The Journal of
Urgent Care Medicine™
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The Official Publication of the **Urgent Care Association of America**
OCTOBER 2006

PREMIER ISSUE

Assessing Syncope
Pearls and Pitfalls

FEATURES

DEPARTMENTS

A **BRAVEHEART** PUBLICATION

Pink eye can run wild.
Get it under control fast.

Pink eye moves quickly. That's why you need to treat it at the speed of VIGAMOX® solution. Recent data show moxifloxacin (VIGAMOX®) reins in key pink-eye-causing pathogens faster and with a broader spectrum of coverage than other ocular anti-infectives.[1]* So get a move on pink eye before it runs wild. Think fast. Think VIGAMOX®.

VIGAMOX® solution is indicated for the treatment of bacterial conjunctivitis. VIGAMOX® solution is contraindicated in patients with a history of hypersensitivity to moxifloxacin, to other fluoroquinolones, or to any of the components in this medication. *In vitro* data are not always indicative of clinical success or microbiological eradication in a clinical setting. The dosing of VIGAMOX® solution is one drop in the affected eye(s) 3 times daily for 7 days.

*Tested vs gentamicin (GENOPTIC†), polymyxin B/trimethoprim sulfate (POLYTRIM†), tobramycin (TOBREX®), ciprofloxacin (CILOXAN® solution), gatifloxacin (ZYMAR†), ofloxacin (OCUFLOX†), and levofloxacin (QUIXIN†).

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Please see brief summary of prescribing information on adjacent page.

Vigamox®

(moxifloxacin hydrochloride ophthalmic solution) 0.5% as base

DESCRIPTION: VIGAMOX® (moxifloxacin HCl ophthalmic solution) 0.5% is a sterile ophthalmic solution. It is an 8-methoxy fluoroquinolone anti-infective for topical ophthalmic use.

Clinical Studies: In two randomized, double-masked, multicenter, controlled clinical trials in which patients were dosed 3 times a day for 4 days, VIGAMOX® solution produced clinical cures on day 5-6 in 66% to 69% of patients treated for bacterial conjunctivitis. Microbiological success rates for the eradication of the baseline pathogens ranged from 84% to 94%. Please note that microbiologic eradication does not always correlate with clinical outcome in anti-infective trials.

INDICATIONS AND USAGE: VIGAMOX® solution is indicated for the treatment of bacterial conjunctivitis caused by susceptible strains of the following organisms:

Aerobic Gram-positive microorganisms:

*Corynebacterium species**, *Micrococcus luteus**, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Staphylococcus haemolyticus*, *Staphylococcus hominis*, *Staphylococcus warneri**, *Streptococcus pneumoniae*, *Streptococcus* viridans group

Aerobic Gram-negative microorganisms:

*Acinetobacter lwoffii**, *Haemophilus influenzae*, *Haemophilus parainfluenzae**

Other microorganisms:

Chlamydia trachomatis

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

CONTRAINDICATIONS: VIGAMOX® (moxifloxacin HCl ophthalmic solution) is contraindicated in patients with a history of hypersensitivity to moxifloxacin, to other quinolones, or to any of the components in this medication.

WARNINGS: NOT FOR INJECTION.

VIGAMOX® solution should not be injected subconjunctivally, nor should it be introduced directly into the anterior chamber of the eye.

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

PRECAUTIONS: General: As with other anti-infectives, prolonged use may result in overgrowth of non-susceptible organisms, including fungi. If superinfection occurs, discontinue use and institute alternative therapy. Whenever clinical judgment dictates, the patient should be examined with the aid of magnification, such as slit-lamp biomicroscopy, and, where appropriate, fluorescein staining. Patients should be advised not to wear contact lenses if they have signs and symptoms of bacterial conjunctivitis.

Information for Patients: Avoid contaminating the applicator tip with material from the eye, fingers or other source.

Systemically administered quinolones including moxifloxacin have been associated with hypersensitivity reactions, even following a single dose. Discontinue use immediately and contact your physician at the first sign of a rash or allergic reaction.

Drug Interactions: Drug-drug interaction studies have not been conducted with VIGAMOX® solution. *In vitro* studies indicate that moxifloxacin does not inhibit CYP3A4, CYP2D6, CYP2C9, CYP2C19, or CYP1A2 indicating that moxifloxacin is unlikely to alter the pharmacokinetics of drugs metabolized by these cytochrome P450 isozymes.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term studies in animals to determine the carcinogenic potential of moxifloxacin have not been performed. However, in an accelerated study with initiators and promoters, moxifloxacin was not carcinogenic in rats following up to 38 weeks of oral dosing at 500 mg/kg/day (approximately 21,700 times the highest recommended total daily human ophthalmic dose for a 50 kg person, on a mg/kg basis). Moxifloxacin was not mutagenic in four bacterial strains used in the Ames *Salmonella* reversion assay. As with other quinolones, the positive response observed with moxifloxacin in strain TA 102 using the same assay may be due to the inhibition of DNA gyrase. Moxifloxacin was not mutagenic in the CHO/HGPRT mammalian cell gene mutation assay. An equivocal result was obtained in the same assay when v79 cells were used. Moxifloxacin was clastogenic in the v79 chromosome aberration assay, but it did not induce unscheduled DNA synthesis in cultured rat hepatocytes. There was no evidence of genotoxicity *in vivo* in a micronucleus test or a dominant lethal test in mice.

Moxifloxacin had no effect on fertility in male and female rats at oral doses as high as 500 mg/kg/day, approximately 21,700 times the highest recommended total daily human ophthalmic dose. At 500 mg/kg orally, there were slight effects on sperm morphology (head-tail separation) in male rats and on the estrous cycle in female rats.

Pregnancy:

Teratogenic Effects. Pregnancy Category C: Moxifloxacin was not teratogenic when administered to pregnant rats during organogenesis at oral doses as high as 500 mg/kg/day (approximately 21,700 times the highest recommended total daily human ophthalmic dose); however, decreased fetal body weights and slightly delayed fetal skeletal development were observed. There was no evidence of teratogenicity when pregnant Cynomolgus monkeys were given oral doses as high as 100 mg/kg/day (approximately 4,300 times the highest recommended total daily human ophthalmic dose). An increased incidence of smaller fetuses was observed at 100 mg/kg/day.

Since there are no adequate and well-controlled studies in pregnant women, VIGAMOX® solution should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

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

Pediatric Use: The safety and effectiveness of VIGAMOX® solution in infants below 1 year of age have not been established.

There is no evidence that the ophthalmic administration of VIGAMOX® has any effect on weight bearing joints, even though oral administration of some quinolones has been shown to cause arthropathy in immature animals.

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

ADVERSE REACTIONS: The most frequently reported ocular adverse events were conjunctivitis, decreased visual acuity, dry eye, keratitis, ocular discomfort, ocular hyperemia, ocular pain, ocular pruritus, subconjunctival hemorrhage, and tearing. These events occurred in approximately 1-6% of patients. Nonocular adverse events reported at a rate of 1-4% were fever, increased cough, infection, otitis media, pharyngitis, rash, and rhinitis.

Reference:

1. Data on file. Alcon Laboratories, Inc. 2005.

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Call for Articles

The *Journal of Urgent Care Medicine* (*JUCM*), the Official Publication of the Urgent Care Association of America, is looking for a few good authors.

Physicians, physician assistants, and nurse practitioners, whether practicing in an urgent care, primary care, hospital, or office environment, are invited to submit a review article or original research for publication in a forthcoming issue.

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

Please e-mail your idea to
JUCM Editor-in-Chief
Lee Resnick, MD at
editor@jucm.com.

He will be happy to discuss it with you.

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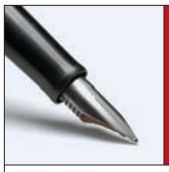

LETTER FROM THE EDITOR-IN-CHIEF

The Evolution of a Specialty

Evolution, by definition, is a process in which something passes by degrees to a more advanced stage. This inaugural issue of *The Journal of Urgent Care Medicine* (*JUCM*) represents an important milestone in the evolution of urgent care medicine as a discipline.

Our intent, and one of my key objectives as Editor-in-Chief, is to make *JUCM* a forum for the sharing of ideas, trends, clinical content, original research, and industry news unique to the practice of urgent care medicine. This journal speaks in an urgent care voice as it expands on the core competencies of our field with practical, clinically relevant content that reflects our unique medical decision-making. It explores the challenges and opportunities revealed in our novel healthcare delivery model.

In my role as Chair of Academics for the Urgent Care Association of America (UCAOA), I am charged with the task of creating an academic vision that is expansive, as well as legitimate and substantive, tackling such issues as credentialing, training, continuing education, and research. *JUCM* is part of that effort.

I believe strongly that a specialty evolves; it does not simply declare itself. We have embarked on a *process* that must encourage reflection, flexibility, collaboration, and discussion. We are navigating our course through a tempestuous sea; the best way through will take careful study, planning, and managed risk-taking. We have begun by asking ourselves: Who are we? What do we do that is unique? What special skills are required? What training is necessary to master those skills? What is our model of healthcare delivery, and how do we accredit facilities that provide it?

We're still in our formative stage, yet we've accomplished a great deal already:

- The establishment of a reproducible training program based on a set of core competencies and learning objectives that reflect the unique skills and decision-making required of an urgent care practitioner
- The birth of an accreditation process that identifies urgent care facilities uniquely qualified to meet recognized standards of operation and oversight
- The development of a committee of UCAOA members dedicated to exploring, debating, and building on the academic mission
- Not least of all, the introduction of this journal

Refining the core competencies and growing the training program will provide the necessary foundation to further the academic agenda. With this essential groundwork in place, we can more effectively explore ways to test competency and recognize those who have achieved a higher level learning through experience, training, and continuing education.

"This journal represents a critical step toward a more evolved discipline, capable of redefining healthcare delivery while providing the highest standard of care for our patients."

This journal represents a critical step toward a more evolved discipline, capable of redefining healthcare delivery while providing the highest standard of care for our patients. I encourage you to make it your own by submitting an article for publication. More than that, however, I hope you will use it as a tool to aid in your own evolution as a clinician.

Sincerely,

Lee A. Resnick, MD
Editor-in-Chief
The Journal of Urgent Care Medicine


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October 2006

VOLUME 1, NUMBER 1

CLINICAL

13 SYNCOPE: Evaluation and Management in an Urgent Care Setting

Your patient tells you things got hazy and next thing he knew, he was on the ground. You need to determine if the cause is something benign, or whether a trip to the ER is warranted.

PRACTICE MANAGEMENT

27 Healthcare in the Express Lane: The Emergence of Retail Clinics

Patients are going to their friendly neighborhood retailer for more than a box of tissues when they get sick these days. Are retail-based health clinics a threat to urgent care's growth?

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The Journal of
Urgent Care Medicine™

EDITOR-IN-CHIEF
Lee Resnick, MD
editor@jucm.com

EDITOR
J. Harris Fleming, Jr.
hfleming@jucm.com

CONTRIBUTING EDITORS
Nahum Kovalski, BSc, MDCM
Frank Leone, MBA, MPH
John Shufeldt, MD, JD, MBA, FACEP
David Stern, MD, CPC

ART DIRECTOR
Tom DePrenda
tdeprenda@jucm.com

BRAVEHEART PUBLISHING

2 Split Rock Road, Mahwah NJ 07430

PUBLISHERS

Peter Murphy
pmurphy@braveheart-group.com
(201) 847-1934

Stuart Williams
swilliams@braveheart-group.com
(201) 529-4004

Mission Statement

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.

The Journal of Urgent Care Medicine (*JUCM*) makes every effort to select authors who are knowledgeable in their fields. However, *JUCM* does not warrant the expertise of any author in a particular field, nor is it responsible for any statements by such authors. The opinions expressed in the articles and columns are those of the authors, do not imply endorsement of advertised products, and do not necessarily reflect the opinions or recommendations of Braveheart Publishing or the editors and staff of *JUCM*. Any procedures, medications, or other courses of diagnosis or treatment discussed or suggested by authors should not be used by clinicians without evaluation of their patients' conditions and possible contraindications or dangers in use, review of any applicable manufacturer's product information, and comparison with the recommendations of other authorities.

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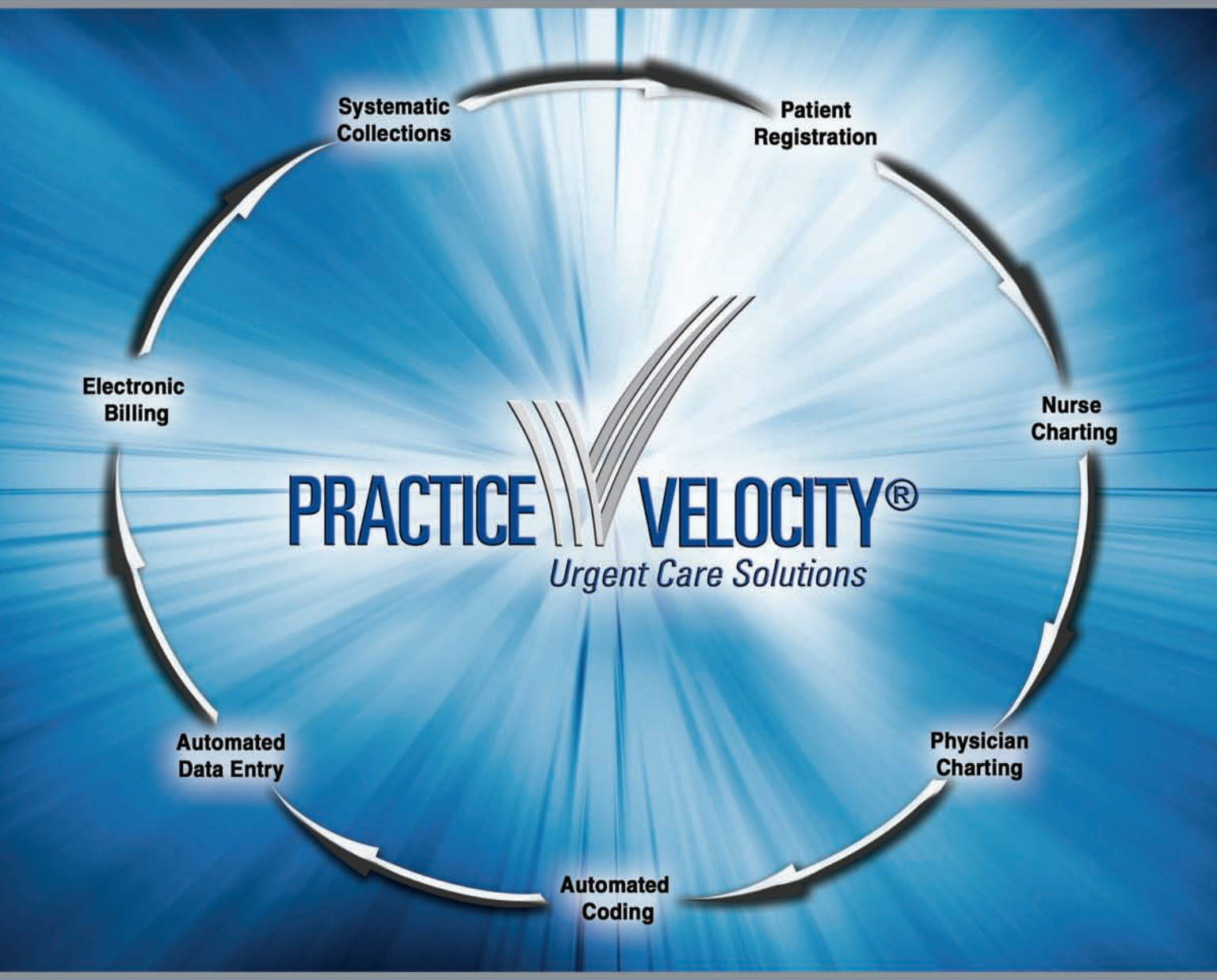

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JUCM wants to ensure that the content we offer reflects state-of-the-art—but real-world—approaches to practicing medicine in the urgent care environment. Our objective in every issue will be to provide information that is of high value to you and, by extension, that will benefit the entire urgent care community.

The following practitioners are devoting their time and expertise to that mission, and to helping us maintain the highest standards of clinical relevance. *JUCM* is very pleased and proud to introduce them as members of the Editorial Board and Advisory Board.

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Medical consultant; author/editor
(*Urgent Care Medicine*)
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Daniel R. Konow, PA-C, MBA
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Steven Lelyveld, MD, FACEP, FAAP
Associate Professor of Medicine and Pediatrics
University of Chicago Pritzker School of Medicine
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Benson S. Munger, PhD
Associate Head, Research
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Tucson, AZ

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Beth Israel/Deaconess Medical Center;
Teaching Attending, Emergency Medicine
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Epidemiology & Biostatistics, Oncology and Sociology
Case Western Reserve University
Cleveland, OH

This is an Exciting Time to be in Urgent Care!

LOU ELLEN HORWITZ

As you will see in this inaugural issue of *The Journal of Urgent Care Medicine*, whether you're trying to get to the root of one of the more common—but potentially foreboding—symptoms that bring patients to your center (see Syncope: Evaluation and Management in an Urgent Care Setting, by Kenneth V. Iserson, MD, MBA, FACEP, FAAEM, starting on page 13) or tracking the myriad business models that are vying for their piece of our industry (see Healthcare in the Express Lane: The Emergence of Retail Clinics, starting on page 27), there is plenty of activity and intrigue to keep us all busy for a long time.

And that's primarily why UCAOA is here: to help you stay connected to the best experts, information, and networking opportunities so you can be successful in this ever-growing and ever-changing business of providing urgent care.

Highlights

If you are already on our e-mail lists, then you know it has been a busy year at UCAOA. Some of the highlights include:

- Record-breaking attendance at our Annual Convention, for participants and exhibitors alike
- Launch of *The Journal of Urgent Care Medicine*, the newest peer-reviewed medical journal in the country
- Addition of new online forums to accommodate increasing discussion traffic
- Our first-ever Fall Conference (October 6 and 7 in Phoenix)
- First fellows beginning in the only urgent care fellowship in the nation

We also recently elected new board members, and would like to recognize the entire 2006/2007 UCAOA Board of Directors and thank them for their ongoing contributions:

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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Still to Come

We're not stopping there, however. Here's what UCAOA is going to bring you in the months to come:

- Launch of a new website that will include an exclusive members-only area
- New toll-free number: 1-877-MYUCAOA (877-698-2262)
- Increase in accredited urgent care centers (see the listing of recently accredited sites in this issue!)
- New national benchmarking survey, covering staffing levels and physician salaries
- Details about the next Annual Convention, May 9-12, 2007 in Daytona Beach, FL, featuring a new advanced business track
- New opportunities for member involvement

We hope you enjoy this issue of *JUCM*. If you would like to become a member of UCAOA, refer a colleague, or just join our mailing list, visit us at *www.ucaoa.org* or call us at 877-MYUCAOA.

We look forward to hearing from you, and I look forward to meeting you in person at an upcoming conference. ■

For more information about the UCAOA 2007 National Conference in Daytona Beach, FL, log on to www.ucaoa.org.

Onward and Upward

WILLIAM MEADOWS, MD

It's been two years since the Board officially approved the bylaws of the Urgent Care Association of America (UCAOA). In reflecting on that, my first thoughts are how much we owe to all of you members who have supported this still-new organization in our infancy. Over 200 of you traveled to Orlando for our first conference in the spring of 2005, and attendance at the 2006 conference in Lake Tahoe was twice that.

We are a member-driven, democratic organization and exist to help make your practice more successful and to bring together members involved in all aspects of urgent care.

As the first issue of our journal comes to publication, I'm struck by what we've accomplished in a relatively short period of time.

As noted above, our annual conferences are increasingly well attended. Each gave members who attended a chance to attend excellent lectures. The opportunity to meet colleagues and network between meetings was every bit as valuable as the conference itself. It was gratifying to see that most members were willing to share experiences with others. This demonstrates the true value of an association like ours.

Encouraged by the attendance and feedback we received in regard to the first two annual conferences, we held our first two-day "mini-conference" this month, geared specifically to new clinic owners and operators.

Our next annual spring conference, May 9-12 in Daytona Beach, FL, will be even larger and more useful than the first two, and will feature both a business track and clinical track.

We've also made great strides internally at UCAOA. Guided by our executive director, Lou Ellen Horwitz, we have a continually improving website that keeps all of us connected in between conferences. It is being updated and will be our link to obtaining information about the changes in urgent care while also providing a forum through which we can share ideas.

William Meadows is president of the Urgent Care Association of America, and is sole owner and medical director of Physicians Care, operating six urgent care centers in and around Chattanooga, TN.

Perhaps most important to the acceptance of urgent care medicine as a discipline in its own right, we've also progressed on the accreditation and training fronts.

Accreditation

We began discussions about accreditation for clinics during our first board meeting in the fall of 2004. Our criteria was ready by the early summer of 2005 and at the 2006 conference, Awards of Distinction were given to 19 newly accredited clinic sites, with others coming on board soon. Our goal is to make UCAOA's accreditation the gold standard for quality assurance for the delivery of urgent care.

Urgent Care Fellowship

The summer of 2006 saw the acceptance of three physicians into the first fellowship in urgent care at the University Hospitals Case Medical Center in Cleveland, OH. Spearheaded by Dr. Lee Resnick, who is also editor-in-chief of *JUCM*, this program is partially sponsored by a $30,000 grant from UCAOA and is a result of collaboration among the Department of Family Medicine, UCAOA, and the University Hospitals Medical Practices. This one-year fellowship is currently open to graduates of accredited Family Medicine and Med/Peds residencies.

Training and future certification in the urgent care specialty are linked in a methodical process that we have turned over to our Academic Committee for review and discussion. The fellowship and our commitment to publish *The Journal of Urgent Care Medicine* represent a big step toward the future training of urgent care physicians.

As we look forward to 2007, we will continue to raise the bar for our organization, and discuss our aspirations in detail whenever we have the opportunity at UCAOA conferences. And as I finish my term as president, I again thank all of you for your support of UCAOA. I have never worked with a better group of people, all of whom care deeply about the direction of our specialty.

I can honestly say there has never been a dull moment and I look forward to seeing you at our spring conference.■

JUCM CONTRIBUTORS

Ken Iserson, MD, MBA, FACEP, FAAEM is professor of emergency medicine and director of the Arizona Bioethics Program at the University of Arizona in Tucson. In addition to emergency medicine, his interest in bioethics and disaster medicine is evident in the books he has authored (*Demon Doctors: Physicians as Serial Killers* and *Death to Dust: What Happens to Dead Bodies?* to name just two) and by his presence on the State of Arizona's Disaster Medical Assistance Team. Somehow, and fortunately for us, he also found time to accept our invitation to sit on the *JUCM* Advisory Board and author the core clinical article for our inaugural issue, Syncope: Evaluation and Management in an Urgent Care Setting (page 13).

We're also very pleased to introduce you to a few experts who will be regular contributors to *JUCM*. Each of them will bring unique insights gleaned from years of experience in his particular field, presented as practical advice relevant to your day-to-day practice.

Nahum Kovalski, BSc, MDCM is an urgent care practitioner and assistant medical director/CIO at Terem Immediate Medical Care in Jerusalem, Israel. He is a member of the Editorial Board of *The Journal of Urgent Care Medicine*. See Abstracts in Urgent Care (page 22).

John Shufeldt, MD, JD, MBA, FACEP is chief executive officer of NextCare, Inc. and sits on the Editorial Board of *The Journal of Urgent Care Medicine*. See Health Law (page 34).

Frank Leone, MBA, MPH is president and CEO of RYAN Associates and executive director of the National Association of Occupational Health Professionals, as well as author of numerous sales and marketing texts and periodicals. See Occupational Medicine (page 36).

David Stern, MD, CPC, is a partner in Physicians Immediate Care, with nine urgent care centers in Illinois and Oklahoma, and chief executive officer of Practice Velocity, which provides charting, coding and billing software for urgent care. See Coding Q&A (page 37).

In addition, we are indebted to **Drs. Michael Talkar** and **Ohad Sheffy** for sharing a couple of interesting cases they came across. You'll find those cases in Insights and Images (page 24), under Case Report and Clinical Challenge, respectively.

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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 or authors names in the order they are to appear, and the name, address, and contact information (mailing address, phone, fax, e-mail) for each author.

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Syncope

Evaluation and Management in an Urgent Care Setting

Urgent message: When a patient presents to urgent care after a syncopal event, the clinician's charge is to determine whether the episode was of benign or potentially life-threatening etiology and whether the patient should be transferred for further evaluation.

Kenneth V. Iserson, MD, MBA, FACEP, FAAEM, Professor of Emergency Medicine, The University of Arizona, Tucson, AZ

Introduction

Syncope is a sudden, transient loss of consciousness with a loss of postural tone (typically, falling). It results from an abrupt, transient, and diffuse cerebral malfunction and is quickly followed by spontaneous recovery. The term *syncope* excludes seizures, coma, shock, or other states of altered consciousness. Many patients will ascribe their syncopal episode to a situationally mediated vasovagal episode.

Despite this, the goals in the urgent care setting include the following:

- Determining whether the patient's episode was actually a syncopal or presyncopal event, and if it could have a life-threatening etiology
- Stabilizing the patient
- Transferring those patients who need further diagnostic studies or therapeutic interventions

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Epidemiology

Syncope accounts for up to 3% of emergency department (ED) visits and up to 6% of hospital admissions each year in the United States.[1,2] At some time in their lives, up to about half the population (12% to 48%) of people may experience syncope.[3]

Syncope occurs in all age groups, but it is most common in adults. Non-cardiac causes tend to be more common in young adults, while cardiac syncope becomes increasingly more frequent with advancing age.[4] The chance of having at least one syncopal episode in childhood is between 15% and 50%.[5] Though a benign cause is usually found, syncope in children warrants prompt detailed evaluation.[6]

With advancing age comes an increased frequency of

coronary artery and myocardial disease, arrhythmia, vasomotor instability, autonomic failure, polyneuropathy, and the use of polypharmacy—all of which can contribute to syncope. Therefore, advanced age is an independent risk factor for both syncope and death.[7]

Table 1. Presyncopal Signs and Symptoms

- Pallor
- Diaphoresis
- Palpitations
- Vertigo
- Weakness
- Epigastric discomfort
- Nausea
- Blurred or faded vision
- Parasthesias

Pathophysiology

Regardless of specific cause, on the most basic level syncope results from the sudden reduction in the delivery of a vital substrate (usually oxygen) to both cerebral hemispheres or to the brainstem's reticular activating system. Most often, this is due to a localized or systemic reduction (35% or more) in blood flow to these areas. Since brain tissue cannot store energy, cessation of cerebral perfusion lasting only three to five seconds will result in syncope. This is most frequently caused by a transiently diminished vagal tone or autonomic nervous system disorders (such as in patients with diabetes). Patients who experience vasovagal reactions have subnormal vagal baroreflex responses with a disappearance of muscle sympathetic nerve activity.[8]

Syncope can, however, also be due to transient hypoglycemia, toxins, metabolic abnormalities, failure of autoregulation, and primary neurological derangements.

The causes of syncope may be categorized into three broad groups: cardiovascular, non-cardiovascular, and unknown. This categorization stratifies the patient's future risk for serious associated illnesses and death; generally, cardiovascular syncope is associated with higher mortality than syncope due to non-cardiovascular or unknown causes.

Cardiovascular Syncope

Cardiovascular syncope may be due to autonomic dysfunction, orthostatic hypotension, obstructive lesions, and dysrhythmias. Each of these has its own etiology.

At all ages, the most common cause of syncope is autonomic dysfunction, which results from a slowing of the heart and decreased cardiac output due to increased vagal tone. This is often described as "fainting." Any number of factors, such as the bradycardia often seen in athletes, may cause increased vagal tone, and some individuals seem more prone to these episodes than others. Emotional stress, hot or crowded conditions, the sight of blood, and pain may often precipitate these events. Diabetics and the elderly often have disruption of their autonomic systems leading to syncope. In all these cases, a good history may help determine whether a syncopal event was vasovagal or due to a more serious cause. (While tilt-testing may eventually suggest that a syncopal event from unknown cause was vasovagal, no real "gold standard" for vasovagal syncope exists.)[9]

Orthostatic hypotension is a clinical syndrome indicating diminished intravascular volume. A commonly encountered cause of syncope that often requires treatment, it is often caused by dehydration (often secondary to acute gastroenteritis), and is also seen with excess intake of medication and acute anemia from hemorrhage.

Dysrhythmias may have multiple causes but, if they cause syncope, are usually of acute onset. Such dysrhythmias may arise from any focus (supraventricular, nodal, or ventricular) and be bradycardic, tachycardic, or unorganized (e.g., ventricular fibrillation). Pacemaker failure results in syncope when the underlying rhythm cannot sustain a sufficient cardiac output. Severe bradycardia, caused by minimal pressure on the carotid, causes carotid sinus syncope. It can be exacerbated by carotid lesions or digitalis toxicity.

Obstructive lesions result from a diminished effective cardiac output due to structural abnormalities. Most commonly, these are in or around the heart—either acquired or congenital lesion—but can also occur with outflow obstruction due to a pulmonary embolus or aortic dissection.

Non-Cardiovascular Syncope

Non-cardiovascular syncope may be due to metabolic derangements, neurologic abnormalities, or psychiatric disease. Again, establishing the root of the suspected cause of the syncope may help clarify management options.

Metabolic derangements can develop slowly (e.g., alcoholism, hypothyroidism) or rapidly (e.g., hypoglycemia, hypoxia). Syncope is the sudden, final common pathway for these disorders. On occasion, they may lead to seizures or coma, rather than syncope.

Neurologic abnormalities are a relatively rare cause of

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*Based on pharmacokinetic data.[1]
Reference: 1. Data on file, UCB, Inc.
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12

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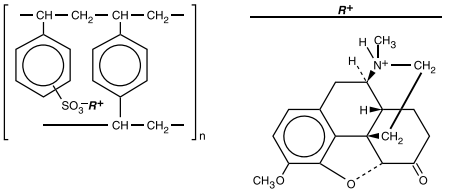
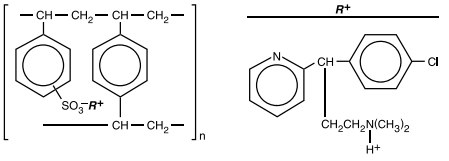
DESCRIPTION: Each teaspoonful (5 mL) of TUSSIONEX Pennkinetic Extended-Release Suspension contains hydrocodone polistirex equivalent to 10 mg of hydrocodone bitartrate and chlorpheniramine polistirex equivalent to 8 mg of chlorpheniramine maleate. TUSSIONEX Pennkinetic Extended-Release Suspension provides 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 4,5α-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 (H_1 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, antianxiety 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).

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syncope. Instead, atypical seizures may initially be described as syncope. Without extensive testing, the two may be difficult to differentiate.

Psychiatric disease or medications may cause syncope due to a vagal effect, hyperventilation, or a drug effect. However, it is dangerous to ascribe a syncopal episode to a psychiatric cause without some investigation, including a good history and physical examination.

Diagnostic Evaluation

History and physical examination are the most specific and sensitive ways to evaluate syncope. Cursory review of the literature shows that diagnosis can be made with a thorough history and physical examination in 50% to 85% of patients.[7] No single laboratory test has greater diagnostic efficacy.

History

Proper diagnosis, or at least correct patient disposition, requires combining patient and bystander history with risk factors (age, cardiac history, and significant other medical history—including medication/drug/alcohol use) and the limited information that can be gained from the physical examination and diagnostic tests.

Witnesses to the syncopal event can often describe its character and time course far better than the patient (who, by definition, was unconscious). Key historical clues include:

- Setting (activities preceding syncope)
- Prodrome (aura, chest pain, dyspnea, vertigo, diaphoresis, graying of vision)
- Abruptness of onset (gradual or sudden)
- Position when it occurred (standing, sitting, supine)
- Movement during/after syncope (tonic-clonic or myoclonic movements)
- Duration (seconds, few minutes, longer)
- Rate of recovery (rapid, slow, incomplete/prolonged)

Presyncope, where there is no loss of consciousness, requires the same evaluation as syncope. While patients with syncope do not remember actually hitting the ground, those experiencing presyncope have the same symptoms, but the event terminates prior to loss of consciousness. Presyncope can still cause the patient to lose postural tone, however.

Prior faintness, dizziness, or light-headedness occurs in 70% of patients experiencing syncope; other presyncopal signs and symptoms may also occur, alone or in combination **(Table 1)**, whether syncope actually follows or not. In dysrythmia-related syncope, presyncopal symptoms last only seconds, though in vasovagal events they can last about 2 ½ minutes.[7]

A group at the University of Calgary, Canada, developed a set of historical questions that can help determine if the patient's syncope was due to a vasovagal episode or something more sinister **(Table 2)**.

If the patient experiences typical pre-seizure aura, this suggests a seizure rather than syncope.

Red Flags

Some specific symptoms or activities associated with the syncopal event should raise concern about life-threatening causes.

- Chest pain, with or without palpitations or dyspnea, may accompany myocardial ischemia or infarctions, aortic dissections, or dysrhythmias. These symptoms may be present as a presyncopal prodrome, following syncope, or both. Ventricular and supraventricular dysrhythmias may not be present on an initial ECG; prolonged monitoring may be necessary. Bradyarrhythmias and pacemaker malfunctions can usually be seen immediately.
- Dyspnea may accompany cardiac-related syncope, or may be a symptom of pulmonary embolus or congestive heart failure, both of which may cause syncope.
- Severe headache or new neurological deficits may indicate a neurological cause for the syncope or a serious consequence of the syncopal event. Neurological syncope may have prodromal symptoms such as vertigo, dysarthria, diplopia, and ataxia. These may suggest a stroke or transient ischemic attack. If symptoms appeared following a fall associated with syncope, trauma should be considered.
- Abdominal or back pain may suggest a source of acute bleeding, such as from a ruptured abdominal aortic aneurism, or in the pregnant patient, an ectopic pregnancy or placental abruption.
- Strenuous exertion just before syncope, especially in young athletes with a cardiac murmur, suggests syncope due to cardiac outflow obstruction. In any group, syncope can be very worrisome if it is due to aortic stenosis, hypertrophic obstructive cardiomyopathy, mitral stenosis, pulmonary stenosis, pulmonary embolus, left atrial myxoma, or pericardial tamponade.

Certain predisposing events may suggest more benign causes of syncope. Even here, however, care should be taken to avoid missing serious underlying disease. A variety of events can increase vagal tone and cause syncope. In these cases, syncope occurs from decreased

Table 2. Questions to Determine if Syncope is Vasovagal in Nature[9]

Question	Points (if answer to question is yes)
Is there a history of at least one of bifascicular block, asystole, supraventricular tachycardia, or diabetes?	-5
At times, have bystanders noted you to be blue during a faint?	-4
Did your syncope start when you were ≤35 years old?	-3
Do you remember anything about being unconscious?	-2
Do you have lightheaded spells, or faint with prolonged sitting or standing?	1
Do you sweat or feel warm before a faint?	2
Do you have lightheaded spells or faint with pain or in medical settings?	3
	Point total

The patient has vasovagal syncope if the point score is ≥-2.

peripheral vascular resistance due to stimulation of efferent vasodepressor reflexes. Asking about the patient's activity prior to syncope may suggest the etiology. These often self-limiting problems are the most common cause of syncope in young adults; behavioral changes may help to avoid a recurrence.

In elderly patients, 45% of orthostatic syncope cases are related to medications. Medications may increase vagal tone and incite these events. In those cases, the dosage may need to be adjusted or the medication changed. Dehydration and decreased intravascular volume can also lead to syncope, but consideration should be given to underlying heat illness, blood loss, or other more serious causes for this condition.

Syncope or Seizure?

A common challenge for the clinician is distinguishing syncope from seizures. While this may require extensive testing in some patients, there are some historical clues that can help. If witnesses note convulsive activity or, especially, postictal confusion, this probably indicates a seizure. Post-syncopal confusion occurs, but rarely lasts more than 30 seconds; confusion following a seizure usually lasts much longer. In addition, patients should be asked if they remember being confused about their surroundings after the event and whether they have oral trauma, incontinence, or myalgias. Witnesses may also be confused by the myoclonic jerks that sometimes accompany syncope, although these usually last only a very short time.

Medication, drug, and alcohol use are relatively common precipitants of syncope, so this history should be taken in detail. Medications that reduce blood pressure (e.g., antihypertensive drugs, diuretics, nitrates), affect cardiac output (e.g., beta-blockers, digitalis, antiarrhythmics), prolong the Q-T interval (e.g., tricyclic antidepressants, phenothiazines, quinidine, amiodarone), or alter the sensorium (e.g., sedating analgesics, hypnotics, anxiolytics) may all cause syncope, for example.

Clinicians should ask about any recent changes in medication dosage, new medications, and anything that may have changed the body's level of the medication, such as food, illness, or dieting. Illicit drug and alcohol use may also cause syncope and, on occasion, may presage serious events (e.g., cocaine-induced myocardial infarction, delirium tremens).

Finally, the clinicians must also inquire about other serious personal and family medical conditions, especially cardiovascular disease. Patients with a history of myocardial infarction, arrhythmia, structural cardiac defects, cardiomyopathy, or congestive heart failure fall into a high-risk group for death and disability. Those with a family history of sudden death or serious cardiac disease should also be considered in this category.

Physical Examination

The physical examination supplements clinical opinions formed from the patient and bystander history. While it may confirm suspicions or add new information, it should only be considered a supplement to the clinical history. During the physical exam, it is important to recognize signs of trauma, since syncope from any cause

can result in injury with significant morbidity and mortality, especially in the elderly[10] **(Table 3)**.

Laboratory/Imaging

Ancillary testing rarely provides additional useful information. The exception is the ECG, which can be diagnostic for acute myocardial ischemia or infarction, dysrhythmias, prolonged Q-T intervals, bundle branch blocks, pacemaker malfunction, and other cardiac disease. Most patients presenting with syncope or presyncope should have an ECG. Patients should be referred if they require prolonged cardiac monitoring to identify intermittent dysrhythmias.

Although diagnostic in less than 2% of syncopal patients, the rapid and inexpensive fingerstick blood glucose always should be checked. In those patients with hypoglycemia, rapid therapy may immediately be instituted. If hyperglycemia is found, a diabetic complication may be considered (ketoacidosis, neuropathy, and autonomic dysfunction). For similar reasons, a dipstick urinalysis should be performed, especially on all elderly patients, since a urinary tract infection may precipitate syncope and can be easily treated.[7]

Likewise, a chest radiograph should be considered in all patients, especially the elderly. It may demonstrate evidence of infectious or aspiration pneumonia, congestive heart failure, a pleural effusion, a lung mass or a widened mediastinum.[7]

Except in unique circumstances, serum electrolyte levels with renal function tests and the complete blood count are of scant utility in making a diagnosis or determining disposition, although one predictive model, the San Francisco Syncope Rule, does use the hematocrit as one factor.[11] Fecal occult blood testing and testing for significant abdominal pain during the physical exam is a far better way of identifying occult blood loss. Electrolyte testing may be needed only if seizure is being seriously considered. If the patient is on antiepileptic medications, those levels may also need to be drawn after consulting with the patient's neurologist.

If the patient warrants having cardiac enzymes or creatine kinase (for a prolonged seizure or period of unconsciousness) drawn, he or she should be sent to the emergency department, and probably admitted to the hospital.

Those patients requiring more intensive imaging (e.g., head CT scan, chest-abdomen scan, pelvic ultrasound, MRI, echocardiography, EEG, or tilt testing) should be referred to an ED or their personal physician, depending upon the urgency of the situation.

Table 3. Post-Syncopal Event Physical Exam Elements

Examine	Look for
Vital signs	Pulse rate and rhythm Respiratory rate and depth Temperature Blood pressure, including orthostatic measurements
General	Evidence of trauma Alertness and orientation
Skin	Color Diaphoresis
HEENT	Evidence of mouth, head or facial trauma Papilledema Smell of acetone
Neck	Jugular venous distention Bruits (carotid sinus massage may precipitate sinus arrest and should not be done in urgent care centers)
Lungs	Equal breath sounds Rales
Heart	Systolic murmur Rub Dysrhythmias
Abdomen	Bruit Pulsatile mass
Rectum	Gross or occult blood
Pelvis	Vaginal bleeding Lower abdominal pain Urinary or fecal incontinence
Extremities	Delayed capillary refill Equal pulses in upper extremities Peripheral neuropathies
Neurologic	Newly altered mental status Focal neurologic findings

HEENT=head, eyes, ears, nose, and throat

Criteria to Transfer/Refer Patients

Two decision rules have been published that help to identify those at most risk after syncope. However, patients not meeting these criteria still were at significant risk for untoward events in the subsequent year.

One model demonstrated that between 58% and 80% of patients with at least three of the following risk

Table 4. Differential Diagnosis*

Cardiovascular Causes

Autonomic (most common cause in children)
- Carotid sinus syncope
- Cough
- Defecation
- Excessive vagal tone (athletes, adolescents)
- Micturition
- Postprandial
- Sneeze
- Swallow
- Valsalva

Orthostatic hypotension
- Adrenal insufficiency
- Autonomic insufficiency/dysfunction: alcoholic, degenerative CNS diseases, diabetic
- Dehydration
- Drug-induced (beta blockers, central antihypertensives, diuretics, drugs/chemicals of abuse, narcotics, sympathetic nervous system blockers, vasodilators)
- Hemorrhage, acute
- Idiopathic

Obstructive lesions
- Aortic dissection
- Aortic, mitral or pulmonary stenosis
- Atrial myxoma
- Cardiac tamponade
- Congenital heart disease
- Hypertrophic cardiomyopathy
- Left ventricular dysfunction
- Pulmonary embolism
- Pulmonary hypertension
- Pulmonary stenosis

Dysrhythmias
- Bradyarrhythmias
- Cardiomyopathy
- Drug-induced (anticonvulsants, antihistamines, beta blockers, digitalis, diuretics, drugs/chemicals of abuse, tricyclic antidepressants, Q-T prolonging)
- Implanted defibrillator malfunction
- Myocardial infarction
- Sick sinus syndrome
- Long Q-T syndrome
- Pacemaker failure
- 2^{o} & 3^{o} blocks
- Supraventricular and ventricular tachyarrhythmias
- Torsades de pointes

Non-Cardiovascular Causes

Metabolic
- Alcoholism
- Carbon monoxide poisoning
- Drug-induced (insulin, oral hypoglycemics)
- Hyperventilation
- Hypoglycemia
- Hypothyroid
- Hypoxia/asphyxiation
- Pheochromocytoma

Neurologic
- Basilar artery migraine
- Cerebrovascular insufficiency/Transient Ischemic Attack (TIA)
- Narcolepsy
- Normal pressure hydrocephalus
- Peripheral polyneuropathy
- Seizure
- Subarachnoid hemorrhage
- Subclavian steal syndrome
- Vertebrobasilar insufficiency
- Increased intracranial pressure

Psychiatric
- Anxiety disorder
- Breath-holding spells
- Conversion reaction
- Drug-induced (anticonvulsants, antihistamines, antiparkinsonians, bromocriptine, cholinesterase inhibitors, CNS depressants, MAO inhibitors, tricyclic antidepressants)
- Panic disorder
- Hysteria
- Major depression

*The cause of syncope cannot be determined in 38% to 47% of cases.

factors suffered identifiable dysrhythmias or death within one year:

- Abnormal ECG findings
- History of ventricular arrhythmia
- History of congestive heart failure
- Age >45 years

Incidence of dysrhythmias or death was 4%-7% among patients with no risk factors, and was 58%-80% for patients with three or four risk factors.[12]

Another model identified patients who are at immediate risk for serious outcomes within seven days, with a 96% sensitivity. Its criteria was the presence of abnormal ECG findings, a history of congestive heart failure, dyspnea, a hematocrit less than 30%, and a blood pressure less than 90 mm Hg.[11]

The question is, will a 4% short-term serious outcome rate be acceptable?

Prognosis

The differential diagnosis **(Table 4)** includes many life-threatening conditions. The clinician's primary goal is to distinguish life-threatening etiologies—mainly due to cardiovascular causes—from those that are more benign. The most common serious causes of syncope are dysrhythmias and myocardial ischemia. Less common serious causes include cerebrovascular events, toxic-metabolic abnormalities, and critical aortic stenosis. Rarely seen, but life-threatening, causes are thoracic aortic dissections, massive pulmonary emboli, and subarachnoid hemorrhages.

Young, healthy patients with a clearly benign cause of the syncopal episode are the only ones that can be discharged safely without a more intense evaluation or additional treatment. Even so, it should be noted that 30% of athletes dying during exercise had syncope as a sentinel event.[13]

Most causes of syncope are benign. Hence, persons with non-cardiovascular causes or syncope of unknown origin have a relatively benign prognosis, with a one-year mortality rate of 12% and 6%, respectively.[2,14] Vasovagal and orthostatic syncope do not increase mortality, though orthostatic syncope often recurs.

Typically, syncope of unknown etiology has a favorable prognosis, with one-year follow-up data showing a low incidence of sudden death (2%), a 20% chance of recurrent syncope, and a 78% remission rate.[7]

However, patients with preexisting cardiovascular disease have a greater risk of short- and long-term mortality after a syncopal episode from any cause. Syncope caused by a cardiac disorder carries a one-year mortality rate of 20% to 30% and a 33% incidence of sudden death over five years.[2,3,14,15] Risk is higher in older patients and those with serious comorbidities, with mortality rates significantly increased within both four weeks and one year after presentation.[1] Elderly patients have a 30% incidence of a recurrent syncopal episode.[13]

Syncope of any etiology in a cardiac patient (to be differentiated from cardiac syncope) has also been shown to imply a poor prognosis. Patients with NYHA functional class III or IV who have any type of syncope have a mortality rate as high as 25% within one year.[7]

Summary

Syncope has a long differential diagnosis that includes many life-threatening conditions. History, from the patient and bystanders, is the key diagnostic tool in urgent care to determine whether a patient needs further evaluation and treatment. Physical examination plays an important, but lesser, role. Except for the ECG, fingerstick glucose, dipstick urinalysis, and chest radiograph, laboratory and imaging do not play an important role in urgent care decisions about patient disposition or treatment after syncope. Any abnormal cardiac findings or potentially serious suspected cause of the syncopal event warrants transfer to an ED. If a life-threatening condition is suspected, patients should be transported immediately via the EMS system. ■

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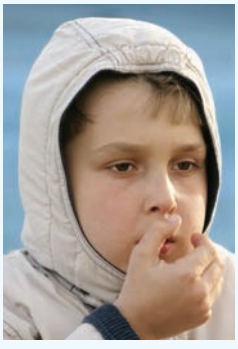
On Croup, Wet Sutures, Fast Tracking the ED, Acetaminophen and ALT, and Stone Formation

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.

Dexamethasone Has Advantage Over Prednisolone in Children with Croup

Citation: Sparrow A, Geelhoed G. Arch Dis Child. 2006;91:580-583.



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Children with croup who are treated with prednisolone are more likely than those treated with dexamethasone to return for additional medical care, researchers in Australia reported in the July issue of the *Archives of Diseases in Childhood*.

A single treatment of oral dexamethasone improves patient outcomes. Prednisolone has pharmacokinetic properties similar to dexamethasone, but has the advantage of being commercially available in liquid form.

The researchers compared the relative efficacy of prednisolone matched for potency to dexamethasone in 133 children between 3 and 142 months old with mild-to-moderate croup. In a double-blinded, controlled trial, the children were randomized to a single oral dose of dexamethasone 0.15 mg/kg or a single oral dose of prednisolone 1 mg/kg.

The main outcome measure was unscheduled re-presentation to medical care, determined by telephone follow-up seven to 10 days after discharge. Secondary outcome measures included croup score, adrenaline use, time in the emergency department, and duration of croup and viral symptoms.

Nineteen of 65 (29%) prednisolone-treated patients re-presented to medical care, compared with five of 68 (7%) dexamethasone-treated children. No significant differences in secondary outcomes were observed.

"Dexamethasone and prednisolone seem equally effective when first given but relapse and re-attendance to medical care is more common with prednisolone which may reflect its shorter half life," the researchers concluded. ■

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

Can Sutures Get Wet? Prospective Randomised Controlled Trial of Wound Management in General Practice

Citation: Heal C, Buettner P, Raasch B, et al. BMJ. 2006;332: 1053-1056.

The purpose of this study was to compare standard management of keeping sutured wounds dry and covered versus allowing sutured wounds to be uncovered and wet within the first 48 hours after minor skin excision.

This was a prospective, randomised, controlled, multicenter trial testing for equivalence of infection rates. The study was done in a primary care regional center in Queensland, Australia; 857 patients were randomised to either keep their wound dry and covered (n=442) or remove the dressing and wet the wound (n=415).

The incidence of infection in the intervention group (8.4%) was not inferior to the incidence in the control group (8.9%) ($P<0.05$).

These results indicate that sutured wounds can be uncovered and allowed to get wet in the first 48 hours after minor skin excision without increasing the incidence of infection. ■

Effects of a Fast-track Area on Emergency Department Performance

Citation: Plunkett PK. First aid, fast track and the fertile fields of peer review. Eur J Emerg Med. 2006;13:1–2.

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To determine if a fast-track area (FTA) would improve emergency department (ED) performance, a historical cohort study was performed in the ED of a tertiary care adult hospital in the United States.

Two consecutive one-year periods, pre-FTA opening from February 1, 2001 to January 31, 2002 and after FTA opening-from February 1, 2002 to January 31, 2003 were studied. Daily values of the following variables were obtained from the ED patient tracking system:

- To assess ED effectiveness: waiting time to be seen (WT), length of stay (LOS).
- To assess ED care quality: rate of patients left without being seen (LWBS) mortality, and revisits.
- To assess determinants of patient homogeneity between periods: daily census, age, acuity index, admission rate and emergent patient rate.

Results showed that despite an increase in the daily census (difference [diff] 8.71, 95% confidence interval [CI] 6 to 11.41), FTA was associated with a decrease in:

- WT (diff -51 min, 95% CI [-56 to -46])
- LOS (diff -28 min, 95% CI [-31 to -23])
- LWBS (diff -4.06, 95% CI [-4.48 to -3.46])
- There was no change in the rates of mortality or revisits

In conclusion, the opening of an FTA improved ED effectiveness, measured by decreased WT and LOS, without deterioration in the quality of care provided, measured by rates of mortality and revisits. ■

Aminotransferase Elevations in Healthy Adults Receiving 4 Grams of Acetaminophen Daily

Citation: Watkins PB, Kaplowitz N, Slattery JT, et al. JAMA. 2006;296:87-93.

During a clinical trial of a novel hydrocodone/acetaminophen combination, a high incidence of serum alanine aminotransferase (ALT) elevations was observed.

The purpose of this study was to characterize the incidence and magnitude of ALT elevations in healthy participants receiving 4 g of acetaminophen daily, either alone or in combination with selected opioids, as compared with participants treated with placebo. This was a randomized, single-blind, placebo-controlled, five-treatment, parallel-group, inpatient, diet-controlled (meals provided), longitudinal study of 145 healthy adults in two U.S. inpatient clinical pharmacology units. Each participant received either placebo (n=39), one of three acetaminophen/opioid combinations (n=80), or acetaminophen alone (n=26). Each active treatment included 4 g of acetaminophen daily, the maximum recommended daily dosage. The intended treatment duration was 14 days.

None of the 39 participants assigned to placebo had a maximum ALT of more than three times the upper limit of normal. In contrast, the incidence of maximum ALT of more than three times the upper limits of normal was 31% to 44% in the four treatment groups receiving acetaminophen, including those participants treated with acetaminophen alone. Compared with placebo, treatment with acetaminophen was associated with a markedly higher median maximum ALT (ratio of medians, 2.78; $P<.001$). Trough acetaminophen concentrations did not exceed therapeutic limits in any participant and, after active treatment was discontinued, often decreased to undetectable levels before ALT elevations resolved.

Initiation of recurrent daily intake of 4 g of acetaminophen in healthy adults is associated with ALT elevations and concomitant treatment with opioids does not seem to increase this effect. History of acetaminophen ingestion should be considered in the differential diagnosis of serum aminotransferase elevations, even in the absence of measurable serum acetaminophen concentrations. ■

Impact of Dietary Habits on Stone Incidence

Citation: Siener R. Urological Res. 2006;34:131-133.


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Changes in dietary habits and lifestyle are suggested to contribute markedly to the rise in the prevalence and incidence of urolithiasis during the past decades.

Insufficient fluid intake and diets rich in animal protein are considered to be important determinants of stone formation.

Overweight and associated dietary pattern additionally contribute to the increasing incidence and prevalence of stone disease. Reduction of overweight through extreme fasting or high-protein weight-loss diets (e.g., Atkins diet) also appear to affect stone formation.

Although there is evidence that changes in dietary habits can reduce urinary risk factors and the risk of stone formation, further randomized controlled clinical trials are necessary to evaluate long-term effects of dietary interventions on stone disease. ■

Pneumomediastinum with No Pneumothorax

Mr. J.V. is a 28-year-old white male who presented to urgent care with a six-hour history of chest pain described as pressure in the sternal area radiating to the left shoulder; back pain was a 5/10 at time of visit, and constant with no accompanying nausea, dizziness, vomiting, or diaphoresis.

The patient described an inability to breathe deeply and a sensation of water stuck in the mid esophagus when drinking.

Of note, he had similar episodes which resolved.

Observations and Findings

Well-appearing male in no distress.
Pmhx: childhood asthma
Meds: Allegra prn
Social hx: no drugs, etoh, or tobacco
Ros: no recent illness, no abd pain, no lbp, no extremity pain, no headache, syncope, no confusion, no cocaine use
Physical: t-96.7, p89, rr14, bp110/80, 02 sat 97% ra, peak flow 500
HEENT: nl neck: no jvd, no retractions
Resp: ctab no wheezes, no crackles
Cor: rrr no m/r/g
Gi: +bs ntnd, no rbnd or grdng, no pulsatile masses
Musculoskeletal: pain on palp along chest wall parasternal but no crepitations
Diagnostic testing: EKG which revealed sinus arrhythmia and incomplete rbbb

Diagnosis

The x-ray reveals extensive pneumomediastinum with air surrounding the heart and anterior aorta and extending into the superior mediastinum and lower neck (**Figure 1**).

Discussion

Pneumomediastinum or mediastinal emphysema is a condition in which air is present in the mediastinum. This can be caused by trauma or disease. It is uncommon and occurs when air leaks from the lung or airways into the mediastinum.

Causes: Excessive coughing, sneezing, vomiting, or repeated valsalva maneuvers such as during childbirth or defecation. It may also occur during rapid ascents in altitude or scuba diving. It can also be associated with pneumothorax or other diseases (e.g., COPD or asthma).

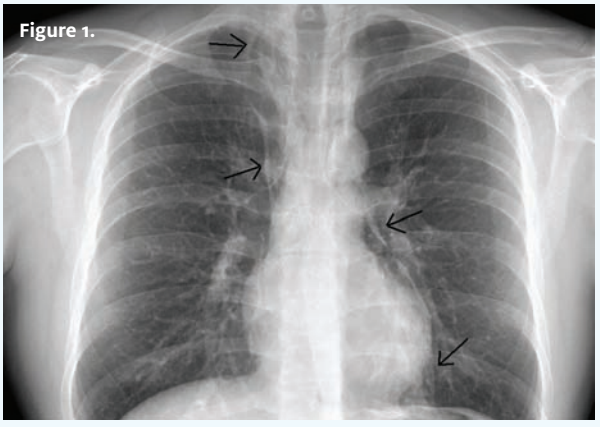


Figure 1.

Symptoms: Usually, chest pain below sternum that may radiate to neck and arms. Pain may be worse with breathing or swallowing.

Signs and tests: On physical, crepitations may be felt. Chest x-ray confirms presence of the abnormality.

Treatment

Often, no treatment is required as air is absorbed from the mediastinum. If pneumothorax is present, a chest tube is required. In rare cases, large amounts of air may compress veins affecting blood pressures.

Course of illness: In our patient, furthur investigation revealed no precipitating cause for the abnormality.

Follow up x-rays revealed reabsorption; the patient returned to normal activity without complaints.

Acknowledgment: Case submitted by Michael Talkar, MD, family/urgent care physician, locum tenens currently on assignment in Arizona.

Submitting a Case to *JUCM*

If you have an interesting case report to share, please e-mail the relevant images and a description of the case to *editor@jucm.com.*

INSIGHTS IN IMAGES

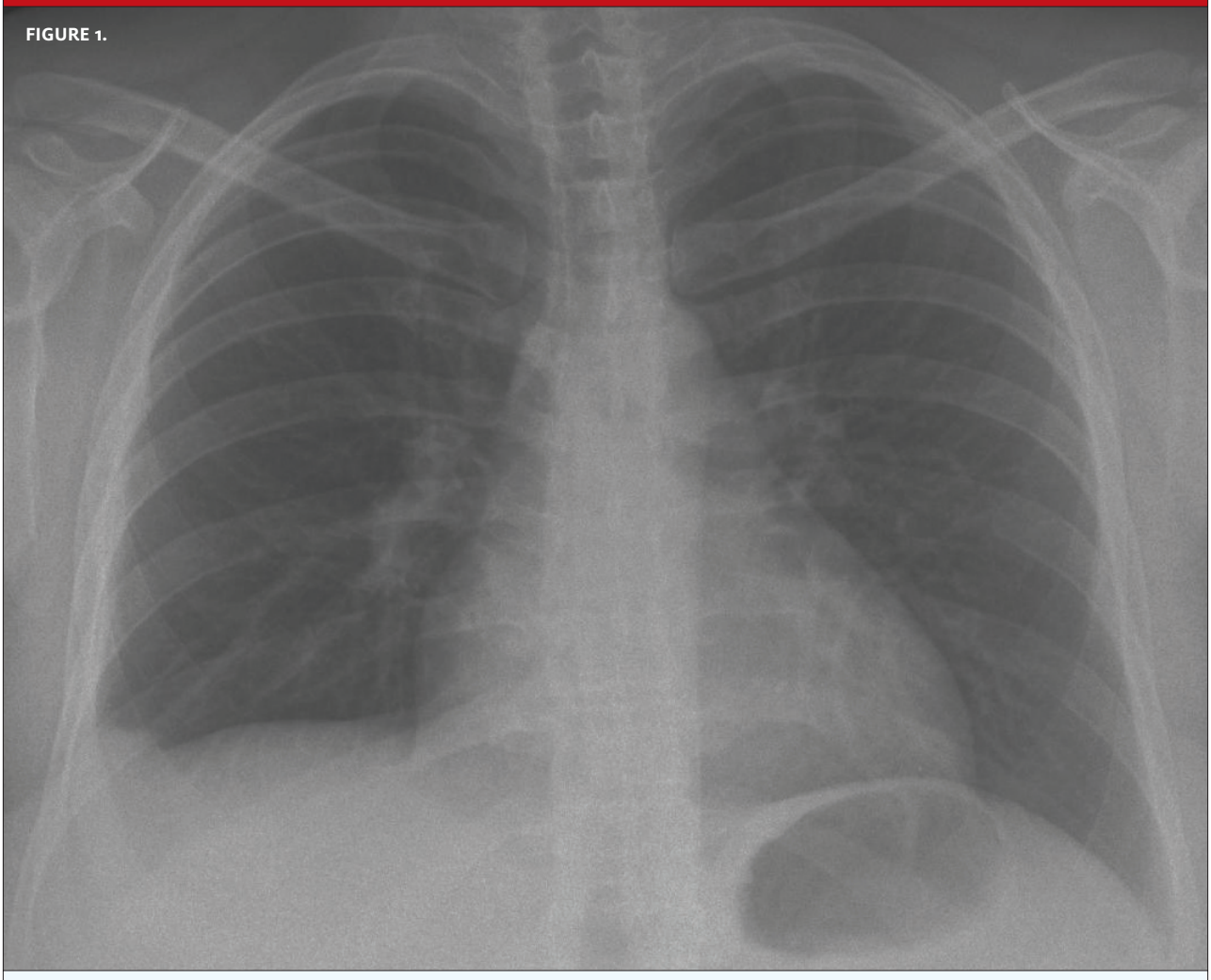
CLINICAL CHALLENGE

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

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

THE CASE

FIGURE 1.



A 36-year-old obese woman presents with upper right back pain 10 days after a normal child birth. Pain is worse on coughing. Otherwise, she is fit and well.

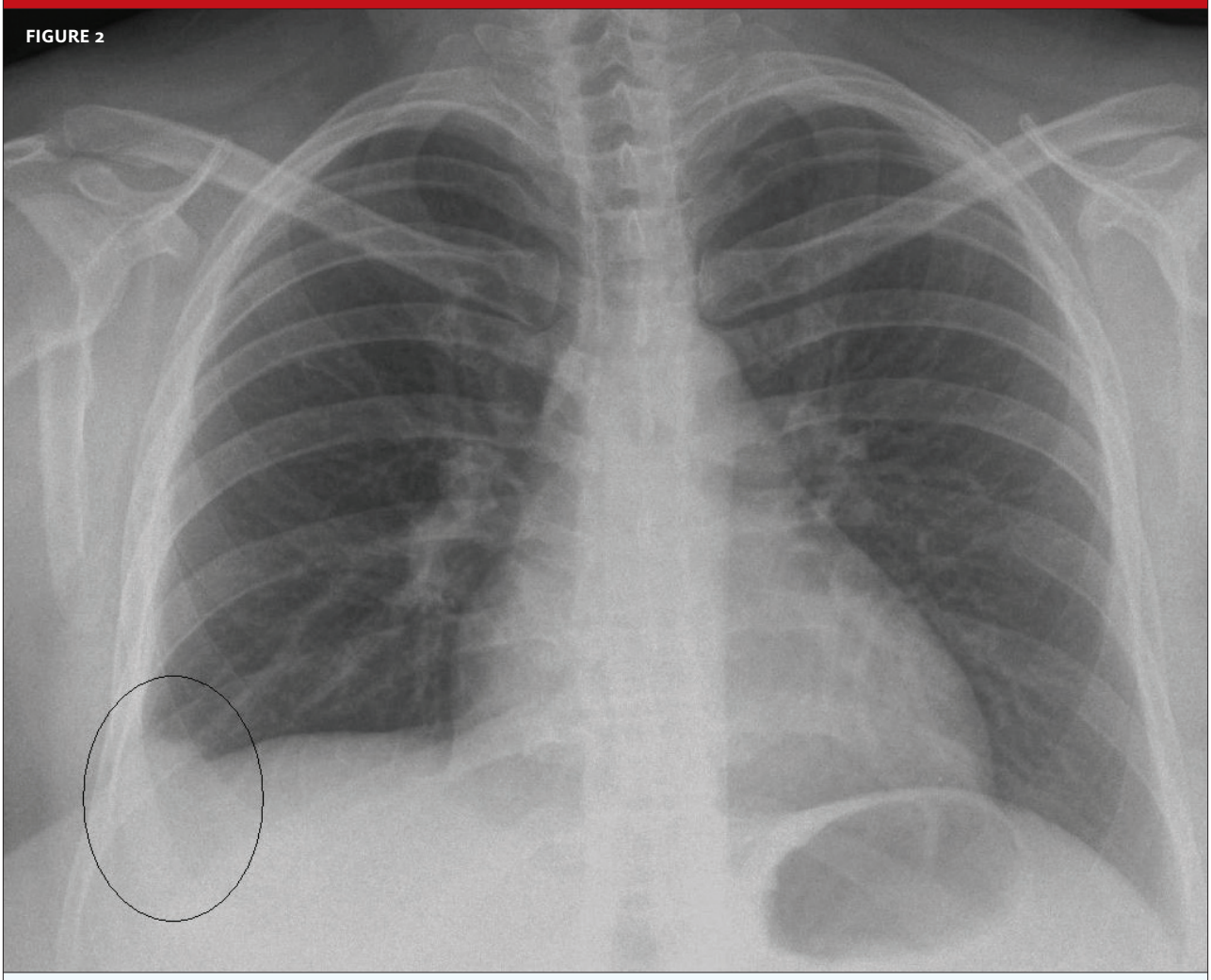
Upon examination, you find:

- No shortness of breath
- Normal oxygen saturation
- Patient is afebrile
- Auscultation: Reduced breathing sounds in right base, fine crackles on right

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.

THE RESOLUTION

FIGURE 2



Initially, the radio-opacity seen in the right base was interpreted as pleural effusion. The official read of the chest x-ray led to suspicion of Hampton's hump in the right lower lobe.

Though the patient never had any shortness of breath, in view of her unusual pain, pathological x-ray, recent childbirth, and obesity, she was referred to hospital, where chest computed tomography showed a massive pulmonary embolus (PE).

Conclusion

It was imperative to rule out PE in this case. Factors that might have led the physician to discount that possibility—no shortness of breath or signs of deep-vein thrombosis and an x-ray that failed to inspire suspicion—should be overshadowed by the patient's risk factors and recognition that plain film may show little evidence of PE (**Figure 2**).

Acknowledgment: Case presented by Ohad Sheffy, MD, who treated and referred the patient described.

Healthcare in the Express Lane:

The Emergence of Retail Clinics

Urgent message: Retail-based healthcare clinics are a growing phenomenon. A report from the California HealthCare Foundation, excerpted here, says public perception is split, and their economic viability remains to be seen. How do their services stack up against those offered by urgent care?

The first in-store clinics appeared in 2000 in the Minneapolis-St. Paul (MN) metropolitan area and were operated by QuickMedx, which later became MinuteClinic. The company's founder, Rick Krieger, says the business idea came to him when he tried to get his son in to see a doctor for a strep throat test. He recalls, "We started talking about why there was not a way to just get a simple question answered or a simple test, like strep throat, done. Why was there not some way to just slip in and be seen quickly? Wasn't there some way to get care in a timely manner for a relatively simple illness? A quick, convenient way to diagnose without waiting in the ER or clinic for two hours? We are not talking about diabetes, cancer or heart disease. We are talking about colds and throat and ear infections."[1]

Krieger and two business partners (one of whom was a family doctor) set up pilot clinics in cooperation with Cub Foods, a local grocery chain. The first clinics charged a $35 flat fee for rapid testing, diagnosis, and prescriptions for 11 common medical conditions, including strep throat, influenza, ear infection, pink eye, and seasonal allergies. They did not accept insurance, which Krieger explains as a deliberate, strategic choice "to compete on a purely retail level and be able to profit on a copayment-type basis."

© Tom DePrenda

The pilot program, though limited, was considered successful, and the founders began to formulate an aggressive growth strategy. In 2005, MinuteClinic appointed a new CEO: Michael Howe, the former CEO of Arby's. Meanwhile, other clinic companies and retailers entered the game, and there are now a dozen clinic operators running about 90 clinics across the country, a dozen more planning to open clinics in the near future, and hundreds of store openings planned for 2007. As the trend has gathered momentum, the medical and busi-

Prepared for the California HealthCare Foundation by Mary Kate Scott, Scott & Company. Reprinted courtesy of the California HealthCare Foundation. The full report can be found at *www.chcf.org*.

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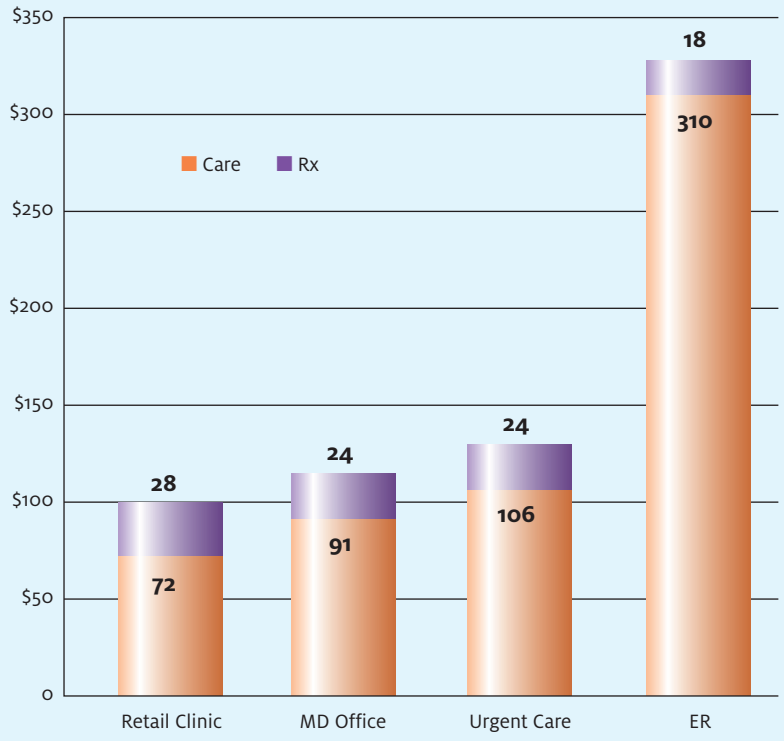
Figure 1. Cost of caring for a patient with strep throat[2]



ness models have shifted. Most now accept insurance and have expanded their range of services.

Description

In-store clinics measure between 200 and 500 square feet and are quite spare with a simple setup of a reception desk and one or two exam rooms. Retailers often use space that is generating less income per square foot than the clinics are anticipated to provide, so some clinics occupy former video game arcades, vending machine areas, or waiting areas near pharmacies. The retailer has a one-time cost of about $20,000–$100,000 to make the space "broom-ready" (upgrading as deemed necessary by the clinic concept and the contract between retailer and clinic company), and the clinic companies pay for the physical retrofitting. This ranges from $25,000 for a basic clinic with one basic room to $145,000 for a multi-exam room clinic offering broader services; the average setup cost is about $50,000.

Most clinics are staffed with nurse practitioners (NPs) supervised by an off-site physician who is available by phone for consultation, but some clinics employ full-time physicians. Salaries for NPs are typically much lower than those of physicians. The average salary for an NP in 2005 was $74,812 nationally and $86,674 in California.[3]

The clinics use proprietary software systems that claim to provide evidence-based treatment guidelines. These serve as a diagnostic tool as well as a checklist to constrain the types of conditions that can be treated at the clinic. There are referral relationships with local physicians or hospitals for more serious or unusual conditions. Clinics are open extended hours and weekends. Most visits take about 15 minutes and don't require an appointment. Prices are clearly posted and range from $40 to $70. Some clinics accept insurance and all provide documentation for consumers to file for reimbursement on their own.

Early usage and cost data, while still quite thin, are beginning to show some patterns. At MinuteClinic, the five most frequently treated conditions are pharyngitis, bronchitis, otitis media, sinusitis, conjunctivitis, and female urinary tract infection. In terms of overhead cost, a preliminary analysis by HealthPartners indicates that on average, MinuteClinic episodes are about 15% less expensive than those initiated at a physician's office or an urgent care setting, based on one year of claims experience—producing a per-visit savings of $31. (See **Figure 1**.)

Retail Approach to Healthcare

In many ways, in-store health clinics are a retail experiment that has captured the attention of the healthcare industry. Their existence depends on retail leases, while their success depends on the patronage of customers who may think of their visit as a convenient extension of a shopping trip, and not necessarily an extension of healthcare. Instead of a suite in a medical building or the wing of a hospital, one Florida clinic describes its location as a storefront in a local shopping mall along with "Starbucks, Quiznos, and Planet Smoothie, right next to El Pollo Loco."[4]

Retailers are naturally consumer-centric and many of the key players in the retail clinic industry come from

consumer backgrounds, such as packaged goods, fast food, and travel companies. It is important to understand how these companies make decisions. Retailers generally see two ways to gain from in-store clinics. On the revenue side, they hope the clinics will attract new customers and drive sales elsewhere in the store, especially prescription and over-the-counter purchases. On the savings side, some retailers see an opportunity to manage the expense of providing healthcare to their employees. Not only are the clinics a relatively cheap way for employers to provide healthcare compared with other care delivery options, but they could reduce absenteeism for doctor's visits because employees could be treated for minor conditions within the workplace.

However, it is important to note that such scenarios come with a basic caveat: If retailers and clinic companies don't achieve the expected results, they will close the clinics. Unlike the healthcare industry, retail product life cycles are very short. Retailers continually try new formats and services and are adept at removing less profitable lines of business. In fact, there have already been closings in areas where the clinics didn't gain sufficient traction. In Baltimore, MinuteClinic is closing its six Target locations after less than two years in operation and opening seven clinics in nearby CVS drugstores. The companies indicated that the closings were not a retreat from the retail clinic concept, but rather a decision to focus on other markets and create different types of service offerings more appropriate to their individual corporate strategies. Either way, this is typical of the retail mentality: fast turnaround, rapid consumer testing, and constant reinvention of the model.

It is also telling that the rollout of in-store clinics has been limited. To put this in perspective, there are more than 3,800 Wal-Mart stores in the United States. Only 14 now have in-store clinics (0.2% of stores) and official plans call for rolling out just 50 more in 2006-2007 (to 1.5% of stores). Of the 100 million people who walk through Wal-Mart's doors each week, only 1,000 visit a clinic. However, this picture could change. The company has formally stated that it will expand the use of in-store clinics.[5] Much will depend on how aggressively Wal-Mart pursues this expansion plan.

Other retailers are approaching these clinics with similar caution, testing them in limited markets and relying on shorter-term contracts with outside clinic companies to evaluate the business impact. This phenomenon could either take off overnight or languish, depending upon whether medical clinics fit into retailers' overall business strategies and relationships with consumers.

Scope of Practice

Scope of practice varies by clinic company, by state, and by retail location, but there are strategic, practical, and regulatory reasons for in-store clinics to maintain a relatively narrow scope of practice.

Strategically, the clinic model relies on low prices, quick throughput of patients, minimal staff, and proprietary software systems that can reliably manage selective medical diagnoses and information. This is only possible with a short list of simple procedures.

Most in-store clinics are housed in small areas with physical limitations. At most, they have one or two exam rooms with a sink and/or toilet close by (and a few do not even have sinks or private rooms). The clinics explicitly aim to treat common ailments that can be diagnosed quickly and accurately, within 15 minutes. This keeps quality control manageable and overhead low. It also effectively constrains for the range of services they are able to provide for patients. Limited medical records are kept (usually electronically, unless paper backups are required by the state), very little medical equipment is needed, there are no patient gowns (hence no laundry service), and no time-consuming examinations. The diagnostic tests typically offered are compact and rapid and offer simple, accurate results, exempting them from the federal regulations that govern more complex lab procedures.[6]

Clinic companies adjust the services they offer in order to maximize profits and respond to local markets, and there are sometimes differences in scope of practice from one location to the next. To date, most clinics have opened in suburban areas, where affluent shoppers might be willing to pay extra for fast, convenient healthcare. They have emphasized convenience in their marketing, with slogans such as, "You're sick. We're quick" (MinuteClinic), "Get well. Stay well…Fast!" (RediClinic), and "Great care. Fast and fair" (Solantic). The clinics initially required consumers to pay in cash for this convenience, but now some insurance companies cover part or all of the in-store clinic visit costs, making the clinics more cost-effective for their subscribers. For these consumers, clinics are at cost parity with a similar visit to a primary care physician, but still have a "time cost" for the consumer to submit the claim.

While the early models focused on "get well" care (diagnosing and treating acute or unexpected illness), the newer model places a greater emphasis on "stay well" care. Web Golinkin, CEO of RediClinic (a subsidiary of InterFit), estimates that his clinics now provide about 75% get-well and 25% stay-well services,

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with some seasonal fluctuation due to flu shots and school physicials.[7]

"We'd like to get to more stay-well," he says. "We believe that convenience and affordability are just as important to consumers in prevention as they are in treatment, and that consumer interest in preventive services will grow over time."

In addition, although the clinics started out mainly in suburban enclaves, they are now appearing in less affluent communities where underinsured and uninsured consumers are willing to pay cash for clinic care, not only because it is convenient, but also because they have limited access to healthcare elsewhere.

In-store vs. Urgent Care

In-store or retail-based clinics differ from the average urgent care center in several ways:

- A limited service offering
- Co-location with a pharmacy
- Lower cost structure

Most in-store clinics don't have much space for private rooms, toilets, or sinks. This means that they tend to focus mostly on noninvasive procedures that don't require fluid samples or disrobing.

Regulatory Trends

Regulation of retail clinics varies from state to state. The clinics are typically staffed with NPs who have different degrees of autonomy in each state. In states such as Minnesota (where clinics have the largest presence), NPs can perform a range of functions with no physician on site. In other states, the physician must be physically present for some or all of the time. Each state has different requirements for credentialing and licensing, as well as for physician oversight. These issues may expand, limit—or even prohibit—in-store clinics and the specific services they can provide on a state-by-state basis. Regulatory requirements for the extent of the physician's involvement make a significant difference in clinics' labor costs, so that in some states, although it is technically possible to operate licensed retail clinics, legal practice parameters would make it unprofitable.

Warns RediClinic CEO Golinkin, "If clinics are going to realize their full potential to provide people with easier access to high-quality, routine healthcare at affordable and transparent prices, some of the regulatory barriers in some states will have to be torn down."

Federal support for consumer-driven healthcare makes clinics more attractive by giving consumers incentives to reduce their healthcare spending. In particular, the Medicare Modernization Act of 2003 offers consumers tax incentives for high-deductible insurance plans coupled with healthcare spending accounts to encourage Americans to manage their healthcare expenditures most cost efficiently and mitigate out-of-pocket costs.[8]

Retail Clinics and the Healthcare Delivery System

Given the many choices consumers have to treat acute episodic ailments, how will the retail clinics compete against or integrate with urgent care clinics, hospital emergency rooms, and primary care physician practices?

Retail-based clinic companies are very careful to distinguish their services from emergency care and primary care providers. They train their staff to refer away any unusual or potentially complicated cases and randomly audit their practitioners on a regular basis to be sure that these standards are being followed.[9] When there is some potential overlap of services, the clinics proceed with caution, even if it means foregoing revenues. For example, all three Quick Quality Care locations in Florida Wal-Marts have fully outfitted x-ray rooms with lead-lined walls but are not yet using the equipment because, according to CEO Jack Tawil, "we want to be clear that we're not an urgent care center."[10]

Primary care physicians, whose practices overlap substantially with retail clinics, have been vocal about the downsides of this new site of care. They have expressed concerns about quality and continuity of care, especially in handling patients with serious or chronic conditions. People with chronic conditions are theoretically attractive to retailers and clinic companies—they are potentially very profitable repeat customers—but critics are quick to point out that clinics are not set up to function as a "medical home" for patients with chronic disease.

In response to these concerns, the clinic operators have been firm about their limited scope of practice. For instance, all of them offer treatment for seasonal allergies but most do not treat asthma. Most do not treat chronic conditions such as diabetes. The clinics also form strong referral relationships with doctors in their communities before they open. Sometimes the referral process even works the other way. Michael Howe, CEO

of MinuteClinic, says, "In established markets, when physicians understand the model they refer patients to MinuteClinic. For example, on weekends when patients call in, the doctor can say if it's within the MinuteClinic [scope of practice], so our clinics allow primary care physicians to provide their patients with a better experience…and it frees them up to focus on high-risk or chronic conditions."[11]

In terms of integrating patient information with other providers, all the clinic companies interviewed indicate that they keep centralized electronic medical records that are accessible from any of their locations. These records include a brief medical history taken at the time of service, prescriptions, and test results. If requested, the clinics will print a copy of the record from each visit for the consumer, but they do not electronically transfer the medical records to the primary care physician or referred physician. Each of the clinic companies indicates that they have invested in software to enable the collection and storage of data for patient records in compliance with state and federal regulations. In terms of electronically sharing records, MinuteClinic medical director Woody Woodburn says, "We're ready to push out data; we're just waiting for national standards of interoerablility."[9] AtlantiCare plans to integrate its electronic medical record system across its retail clinics, hospitals, urgent care, and primary care locations within 12 to 18 months.

For consumers with insurance, retail clinics can cost more out of pocket than typical copayments for care at other sites. Even clinics that accept insurance usually charge $20 to $25 for a visit (insurers simply discount the standard "menu price" of care by some amount), compared with $10 to $25 copayments for physician office visits and $20 to $100 copayments at the emergency room. Clinics that don't accept insurance cost much more out of pocket and the charges may or may not be reimbursable if submitted to the insurer. Until this payment disincentive is resolved, clinics will continue to appeal mainly to high-income consumers who are willing to pay more for convenience, and uninsured consumers who either have no cheaper alternative or cannot afford the wait time or missed work that a visit to a clinic or ER typically entails.

Early Conclusions

Whether retail clinics are a flash in the pan or become a permanent part of the healthcare landscape, their emergence and the reaction of consumers and providers to them raises a series of interesting issues.

As the cost of healthcare continues to rise, employers and governments will continue to shift some of that burden onto employees and will structure incentives for them to seek cheaper care. In the past few years, employers offered reduced copayments for generic prescriptions along with significantly higher copayments for brand name drugs, and consumers responded by opting for generics more frequently. Insurers have already begun to offer a similar financial incentive to use a retail clinic versus the more expensive family doctor, urgent care, or emergency room options. Given the rising number of employers offering high-deductible health plans, this paradigm of consumer financial incentives and disincentives has already started to change the way Americans select and receive healthcare.

The American Academy of Family Physicians, American Academy of Nurse Practitioners, and American Medical Association have all gone on record with opinions about retail clinics. Physician groups urge close physician oversight of non-physician providers working in the retail clinic setting, and nurse practitioners point to the needs of uninsured and under-insured Americans and the potential of retail clinics to offer access. As the clinics become more widespread and more patients and providers have experiences with them—positive and negative—will providers embrace retail clinics as a cost-effective, appropriate adjunct to a primary care provider? Or will physicians and others in the industry reject the clinics?

Retail clinics are a market phenomenon—people elect to use them and generally pay out of pocket. As more Americans use the clinics, we can expect them to "vote with their feet." People are frustrated with the current system, and most surveyed to date are open to trying clinics but worried that they might be misdiagnosed.[12] ■

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COMPLICATIONS: Informed Consent and Treating Minors in Urgent Care

JOHN SHUFELDT, MD, JD, MBA, FACEP

STATES HAVE ENACTED STATUTES, and courts have proffered an abundance of case law on the treatment of minors. There have been no reports of physicians being held liable for rendering emergent or urgent care to minors prior to obtaining parental consent.

Still, informed consent issues surrounding the care and treatment of minors are often a source of confusion and are, at best, problematic.

Essentially, competency to give consent is determined in the same way for both minors and adults:

- Does the individual understand what he or she is consenting to?
- Can the person paraphrase the information given?
- Can the patient think in the abstract and have an understanding of the future consequences of either accepting or refusing the treatment?
- Is the decision entered into voluntarily, without duress?
- Given the nature of the decision, does the patient understand the risks and benefits and its reversibility?

If a minor is legally capable of giving consent, the patient's right of confidentiality also attaches. However, it is prudent to try to persuade the minor to allow notification of the guardian so the parent can take part in the decision-making process; this is especially preferable if the minor is seriously ill. Statutes allowing minors to consent do not mandate parental notification unless the failure to do so would place the minor in additional risk.

Historically, issues surrounding parental availability were uncommon. Today, however, family dynamics have changed and children may be left unattended for long periods or left in the care of siblings, neighbors, grandparents or babysitters. During these times, who can consent for the child's care? Who can refuse care and how does an urgent care provider sift through this web to do what is best for the child?

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

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"Competency to give consent is determined in the same way for minors and adults."

Low Risk: Emergency Care

The most clear-cut scenario is when an emergency situation exists. Care should never be delayed while waiting for consent when evaluating a child with an emergency condition. In an emergent or urgent situation, any patient young or old can be

treated without consent, since consent is implied. What constitutes an emergency condition is broadly defined and courts are reluctant to second guess a practitioner's subjective interpretation surrounding the facts of the situation.

Parental consent to treat the minor is also not required in cases of alleged or suspected child abuse; the proper governmental authorities must be contacted in such a situation.

In some states, a caretaker can assume a parental role by acting in *loco parentis* (in the place of a parent). However, physicians should still attempt to contact the parents as soon as possible and document those attempts in the medical record.

"The definition of an emancipated minor varies from state to state."

Most importantly, again: urgent care physicians should never delay the urgent or emergent care of a minor while waiting for consent. Common sense should prevail; thus, physicians should be guided by the proviso to provide what is in the patient's best interest.

The Question of Competence

In some instances, a minor is deemed competent to consent for his own treatment. This competence is closely aligned to cognitive ability, as opposed to being strictly tied to chronological age. All states allow a minor to consent for the diagnosis and treatment of drug- and alcohol-related issues and for the diagnosis and treatment of sexually transmitted disease. Some states also allow for the diagnosis and treatment of issues surrounding pregnancy, HIV, and AIDS.

Many state's statutes also address consent issues surrounding an emancipated minor. However, the definition of an emancipated minor varies from state to state. Some of the typical conditions which define "emancipation" are marriage, minors in the military, pregnancy, minors emancipated by court order or decree, minor mothers, and minors who are supporting themselves.

When minors present in a non-emergency situation, or with a condition other than the aforementioned exceptions, consent for treatment must be obtained from the parent or guardian.

For routine health matters, consent may be given by any number of persons acting in *loco parentis* (e.g., foster guardians, adult relatives, officials in child welfare agencies, or the juvenile justice system). If the minor is not legally competent to consent for treatment and presents with a guardian, the provider should still make every effort to inform the minor patient of the treatment to the extent of their cognitive capacity.

When Minors Refuse Care

The clinician should be extremely wary of treating a minor patient who declines treatment. If a minor refuses routine care after its explanation and has an intelligent understanding of the treatment and available options, a provider who continues with the treatment over the minor's reasonable objections runs a considerable legal risk unless a medical emergency makes the treatment time critical.

If the treatment is needed in the immediate future, the provider should obtain a court order before proceeding; this can be obtained directly via the judicial system or indirectly through the state's child protection agency.

If the treatment is not necessary in the reasonably foreseeable future, the minor should be discharged with an appropriate follow-up referral.

Generally, providers should not order drug or alcohol screens on a minor unless medically justified.

Summary

Urgent care physicians should have an understanding of their own state's statutes surrounding the treatment of minors. To date, courts have not held physicians who acted in good faith liable for initiating the emergent or urgent care of minors. Generally, you should be guided by what is in the patient's best interest; however, it is important to document your attempts to reach a guardian and why you believed the minor's condition warranted treatment prior to obtaining parental consent.

In non-emergent situations, physicians should proceed with extreme caution with minors who do not meet the criteria for legal capacity or emancipation and who refuse care despite the ability to make an intelligent decision.

Minors who present without a parent and whose condition does not require treatment in the foreseeable future should be discharged with appropriate follow-up. It is prudent for the urgent care physician to form relationships with local emergency departments, child protective agencies, and the courts to prospectively formulate guidelines surrounding the care and treatment of minors. ■

TAKE-HOME POINTS

- Care should never be delayed to wait for consent in an emergency situation.
- Rules on "patient competency" can be tricky.
- Try to persuade the minor to let the parent take part in decision-making.
- No parental consent is required for STD treatment or if child abuse is alleged or suspected.
- Be guided by what is in the patient's best interest.
- Treating a minor patient who declines treatment places the clinician in legal risk.

Developing a Marketing Mindset for Occupational Medicine Services

FRANK H. LEONE, MBA, MPH

From a business perspective, successful operation of an urgent care clinic is predicated on the owner's ability to promote services in an aggressive and meaningful, yet cost effective, manner.

This necessity is even more pronounced when occupational health services are included in the mix because such a "blended clinic" deals with two different prospect universes.

The starting point in promoting an urgent care practice is to develop and commit to a forward-thinking marketing mindset.

Six basic principles govern this mindset:

Marketing is all about tomorrow. Marketing initiatives are often uninspired repeats of what has worked for you in the past, or what is working elsewhere. Yet marketing, by definition, involves getting the attention of your prospects, which implies that you need to be fresh, innovative, and different.

Try new approaches. To set your clinic apart from competitors, *force yourself* to introduce at least two new marketing techniques every year. To reduce risk, experiment with marketing initiatives that are neither too expensive nor time consuming.

Embrace technology. Over the past two decades, innovations in communications technology—from cell phones to the Internet—have driven many new marketing ideas. Further advances in technology are anticipated. It behooves the creative marketer to keep an eye on this ball and react quickly when new communication mechanisms become available and trendy.

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*.

Collectively brainstorm. To generate nouveau marketing tactics, sit down for 30 minutes and list every wild and crazy idea you can think of—and ask your colleagues to do the same. Sure, you may throw away 90% of the ideas (and generate some laughter), but the chance of coming up with a genuine winner will increase dramatically.

Recognize linkages. Tie marketing efforts to your business activities. For example, if you are opening a new clinic, don't just send out open house invitations; the one-shot approach may not be the best way to capitalize on your investment.

Instead, build momentum for a grand opening by publicizing the new location through e-mail and voicemail messages, running ads, placing signs in existing facilities and/or sponsoring a contest with prizes donated by local merchants who will receive publicity in return.

The objective is to make prospective clients and patients *think* about your new clinic—an essential first step in getting them to come to your scheduled open house.

Hedge your bets. Think of your package of marketing techniques as a portfolio, similar to your personal investment portfolio. Balance no-risk and moderate-risk tactics with higher-risk activities. Maintain some tried-and-true techniques each year, consistently divest of tired techniques, and add new tactics in an incremental manner.

In summary, it is essential to think ahead and adopt a marketing plan that is not simply reactive to norms of the day. This takes discipline, creativity, and brainstorming. Make the commitment, and you'll discover a bonus: innovation is invariably fun, and having fun seems to be inevitably correlated with effective marketing. ■

CODING Q&A

Evaluation and Management: Coding Details

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, our inaugural issue, he tackles the key issue of evaluation and management (E/M) coding.

Q. Why is the (E/M) code important in urgent care?

A. Because the majority of urgent care revenue is derived from E/M codes (mostly codes 99210-99215), accurate E/M coding is the most important coding variable in urgent care revenue. Inaccurate E/M coding is, also, the number-one reason that urgent care centers run into compliance issues with payors and regulatory agencies.

Q. I see that the Centers for Medicare and Medicaid Services (CMS) lists two sets of guidelines, 1995 and 1997, for coding E/M codes. Which one should I use? May I use either? May I use both?

A. You can use either. CMS has instructed its auditors to code the chart using both E/M guidelines and to use whichever set of results is most in the physician's favor. Thus, you may use either set of E/M guidelines to code any given chart; however, you may not mix and match the aspects of each set of guidelines to code a given chart. In other words, you may not use the level of history from the 1997 Guidelines and the level of physical exam from the 1995 Guidelines to determine the E/M level for a single visit.

David Stern is a partner in Physicians Immediate Care, with nine urgent care centers in Illinois and Oklahoma, and chief executive officer of Practice Velocity (www.practicevelocity.com), a provider of charting, coding and billing software for urgent care. He may be contacted at *dstern@practicevelocity.com*.

Q. What are the major differences between the 1995 and 1997 guidelines for E/M coding?

A. The major difference between the two guidelines lies in the documentation of the physical exam. The 1995 guidelines are more imprecise. For example, they allow the physician (and the auditor) to choose their own definitions of a "detailed" examination of an organ system. On audit, this vagueness often leads to differences of opinion—even among expert coders—on the appropriate level of exam on any given chart. The 1997 guidelines are much more explicit, listing specific elements and specific counts of these elements that count toward each specific level of physical examination.

Q. For E/M coding, can I count the same item in both the History of Present Illness (HPI) section and the Review of System (ROS) section?

A. Yes. Although some coders avoid this and call it "double dipping," CMS actually allows the provider to get credit for the same documented elements in both the HPI and ROS. For example, if you document "fever" in the ROS, you can also count "fever" toward the "related symptoms" in the HPI. A well-documented chart, however, rarely needs to nab elements from other sections to justify a specific coding level.

Note: Auditors for some payors do reject the CMS standard and will not credit the physician for the same information in both the HPI and ROS, so some practices have decided to accept a few lower E/M code levels by adopting a policy of no "double dipping" for all claims. This helps avoid nuisance problems with payor audits.

Q. If I do count the same item in both the HPI in the ROS section, do I need to document the item twice?

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CODING Q & A

A. No. It does not matter where the information is located, as long as it is documented somewhere on the chart.

Q. **May I count the same item toward two different elements in the HPI?**

A. No. For example, if the patient tells you that the cough is produced when "lying down," this element cannot count toward both "context" and "modifying factors" of the HPI.

Q. **What if the item is documented in the section labeled Past Medical History (PMH); can I still count it toward ROS or HPI**?

A. Absolutely. Coders should not be bound to any of the labels on your chart template. For example, if the date of last menses is listed in the PMH, this item may be used to count toward the genitourinary section of the ROS; or, if the patient is complaining of amenorrhea, this item could be used as documentation of duration in the HPI. Note: It is still best to try to document the appropriate information needed for each code in the appropriate section, as many auditors for payors may lack the clinical acumen to recognize such fine distinctions.

Q. **What is the so-called "bell curve" for E/M codes for urgent care centers?**

A. There is no specific bell curve (percentage distributions of 99201-99205 and 99211-99215) published for urgent care centers. CMS has published the bell curves for many other specialties, and these all tend to be quite similar, with peaks on 99203 and 99213 in most specialties.

For two reasons, however, urgent care physicians may be undercoding and losing significant revenue if they emulate these bell curves.

First, urgent care centers see patients with new problems which may increase the complexity of medical decision making.

In addition, many studies of physicians find that 30% to 50% of charts are undercoded by at least one level.

Thus, following the bell curve of other practicing physicians may simply be emulating their patterns of undercoding, resulting in reduced revenue for the urgent care practice in 30% to 50% of patient visits. ■

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Next month in Coding Q & A: Get the low-down on the newer code S9088, "Services provided in an urgent care center."

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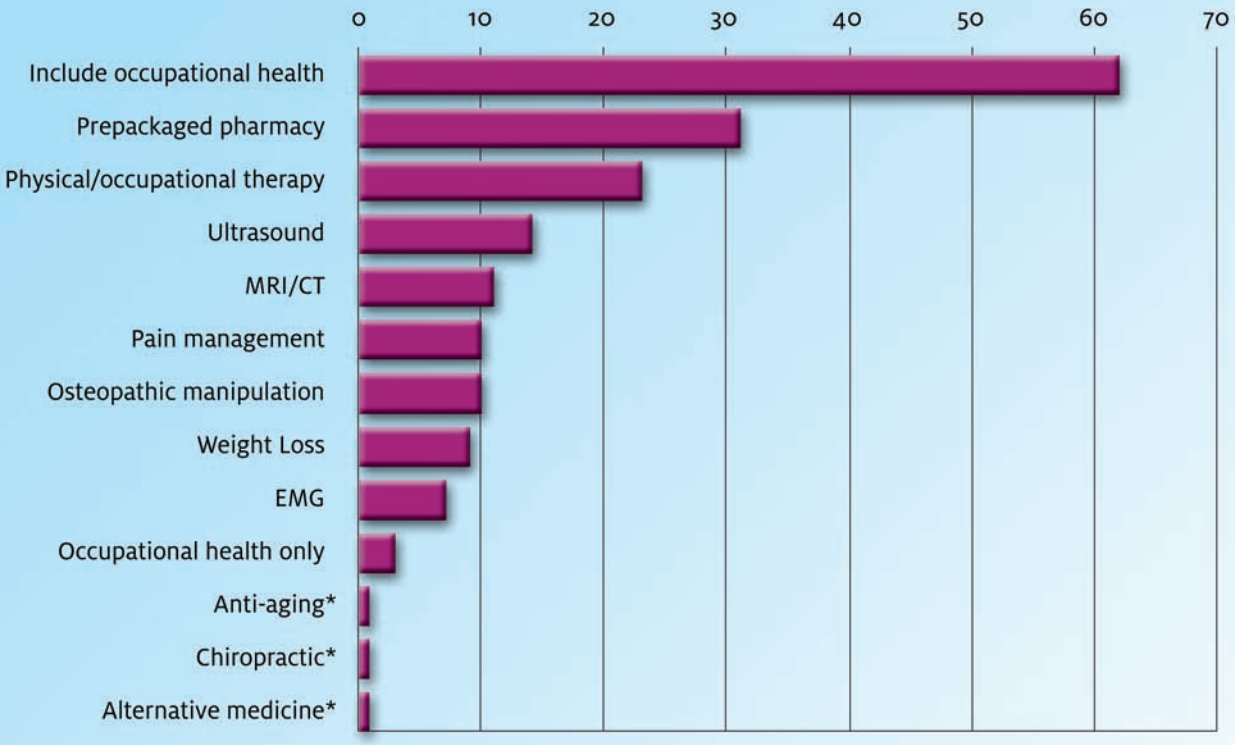
DEVELOPING DATA

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, a look at the breadth of services offered by respondents to the survey:

URGENT CARE SERVICES RENDERED



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

MRI, magnetic resonance imaging; CT, computed tomography; EMG, electromyography.
*Offered by a statistically insignificant number of respondents.

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****: How patients pay their bills, and what that adds up to for you.*

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 fluoroquinolones also produce similar erosions in the 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 acute respiratory distress), 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 uncertain 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; anemia, including hemolytic and aplastic; thrombocytopenia, including thrombotic thrombocytopenic purpura; leukopenia; agranulocytosis; 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, hypoesthesias, dysesthesias and weakness have been reported in patients receiving 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 subsequent to the administration of any antibacterial agent.

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 can 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) or 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, they 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 Videx® (didanosine) should be taken at least two hours before or two hours after oral 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 tendinitis 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 and a hypoglycemic reaction occurs, 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 Videx® (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, sucralfate, multivitamins, Videx® (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. There have been reports 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, elevated serum levels of cyclosporine have been reported in the patient population when co-administered with some other quinolones. Levofloxacin C_{max} and k_e 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, the changes were not high enough to warrant dosage adjustment for levofloxacin when probenecid or cimetidine is 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 comparison, 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/IU cell line) assays.

Levofloxacin caused no impairment of fertility or reproductive performance in rats at oral doses as high as 810 mg/kg/day, corresponding 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 between 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 concomitant 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 was 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 pruritis 0.1%, headache 0.2%, nervousness 0.1%, rash erythematous 0.1%, urticaria 0.1%, anorexia 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 1.3%, 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: Ascites, 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, involuntary muscle contractions, migraine, paresthesia, paralysis, speech disorder, stupor, tremor, vertigo, encephalopathy, abnormal gait, leg cramps, intracranial hypertension, ataxia; Gastro-Intestinal System Disorders: Dry mouth, dysphagia, esophagitis, gastritis, gastroesophageal reflux, G.I. 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, tachycardia; Liver and Biliary System Disorders: Abnormal hepatic function, cholecystitis, 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, arthritis, arthrosis, myalgia, osteomyelitis, skeletal pain, synovitis, tendonitis, tendon disorder; Myo, Endo, Pericardial and Valve Disorders: Angina pectoris, myocardial infarction; Neoplasms: Carcinoma, thrombocythemia; 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, hallucination, impotence, nervousness, paroniria, sleep disorder, somnolence; Red Blood Cell Disorders: Anemia; Reproductive Disorders: Dysmenorrhea, leucorrhea; Resistance Mechanism Disorders: Abscess, bacterial infection, fungal infection, herpes simplex, moniliasis, otitis media, sepsis, infection; Respiratory System Disorders: Airways 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: Flushing, cerebrovascular disorder, gangrene, phlebitis, purpura, thrombophlebitis (deep); Vision Disorders: Abnormal vision, eye pain, conjunctivitis; 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, dysphonia, 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.

ORTHO-McNEIL

OMP DIVISION
ORTHO-McNEIL PHARMACEUTICAL, INC.
Raritan, New Jersey, USA 08869

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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 µg/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.

PriCara™ Unit of Ortho-McNeil, Inc.

For more information, visit us at **www.levaquin.com**

DAIICHI

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LEVAQUIN. For today's respiratory infections*†

750 mg/QD/5 days for CAP§ and ABS

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Lēvaquin®

(levofloxacin) Tablets/Injection

(levofloxacin in 5% dextrose) Injection

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