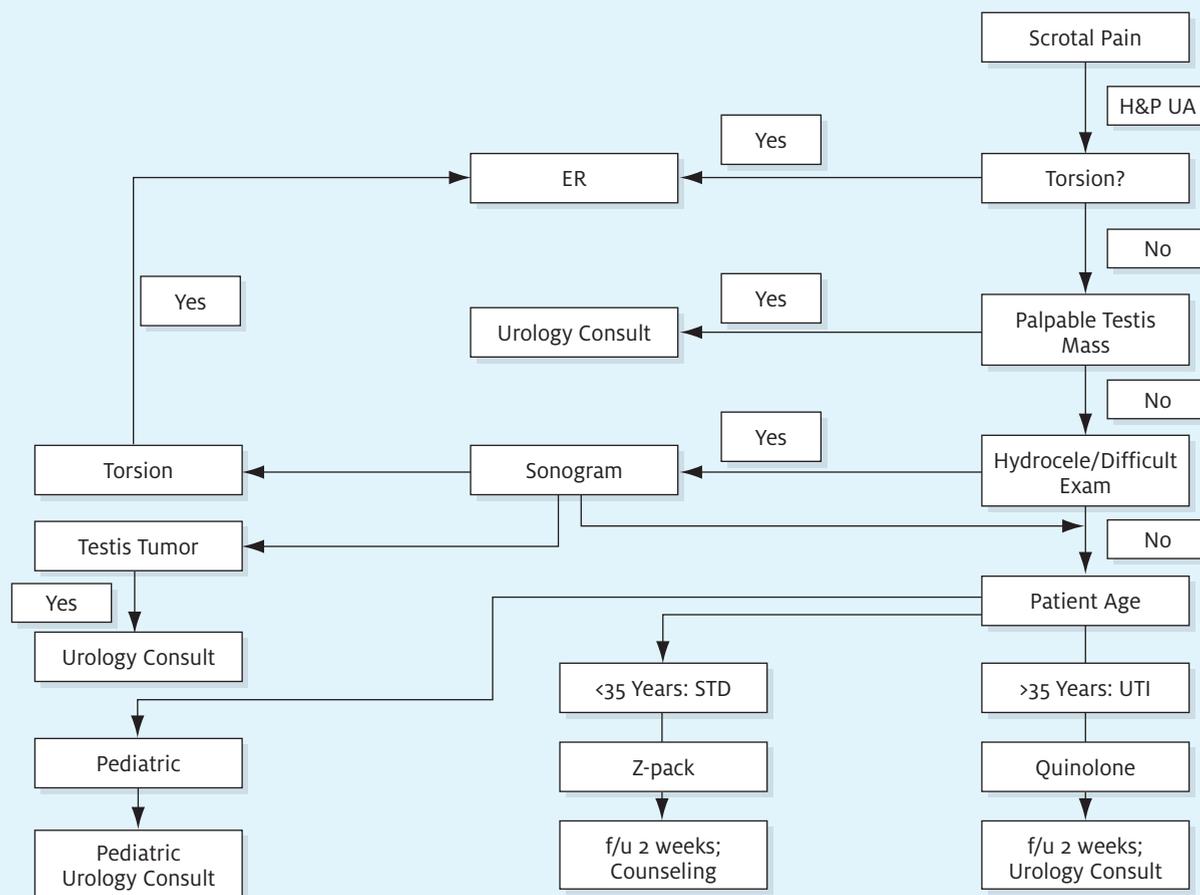
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Figure 2. Evaluation and treatment algorithm for epididymitis.



antimicrobial spectrum of activity and for patient compliance.

Affected men should be counseled regarding the sexual transmissibility of the disease and their partners should be evaluated. In addition, it is prudent for the treating physician to discuss safe sex practices and barrier protection with the patient and to document the discussion in the medical record. Resumption of unprotected sexual intercourse with untreated partners is a vehicle for reinfection.

In older men, among whom *E coli* from either cystitis or a bacterial prostatitis source is the most common uropathogen, treatment with a fluoroquinolone antibiotic is preferred. The fluoroquinolone class of antibiotics is optimal due to the pharmacological properties of these agents, which allow them to pen-

etrate the male reproductive tract, specifically the prostate, in high bacteriocidal levels.

The quinolones are also effective in the presence of bacterial pseudomembranes and even biofilms. Other antibiotic classes, such as the penicillins, lack these important pharmaco-qualities and their usage, while acceptable, is associated with higher treatment failure rates and disease recurrence rates. The duration of therapy can range from 14 days to six weeks, depending upon the underlying etiology of the epididymitis, its severity, and its responsiveness to treatment. For example, in men whose epididymitis was caused by an underlying bacterial prostatitis, an extended four-to-six-week treatment period is indicated.¹⁸⁻²²

In the pediatric population, epididymitis is considered a UTI and is treated as appropriate. In general,

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a course of an antibiotic such as sulfamethoxazole/trimethoprim, nitrofurantoin, or amoxicillin can be given with a patient referral to a urologist or pediatric urologist. Quinolones are contraindicated for use in children in the United States due to perceived issues relating to cartilage growth. In addition, doxycycline can cause permanent teeth staining and must not be used in the pediatric population.

See **Figure 2** for an algorithm regarding optimal evaluation and management of acute scrotal pain and epididymitis in the urgent care setting.

Follow-up

Patients with acute epididymitis do well and the condition typically resolves without sequelae when treated appropriately. Young men with the STD variant of epididymitis can expect rapid improvement in their symptoms in a matter of one to two days, though this rapid improvement occasionally results in treatment non-compliance and recurrences. Rarely, men with inadequately treated epididymitis can develop infertility due to epididymal obstruction as a late complication. This process is analogous to pelvic inflammatory disease in women.

Patients should be seen back in the office in two weeks, at which time compliance is assessed and follow-up cultures are performed. After this, patients can be seen on a PRN basis.

Pediatric patients with epididymitis should be referred to a urologist or, if available, a pediatric urologist for follow-up.

Older men with the *E coli*-induced epididymitis, likewise, do very well after antimicrobial therapy. Patients should be followed up in two to three weeks to see if their pain has resolved. In addition, patients are instructed to call sooner if their symptoms do not improve or get worse.

Some cases of epididymitis are associated with reactive hydroceles, as previously mentioned; the hydroceles often take several weeks to months to resolve, if they resolve at all. Men with large persistent reactive hydroceles can be referred to a urologist for counseling and, if the hydrocele causes the man bother, surgical correction.

Lastly, some men develop a persistent nonspecific scrotal or epididymal pain after an episode of epididymitis. The etiology of this pain is unclear, but infection with standard uropathogens is unlikely. Men who complain of this type of complication are best referred to a urologist for evaluation and management that can include trials of NSAIDs, low-dose tri-

cyclic antidepressants, and alpha-blocker therapy, among others.

Summary

Epididymitis is common and affects all ages without race predilection. Affected patients will have scrotal pain of varying severity and associated findings. After a thorough history and physical exam, adjunctive tests such as the UA and the scrotal sonogram may aid in the diagnosis. In young men, epididymitis is generally caused by GC or *Chlamydia* and is thus an STD. In older men, epididymitis is typically caused by *E coli* and is thus a UTI. Boys with epididymitis are also viewed as having UTIs and are to be managed as such.

When treated appropriately, epididymitis resolves without sequelae in the majority of men. ■

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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 C₁₇H₁₈FN₃O₃·HCl·H₂O. 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 C₂₂H₂₉F05.

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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-mg³¹. 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 dose³¹. 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 to two minutes to avoid dizziness which may result from the instillation of a cold solution. The patient should lie with the affected ear upward, and then the drops should be instilled. The tragus should then be pumped 5 times by pushing inward to facilitate penetration of the drops into the middle ear. This position should be maintained for 60 seconds. Repeat, if necessary, for the opposite ear (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 to two minutes to avoid dizziness which may result from the instillation of a cold solution. The patient should lie with the affected ear upward, and then the drops should be instilled. This position should be maintained for 60 seconds to facilitate penetration of the drops into the ear canal. Repeat, if necessary, for the opposite ear (see **DOSAGE AND ADMINISTRATION**).

Drug Interactions: Specific drug interaction studies have not been conducted with CIPRODEX® Otic. **Carcinogenesis, Mutagenesis, Impairment of Fertility:** Long-term carcinogenicity studies in mice and rats have been completed for ciprofloxacin. After daily oral doses of 750 mg/kg (mice) and 250 mg/kg (rats) were administered for up to 2 years, there was no evidence that ciprofloxacin had any carcinogenic or tumorigenic effects in these species. No long term studies of CIPRODEX® Otic have been performed to evaluate carcinogenic potential. Eight *in vitro* mutagenicity tests have been conducted with ciprofloxacin, and the test results are listed below: *Salmonella/Microsome Test* (Negative), *E. coli* DNA Repair Assay (Negative), Mouse Lymphoma Cell Forward Mutation Assay (Positive), Chinese Hamster V79 Cell HGPRT Test (Negative), Syrian Hamster Embryo Cell Transformation Assay (Negative), *Saccharomyces cerevisiae* Point Mutation Assay (Negative), *Saccharomyces cerevisiae* Mitotic Crossover and Gene Conversion Assay (Negative), Rat Hepatocyte DNA Repair Assay (Positive). Thus, 2 of the 8 tests were positive, but results of the following 3 *in vivo* test systems gave negative results: Rat Hepatocyte DNA Repair Assay, Micronucleus Test (Mice), Dominant Lethal Test (Mice). Fertility studies performed in rats at oral doses of ciprofloxacin up to 100 mg/kg/day revealed no evidence of impairment. This would be over 100 times the maximum recommended clinical dose of otological ciprofloxacin based upon body surface area, assuming total absorption of ciprofloxacin from the ear of a patient treated with CIPRODEX® Otic twice per day according to label directions. Long term studies have not been performed to evaluate the carcinogenic potential of topical otic dexamethasone. Dexamethasone has been tested for *in vitro* and *in vivo* genotoxic potential and shown to be positive in the following assays: chromosomal aberrations, sister-chromatid exchange in human lymphocytes and micronuclei and sister-chromatid exchanges in mouse bone marrow. However, the Ames/Salmonella assay, both with and without S9 mix, did not show any increase in His+ revertants. The effect of dexamethasone on fertility has not been investigated following topical otic application. However, the lowest toxic dose of dexamethasone identified following topical dermal application was 1.802 mg/kg in a 26-week study in male rats and resulted in changes to the testes, epididymis, sperm duct, prostate, seminal vesicle, Cowper's gland and accessory glands. The relevance of this study for short term topical otic use is unknown.

Pregnancy

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

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

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

ADVERSE REACTIONS

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

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

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

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

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

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

DOSAGE AND ADMINISTRATION

CIPRODEX® OTIC SHOULD BE SHAKEN WELL IMMEDIATELY BEFORE USE

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

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

HOW SUPPLIED

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

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

References:

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U.S. Patent Nos. 4,844,902; 6,284,804; 6,359,016
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CIPRODEX[®] Otic is indicated in patients 6 months and older for acute otitis media with tympanostomy tubes due to *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis* and *Pseudomonas aeruginosa*. CIPRODEX[®] Otic is contraindicated in patients with a history of hypersensitivity to ciprofloxacin, other quinolones and viral infections. 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 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%).

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Emergencies in the Office

Why Are 911 Calls Placed From Family Medicine and Urgent Care Offices?

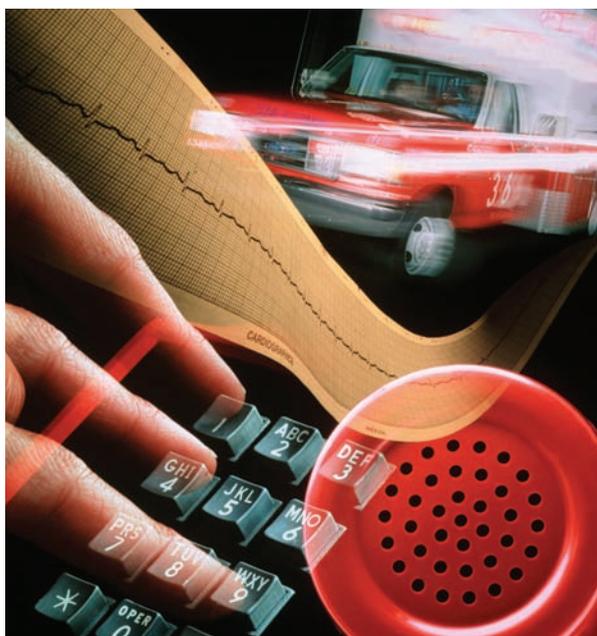
Urgent message: New data indicate that calls to 911 from family medicine and urgent care offices and subsequent transport to ED occur for a wide range of reasons, with the distribution varying to a large degree based on the age of the patient and the practice setting.

Robert J. Dachs, MD, FAAFP, Ephraim Back, MD, FAAFP, Brian Glick, PA-C

Introduction

Life-threatening emergencies have been reported to occur in primary care medical offices.^{1,2} However, the type of medical emergencies that occur remains unclear. Previous studies that have attempted to evaluate emergencies taking place in physician offices have been hindered by recall bias and what defines a medical “emergency.”²⁻⁸ Heath et al demonstrated this problem when seven members of the same pediatric office staff were asked how many emergencies occurred during one year; one member estimated four, two estimated 50, and four reported 100 emergencies.³

One would expect that the type of medical emergency encountered in the office setting would vary based upon the type of patient population cared for by a specific practice. For example, a prospective study of 38 pediatric practices in Vermont demonstrated that three-



quarters of the emergencies were respiratory in origin.³ However, no data exist for any other patient population or practice setting.

The goal of this study was to evaluate what types of medical emergencies occur in family medicine and urgent care offices from a mix of urban, suburban, and rural practices in northeastern New York. By directly reviewing calls from these offices to the regional 911 system, the problem of recall bias and defining an “emergency” can be eliminated. An understanding of the types of emergencies that present to these practices

may better prepare the family medicine and urgent care physician for such emergency situations in the future.

Methods

Thirty-four family medicine office locations and nine urgent care centers from Albany, Schenectady, and Saratoga counties of northeastern New York were iden-

Background: Previous studies have documented that medical emergencies can occur during a patient's visit to a physician's office. However, the types of patients and conditions that prompt a call to 911 from the primary care office have not been previously evaluated.

Methods: The authors abstracted the age, sex, and chief complaint of all 911 calls from 16 freestanding family medicine and six freestanding, privately owned urgent care practices in northeastern New York from January 1, 2002 through December 31, 2003. These practices represented a mix of urban, suburban, and rural practice locations.

Results: Seven hundred and six calls were made to 911 from the 22 practice locations during the study period: 310 calls originated from family medicine practices, with the remaining 396 calls coming from urgent care practices. Patients of all ages were noted, with the majority of calls made for adult patients (95.2% of all calls were for patients 20 years or older, 74.1% for patients 45 years or older, and 40.1% for patients 65 or older). The nature of complaints varied widely, with chest pain being the most common complaint (about one third of all calls). Respiratory conditions were the second most common reason (23.9% of all calls) for a 911 call from the office, and the most common reason for calls in patients younger than 20 years of age.

Conclusion: This study demonstrates that while older patients with chest pain and respiratory complaints dominate data regarding the types of emergencies encountered in family medicine and urgent care practices, a broad range of patients and medical conditions result in calls to 911 from these locations.

tified for study. These practices were identified by one of three methods: 1) review of regional telephone and computer yellow pages, 2) registered members of the New York State Chapter of the American Academy of Family Physicians and 3) review of the New York State Physician Profile system (a statewide online system of physician background and practice location).

The inclusion/exclusion criteria for a practice to be included in the study were: 1) a practice could not be located on a hospital campus, 2) the practice remained in the same location during the study period (January 1, 2002 through December 31, 2003), and 3) the practice evaluated patients of all ages, indicative that it practiced the full breadth of primary care medicine (although obstetrics was optional). These criteria were assessed by telephone interview with each practice.

Furthermore, a practice was included in the study only if it was located in a community where emergency medical service (EMS) computer records documented all 911 calls from that location during the two-year study period. In the case of two less-populated communities (Clifton Park and Duanesburg, NY), manual review of EMS reports easily identified the practice

Table 1. Classification of Complaints Prompting 911 Call

A. Unknown	No recorded complaint
B. Chest Pain	Chest pain or "heart attack"
C. Blood pressure	High or low blood pressure
D. Heart rate	Abnormal or irregular heart rate, palpitations, or dysrhythmia
E. EKG changes	EKG abnormalities
F. Respiratory	Dyspnea, airway compromise, asthma, COPD, or pneumonia
G. Abdominal pain	Abdominal or flank pain
H. Dehydration	Vomiting, diarrhea, or dehydration
I. Neurologic	Neurologic symptoms, dizziness, or headache
J. Psychiatric/toxicology	Psychiatric symptoms, overdoses, or toxic ingestions
K. Diabetes	Low or high blood sugar
L. Allergy	Allergic reactions, hives, or insect stings
M. Trauma	Trauma
N. OB/Gyn	Pregnancy-related complaints
O. CPR/cardiac arrest	Cardiac arrest and initiation of CPR
P. GI bleed	Gastrointestinal bleeding
Q. Fever/infectious disease	Febrile illness or need for antibiotic therapy
R. Syncope	Syncope or near syncope

location as the site of the EMS visit. Ultimately, a total of 16 family medicine practices and six urgent care practices were included in the analysis.

A review of all calls placed to 911 from the predefined medical practices over the study period (January 1, 2002 to December 31, 2003) was collected from the EMS records in the following New York communities: Albany, Bethlehem, Colonie, Berne, Guilderland, Schenectady, Niskayuna, Clifton Park, and Duanesburg. For each call, the following data were recorded: date and time of the call from the office, patient age and sex, and the chief complaint as documented by the EMS dispatcher. Complaints were classified according to the designated categories shown in **Table 1**. When more

than one chief complaint was recorded, such as “chest pain with shortness of breath,” both complaints were recorded in their predefined category.

Statistical analysis was performed using EpiInfo 2000 software (Centers for Disease Control, Atlanta, GA). Bivariate associations between practice type (family medicine or urgent care) and demographic or clinical variables were tested using the uncorrected χ^2 test. Age difference among groups was analyzed with the ANOVA (analysis of variance between groups) test. A probability of less than 0.05 was considered significant. Odds ratios are not reported, as they did not add any additional information to this descriptive study.

The Institutional Review Boards of St. Clare’s Hospital, Schenectady, NY and the Regional Emergency Medical Organization (REMO) of Northeast New York approved the study protocol prior to initiation of the study.

Results

Of the 706 calls to 911 recorded, 310 came from family medicine offices and 396 from urgent care practices. In 102 cases, more than one chief complaint was recorded, resulting in a total of 808 complaints being documented. All patients for whom 911 was called were transported to an ED.

Table 2. Age and Sex Distribution of Patients

	Family Practice (n=310)	Urgent Care (n=396)	Total (n=706)
Demographic	n (%)	n (%)	n (%)
Age			
0-4	7 (2.3)	7 (1.8)	12 (2.0)
5-19	6 (1.9)	28 (7.0)	34 (4.8)
20-44	54 (17.4)	95 (23.9)	149 (21.0)
45-64	92 (29.7)	142 (35.7)	234 (33.1)
≥65	122 (39.4)	107 (26.9)	229 (32.3)
Not recorded	29 (9.4)	17 (4.3)	46 (6.5)
Mean age	58.1	51.5	54.2
Median age	60	52	54
Sex			
Male	131 (42.3)	178 (44.9)	309 (43.8)
Female	161 (51.9)	204 (51.5)	365 (51.7)
Not recorded	18 (5.8)	14 (3.5)	32 (4.5)

*P=0.0001

Table 3. Number and Type of 911 Calls by Practice

	Family Practice (n=310)	Urgent Care (n=396)	Total (n=706)	p value
Type of 911 Call	n (%)	n (%)	n (%)	
Chest pain	96 (25.5)	139 (32.3)	235 (29.1)	N/S
Respiratory	82 (21.8)	87 (20.1)	169 (20.9)	N/S
Neurologic	34 (9.0)	30 (6.9)	64 (7.9)	N/S
Abdominal pain	19 (5.1)	37 (8.6)	56 (6.9)	N/S
Trauma	9 (2.4)	38 (8.8)	47 (5.8)	0.0002
Heart rate	18 (4.8)	16 (3.7)	34 (4.2)	N/S
Miscellaneous	22 (5.9)	12 (2.8)	34 (4.2)	N/S
EKG changes	19 (5.1)	8 (1.9)	27 (3.3)	0.004
Syncope	11 (2.9)	16 (3.7)	27 (3.3)	N/S
Dehydration	13 (3.5)	9 (2.1)	22 (2.7)	N/S
Psychiatric/toxicology	14 (3.7)	6 (1.4)	20 (2.5)	0.015
Blood pressure	11 (2.9)	2 (0.5)	13 (1.6)	0.003
GI bleed	7 (1.9)	5 (1.2)	12 (1.5)	N/S
Diabetes	5 (1.3)	5 (1.2)	10 (1.2)	N/S
Allergy	4 (1.1)	5 (1.2)	9 (1.1)	N/S
Fever/infectious disease	2 (0.5)	7 (1.6)	9 (1.1)	N/S
Unknown	3 (0.8)	5 (1.2)	8 (1.0)	N/S
CPR	3 (0.8)	4 (0.9)	7 (0.9)	N/S
OB/Gyn	4 (1.1)	1 (0.2)	5 (0.6)	N/S
Total	376 (46.5)	432 (53.5)	808 (100.0)	



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Age and Sex Distribution

The median age of patients for all calls was 54 years. Patients from urgent care practices who required EMS services were younger (median age=52) than were patients from family medicine offices requiring the same services (median age=60, $p=0.0001$). **Table 2** shows the age distribution of all patients for whom 911 calls were made.

For calls in which sex was identified, 54.2% of patients were women and 45.8% were men. This finding is consistent with the data from the National Ambulatory Medical Care Survey (NAMCS) in 2001 that noted women accounted for 59.1% of all office visits.⁹

Reason for 911 calls

The complaints associated with all calls to 911 are noted in **Table 3**. The most frequent complaint leading to an EMS call to either family medicine or urgent care offices was chest pain, which accounted for one-third of all calls. Respiratory complaints accounted for almost

one-quarter of calls. The types of conditions that initiated 911 calls were similar between family medicine and urgent care practices. Only trauma-related conditions were noted to be statistically more common in urgent care practices, while EMS calls for EKG changes, blood pressure abnormalities, and psychiatric and toxicologic conditions were statistically more common in family medicine practices.

Complaints were also stratified according to age (**Table 4**). Five age groups were defined as typical groupings: a) infant and young children (ages 0-4), b) older children and adolescents (ages 5-19), c) young adults (age 20-44), d) older adults (ages 45-64) and e) geriatric patients (age ≥ 65). While respiratory complaints were the most common reason that EMS was summoned for patients younger than 20, chest pain was the predominant reason for 911 calls in adult patients.

Discussion

By reviewing EMS data for 911 calls from family medicine and urgent care practices, we have demonstrated that emergencies prompting these calls occurred in patients of all age groups with a wide range of medical conditions. However, some specific trends do emerge from our data:

- First, older patients were most likely to require

EMS services. This appears to be consistent with the NAMCS report in 2001, which noted that the number of visits to office-based physicians increases with patient age.⁹

- The emergencies in this older population of patients appear more likely to be cardiopulmonary in origin.
- Younger patients in the primary care office setting who require emergency services are more likely to have respiratory complaints, which is also consistent with previous studies.³

These data suggest that family medicine and urgent care physicians need to be prepared to deliver care for a diverse group of patients with a wide variety of emergency conditions.

"It is possible that the need for EMS and emergency care in the family medicine and urgent care office may increase."

Perhaps the most dramatic of all emergencies that can occur in the office is the patient who sustains a cardiac arrest. In our series, seven cases of cardiac arrest occurred in five different practices (two urgent care, three family medicine) and accounted for 1% of all calls to EMS. The youngest vic-

tim was 9 months of age; the oldest was 80 years of age. In a review of 142 cardiac arrests in medical and dental practices in King County, WA, family medicine and urgent care practices were just as likely to have a cardiac arrest occur in the office as were cardiology and internal medicine practices. Only dialysis centers were more likely than these office settings to have a patient sustain a cardiac arrest.¹

Data from the NAMCS report note that between 1992 and 2001, office visits became more complex, involving older patients with more diagnoses per visit and more multiple medications to manage.⁹ If this trend of older, more complex and ill patients making office visits continues, it is possible that the need for EMS and emergency care in the family medicine and urgent care office may increase, as well.

Strengths and Limitations

Previous surveys of pediatric office practices attempted to identify the frequency of emergencies in the office, but such studies were plagued by recall bias and what defines an emergency.²⁻⁸ By identifying a clear and reproducible definition of an emergency (i.e., a call to 911 from the medical office), we have been able to avoid this dilemma.

Table 4. Most Common Complaint by Group

Complaint ranking	Age Group (years)				
	0-4 (n=14)	5-19 (n=34)	20-44 (n=140)	45-64 (n=234)	≥65 (n=229)
1	Respiratory (n=11; 78.6%)	Respiratory (n=9; 26.5%)	Chest pain (n=48; 32.2%)	Chest pain (n=113; 48.3%)	Respiratory (n=65; 28.4%)
2	CPR (n=1; 7.1%)	Abdominal pain (n=9; 26.5%)	Respiratory (n=29; 19.5%)	Respiratory (n=49; 20.9%)	Chest pain (n=62; 27.1%)
3	Dehydration (n=1; 7.1%)	Trauma (n=8; 23.5%)	Abdominal pain (n=18; 12.1%)	Abdominal pain (n=16; 6.8%)	Neurologic (n=30; 13.1%)
4	Psych/tox (n=1; 7.1%)	Psych/tox (n=2; 5.9%)	Neurologic (n=15; 10.1%)	Neurologic (n=14; 6.0%)	EKG changes (n=18; 7.9%)
5	Miscellaneous (n=1; 7.1%)	Chest pain (n=2; 5.9%)	Miscellaneous (n=8; 5.4%)	Heart rate (n=14; 6.0%); trauma (n=14; 6.0%)	Heart rate (n=15; 6.5%); trauma (n=15; 6.5%)

The locations of the office practices used in our study represented a mix of urban, suburban, and rural practice locations and varied in their distances to the nearest acute care hospital (**Table 5**). The practice types also ranged from solo practitioner to large group practices. All were private practices, including one family medicine residency clinic site. The breadth of practice locations, types of practices, and large sample size represent the broad range of family medicine and urgent care practices in which medical emergencies may be encountered. However, regional trends in practice patterns—in particular the limited amount of obstetrics performed by family physicians in northeastern New York state—may limit the “generalizability” of our results.

In this study, only three of 16 family medicine and none of the urgent care offices cared for obstetric patients. Therefore, the low frequency of obstetrical emergencies in our study may be underrepresented when compared with other regions of the country.

All of the practices included in this study were contacted in hopes of obtaining the number of patients evaluated at each facility during the study period, so that a rate of 911 calls from the office could be calculated. However, either due to unwillingness or lack of available data, a number of offices could not provide the requested data,

thus limiting a calculation of rates for these occurrences. Since a demographic base of all patient visits was not available for the practices studied, only limited, indirect comparison with the NAMCS data was possible.

Misclassification of the chief complaint might be possible if the EMS dispatcher incorrectly documented the chief complaint in the computer record or the EMS provider incorrectly documented the chief complaint on the documentation form in the two smaller communities without computerized EMS documentation. Since we were unable to obtain either audio recordings of the 911 calls or the subsequent admission and discharge diagnosis in this study group, misclassification of some of our cases is possible. However, we believe that this lack of validation does not diminish the conclusions of this large descriptive study since, in most cases, the chief complaint was unambiguous and in cases where multiple complaints were present, all complaints were recorded.

Finally, our study did not address the question of preparedness for emergencies in the office setting. One survey of family physician preparedness for pediatric emergencies conducted in North Carolina suggested that family physicians were less likely to have pediatric resuscitation equipment or Pediatric Advanced

Table 5. Types and Locations of Practices in the Study

Practice*	No. of EMS calls	Miles to hospital [†]	Location [‡]	Practice size [§]
FP 1	52	12	Rural	Solo
FP 2	41	1	Urban	Large
FP 3	36	12	Suburban	Medium
FP 4	33	4	Suburban	Medium
FP 5	32	6	Suburban	Large
FP 6	28	7	Suburban	Medium
FP 7	19	10	Suburban	Medium
FP 8	18	9	Suburban	Medium
FP 9	12	1	Urban	Medium
FP 10	9	9	Suburban	Medium
FP 11	7	12	Suburban	Medium
FP 12	6	20	Rural	Solo
FP 13	6	24	Rural	Medium
FP 14	6	2	Suburban	Large
FP 15	4	6	Urban	Solo
FP 16	1	7	Suburban	Solo
UC 1	200	12	Suburban	Medium
UC 2	120	8	Suburban	Medium
UC 3	27	8	Urban	Medium
UC 4	27	6	Suburban	Medium
UC 5	20	4	Suburban	Solo
UC 6	2	6	Suburban	Solo

*FP = Family practice; UC = Urgent care; †Rounded to closest mile, as calculated by Mapquest; ‡Per 2004 U.S. census population estimates; §Solo=1 physician with possible midlevel provider; medium=2-5 physicians; large=>5 physicians

Life Support (PALS) training, when compared with pediatricians.⁴ No other studies of preparedness for emergencies of any kind in the primary care office setting could be identified. We believe this question would be worthy of future evaluation.

Conclusion

We have demonstrated that 911 calls from family medicine and urgent care practices in northeastern New York were placed for patients of all ages and a wide variety of medical conditions. Older patients were most likely to require EMS services in the office setting, with chest pain the most common chief complaint. In pediatric patients, respiratory emergencies were the most common reason for a 911 call from the office setting. ■

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On Stone Passage, Wait-and-See Prescriptions, Foreign Bodies, and Wireless Prescribing

■ NAHUM KOVALSKI, BSC, MDCM

Each month, Dr. Nahum Kovalski will review 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.

Medical Therapy to Facilitate Urinary Stone Passage: A Meta-analysis

Citation: Hollingsworth JM, Rogers MA, Kaufman SR, et al. *Lancet*. 2006;368:1171-1179.

URL: <http://www.thelancet.com/journals/lancet/article/PIIS0140673606694749/abstract>

Key point: Medical therapy is an option for facilitation of urinary-stone passage.

Medical therapies to ease urinary-stone passage have been reported, but are not generally used. If effective, such therapies would increase the options for treatment of urinary stones.

The authors searched MEDLINE, Pre-MEDLINE, CINAHL, and EMBASE, as well as scientific meeting abstracts, up to July 2005. All randomized controlled trials in which calcium-channel blockers or α -blockers were used to treat ureteral stones were eligible for inclusion in the analysis. Data from nine trials (N=693) were pooled. The main outcome was the proportion of patients who passed stones.

Patients given calcium-channel blockers or α -blockers had a 65% (absolute risk reduction=0.31) greater likelihood of stone passage than those not given such treatment. The pooled risk ratio for α -blockers was 1:54 and for calcium-channel blockers with steroids 1:90. The proportion of heterogeneity not

explained by chance alone was 28%. The number needed to treat was 4.

Comment: The authors note that although a high-quality randomized trial is necessary to confirm its efficacy, these findings suggest that medical therapy is an option for facilitation of urinary-stone passage for patients amenable to conservative management, potentially obviating the need for surgery. ■

Wait-and-See Prescription (WASP) for the Treatment of Acute Otitis Media: A Randomized Controlled Trial

Citation: Spiro DM, Tay KY, Arnold DH, et al. *JAMA*. 2006;296:1235-1241.

URL: http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=retrieve&db=pubmed&list_uids=16968847&dopt=Abstract

Key point: The WASP approach substantially reduced unnecessary use of antibiotics in children with acute otitis media (AOM) seen in an emergency department.



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AOM is the most common diagnosis for which antibiotics are prescribed for children. Previous trials that have evaluated a “wait-and-see prescription” (WASP) for antibiotics, which parents are asked not to fill unless the child either is not better or is worse in 48 hours, have excluded children with severe AOM. None of these trials were conducted in an emergency department.

This was a randomized controlled trial, from July 12, 2004 to



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

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July 11, 2005, involving children with AOM aged 6 months to 12 years seen in an ER. These children were randomly assigned to receive either a WASP or a standard prescription (SP). Overall, 283 patients were randomized either to the WASP group (n=138) or the SP group (n=145).

Substantially more parents in the WASP group did not fill the antibiotic prescription (62% vs. 13%; $P<.001$). There was no statistically significant difference between the groups in the frequency of subsequent fever, otalgia, or unscheduled visits for medical care.

Within the WASP group, both fever (relative risk [RR], 2.95; $P<.001$) and otalgia (RR, 1.62; $P<.001$) were associated with filling the prescription. ■

Foreign Body Removal From the External Auditory Canal in a Pediatric Emergency Department

Citation: Marin JR, Trainor JL. *Pediatr Emerg Care*. 2006; 22:630-634.

URL: http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=pubmed&cmd=Retrieve&dopt=AbstractPlus&list_uids=16983246&query_hl=o&itool=pubmed_DocSum

Key point: Referral to otolaryngology should be considered if more than one attempt or instrument is needed for removal of a foreign body in the ear canal.



Physicians in the authors' pediatric emergency department successfully removed 204 (80%) of 254 foreign bodies. In 30 cases (12%), there was a complication. Multiple attempts at removal were associated with failure (relative risk [RR], 6.0) and complications (RR, 3.1). The use of multiple instruments was also associated with failure (RR, 5.4) and complications (RR, 4.0).

Of the 244 patients in whom emergency department attempts at removal were made, 26 were successfully removed in otolaryngology clinic, and 14 were removed in the operating room.

Foreign bodies present in the canal for more than 24 hours were not at higher risk of failed removal or complications. Patients younger than 4 years also were not at increased risk of having failed removal or complications.

Comment: In medicine, proper resource management means filtering out cases that can be handled by the more immediate and readily available ER/urgent care doctor, before referral onto specialty care. Eighty percent of these FBs can be successfully removed by the first-line doctor. And if the first attempt failed, then this group—only 20% of the original—can

be referred on. For those FBs removed in the ENT clinic, one could ask what special equipment made this possible (e.g., suction, finer instruments, magnification). One could then look into duplicating some of these tools (like the suction) in other settings to further increase first-line success. ■

Wireless Handheld Computers and Voluntary Utilization of Computerized Prescribing Systems in the Emergency Department

Citation: Shannon T, Feied C, Smith M, et al. *J Emerg Med*. 2006;31:309-315.

URL: <http://www.imesi.org/docs/Azyxxi//Papers/PDA%20prescribing%20-07a%20for%20pdf.pdf>

Key point: Physicians are amenable to using wireless handheld computers for prescribing.

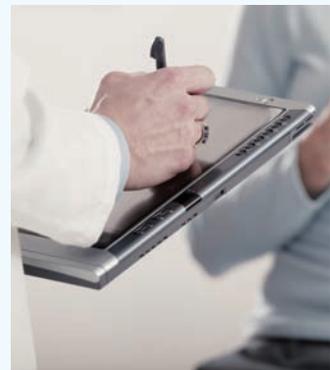
Illegible or invalid handwritten prescriptions can result in avoidable medical errors. Computer-based prescribing can mitigate the problem.

An observational study was performed to examine the effect of wireless handheld computers (handhelds) on voluntary utilization of computerized prescribing within an emergency department. Handhelds with prescription-writing software were provided to physicians and the numbers of hand-written and computer-generated prescriptions were compared before and after the introduction of the handhelds.

The resulting increase in computer-based prescribing was statistically significant and was observed largely among physicians who already used desktop computers for prescribing.

The study concluded that handhelds increased voluntary utilization of computerized prescribing, but that the physicians most likely to use handhelds were those who already used desktop-based prescribing.

Comment: The approach that this group adopted is an interesting and successful one. Rather than force the staff to move, altogether, over to the new digital prescribing system, the doctors were allowed to choose which system they preferred. As the years pass, and more and more doctors are young enough to have played with video games as a child, e-prescribing (as well as all forms of digital medical records) will become the de-facto standard. The key to the success of any digital medical system is improved physician productivity which should translate into greater reimbursements, or at least, reduced medicolegal risk. ■

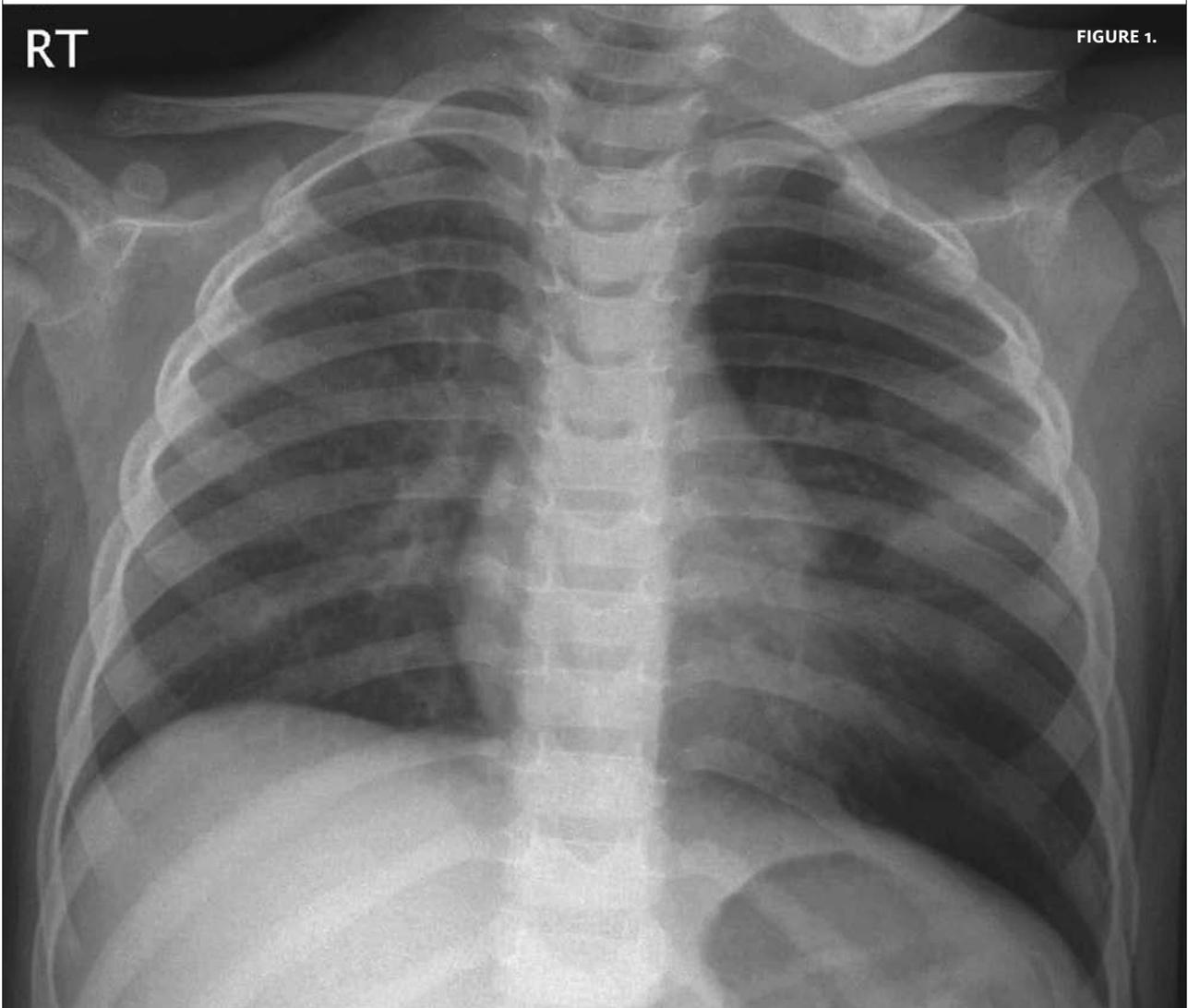


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In each issue, *JUCM* will challenge your diagnostic acumen with a glimpse of x-rays, electrocardiograms, and photographs of dermatologic conditions that real urgent care patients have presented with.

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



A 2 ½-year-old child presents with a three-day history of cough but no fever.

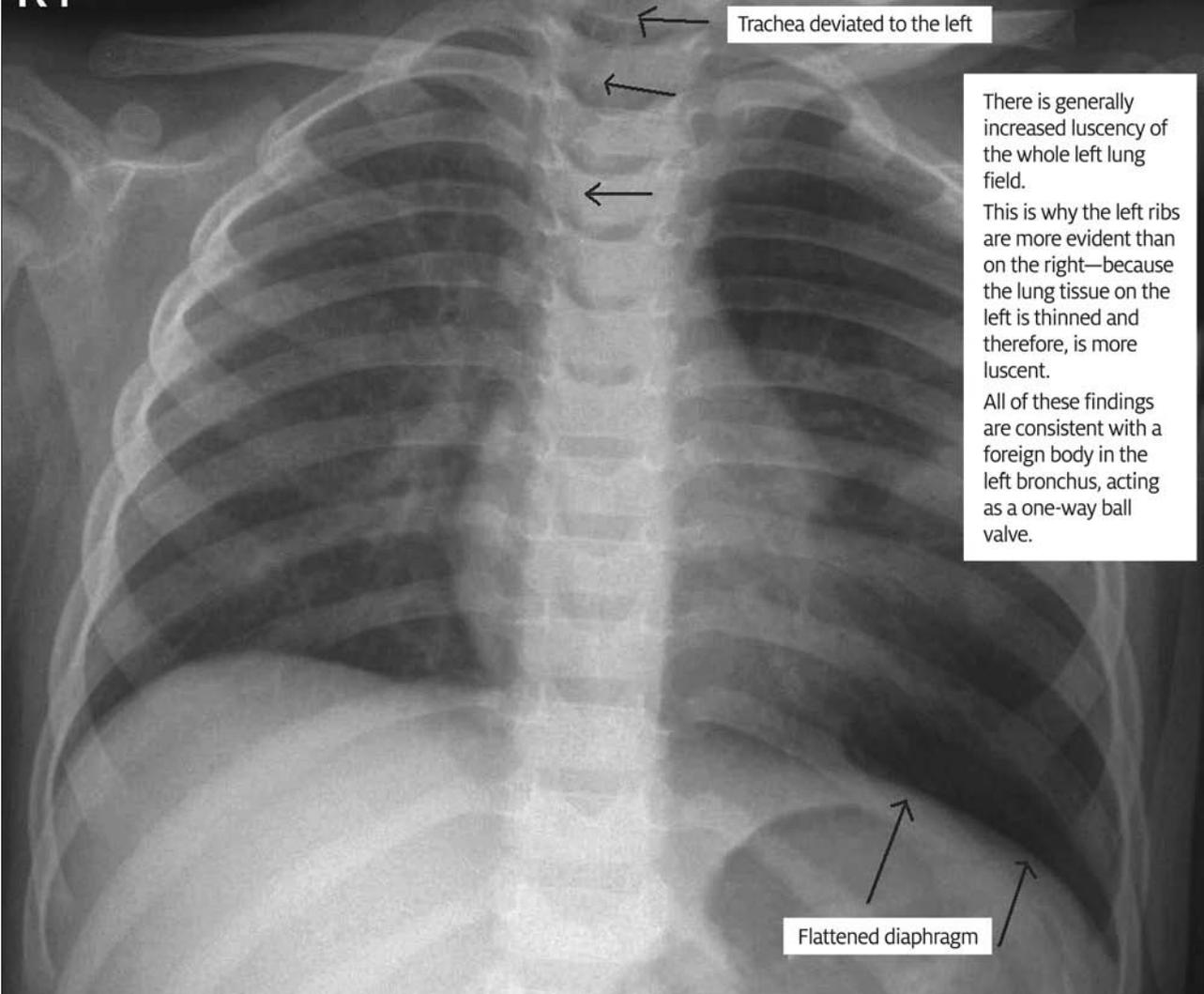
Upon examination, you find:

- Oxygen percent saturation 95%
- Resting respiration 31/min
- Pulse 145/min

■ Decreased air entry over the left chest
View **Figure 1**, take these findings into account, and consider what your next steps would be. Resolution of the case is described on the next page.

XP
RT

FIGURE 2



THE RESOLUTION

The reading of the chest x-ray was “suspected foreign body in the left main bronchus.” This reading was based on overinflation of the left lung with deviation of the trachea, increased lucency of the left lung area, and flattening of the left diaphragm. The increased lucency makes the ribs and scapula more prominent on the left.

The child was sent to the ER and was bronchoscoped. No foreign body was found, although there was inflammation along the main bronchus. The initial impression of the ER physicians was that a foreign body had been present but since been expelled. The child is still under observation.

Acknowledgment: Case managed by Drs. Scott Fields (radiologist) and Aryeh Poms (primary physician).



FIGURE 1.



A 53-year-old female presents after experiencing a fall with a blow to the knee several hours earlier.

Upon examination, you find:

- No fluid in the knee
- The knee is stable
- Patient is able to put weight on the affected knee
- Mildly decreased range of motion due to generalized pain in the area (though not over the patella)

View **Figure 1**, take these findings into account, and consider what your next steps would be. Resolution of the case is described on the next page.

FIGURE 2



THE RESOLUTION

The diagnosis of the orthopedist who saw this case was bipartate patella. However, the radiologist suspected that this was in fact a fracture.

Nonetheless, the orthopedist felt that it was not a fracture because (a) the pain was not over the patella and (b) comparison with old films (which the radiologist had not seen) showed that nothing had changed on the new films.

This is a perfect example of the need to have as much relevant clinical information as possible, and the importance of accessing old films when

available. Without this information, neither the orthopedist nor the radiologist could have given an absolute final diagnosis. This case also reminds us of the need to provide all of the clinical information to the radiologist in all cases.

Interestingly, both the orthopedist and the radiologist noted that the patient should have a CT to confirm the status of the patella.

Acknowledgment: Case managed by Drs. Rafold Livshin (orthopedist), Uri Frankl (orthopedist), and Scott Fields (radiologist).



Protecting Yourself Against Medical Malpractice Claims, Part 2

■ JOHN SHUFELDT, MD, JD, MBA, FACEP

In the December issue of JUCM, Dr. Shufeldt introduced a discussion on how to not be named in a malpractice suit by suggesting that providing excellent customer service, never saying “no” to a patient, and thorough documentation of the pertinent positives and negatives are viable techniques to reduce your malpractice exposure. Here, he continues the discussion with other precautions you can take.

Failure to make an appropriate referral is a reason commonly cited when providers are sued. This broad category includes failure to suggest hospitalization, failure to call for a consult, and failure to prescribe a specific plan or treatment. For example, if a patient admits to being a smoker and you diagnose bronchitis or some other respiratory condition exacerbated by smoking, your chart or aftercare instructions would be incomplete if you did not discuss—and document—smoking cessation as part of the treatment plan.

This may sound painfully obvious, but I assure you that cases have been lost for even more trivial reasons than that. You don't want to be the defendant when the patient is on the witness stand testifying that, “If the physician had only told me to (lose weight, quit shooting heroin, quit smoking meth, wear a helmet, etc.) I would certainly have followed his advice and altered my behavior. I had no idea that was dangerous!”

If you are treating a patient whose symptoms, exam, and lab findings are not adding up, or if your gut is telling you something is wrong with the patient despite your objective findings, trust your gut! I cannot tell you how many *horrendomas* I have found purely through dumb luck and listening to my gut.

The “out” we have in urgent care medicine is simply to tell the patient that their symptoms, exam, findings, etc. warrant

further evaluation in the hospital. Document your discussion, copy your notes for the patient to give to the emergency physician, and send them off to the ED.

Err on the Side of Caution

Since we do not typically have an ongoing relationship with the patient or the patient's family, it is much better to err on the side of caution. That includes treating the patient even if only “soft” evidence is available.

For example, I would manage patients who present with a sore throat and have a negative rapid strep and no evidence of mono by writing scripts for pain medicine and an appropriate antibiotic with the admonition to not fill the antibiotic prescription unless the symptoms worsen or are no better after two more days.

Before the evidence-based crowd calls for my head on a platter, consider this: Rapid streps are notoriously unreliable, patients with a viral sore throat will usually be better in two days, and very often patients who do not “get a prescription like my regular doctor gives me” simply go to their PCP to get the script you refused to give them and incur the cost of two visits. Again, I know this is not evidence based; however, it is practicality based and much more patient friendly.

You may have heard the statement, “every patient is a potential plaintiff.” Unfortunately, this blatantly pessimistic statement is true. As providers, we must evaluate every patient as if we will be sitting across the mediator's table—or worse, the courtroom—from them.

In emergency medicine, we are obligated to take all comers; we do not have the luxury of dismissing patients from our practice. This is not true in urgent care medicine, however. If you are faced with a patient who is unruly or rude or repeatedly non-compliant or abusive, you do not need to continue to provide care for them. In fact, if it is their first visit and they are abusive in the waiting room, take this an omen that you will ultimately not want them in your practice and ask them to seek care elsewhere.



John Shufeldt is chief executive officer of NextCare, Inc. and sits on the Editorial Board of *JUCM* *The Journal of Urgent Care Medicine*.



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HEALTH LAW

Once you start treatment, however, you are obligated to complete it for the particular episode of illness. If it is a recurrent patient, send a certified letter advising them that they should seek care elsewhere and provide a list of other urgent care centers. Also, tell them you will continue to see them over the next 30 days but after that you will no longer provide any services. A certified letter in the urgent care environment is probably overly cautious, but it covers the bases for a claim of patient abandonment.

Beware the Minimizer!

Minimizers are patients who are often “forced” to seek care by loved ones who may have been clued in to some change in behavior or condition that has them concerned. One common chief complaint that I have heard countless times when asking males why they are here today is, “I don’t know; my wife made me come in.”

These patients should set off alarms. This is the 55-year-old, out-of-shape guy who complains of intermittent, reproducible shoulder pain aggravated by the “honey dos” that his significant other has him performing. He’s the same guy who walks you down the path of a repetitive trauma condition or muscle strain and is discharged after a negative shoulder x-ray and no EKG, then drops dead of a myocardial infarction.

When you sense you have a patient who is “dismissive” of his own complaints, be aware that the non-issues may be a harbinger for serious illness.

You may have also heard this before: “I would like to have that test, but I just can’t afford it,” or, “Can’t you just treat me, I am sure I am fine.” Basing prescribed treatment on the patient’s financial status is wrought with danger. Clearly, some patients cannot afford the “correct way” to work up an issue. However, this should not stop you from ordering the test, medications, etc., and allowing the patient to decide whether or not to spend the money.

This is the basis of informed consent: giving patients enough information to decide for themselves after weighing everything. Remember, “cost effectiveness” does not carry weight in a standard-of-care determination. The take-home point here is to practice good medicine, foster informed consent, and document everything.

Ultimately, not being named in a malpractice suit requires a good deal of luck. However, avoiding issues commonly cited as reasons that providers are named in suits will also lower your chances for ending up at the defendant’s table.

In summary, being kind and respectful to patients and families, thoroughly documenting the treatment and the plan, facilitating informed consent, identifying the patient who is non-compliant, abusive or minimizing, and not letting patient’s finances dictate your prescribed treatment will significantly reduce your risk of being named in a malpractice suit. ■



Coding Conundrum: E/M with a Procedure

■ DAVID STERN, MD, CPC

The urgent care practitioner may not live by coding alone, but proper reimbursement depends on it. To that end, Dr. David Stern, a certified coder who is in great demand as a speaker and consultant on coding in urgent care, will offer answers to commonly asked questions in every issue of *JUCM*.

In this issue: proper coding for evaluation and management (E/M) in addition to other procedures.

Q. We always get denials for the E/M code in addition to a procedure. Are we doing something wrong?

A. Denials for payment for an E/M in addition to a procedure may stem from several sources:

■ **Missing modifier**

If you perform a procedure with a 0- or 10-day global period and you perform and document a separate E/M on the same day, always attach modifier -25 to the E/M to reduce denials and costs of rebilling. Use modifier -57 for an E/M performed on the same day as a procedure with a 90-day global period.

■ **Payor policy**

Some payors routinely deny payment for an E/M in addition to certain (rarely all) procedures.

■ **Bundling issues**

Generally, procedure codes include a basic level of evaluation of management within the procedure code. In the urgent care setting, however, bundling the E/M into the procedure code is frequently not appropriate.

■ **Lack of supporting documentation**

Some payors automatically deny an E/M in addition to a procedure, or at least in addition to a certain procedure. For

example, some payors deny payment for an E/M when billed in a claim along with a code for ear wax removal. Even in these cases, however, payment might be obtained by submitting proper documentation.

Q. What urgent care procedures require modifier -25?

A. In general, all procedures with a 10-day global period (and many others with a 0-day global period) should have modifier -25 attached to the E/M code.

Q. When is modifier -25 used?

A. Per the AMA definition, modifier -25 should be used when a “significant, separately identifiable E/M service above and beyond the other service provided or beyond the usual preoperative and postoperative care associated with the procedure that was performed” is required. The interpretation of this rule is sometimes difficult and there are a few gray areas where not all coders or payors agree. For example:

Patients who are new to a practice The initial E/M (99201-99205) for a new patient who also has a minor procedure (0- to 10-day global period) performed on the same day should not require the -25 modifier on the E/M code. This makes sense, as the patient is not known to the provider and all of the baseline history, medications and basic health status must be determined prior to doing the “usual preoperative care.”

New problems that require significant evaluation beyond the procedure For example, a patient may present with knee pain. After evaluation of the knee, the physician determines that the problem may be gout or infectious arthritis, and that it is necessary to aspirate the joint and send the fluid to the lab for analysis to help confirm the diagnosis. Code with the E/M with modifier (for example, 99213-25) and 20610 for the knee joint aspiration. Thus, a new problem that requires more than a cursory review also, generally, qualifies for an E/M with modifier -25.

“Established patients” with additional medical problems



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Patients undergoing a procedure that is made more complicated because of an underlying medical problem should have that problem evaluated and managed appropriately. Take, for example, a patient who presents with an abscess and who also suffers from AIDS, diabetes, valvular heart disease, or elevated blood pressure. In this case, the physician should document evaluation and management of both the problem that is addressed by the procedure and the E/M of the complicating problem. An E/M with modifier -25 is always appropriate in addition to the code for the procedure.

“Established patients” with a second medical problem that requires attention An E/M is always appropriate for patients receiving evaluation and management services for diagnoses in addition to the problem necessitating the procedure. For example, a patient may present with a laceration, but in the course of evaluation and management the physician determines that the patient has also been suffering from chronic diarrhea. The physician begins the work-up by ordering collection of a stool specimen for culture and microscopic examination for ova and parasites. The laceration code and the E/M code with modifier -25 should be used.

“Established patients” seen in the urgent care setting A typical urgent care center is quite different from a typical physician office. In the urgent care center, very few patients are truly established with the provider who is providing the services. Essentially, these are new patients who truly need a thorough history and physical prior to the initiation of the usual preoperative care. Thus, in the urgent care center a full history and physical are almost always required to evaluate the past medical history, medications, and current symptoms prior to initiating the usual preoperative care that would be provided to a patient who was truly established and, thus, well known to the provider.

It is one thing for Dr. Welby to walk in the room and say, “Oh, Johnny, so you cut your finger again. You need to be more careful with your whittling knife. Don’t worry, we’ll sew that up in a jiffy. Since you don’t have any other problems except for that heart murmur, you should do great.”

It is another matter entirely for Dr. Urgentowitz to see the same patient, and inquire about diabetes, history of infections, the relevance of the heart murmur, and the patient’s experience with previous injuries. Then the urgent care doctor examines the patient’s skin, eyes, heart, lungs, and peripheral vasculature to evaluate the status of any known conditions and to see if there are any additional underlying or complicating medical conditions.

Generally, a separate E/M is appropriate for patients seen in the urgent care center. Of course, if the urgent care physician also functions as the primary care provider for the patient, the patient is truly *established* with the practice and an additional E/M is often not appropriate.

Q. Must I have a separate diagnosis to code modifier -25?

A. One myth that seems to have a life of its own is that the patient must have a “significant separately identifiable” problem that is managed on this visit. But the AMA definition of modifier -25 clearly states:

“The E/M service may be prompted by the symptom or condition for which the procedure and/or service was provided. As such, different diagnoses are not required for reporting of the E/M services on the same date.”

The problem and confusion arises, however, when overzealous payors (in direct contradiction of AMA guidelines) require physicians to treat a second condition before they will consider payment for an E/M with modifier -25. It is the E/M note, not a second presenting problem, which must be “significant and separately identifiable.” Nonetheless, several large payors continue to apply the tightfisted requirement that the physician must supply both documentation of a second diagnosis and medical records supporting separate E/M services for that second diagnosis.

Q. Will attaching modifier -25 to an E/M where the modifier was not required trigger a denial?

A. No, payors almost never deny payment for attaching modifier -25 to an E/M code where the modifier was not required. Be careful to use modifier -25 only when a procedure is performed, as overuse of the modifier may trigger a payor audit.

Q. I was audited and the carrier denied payment because of inadequate documentation. Do I simply need a longer visit note?

A. It is not the length, but the content of the visit record that is important. In order to support both an E/M code and a procedure code, the patient record must contain documentation of the level of *evaluation and management AND a significant, separately identifiable procedure note*. It is best to not include the procedure note within the evaluation and management note, as some auditors will deny the code because the procedure note was not “separately identifiable” from the evaluation and management documented in the patient record. Some coders go so far as to recommend a separate page, template, or dictation for each E/M and each procedure note. ■

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Keeping Your Ear to the Customer

■ FRANK H. LEONE, MBA, MPH

“Keep your ear to the customer” is a central tenet of effective marketing. Awareness of how your services are used and valued can be especially important in a field like occupational medicine, where the people you treat are often not the ones who contract for those services.

There are many ways to keep your ear to the customer, and there are many customer subgroups. “Customers” might include patients, employers, carriers/payors, or specialists. Keeping close to these constituents invariably involves the use of multiple modalities such as e-mails, periodic phone calls, patient satisfaction instruments, and questionnaires.

Why Assess?

Urgent care clinic operators often rely on intuition or anecdotal information to assess how their clinic is viewed in their community. Invariably, this information lags behind reality. You need to be proactive in seeking out real customer feedback. A simple questionnaire survey administered to a sample of patients and/or client companies can:

- tell you how well you are doing in a variety of service areas and turn up suggestions for improved performance.
- generate accolades that can later be used in marketing material and to enhance staff morale.
- provide you with cross-selling opportunities for other services
- help you identify (and rectify) areas in which your clinic is slipping and, conversely, provide objective validation of how a clinic has improved.

How to Assess

While your survey should reflect your particular needs, following a few general rules may help ensure the effort is worth your while:

1. Do the survey annually.



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 extensive experience training medical professionals on sales and marketing techniques. E-mail him at fleone@naohp.com.

2. Keep it simple and short—one two-sided sheet of paper.
3. Allow participants to complete the questionnaire via hard copy (mail) or electronically via e-mail.
4. Send out a second questionnaire (and/or e-mail blast) to non-respondents after a few weeks.
5. Offer the chance to win a prize on the back end. It can be something simple, such as dinner for two at a local restaurant.
6. E-mail respondents with a “thank you” and a summary of selected findings.

What to Assess

Ask participants:

- what they think of your clinic, and what you can do better
- if there are other valuable services you could offer
- if one or more of your staff warrant special praise
- about multiple aspects of your clinic using a scale of 1 (poor) to 5 (excellent)
- about their receptiveness to and the viability of any changes you’ve made in the clinic during the previous year; for example, a reconfigured waiting area
- about any other pressing issue of the moment, e.g., if and where to open another clinic.

More Than Information

The value of a questionnaire survey goes beyond data.

Constituents appreciate being asked their opinion. It doesn’t hurt to make that point in your cover letter and/or e-mail overview: “Because you are a valued Med Center client, we are deeply interested in your thoughts about and suggestions for our clinic...”

Marketing is about calling attention to your clinic and using multiple hits to remind clients, partial clients, and prospects that your clinic is alive and well and operating in a professional manner.

Conducting an annual questionnaire survey is not particularly time-consuming or expensive. It is an excellent way to stay in touch with your best customers or patients, learn more about the community’s perception of your clinic, maintain an up-to-date information base, and remain visible.

If you would like to receive a sample survey questionnaire to see how these suggestions are carried out by, please e-mail Janelle Schueler at jschueler@naohp.com. ■



DEVELOPING DATA

UCAOA'S Survey Committee drew two important conclusions from its first industry-wide survey: urgent care is a growing industry nationwide, and those within the industry are hungry for benchmarking data. In each issue of *JUCM*, **Developing Data** will seek to fulfill that need.

In this issue, who owns, who leases, and where are they located?

TYPE OF STRUCTURES HOUSING URGENT CARE CLINICS



Source: *Benchmarking Your Urgent Care*, ©2006, Urgent Care Association of America.

More than half (53%) of the survey participants own the buildings in which their practice is located; 47% lease. The average business consists of 2.66 centers.

Areas covered in the initial UCAOA industry survey included urgent care structures and organization, services offered, management of facilities and operations, patients and staffing, and financial data. UCAOA members who have ideas for future surveys should e-mail J. Dale Key, UCAOA Survey Committee chair, at dkey@medachealth.com.

Next month in **Developing Data:**

One of the benefits of urgent care, from a patient's perspective, is the time savings and more convenient access to medical care compared with a visit to the ER or family practice. But just what are "average" hours (and days) of operation for an urgent care clinic?

LEVAQUIN® (levofloxacin) TABLETS
LEVAQUIN® (levofloxacin) ORAL SOLUTION
LEVAQUIN® (levofloxacin) INJECTION
LEVAQUIN® (levofloxacin in 5% dextrose) INJECTION

Brief Summary

The following is a brief summary only. Before prescribing, see complete Prescribing Information in LEVAQUIN Tablets/Oral Solution/Injection labeling.

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

CONTRAINDICATIONS: Levofloxacin is contraindicated in persons with a history of hypersensitivity to levofloxacin, quinolone antimicrobial agents, or any other components of this product.

WARNINGS: THE SAFETY AND EFFICACY OF LEVOFLOXACIN IN PEDIATRIC PATIENTS, ADOLESCENTS (UNDER THE AGE OF 18 YEARS), PREGNANT WOMEN, AND NURSING WOMEN HAVE NOT BEEN ESTABLISHED. (See **PRECAUTIONS: Pediatric Use, Pregnancy, and Nursing Mothers** subsections.)

In immature rats and dogs, the oral and intravenous administration of levofloxacin resulted in increased osteochondrosis. Histopathological examination of the weight-bearing joints of immature dogs dosed with levofloxacin revealed persistent lesions of the cartilage. Other findings included similar lesions of the intervertebral weight-bearing joints and other signs of arthropathy in immature animals of various species. The relevance of these findings to the clinical use of levofloxacin is unknown. (See **ANIMAL PHARMACOLOGY** in full Prescribing Information.)

Convulsions and toxic psychoses have been reported in patients receiving quinolones, including levofloxacin. Quinolones may also cause increased intracranial pressure and central nervous system stimulation which may lead to tremors, restlessness, anxiety, light-headedness, confusion, hallucinations, paranoia, depression, nightmares, insomnia, and rarely, suicidal thoughts or acts. These reactions may occur following the first dose. If these reactions occur in patients receiving levofloxacin, the drug should be discontinued and appropriate measures instituted. As with other quinolones, levofloxacin should be used with caution in patients with a known or suspected CNS disorder that may predispose to seizures or lower the seizure threshold (e.g., severe cerebral arteriosclerosis, epilepsy) or in the presence of other risk factors that may predispose to seizures or lower the seizure threshold (e.g., certain drug therapy, renal dysfunction). (See **PRECAUTIONS: General, Information for Patients, Drug Interactions and ADVERSE REACTIONS**.)

Serious and occasionally fatal hypersensitivity and/or anaphylactic reactions have been reported in patients receiving therapy with quinolones, including levofloxacin. These reactions often occur following the first dose. Some reactions have been accompanied by cardiovascular collapse, hypotension/shock, seizure, loss of consciousness, tingling, angioedema (including tongue, laryngeal, throat, or facial edema/swelling), airway obstruction (including bronchospasm, shortness of breath, and/or facial edema/swelling), dyspnea, urticaria, itching, and other serious skin reactions. Levofloxacin should be discontinued immediately at the first appearance of a skin rash or any other sign of hypersensitivity. Serious acute hypersensitivity reactions may require treatment with epinephrine and other resuscitative measures, including oxygen, intravenous fluids, antihistamines, corticosteroids, pressor amines, and airway management, as clinically indicated. (See **PRECAUTIONS and ADVERSE REACTIONS**.)

Serious and sometimes fatal events, some due to hypersensitivity, and some due to a unclear etiology, have been reported rarely in patients receiving therapy with quinolones, including levofloxacin. These events may be severe and generally occur following the administration of multiple doses. Clinical manifestations may include one or more of the following: fever, rash or severe dermatologic reactions (e.g., toxic epidermal necrolysis, Stevens-Johnson Syndrome); vasculitis; arthralgia; myalgia; serum sickness; allergic pneumonitis; interstitial nephritis; acute renal insufficiency or failure; hepatitis; jaundice; acute hepatic necrosis or failure; aneurysm, including hemolytic or aplastic; thrombocytopenia, including thrombotic thrombocytopenic syndrome; leukopenia; pancytopenia; and/or other hematologic abnormalities. The drug should be discontinued immediately at the first appearance of a skin rash or any other sign of hypersensitivity and supportive measures instituted. (See **PRECAUTIONS: Information for Patients and ADVERSE REACTIONS**.)

Peripheral Neuropathy: Rare cases of sensory or sensorimotor axonal polyneuropathy affecting small and/or large axons resulting in paresthesias, hypoesthesia, dyesthesia and weakness have been reported in patients receiving therapy with quinolones, including levofloxacin. Levofloxacin should be discontinued if the patient experiences symptoms of neuropathy including pain, burning, tingling, numbness, and/or weakness or other alterations of sensation including light touch, pain, temperature, position sense, and vibratory sensation in order to prevent the development of an irreversible condition.

Pseudomembranous colitis has been reported with nearly all antibacterial agents, including levofloxacin, and may range in severity from mild to life-threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhea that begins shortly after the start of antibacterial agent therapy.

Treatment with antibacterial agents alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of "antibiotic-associated colitis."

After the diagnosis of pseudomembranous colitis has been established, therapeutic measures should be initiated. Mild cases of pseudomembranous colitis usually respond to drug discontinuation alone. In moderate to severe cases, consideration should be given to management with fluids and electrolytes, protein supplementation, and treatment with an antibacterial drug clinically effective against *C. difficile* colitis. (See **ADVERSE REACTIONS**.)

Tendon Effects: Ruptures of the shoulder, hand, Achilles tendon, or other tendons that required surgical repair or resulted in prolonged disability have been reported in patients receiving quinolones, including levofloxacin. Post-marketing surveillance reports indicate that this risk may be increased in patients receiving concomitant corticosteroids, especially the elderly. Levofloxacin should be discontinued if the patient experiences pain, inflammation, or rupture of a tendon. Patients should rest and refrain from exercise until the diagnosis of tendonitis or tendon rupture has been confidently excluded. Tendon rupture may occur during or after therapy with quinolones, including levofloxacin.

PRECAUTIONS: General Prescribing LEVAQUIN in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria. Because a rapid or bolus intravenous injection may result in hypotension, LEVOFLOXACIN INJECTION SHOULD ONLY BE ADMINISTERED BY SLOW INTRAVENOUS INFUSION OVER A PERIOD OF 60 OR 90 MINUTES DEPENDING ON THE DOSAGE. (See **DOSAGE AND ADMINISTRATION** in full Prescribing Information.)

Although levofloxacin is more soluble than other quinolones, adequate hydration of patients receiving levofloxacin should be maintained to prevent the formation of a highly concentrated urine.

Administer Levofloxacin with caution in the presence of renal insufficiency. Careful clinical observation and appropriate laboratory studies should be performed prior to and during therapy since elimination of levofloxacin may be reduced. In patients with impaired renal function (creatinine clearance <50 mL/min), adjustment of the dosage regimen is necessary to avoid the accumulation of levofloxacin due to decreased clearance. (See **CLINICAL PHARMACOLOGY and DOSAGE AND ADMINISTRATION** in full Prescribing Information.)

Moderate to severe phototoxicity reactions have been observed in patients exposed to direct sunlight while receiving drugs in this class. Excessive exposure to sunlight should be avoided. However, in clinical trials with levofloxacin, phototoxicity has been observed in less than 0.1% of patients. Therapy should be discontinued if phototoxicity (e.g., a skin eruption) occurs.

As with other quinolones, levofloxacin should be used with caution in any patient with a known or suspected CNS disorder that may predispose to seizures or lower the seizure threshold (e.g., severe cerebral arteriosclerosis, epilepsy) or in the presence of other risk factors that may predispose to seizures or lower the seizure threshold (e.g., certain drug therapy, renal dysfunction). (See **WARNINGS and Drug Interactions**.)

As with other quinolones, disturbances of blood glucose, including symptomatic hyper- and hypoglycemia, have been reported, usually in diabetic patients receiving concomitant treatment with an oral hypoglycemic agent (e.g., glyburide/glibenclamide) with insulin. In these patients, careful monitoring of blood glucose is recommended. If a hypoglycemic reaction occurs in a patient being treated with levofloxacin, levofloxacin should be discontinued immediately and appropriate therapy should be initiated immediately. (See **Drug Interactions and ADVERSE REACTIONS**.)

Torsades de pointes: Some quinolones, including levofloxacin, have been associated with prolongation of the QT interval on the electrocardiogram and infrequent cases of arrhythmia. Rare cases of torsades de pointes have been spontaneously reported during post-marketing surveillance in patients receiving quinolones, including levofloxacin. Levofloxacin should be avoided in patients with known prolongation of the QT interval, patients with uncorrected hypokalemia, and patients receiving class IA (quinidine, procainamide), or class III (amiodarone, sotalol) antiarrhythmic agents.

As with any potent antimicrobial drug, periodic assessment of organ system functions, including renal, hepatic, and hematopoietic, is advisable during therapy. (See **WARNINGS and ADVERSE REACTIONS**.)

Information for Patients

Patients should be advised:

- Patients should be counseled that antibacterial drugs including LEVAQUIN® (levofloxacin) should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When LEVAQUIN is prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by LEVAQUIN or other antibacterial drugs in the future;
- that peripheral neuropathies have been associated with levofloxacin use. If symptoms of peripheral neuropathy including pain, burning, tingling, numbness, and/or weakness develop, patients should discontinue treatment and contact their physicians;
- to drink fluids liberally;
- that antacids containing magnesium, or aluminum, as well as sucralfate, metal cations such as iron, and multivitamin preparations with zinc or Vider® (didanosine) should be taken at least two hours before or two hours after levofloxacin administration. (See **Drug Interactions**);
- that levofloxacin oral tablets can be taken without regard to meals;
- that levofloxacin oral solution should be taken 1 hour before or 2 hours after eating;
- that levofloxacin may cause neurologic adverse effects (e.g., dizziness, lightheadedness) and that patients should know how they react to levofloxacin before they operate an automobile or machinery or engage in other activities requiring mental alertness and coordination. (See **WARNINGS and ADVERSE REACTIONS**);
- to discontinue treatment and inform their physician if they experience pain, inflammation, or rupture of a tendon, and to rest and refrain from exercise until the diagnosis of tendonitis or tendon rupture has been confidently excluded;
- that levofloxacin may be associated with hypersensitivity reactions, even following the first dose, and to discontinue the drug at the first sign of a skin rash, hives or other skin reactions, a rapid heartbeat, difficulty in swallowing or breathing, any swelling suggesting angioedema (e.g., swelling of the lips, tongue, face, tightness of the throat, hoarseness), or other symptoms of an allergic reaction. (See **WARNINGS and ADVERSE REACTIONS**);
- to avoid excessive sunlight or artificial ultraviolet light while receiving levofloxacin and to discontinue therapy if phototoxicity (i.e., skin eruption) occurs;
- that if they are diabetic and are being treated with insulin or an oral hypoglycemic agent, a hypoglycemic reaction may occur. They should discontinue levofloxacin and consult a physician. (See **PRECAUTIONS: General and Drug Interactions**.);
- that concurrent administration of warfarin and levofloxacin has been associated with increases of the International Normalized Ratio (INR) or prothrombin time and clinical episodes of bleeding. Patients should notify their physician if they are taking warfarin.
- that convulsions have been reported in patients taking quinolones, including levofloxacin, and to notify their physician before taking this drug if there is a history of this condition.

Drug Interactions: Antacids, Sucralfate, Metal Cations, Multivitamins

LEVAQUIN Tablets: While the chelation by divalent cations is less marked than with other quinolones, concurrent administration of LEVAQUIN Tablets with antacids containing magnesium, or aluminum, as well as sucralfate, metal cations such as iron, and multivitamin preparations with zinc may interfere with the gastrointestinal absorption of levofloxacin, resulting in systemic levels considerably lower than desired. Tablets with antacids containing magnesium, aluminum, as well as sucralfate, metal cations such as iron, and multivitamins preparations with zinc or Vider® (didanosine) may substantially interfere with the gastrointestinal absorption of levofloxacin, resulting in systemic levels considerably lower than desired. These agents should be taken at least two hours before or two hours after levofloxacin administration.

LEVAQUIN Injection: There are no data concerning an interaction of intravenous quinolones with oral antacids, multivitamins, Vider® (didanosine), or metal cations. However, no quinolone should be co-administered with any solution containing multivalent cations, e.g., magnesium, through the same intravenous line. (See **DOSAGE AND ADMINISTRATION** in full Prescribing Information.)

Theophylline: No significant effect of levofloxacin on the plasma concentrations, AUC, and other disposition parameters for theophylline was detected in a clinical study involving 14 healthy volunteers. Similarly, no apparent effect of theophylline on levofloxacin absorption and disposition was observed. However, concomitant administration of other quinolones with theophylline has resulted in prolonged elimination half-life, elevated serum theophylline levels, and a subsequent increase in the risk of theophylline-related adverse reactions in the patient population. Therefore, theophylline levels should be closely monitored and appropriate dosage adjustments made when levofloxacin is co-administered. Adverse reactions, including seizures, may occur with or without an elevation in serum theophylline levels. (See **WARNINGS and PRECAUTIONS: General**.)

Warfarin: No significant effect of levofloxacin on the peak plasma concentrations, AUC, and other disposition parameters for R- and S-warfarin was detected in a clinical study involving healthy volunteers. Similarly, no apparent effect of warfarin on levofloxacin absorption and disposition was observed. Therefore, these have been reported during the post-marketing experience in patients that levofloxacin enhances the effects of warfarin. Elevations of the prothrombin time in the setting of concurrent warfarin and levofloxacin use have been associated with episodes of bleeding. Prothrombin time, International Normalized Ratio (INR), or other suitable anticoagulation tests should be closely monitored if levofloxacin is administered concomitantly with warfarin. Patients should also be monitored for evidence of bleeding.

Cyclosporine: No significant effect of levofloxacin on the peak plasma concentrations, AUC, and other disposition parameters for cyclosporine was detected in a clinical study involving healthy volunteers. However, an increase in the risk of cyclosporine-related adverse reactions in the patient population when co-administered with some other quinolones. Levofloxacin C_{max} and t_{1/2} were slightly lower while t_{max} and t_{1/2} were slightly longer in the presence of cyclosporine than those observed in other studies without concomitant medication. The differences, however, are not considered to be clinically significant. Therefore, no dosage adjustment is required for levofloxacin or cyclosporine when administered concomitantly.

Digoxin: No significant effect of levofloxacin on the peak plasma concentrations, AUC, and other disposition parameters for digoxin was detected in a clinical study involving healthy volunteers. Levofloxacin absorption and disposition kinetics were similar in the presence or absence of digoxin. Therefore, no dosage adjustment for levofloxacin or digoxin is required when administered concomitantly.

Probenecid and Cimetidine: No significant effect of probenecid or cimetidine on the rate and extent of levofloxacin absorption was observed in a clinical study involving healthy volunteers. The AUC and t_{1/2} of levofloxacin were 27-38% and 30% higher, respectively, while CL/F and CL_R were 21-35% lower during concomitant treatment with probenecid or cimetidine compared to levofloxacin alone. Although these differences were statistically significant, little changes were observed in enough to warrant dosage adjustment for levofloxacin when probenecid or cimetidine are co-administered.

Non-steroidal anti-inflammatory drugs: The concomitant administration of a non-steroidal anti-inflammatory drug with a quinolone, including levofloxacin, may increase the risk of CNS stimulation and convulsive seizures. (See **WARNINGS and PRECAUTIONS: General**.)

Antidiabetic agents: Disturbances of blood glucose, including hyperglycemia and hypoglycemia, have been reported in patients treated concomitantly with quinolones and an antidiabetic agent. Therefore, careful monitoring of blood glucose is recommended when these agents are co-administered.

Interaction with Laboratory or Diagnostic Testing: Some quinolones, including levofloxacin, may produce false-positive urine screening results for opiates using commercially available immunoassay kits. Confirmation of positive opiate screens by more specific methods may be necessary.

Carcinogenesis, Mutagenesis, Impairment of Fertility: In a lifetime bioassay in rats, levofloxacin exhibited no carcinogenic potential following daily dietary administration for 2 years; the highest dose (100 mg/kg/day) was 1.4 times the highest recommended human dose (750 mg) based upon relative body surface area. Levofloxacin did not shorten the time to tumor development of UV-induced skin tumors in hairless albino (Skh-1) mice at any levofloxacin dose level and was therefore not photo-carcinogenic under conditions of this study. Dermal levofloxacin concentrations in the hairless mice ranged from 25 to 42 µg/g at the highest levofloxacin dose level (300 mg/kg/day) used in the photo-carcinogenicity study. By the oral route, dermal levofloxacin concentrations in human subjects receiving 750 mg of levofloxacin averaged approximately 11.8 µg/g at C_{max}.

Levofloxacin was not mutagenic in the following assays: Ames bacterial mutation assay (*S. typhimurium* and *E. coli*), CHO/HGPRT forward mutation assay, mouse micronucleus test, mouse dominant lethal test, rat unscheduled DNA synthesis assay, and the mouse sister chromatid exchange assay. It was positive in the *in vitro* chromosomal aberration (CHL cell line) and sister chromatid exchange (CHL/II cell line) assays.

Levofloxacin caused no impairment of fertility or reproductive performance in rats at oral doses as high as 360 mg/kg/day, corresponding to 4.2 times the highest recommended human dose based upon relative body surface area and intravenous doses as high as 100 mg/kg/day, corresponding to 1.2 times the highest recommended human dose based upon relative body surface area.

Pregnancy: Teratogenic Effects. Pregnancy Category C: Levofloxacin was not teratogenic in rats at oral doses as high as 810 mg/kg/day which corresponds to 9.4 times the highest recommended human dose based upon relative body surface area, or at intravenous doses as high as 160 mg/kg/day corresponding to 1.9 times the highest recommended human dose based upon relative body surface area. The oral dose of 810 mg/kg/day to rats caused decreased fetal body weight and increased fetal mortality. No teratogenicity was observed when rabbits were dosed orally as high as 50 mg/kg/day which corresponds to 1.1 times the highest recommended human dose based upon relative body surface area, or when dosed intravenously as high as 25 mg/kg/day, corresponding to 0.5 times the highest recommended human dose based upon relative body surface area.

There are, however, no adequate and well-controlled studies in pregnant women. Levofloxacin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. (See **WARNINGS**.)

Nursing Mothers: Levofloxacin has not been measured in human milk. Based upon data from ofloxacin, it can be presumed that levofloxacin will be excreted in human milk. Because of the potential for serious adverse reactions from levofloxacin 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: Safety and effectiveness in pediatric patients and adolescents below the age of 18 years have not been established. Quinolones, including levofloxacin, cause arthropathy and osteochondrosis in juvenile animals of several species. (See **WARNINGS**.)

Geriatric Use: In phase 3 clinical trials, 1,190 levofloxacin-treated patients (25% were ≥65 years of age). Of these, 675 patients (14%) were over the ages of 65 and 74 and 515 patients (11%) were 75 years or older. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Elderly patients may be more susceptible to drug-associated effects on the QT interval. Therefore, precaution should be taken when using levofloxacin with antiarrhythmic drugs that can result in prolongation of the QT interval (e.g. class IA or class III antiarrhythmics) or in patients with risk factors for torsades de pointes (e.g. known QT prolongation, uncorrected hypokalemia). (See **PRECAUTIONS: GENERAL: Torsades de Pointes**.)

The pharmacokinetic properties of levofloxacin in younger adults and elderly adults do not differ significantly when creatinine clearance is taken into consideration. However since the drug is known to be substantially excreted by the kidney, the risk of toxic 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.

ADVERSE REACTIONS: The incidence of drug-related adverse reactions in patients during Phase 3 clinical trials conducted in North America was 6.7%. Among patients receiving levofloxacin therapy, 4.1% discontinued levofloxacin therapy due to adverse experiences. In all Phase III trials, the overall incidence, type and distribution of adverse events were similar in patients receiving levofloxacin doses of 750 mg once daily, 250 mg once daily, and 500 mg once or twice daily.

In clinical trials, the following events were considered likely to be drug-related in patients receiving levofloxacin: nausea 1.5%, diarrhea 1.2%, vaginitis 0.5%, insomnia 0.4%, abdominal pain 0.4%, flatulence 0.2%, pruritus 0.2%, dizziness 0.3%, rash 0.3%, dyspepsia 0.3%, genital moniliasis 0.1%, moniliasis 0.2%, taste perversion 0.2%, vomiting 0.3%, injection site pain 0.2%, injection site reaction 0.1%, injection site inflammation 0.1%, constipation 0.1%, fungal infection 0.1%, genital pruritus 0.1%, headache 0.2%, nervousness 0.1%, rash erythematous 0.1%, urticaria 0.1%, anemia 0.1%, somnolence 0.1%, agitation 0.1%, rash maculo-papular (<0.1%), dry mouth 0.2%, tremor 0.1%, condition aggravated 0.1%, allergic reaction 0.1%.

In clinical trials, the following events occurred in <3% of patients, regardless of drug relationship: nausea 6.8%, headache 5.8%, diarrhea 5.4%, insomnia 4.6%, constipation 3.1%.

In clinical trials, the following events occurred in 1 to 3% of patients, regardless of drug relationship: abdominal pain 2.5%, dizziness 2.4%, vomiting 2.4%, dyspepsia 2.3%, vaginitis 1.2%, rash 1.4%, chest pain 1.2%, pruritus 1.2%, sinusitis 1.1%, dyspnea 1.3%, fatigue 1.2%, flatulence 1.2%, pain 1.3%, back pain 1.2%, rhinitis 1.2%, pharyngitis 1.1%.

In clinical trials, the following events, of potential medical importance, occurred at a rate of 0.1% to 0.9%, regardless of drug relationship:

Body as a Whole - General Disorders: Acites, allergic reaction, asthenia, edema, fever, headache, hot flashes, influenza-like symptoms, leg pain, malaise, rigors, substernal chest pain, syncope, multiple organ failure, changed temperature sensation, withdrawal syndrome, Cardiovascular Disorders, General: Cardiac failure, hypertension, hypertension aggravated, hypotension, postural hypotension; Central and Peripheral Nervous System Disorders: Convulsions (seizures), hyperesthesia, hyperkinesia, hypertonia, hypoesthesia, incontinence, muscular contractions, migraine, parosmia, paralysis, speech disorder, stupor, vertigo, encephalopathy, abnormal gait, leg cramps, intracranial hypertension, ataxia; Gastro-Intestinal System Disorders: Dry mouth, dysphagia, esophagitis, gastritis, gastroesophageal reflux, GI hemorrhage, glossitis, intestinal obstruction, pancreatitis, tongue edema, melena, stomatitis; Hearing and Vestibular Disorders: Earache, ear disorder NOS, tinnitus; Heart Rate and Rhythm Disorders: Arrhythmia, arrhythmia ventricular, atrial fibrillation, bradycardia, cardiac arrest, ventricular fibrillation, heart block, palpitation, supraventricular tachycardia, ventricular tachycardia; Liver and Biliary System Disorders: Abnormal hepatic function, cholelithiasis, cholelithiasis, hepatic enzymes increased, hepatic failure, jaundice; Metabolic and Nutritional Disorders: Hypomagnesemia, thirst, dehydration, electrolyte abnormality, fluid overload, gout, hyperglycemia, hyperkalemia, hypernatremia, hypoglycemia, hypokalemia, hyponatremia, hypophosphatemia, nonprotein nitrogen increase, weight decrease; Musculo-Skeletal System Disorders: Arthralgia, arthrosis, arthritis, back pain, bone pain, bone pain, synovitis, tendonitis, tendon disorder, Myo, Endo, Pericardial and Valve Disorders: Angina pectoris, myocardial infarction; Neoplasms: Carcinoma, thrombocytopenia; Other Special Senses Disorders: Parosmia, taste perversion; Platelet, Bleeding and Clotting Disorders: Hematoma, epistaxis, prothrombin decreased, pulmonary embolism, purpura, thrombocytopenia; Psychiatric Disorders: Abnormal dreaming, agitation, anorexia, anxiety, confusion, depression, hallucinations, impotence, nervousness, paranoia, sleep disorder, somnolence; Red Blood Cell Disorders: Anemia; Reproductive Disorders: Dysmenorrhea, leucorrhoea; Resistance Mechanism Disorders: Abscess, bacterial infection, fungal infection, herpes simplex, moniliasis, otitis media, sepsis, infection; Respiratory System Disorders: Airway obstruction, aspiration, asthma, bronchitis, bronchospasm, chronic obstructive airway disease, coughing, hemoptysis, epistaxis, hypoxia, laryngitis, pleural effusion, pleurisy, pneumonitis, pneumonia, pneumothorax, pulmonary edema, respiratory depression, respiratory disorder, respiratory insufficiency, upper respiratory tract infection; Skin and Appendages Disorders: Alopecia, bullous eruption, dry skin, eczema, genital pruritus, increased sweating, rash, skin disorder, skin exfoliation, skin ulceration, urticaria; Urinary System Disorders: Abnormal renal function, acute renal failure, hematuria, oliguria, urinary incontinence, urinary retention, urinary tract infection; Vascular (Extracardiac) Disorders: Edema, headache, cerebrovascular disorder, gangrene, phlebitis, purpura, thrombosis, thrombotic thrombocytopenic syndrome, thrombocytopenia, thrombotic thrombocytopenic syndrome; Vision Disorders: Abnormal eye tests, abnormal eye examinations; White Cell and RES Disorders: Agranulocytosis, granulocytopenia, leukocytosis, lymphadenopathy, WBC abnormal NOS.

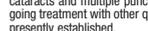
In clinical trials using multiple-dose therapy, ophthalmologic abnormalities, including cataracts and multiple punctate lenticular opacities, have been noted in patients undergoing treatment with other quinolones. The relationship of the drugs to these events is not presently established.

Crystalluria and cylindruria have been reported with other quinolones.

The following markedly abnormal laboratory values appeared in >2% of patients receiving levofloxacin. It is not known whether this abnormality was caused by the drug or the underlying condition being treated.

Hematology: decreased lymphocytes (2.2%)

Post-Marketing Adverse Reactions: Additional adverse events reported from worldwide post-marketing experience with levofloxacin include: allergic pneumonitis, anaphylactic shock, anaphylactoid reaction, dyspnea, abnormal EEG, encephalopathy, eosinophilia, erythema multiforme, hemolytic anemia, multi-system organ failure, increased International Normalized Ratio (INR)/prothrombin time, peripheral neuropathy, rhabdomyolysis, Stevens-Johnson Syndrome, tendon rupture, torsades de pointes, vasodilation.



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Indications:

- * LEVAQUIN is indicated for adults with acute bacterial sinusitis due to *S. pneumoniae*, *H. influenzae*, or *M. catarrhalis*.
- † LEVAQUIN is indicated for adults with community-acquired pneumonia due to *S. aureus*, *S. pneumoniae* (including multidrug-resistant strains [MDRSP[†]]), *H. influenzae*, *H. parainfluenzae*, *K. pneumoniae*, *M. catarrhalis*, *M. pneumoniae*, *C. pneumoniae*, or *L. pneumophila*.
- ‡ MDRSP (multidrug-resistant *S. pneumoniae*) isolates are strains resistant to two or more of the following antibiotics: penicillin (MIC ≥ 2 $\mu\text{g/mL}$), 2nd generation cephalosporins, eg, cefuroxime, macrolides, tetracyclines, and trimethoprim/sulfamethoxazole.
- § Efficacy of this alternative regimen has been demonstrated to be effective for infections caused by *S. pneumoniae* (excluding MDRSP), *H. influenzae*, *H. parainfluenzae*, *M. pneumoniae*, and *C. pneumoniae*.

Important Safety Information

The most common drug-related adverse events in US clinical trials were nausea (1.5%) and diarrhea (1.2%).

The safety and efficacy of levofloxacin in pediatric patients, adolescents (under 18), pregnant women, and nursing mothers have not been established. Levofloxacin is contraindicated in persons with a history of hypersensitivity to levofloxacin, quinolone antimicrobial agents, or any other components of this product. Serious and occasionally fatal events, such as hypersensitivity and/or anaphylactic reactions, as well as some of unknown etiology have been reported in patients receiving therapy with quinolones, including levofloxacin. These reactions may occur following the first dose or multiple doses. The drug should be discontinued at the first appearance of a skin rash or any other sign of hypersensitivity.

As with other quinolones, levofloxacin should be used with caution in patients with known or suspected central nervous system disorders, peripheral neuropathy, or in patients who have a predisposition to seizures.

Tendon ruptures that required surgical repair or resulted in prolonged disability have been reported in patients receiving quinolones, including levofloxacin, during and after therapy. This risk may be increased in patients receiving concomitant corticosteroids, especially the elderly. The quinolone should be discontinued in patients experiencing pain, inflammation, or rupture of a tendon.

Some quinolones, including levofloxacin, have been associated with prolongation of the QT interval, infrequent cases of arrhythmia, and rare cases of torsades de pointes. Levofloxacin should be avoided in patients with known risk factors such as prolongation of the QT interval, patients with uncorrected hypokalemia, and patients receiving class IA (quinidine, procainamide), or class III (amiodarone, sotalol) antiarrhythmic agents.

Antacids containing magnesium or aluminum, as well as sucralfate, metal cations such as iron, and multivitamin preparations with zinc, or Videx[®] (didanosine) chewable/buffered tablets or the pediatric powder for oral solution, should be taken at least 2 hours before or 2 hours after levofloxacin administration.

For information on Warnings, Precautions, and additional Adverse Reactions that may occur, regardless of drug relationship, please see full Prescribing Information.

¶ Videx is a registered trademark of Bristol-Myers Squibb Company.

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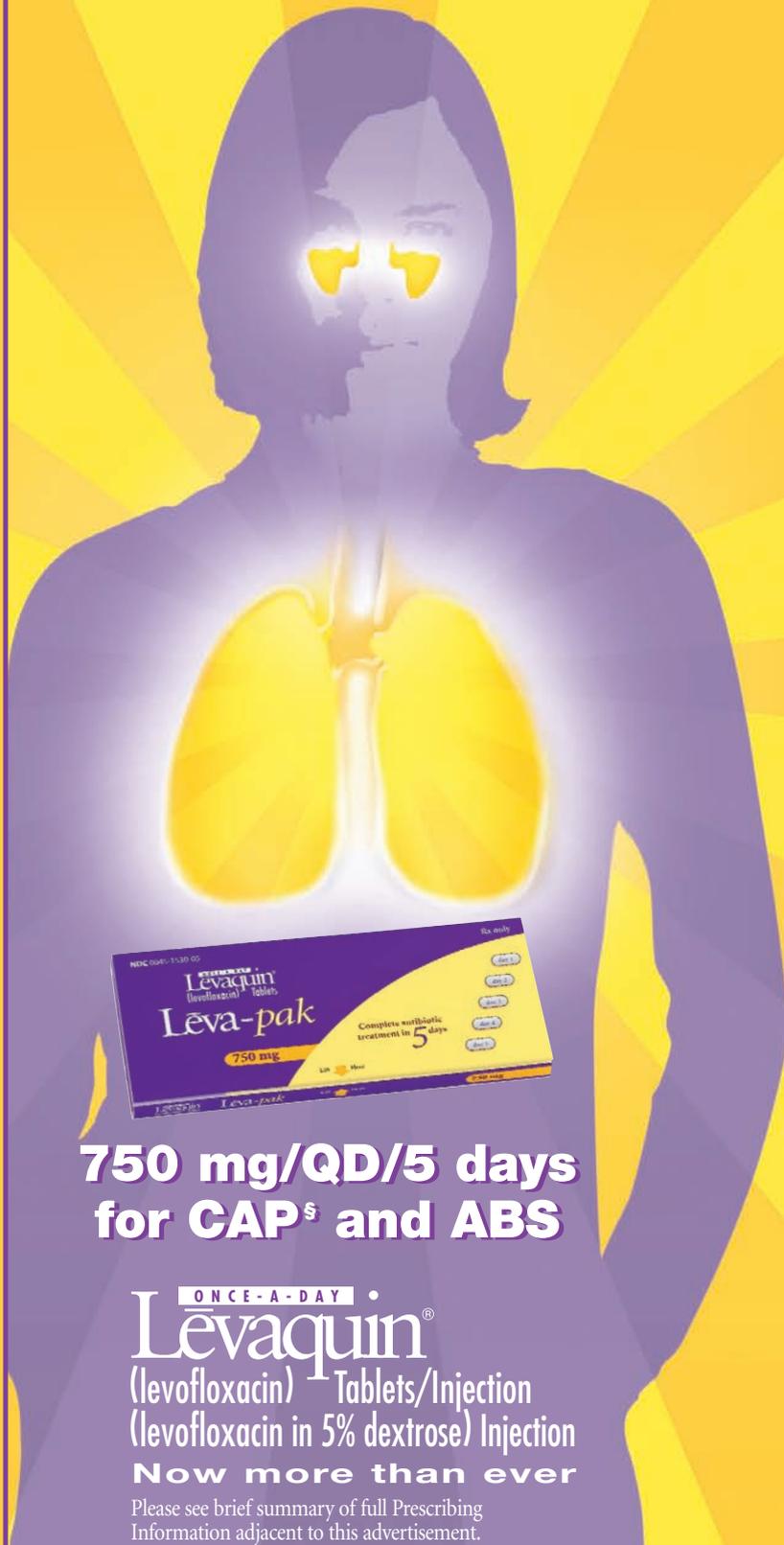
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