

JUJCM

THE JOURNAL OF URGENT CARE MEDICINE™

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DECEMBER 2006

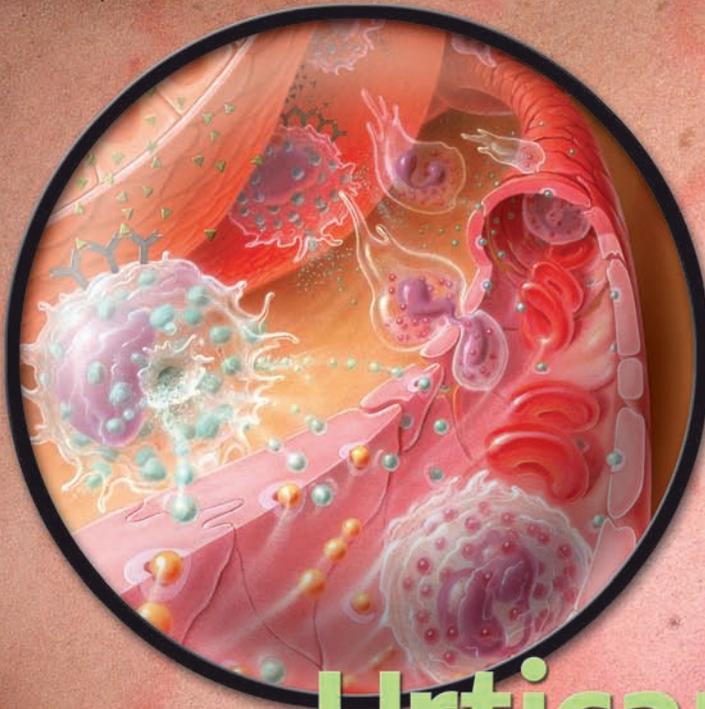
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Urticaria and Angioedema: A Case-Based Discussion

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The Power of Research



Medical progress is driven by research. Opinions must be continuously challenged in order to assure the greatest likelihood of efficacy, quality, and safety. Over the last century, research has focused on examining the innovative diagnostic and therapeutic approaches to disease and prevention that form the backbone of clinical medicine as we know it today.

While science continues to make expansive strides along multiple clinical fronts, a new area of research interest evolves: Let's call it Healthcare Delivery: Models and Quality. The study of issues such as accessibility, cost, patient satisfaction, efficiency, and clinical integration has generated keen interest by the likes of such policy giants as the Robert Wood Johnson Foundation and the Agency for Healthcare Research and Quality (AHRQ). Examining the use of technology to support improved healthcare delivery and quality is also generating excitement in the research community. Conquering the problems that plague our nation's emergency services system deserves additional notice, as well.

Urgent care medicine is positioned uniquely to play a leading role in the study of unique healthcare delivery paradigms. I need not convince all of you of the role urgent care plays in addressing the issues of access, cost, quality, satisfaction, and the use of technology to improve healthcare delivery.

We do, however, collectively need to convince the scientific and public communities of such.

JUCM[™], *The Journal of Urgent Care Medicine* is unique in that it serves as a forum for ALL of us to challenge our assumptions, to prove and reprove the value of urgent care medicine and its role in improving healthcare delivery and quality. Consider the following potential topics:

- Cost-of-care savings in urgent care vs. ED for non-life threatening illness and injury
- Management of chest pain in urgent care: outcomes analysis
- Efficacy of return-to-work programs/efficacy of urgent cares vs. primary care and orthopedics at minimizing lost days due to injury
- Use of technology to reduce errors and improve efficiency

Ultimately, these research topics, and many others like them, will raise urgent care medicine where it belongs—to the forefront of the healthcare delivery discussion.

I encourage all of our readers to transform the undeniable enthusiasm and passion you have for the value and virtues of urgent care medicine into an equivalent passion for proving its value and virtues. There are many research resources available through your local medical schools, hospitals, and medical societies, as well as grant money available through many health policy foundations like Robert Wood Johnson and AHRQ.

“We are positioned uniquely to play a role in the study of unique healthcare delivery paradigms.”

You do not have to have any research experience to produce a simple study of excellent quality, and, often, research money is earmarked for non-academic physicians and practices to ensure a “real-world” perspective.

JUCM is already working to publish several pieces of original research that will both highlight the value of our discipline and analyze some of its finer points. Our pledge is to disseminate original research designed by urgent care clinicians for urgent care clinicians as often as possible. I encourage you to join the ranks of the researchers who will fuel the continued growth of our dynamic discipline.

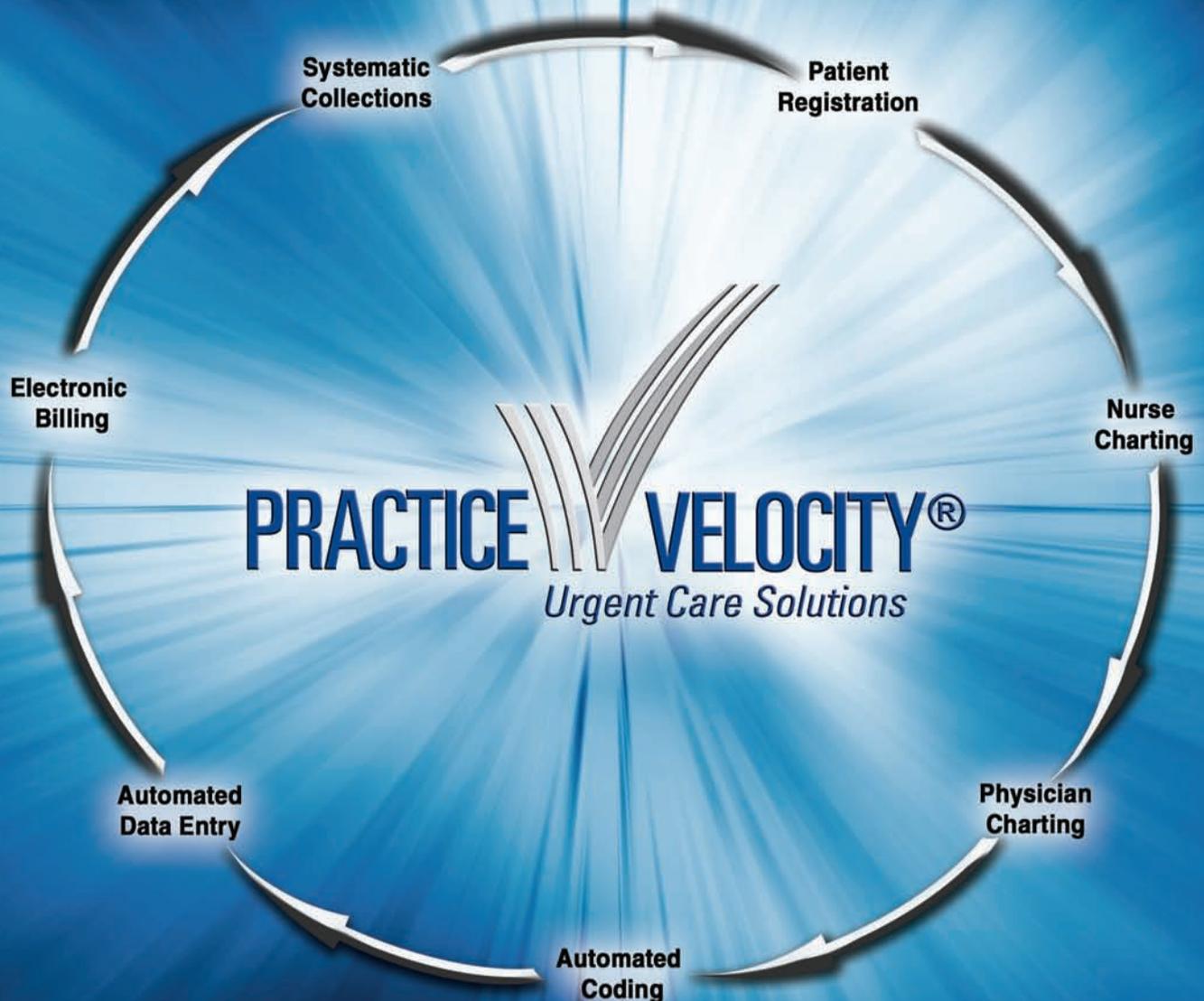
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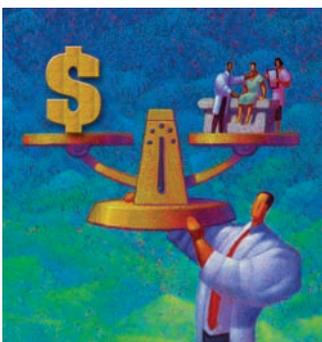
10 Urticaria and Angioedema: A Case-based Discussion

The intense itchiness and discomfort of acute urticaria and angioedema bring many to urgent care, seeking relief and a reassuring explanation. Your goal: identify the likely cause(s) and implement a treatment plan. See how three distinct cases were resolved.

By Kent Knauer, MD

PRACTICE MANAGEMENT

29 A Delicate Balance: Managing Your Practice, Caring for Your Patients



You earned multiple degrees, made it through internship and residency, and established yourself as a competent clinician. Now you're wrestling with the same financial issues as every other entrepreneur. Here's an overview of some key challenges.

By Kevin J. Ralofsky, MBA

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From the Executive
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Mission Statement

JUCM The Journal of Urgent Care Medicine supports the evolution of urgent care medicine by creating content that addresses both the clinical practice of urgent care medicine and the practice management challenges of keeping pace with an ever-changing healthcare marketplace. As the Official Publication of the Urgent Care Association of America, JUCM seeks to provide a forum for the exchange of ideas and to expand on the core competencies of urgent care medicine as they apply to physicians, physician assistants, and nurse practitioners.

JUCM 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.



JUCM CONTRIBUTORS



As director of the Allergy and Asthma Center at University Hospitals in Cleveland, OH, as well as a clinician and researcher, **Kent Knauer, MD** is well qualified to address the topic of this month's cover article: urticaria and angioedema in the urgent care setting (page 10). Dr. Knauer has lectured and written extensively on asthma and other allergic conditions and is a member of the American Academy of Allergy, Asthma, and Immunology, as well as a fellow of the American College of Allergy, Asthma, and Immunology. He sits on the speaker's bureau for AstraZeneca, GlaxoSmithKline, Merck, and Pfizer and has received research grants from Mead Johnson, Novartis/Genentech and GlaxoSmithKline.

UCAOA members may be familiar with **Kevin Ralofsky, MBA** by virtue of his position as the association's treasurer. Having successfully owned and sold an urgent care center, he founded Med-Capital, a growth and strategy consulting firm. He came to our attention at this year's Fall Urgent Care Conference in Phoenix, where he led a session on Financial Issues for Urgent Care Centers. We thought it was so worthwhile—an opinion borne out by the number of attendees who lined up afterward to ask questions—that we asked him to script an article on that very topic (page 29). We're pleased that he also accepted our invitation to share his expertise as a columnist in future issues of *JUCM*. Look for the first of what we hope will be many such contributions in the January issue.



We are also indebted to **Nahum Kovalski, BSc, MD** of

Terem Immediate Medical Care in Jerusalem, Israel; **John Shufeldt, MD, MD, MBA, FACEP**, CEO of NextCare, Inc.; **Frank Leone, MBA, MPH**, president and CEO of RYAN Associates, as well as founder and executive director of the National Association of Occupational Health Professionals; and **David Stern, MD, CPC**, a partner in Physicians Immediate Care and chief executive officer of Practice Velocity, for sharing their time and expertise as regular contributors to *JUCM*.

In addition, **Michael Talkar, MD** has again provided an insightful Case Report that can be found on page 20. The Clinical Challenges for this issue were contributed by **Fred Carol, MD** and **Scott Field, MD** (pages 23 and 25, respectively).

Finally, we wanted to introduce a physician who is deeply committed to the ongoing growth of urgent care medicine as a discipline—our editor-in-chief, **Lee Resnick, MD**. As a member of the Board of Directors and the chair of academics for UCAOA, medical director of University Hospitals Urgent Care (University Hospitals Medical Practice, Inc.), and assistant clinical professor in the Department of Family Medicine at University Hospitals Case Medical Center in Cleveland, OH, he leads the effort to promote academic rigor in urgent care medicine. As editor-in-chief of *JUCM*, he sets the clinical tone for this publication and is at the forefront of our efforts to inform, enlighten, and spark discussion among urgent care practitioners.

If you'd like to take an active part in that discussion, feel free to send a Letter to the Editor via e-mail to editor@jucm.com. We'd like to know your thoughts on any of the articles you read in *JUCM*, or even your perspective on the direction of urgent care medicine.

To Submit an Article to *JUCM*

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

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

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

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

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

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FROM THE EXECUTIVE DIRECTOR

Syn·chro·nic·i·ty (sing'krə-nis' i-tē)

■ LOU ELLEN HORWITZ

The American Heritage Dictionary defines *synchronicity* as “coincidence of events that seem to be meaningfully related.” Sometimes in our professional lives we are fortunate enough to be part of something that is truly special—a moment or two when we can witness the coming together of the right mix of people with a shared purpose in the right setting at the right time.

Just such a moment happened at UCAOA's 2006 Fall Conference in Phoenix, AZ in October. If you were there, then you know what I mean.

The excitement was palpable as attendees were able to connect with each other and the faculty, to speak the same language, problem-solve together, and go home with renewed energy and focus for taking their urgent care centers forward.

We also got to experience some great energy just a couple of weeks later at the National Association of Occupational Health Professionals conference in Philadelphia. As many of you obviously know (considering that about 65% of urgent care centers also have occupational health services), occupational medicine services can be an important addition to your urgent care center, providing a steady stream of revenue to help offset the ups and downs of the cash-flow cycle experienced by some centers. (UCAOA Treasurer and frequent conference speaker Kevin Ralofsky touches on the subject of cash flow, as well as other financial challenges, in *A Delicate Balance: Managing Your Practice, Caring for Your Patients*, beginning on page 29 of this month's issue.)

For those of you who couldn't join us in Phoenix or Philadelphia, I wanted to share a few informational tidbits from those conferences:

Cash-only doesn't work. Most centers that started out as cash-pay only have had to change their policy to accept patient insurance because the volume of cash-paying patients

just isn't enough to sustain a center. Many still offer a cash-pay discount to incentivize that behavior, however. (To see a breakdown on the various methods patients use to pay their bills, see this month's Developing Data graph on page 40.)

“Occupational medicine services can provide a steady stream of revenue to help offset the ups and downs of the cash-flow cycle.”

Corner your x-ray. If you are building a new urgent care center, put your x-ray suite in the corner of your building. You should save money because the two external walls don't require additional shielding.

Keeping score. You want to measure your provider performance, but you don't have national performance benchmarks to measure against? It's true that such benchmarks are hard to come by. One solution: measure your providers against each other. You can start by creating an overall baseline of all of your provider data averaged together, then compare the providers individually against the collective. It's not a perfect solution, but it will give you some indication of how they stack up.

Next Stop: Daytona Beach

As we move toward the end of the year, we are most looking forward to finally sharing the details of the UCAOA 2007 Annual Convention (May 9-12, 2007 in Daytona Beach, FL) with you.

We will offer four concurrent pre-conference sessions. These are focused one-day programs that drill down into specific areas for a full immersion into a topic.

If you are new to one of the following aspects of urgent care, we highly recommend attending one of these sessions prior to the main conference:

■ **Starting a New Urgent Care Center**

If you are considering opening your first or second



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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center, or are already in the process, this session—which will be led by both topic experts and on-the-ground owners and operators—is designed to help you avoid common mistakes and pick up a trick or two.

■ **Integrating Occupational Medicine**

As we mentioned earlier, bringing occ med into your clinic can be a significant financial help as well as a service to the employers and employees in your community. Maximizing the benefit to your practice requires specific preparation and marketing considerations, however.

■ **Essentials of Urgent Care Billing**

Specifically for those new to the industry, this program details the billing and coding issues that are particular to urgent care (and there are many). Learn how to maximize the reimbursement you receive for your services.

■ **Procedure Clinic**

This is where the rubber meets the road; all the good business practices in the world won't add up to much without the clinical expertise and patient care to back it up. This program will focus on treatment techniques necessary for good urgent care.

Remember, that's just a rundown of the one-day pre-conference sessions. The main conference will feature three concurrent tracks, as detailed below. The courses will run simultaneously, so you may want to bring more than one person from your organization to cover all of your areas of interest.

Clinical Track

This program will cover clinical topics ranging from evaluating the abdominal pain patient to eye infections to shoulder and knee injuries to pediatrics and EMG services. In addition, the Clinical Track attendees will have some joint sessions with the Business Track in areas like medical malpractice and a roundtable discussion.

Introductory Business Track

This track takes the broadest view of the essentials of the business side of urgent care medicine. Topics include policy and procedure manuals, billing and collections, marketing strategies, basics of occupational medicine, and managed care contracting.

Advanced Business Track

Designed for our past Business Track attendees and those who have been delivering urgent care for several years,

this program takes a closer look at some of the more advanced business topics: leadership development, staff training and the physician's role when integrating occupational medicine, and advanced managed care contracting issues. Breakout sessions with both of our keynote speakers are also planned.

So, if the idea of synchronicity appeals to you, you're certain to find it in Daytona Beach May 9-12, 2007. Plan to join us there.

“The UCAOA website has been redesigned to help you connect with each other and to access the online resources we have for you. Visit www.ucaoa.org to check it out.”

New Projects

Besides planning the national conference, we've been hard at work developing new communication tools for UCAOA members.

The UCAOA website has been completely redesigned with an eye toward helping you to connect with each other and to access all the online resources that we have for you. Visit www.ucaoa.org to check it out.

In addition, we are asking for your help in launching a project to help address a need of new startups, as well as existing centers. The *Policy and Procedure Manual* we're producing will offer good examples of policies and procedures that are already working well in urgent care centers. We are not asking you to divulge the full content of your manual, just to share a section or two that might serve as an example of what a policy and procedure manual *should* look like. This will be a collaborative project as we compile sections from contributors throughout the country.

If you have a section you are willing to share, please e-mail me. However, please *don't* e-mail if you're looking for a copy of the manual right now. We're just beginning this project and we will make it available to all members as soon as it is ready.

I hope you enjoy this issue of **JUCM** *The Journal of Urgent Care Medicine* and that you will find a few synchronicities of your own this month. ■

Urticaria and Angioedema

A Case-based Discussion

Urgent message: Patients often present to urgent care with symptoms associated with urticaria and angioedema. Identifying the probable cause can provide relief of symptoms and abate patient concerns.

Kent A. Knauer, MD, Director, Allergy and Asthma Center, University Hospitals, Cleveland, OH

Urticaria and angioedema are rarely life threatening, but they are extremely disruptive to quality of life and sleep. In addition, hives may be alarming and lead patients to wonder if something serious is afoot. Swelling of the tongue or throat is particularly likely to be the source of some concern.

Small wonder, then, that patients with acute urticaria and angioedema are often first evaluated in an urgent care center.

In this article, we will discuss urticaria and angioedema from my perspective as director of the Allergy and Asthma Center at University Hospitals in Cleveland, OH and as presented in three distinct patients who were treated in an urgent care setting. I will also offer some perspective on when to refer to a specialist and will provide a few illustrative cases along the way.

Patients can adapt to many symptoms (including even moderate pain), but pruritis is not among them. Scratching is a response built into the nervous system; it cannot be denied and should be taken seriously.

The goals of management are to identify the likely cause(s), and to eliminate the urticaria or, when that is not possible, to alleviate the symptoms.

It may not be practical or even necessary to make a definitive diagnosis in the urgent care setting, but you should be able to make a reasonable educated guess and create a treatment plan.



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In most cases, the goal for urgent care is to initiate treatment and prescribe sufficient medications to get the person to their primary physician. It is when patients return to urgent care because of treatment failure and are still uncomfortable that diagnostic testing is indicated.

There are five provable etiologies of urticaria including allergy, infection, autoimmune processes, medication induced, and physical forms of urticaria. Most cases of idiopathic urticaria are probably autoimmune in nature.

Table 1. Guide to Urticaria and Angioedema

	Normal urticaria—common	Complicated urticaria	Refractory urticaria
Histology	Bland—no cells	Intermediate—increasing mononuclear cells and eosinophils around venules	Mixed perivascular infiltrate with RBC extravasation from venules
Character of rash	Raised, well demarcated, blanch with pressure and leave no mark; transient and come and go in crops	Urticaria and some angioedema, blanch with pressure and leave no mark; individual hive may last more than 72 hours	Angioedema is common, especially on the face. Some hive lesions appear bruised or may not blanch; may be tender; lesions persist for days or even a week in certain areas
Hive symptoms	Intensely pruritic	Pruritic or non-pruritic	Often stinging, burning, or painful itch
Associated symptoms	Usually none, possibly other allergy symptoms	Non-specific systemic symptoms such as fatigue, malaise	Possible joint pain or aching, sometimes fever, chills, sweats
Underlying cause	Allergy to food or environmental allergen; physical forms of urticaria such as dermatographism, insect allergy	Allergic drug reaction, autoimmune urticaria, occult infection—often sinuses, most cases of “idiopathic” urticaria	Serum sickness or other drug reaction, rare familial urticaria, autoimmune, occasionally infection
Response to therapy	Good response to antihistamine, complete response to steroid	Partial response to antihistamine, partial response to steroid	No response to antihistamine, partial or no response to steroid

It is not my purpose here to give an exhaustive review, but rather to provide some helpful background information, my personal strategy for a differential diagnosis when evaluating urticaria, and a framework for treatment. The bibliography contains some recent reviews that provide other points of view.

Case 1

C.R. is a 43-year-old woman who was referred to a specialist by an urgent care physician because of the new onset of urticaria and angioedema of four weeks duration. She was in urgent care six months earlier, in the spring, because of acutely worsened sinus pressure and mucopurulent drainage. She had a long history of sinus

symptoms and a strong family history of allergy. The physician prescribed amoxicillin and a steroid nasal spray. The patient improved and had no further problems until she presented with urticaria. At her initial visit for urticaria, she was given a Medrol Dosepak and an antihistamine; initially, she showed improvement but then worsened and returned to urgent care.

On her second visit, she had generalized urticaria and facial angioedema. She was given a two-week tapering course of prednisone. By the time she got in to see me she was hive free, but kept the appointment because she wanted to find out what caused the urticaria and swelling. What would be your differential diagnosis?



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Although most hives look similar on exam, biopsy results show a spectrum of histological findings. (See **Table 1**.) Most of the time the tissue simply looks like saline was injected intradermally—devoid of signs of inflammation—and on the other extreme it reveals an intense mixed perivascular infiltrate with extravasation of red cells from small venules.

Often, there is an intermediate picture with several perivascular mononuclear cells and perhaps a few eosinophils. This cell infiltrate (or lack thereof) correlates with benign forms of urticaria to progressively more aggressive forms of urticaria and, at worst, to urticarial vasculitis—the most severe form of urticaria with a more serious differential diagnosis and prognosis.

So, how does this help us?

The presence of a cellular infiltrate is associated with relative resistance to antihistamine therapy and increasing resistance to corticosteroid therapy, especially that element of the anti-inflammatory effect which occurs within hours or up to a few days. **Table 1** shows the causes of some of these histological patterns, and we will find that certain skin symptoms and various associated systemic symptoms can lead us to a reasonable differential and treatment plan.

If we look at patient C.R. in light of **Table 1**, we see that her response to antihistamines and steroids place her in the complicated or refractory category, and that her history of sinusitis suggests the need to consider underlying infection as a cause.

There may also be an allergic component based on her family history. One could empirically prescribe an antibiotic, but if a limited CT of the sinus is readily available it would be very helpful. The treatment of infection-related urticaria is treatment of the underlying infection; usually, the hive response abates in 48 to 72 hours.

I performed skin tests and found allergy to seasonal



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“The treatment of infection-related urticaria is treatment of the underlying infection; usually, the hive response abates in 48-72 hours.”

and perennial allergens. I elected to restart the nasal steroids and follow up with her in four weeks.

In retrospect, it seems likely that her urticaria and angioedema were related to both allergy and sinusitis. I believe that the steroids suppressed the allergic swelling in the sinuses and nasal passages and she was able to recover from infection on her own, but this is not the rule. She would have been better sooner and with fewer days of steroids if antibiotics had been prescribed on her second urgent care visit. In most patients with steroid refractory urticaria you should think of occult infection, usually in the sinuses. The patient may be unaware of infection, at least in part because the

medications prescribed for urticaria suppress but do not alleviate the sinusitis symptoms.

Case 2

S.B. is a 32-year-old female who presented to urgent care with a two-week history of urticaria. Her hives were generalized but not particularly itchy, and occasionally mildly stinging. S.B. had a history of intermittent urticaria for the last year, but the symptoms never lasted more than a few days. On one occasion, she had slight swelling of her lower lip. There was no history of gastrointestinal or respiratory symptoms. She was postpartum 18 months with uneventful pregnancy and delivery. There was no history of any other medical problems or food allergy. She had taken loratidine regularly with little or no relief of the rash. She had no family history of allergy, urticaria, or eczema, but there was a maternal history of thyroid disease. She was taking only oral contraceptives and prenatal vitamins, and denied over-the-counter drugs, including NSAIDs.

Two days prior to this recent episode she had eaten a “shrimp fest special” at a seafood restaurant. There was no known allergy to medication. Exam showed well-

demarcated, typical urticaria lesions measuring 1 cm to 2 cm which blanched with pressure. The physician told her to change her laundry detergent and to avoid shellfish and gave her prescriptions for fexofenadine 180 mg and ranitidine 300 mg, both to be taken daily.

A week later, S.B. returned complaining of worsening urticaria and swelling of her face on the right side. The physician ordered a CBC, sed rate, ANA and a C1 esterase inhibitor level. She also ordered a medrol dose-pak in addition to the prior medications. A week later the patient was back with some improvement but then another relapse, and all lab work was within normal limits. What would be your differential diagnosis?

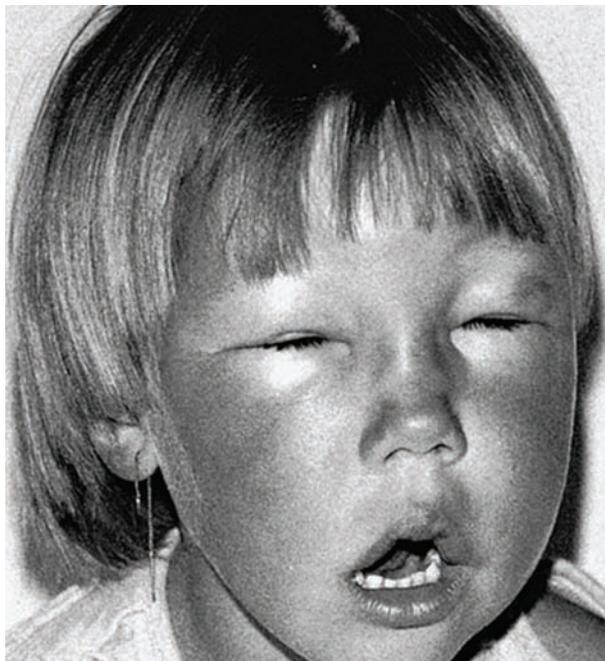
The scenario described here reveals several errors and misconceptions.

First, laundry detergent is virtually never a cause for hives, although it may possibly produce a flat, slightly red irritant reaction. There are only a few causes of contact urticaria; they include latex, benzoyl peroxide, and some make-ups.

Secondly, hereditary angioedema is a rare disease, and when it does occur urticaria is never part of the syndrome. In other words, if angioedema is accompanied by urticaria, C1 esterase inhibitor deficiency is never in the differential diagnosis.

Also, food allergy causes urticaria by an immediate hypersensitivity reaction which occurs minutes to hours after exposure, but never days later. Therefore, we can rule out contact, food, and C1 esterase deficiency as causes.

There is no evidence for drug allergy or physical forms of hives. Refractoriness to antihistamine and steroid suggests autoimmune or infectious etiology. In the event of poor or no response to antihistamines, it is



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“Food allergy causes urticaria by an immediate hypersensitivity reaction which occurs minutes to hours after exposure, but never days later.”

pointless to add an H2 blocker.

In the absence of anything to suggest infection, I would make a tentative diagnosis of autoimmune urticaria. S.B. has a family history of thyroid disease and a sputtering onset of hives, leading me to suspect thyroid autoimmunity. This is sometimes seen postpartum, or even during pregnancy.

Urticaria is frequently the presenting sign, even before thyroid function is abnormal. This may be documented by the presence of serum anti-thyroid peroxidase antibodies. The levels of auto-antibodies over time may correlate with the severity of urticaria. This form of urticaria can be difficult to control, but may be helped by treating hypothyroidism if present, and may spontaneously remit over months or years.

I usually bargain with the patient for 80% control of symptoms by means of a daily antihista-

mine and/or a small dose of oral corticosteroid on an every-other-day basis and hope it just goes away. This patient needs to be followed up by a specialist.

Case 3

Our last patient, J.B., is a 4-year-old Amish girl brought in by her father on a beautiful early September afternoon because of swollen face and eyes.

J.B. had no prior history of hives, swelling, or allergy. She had taken no medicines and eaten no new foods. The family had come from the Geauga County Fair where they had purchased a horse.

J.B. was experiencing very slight nasal congestion and generalized pruritis, but no respiratory or other symptoms. On exam, she was in no acute distress, but was scratching her forearms. Her left upper lip was

swollen, but mouth and tongue were normal. Upon opening the eyes there was moderate conjunctivitis.

The rest of the exam was normal, but where she was scratching there were linear welts. She responded in an hour to diphenhydramine and injected corticosteroids.

She was referred to me for follow-up, and skin testing showed a strong positive test to ragweed, and horse was negative. Her father and teenage sibling reported a history of hayfever, but no family member had hives or swelling.

This case illustrates the occasional presentation of acute seasonal allergy with exclusive skin manifestations, along with conjunctivitis here.

Another variation is generalized hives or dermatographism presenting along with respiratory manifestations of environmental allergy. A possible clue, as was the case here, is presentation during the peak of a pollen season, or after exposure to a very potent allergen such as dust mite or animal dander. Apparently, enough environmental allergen can be inhaled and ingested to cause a generalized hive reaction.

In the Midwest, the ragweed season peaks in the first week of September, and usually Labor Day weekend has high pollen counts. Some cases of chronic urticaria are purely allergic in nature and respond to avoidance and antihistamines on a regular basis.

Summary

As can be seen from the preceding cases, treatment with antihistamines is the first step for treating urticaria, and the response to antihistamine may have diagnostic implications, as well. Oral antihistamines should never be prescribed for prn use, since they are preventative by occupying the H1 histamine receptor.

Patients often assume that antihistamines are to be used prn unless they are specifically instructed to take them on a daily basis, even if they have no hives.

Similarly, oral corticosteroids are usually very effective for treating urticaria and angioedema, and their failure implies a complicated or severe form of the disease.

You may have noticed absence of discussion of the role of epinephrine in the treatment of urticaria and angioedema. Epinephrine is the first-line treatment for anaphylaxis, and there may be some difficulty at times determining whether severe hives and angioedema actually are the

presenting signs for anaphylaxis. Of course, in that case epinephrine should be administered.

Epinephrine is never a routine choice in most cases of hives, however, because first there is some risk involved in giving the drug and, secondly, because it has a dura-

tion of action of only a few hours at best. Dermatographism is a frequent feature of many patients with urticaria, and has no special diagnostic implications. Other physical forms of hives, such as pressure-induced, solar, and cold-induced urticaria are usually self evident. Likewise, angioedema has no special sig-

nificance unless it presents without hives, and even then I see it mostly in patients taking ACE inhibitors.

There is no pressing need to have a definitive diagnosis at the urgent care level, except in the case of underlying infection, which usually responds only to antibiotic treatment.

It is appropriate for the urgent care provider to refer the patient on oral antihistamines or a short burst of corticosteroid back to their primary physician. If an allergic cause is strongly suspected, then referral to an allergist may be appropriate.

I hope that these insights, gleaned over 20 years of practice, and **Table 1** will provide a framework for managing urticaria and angioedema.

These may also help you with patient communications. On a daily basis, you deal with many serious medical conditions, but none that beg the question “why?” more than urticaria. Patients literally lie awake at night wondering what caused their hives. It is very helpful to reassure them that much of the time a cause can be found and it is usually benign—and, more importantly, that the symptoms can be controlled. ■

Suggested Reading

- Kaplan AP. Clinical practice. Chronic urticaria and angioedema. *N Engl J Med*. 2002; 17;346:175-179.
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- Gompels MM, Lock RJ. C1 inhibitor deficiency: diagnosis. *Clin Exp Dermatol*. 2005;30:460-462.
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“There is no pressing need to have a definitive diagnosis at the urgent care level, except in the case of underlying infection.”



On Injured Skaters, Diverticulitis, Fluticasone vs. Oral Prednisolone, and NT-proBNP

■ 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.

Differences in the Risk Associated with Head Injury for Pediatric Ice Skaters, Roller Skaters, and In-Line Skaters

Citation: Knox CL, Comstock RD, McGeehan, et al. *Pediatrics*. 2006;118:549-554.

URL: <http://pediatrics.aappublications.org/cgi/content/abstract/118/2/549?etoc>



Key point: Ice skating carries a greater risk of head and facial injuries than roller or in-line skating.

The goals were to describe the epidemiologic features of pediatric skating-related injuries sustained from 1993 to 2003 and to compare ice skating-related injuries with roller skating- and in-line skating-related injuries. This analysis of

pediatric skating-related injury data came from the National Electronic Injury Surveillance System of the U.S. Consumer Product Safety Commission.

An estimated 1,235,467 pediatric skating participants presented to hospital emergency departments with injuries between 1993 and 2003. These children had a mean age of 10.9 years (SD: 3.2 years; range: 1–18 years), and half were male. The

most common mechanism of injury was a fall (83.1%). Ice skaters sustained a greater proportion of head injuries (13.3%), compared with roller skaters (4.4%) and in-line skaters (5.0%). Ice skaters also experienced a greater proportion of concussions (4.3%), compared with roller skaters (0.6%) and in-line skaters (0.8%). The proportion of facial injuries was greater among ice skaters than among roller skaters and in-line skaters. The majority of roller skating- and in-line skating-related injuries were upper-extremity fractures (53.9% and 59.7%, respectively). Children ≤ 6 years of age experienced a greater proportion of head and facial injuries than did older children in each skating activity.

Comment: There is a need to continuously reinforce the importance of head and limb protection when children skate. Any patient encounter is an opportunity to review these issues, both with the child and parents. In the case of ice skating, especially in a closed rink, proper protective gear can be enforced. ■

CT and Clinical Features of Acute Diverticulitis in an Urban U.S. Population: Rising Frequency in Young, Obese Adults

Citation: Zaidi E, Daly B. *AJR Am J Roentgenol*. 2006;187:689-694. <http://www.ajronline.org/cgi/content/abstract/187/3/689>

Key point: The increasing prevalence of diverticulitis in younger age groups may be partially related to obesity.

On the basis of our experience in recent years, the authors hypothesized that acute diverticulitis occurs more frequently in young adult patients (age ≤ 50 years) now than previously recognized. The authors reviewed hospital and radiology databases to identify 104 adult patients with both computed



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tomography (CT) and clinical diagnoses of acute diverticulitis.

The study group was composed of 55 men and 49 women (age range, 22-88 years; mean age, 52.2 years; median age, 49.0 years). Fifty-six (53.8%) were 50 years old or younger, and 22 were 40 years old or younger. Forty-one complications were noted in 38 patients (36%).

There was no significant age difference between the 50 and >50-years-old age groups for hospital admission (90 patients, 86.5%), medical therapy (76, 73.1%), or surgery or percutaneous abscess drainage (28, 26.9%). Abdominal obesity was present in 48 (85.7%) and 37 (77%) of the 50 and > 50-years-old age groups, respectively.

To conclude, in this urban population, acute diverticulitis occurred more frequently than previously recognized in patients 20-to-50 years old. This group had significantly greater abdominal obesity than the older group. Severe disease requiring hospital admission, surgery, or percutaneous drainage (or both surgery and percutaneous drainage) was common in all age groups.

Comment: In a 30-year-old with abdominal pain, diverticulitis tends to be low on the differential. But such a patient, especially if obese, may be brewing an acute infection that gets missed due to low clinical suspicion. CT will identify these lesions regardless of age, but if the CT is not ordered, the diagnosis may be missed. Obese patients may show little anterior abdominal findings with any intra-abdominal infection, making the diagnosis more difficult. ■

High-Dose Inhaled Fluticasone Does Not Replace Oral Prednisolone in Children with Mild to Moderate Acute Asthma

Citation: Schuh S, Dick PT, Stephens D, et al. *Pediatrics*. 2006;118:644-650.

URL: <http://pediatrics.aappublications.org/cgi/content/abstract/118/2/644?etoc>



Key point: Oral corticosteroids play an important role in all degrees of asthma.

Inhaled corticosteroids are not as effective as oral corticosteroids in school-aged children with severe acute asthma. It is uncertain how inhaled corticosteroids compare with oral corticosteroids in mild to moderate exacerbations.

This was a randomized, double-blind controlled trial conducted between 2001 and 2004 in a tertiary care pediatric emergency department. The authors studied a convenience sample of 69 previously healthy children 5 to 17 years of age with acute asthma and forced expiratory volume

in one second at 50% to 79% predicted value. Albuterol was given in the emergency department and salmeterol was given after discharge to all patients, as well as either fluticasone or oral prednisolone.

At 240 minutes, the forced expiratory volume in one second increased by 19.1% ± 12.7% in the fluticasone group and 29.8% ± 15.5% in the prednisolone group. At 48 hours, this difference was no longer significant. The relapse rates by 48 hours were 12.5% in the fluticasone group and 0% in the prednisolone group.

Comment: I continue to encounter patients who express extreme fear of any oral dosing of a corticosteroid. Oral steroids remain a critical component of the successful treatment of asthma exacerbations. Clear explanation of the safety and efficacy of a short course of oral steroids is usually sufficient to allay patients' families' fears. ■

Is NT-proBNP a Useful Test to Detect Congestive Heart Failure? It's too early to tell.

[Commentary on "Potential Impact of N-Terminal pro-BNP Testing on the Emergency Department Evaluation of Acute Dyspnea."]

Citation: Koenig KL. *Can J Emerg Med*. 2006;8:251-258. <http://emergency-medicine.jwatch.org/cgi/content/full/2006/804/1>

Key point: There is a great need for a test that distinguishes various causes of dyspnea. NT-proBNP is not powerful enough to make the diagnosis if clinical suspicion of CHF falls in the gray zone.

In a prospective cohort study, researchers assessed the effect of adding NT-proBNP testing to the routine work-up in a convenience sample of adults who presented to a single emergency department with acute dyspnea. Treating physicians, who were blinded to the test results, assessed the likelihood that dyspnea was due to congestive heart failure (CHF).

Complete data were available for 139 visits by 129 patients (median age, 76; 59% admitted). Serum NT-proBNP results were positive in 86% of cases overall, including in 75% of cases considered unlikely to be due to CHF and in 86% of cases for which the physician was unsure about the likelihood of CHF. Overall, NT-proBNP levels were higher in patients considered likely to have CHF, but the ranges of values overlapped considerably among the groups with different physician-assessed likelihoods. The authors conclude that there is high discordance between clinical suspicion of CHF and NT-proBNP values, and that the test is not specific in an unselected population of dyspneic patients.

Comment: Missing CHF as the cause of dyspnea leads to greater morbidity and mortality. Overdiagnosing CHF can lead a physician to miss alternate diagnoses such as GE reflux,

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COPD, asthma and allergies. Still, any test that at least helps confirm CHF in specific cases can save critical time and money for the patient. NT-ProBNP has a role in emergent and primary care. This role has not yet been clearly defined. ■

How Safe Is Triage by an After-Hours Telephone Call Center?

Citation: Kempt A, Bunik M, Ellis J, et al. *Pediatrics*. 2006;118:457-463.
<http://pediatrics.aappublications.org/cgi/content/abstract/118/2/457?etoc>



Key point: Telephone triage is an effective way to manage patients with after-hour medical concerns.

The authors' goals were to assess (1) compliance with nurse disposition recommendations, (2) frequency of death or potential underreferral associated with hospitalization within 24 hours after a call, and (3) factors associated with potential underreferral for children receiving care within an integrated healthcare delivery organization who were triaged by a pediatric after-hours call center.

The study population included all pediatric patients enrolled in Kaiser Permanente Colorado whose families called the Children's Hospital after-hours call center in Denver, CO, between October 1, 1999, and March 31, 2003. Post-call disposition recommendations were categorized as urgent (visit within four hours), next day (visit between four and 24 hours), later visit (visit in >24 hours), or home care (care at home without a visit). Compliance with the nurses' triage disposition recommendations was calculated as the proportion of cases for which utilization data matched the disposition recommendations.

Of the 32,968 eligible calls during the study period, 21% received urgent, 27% next day, 4% later visit, and 48% home care disposition recommendations. Rates of compliance with both urgent and home care disposition recommendations were 74%, and the rate of compliance with next day recommendations was 44%. No deaths occurred within one week after the after-hours calls. The rate of potential underreferral with subsequent hospitalization was 0.2%, or one case per 599 triaged calls. In multivariate modeling, age of <6 weeks or >12 years and being triaged after 11 p.m. were associated with higher rates of potential underreferral.

Comment: Large databases of clinical data are critical for iden-

tifying at-risk populations for any medical issue. In this case, neonates and teens were at a greater risk of underreferral. As such, it is possible to lower the threshold for referral for these groups, and then reassess the success of this approach within a few months. Over time, it will likely be possible to generate very specific risk scores for each patient type who calls in to such a telephone center. ■

Sonography of the Hip-joint by the Emergency Physician (SHEP): Its Role in the Evaluation of Children Presenting With Acute Limp

Citation: Shavit I, Eidelman M, Galbraith, R. *Pediatr Emerg Care*. 2006;22:570-573.
<http://www.pec-online.com/pt/re/pec/abstract.00006565-200608000-00007.htm;jsessionid=GzLQJslJ1cjXmvSlJfpPoz-Mp3y83n2DNYzMgNI2j58S9sQjh7Rhh!740363489!-949856144!8091!-1>

Key point: SHEP has the potential to identify critical diagnoses such as septic arthritis and osteomyelitis of the femur.

This paper describes a new imaging bedside test called Sonography of the Hip-joint by the Emergency Physician (SHEP) and considers whether its use as a triage tool for the presence of fluid in the hip joint can guide the emergency physician to the right diagnosis.

This was a case series of five children who presented to the ED with an acute onset of limp. In addition to a careful clinical history and physical examination, each child received SHEP. Follow-up confirmed that the presumptive diagnosis made in the ED was correct. The SHEP tests were found helpful in diagnosing transient synovitis (three cases), septic arthritis (one case), and osteomyelitis of the femur (one case).

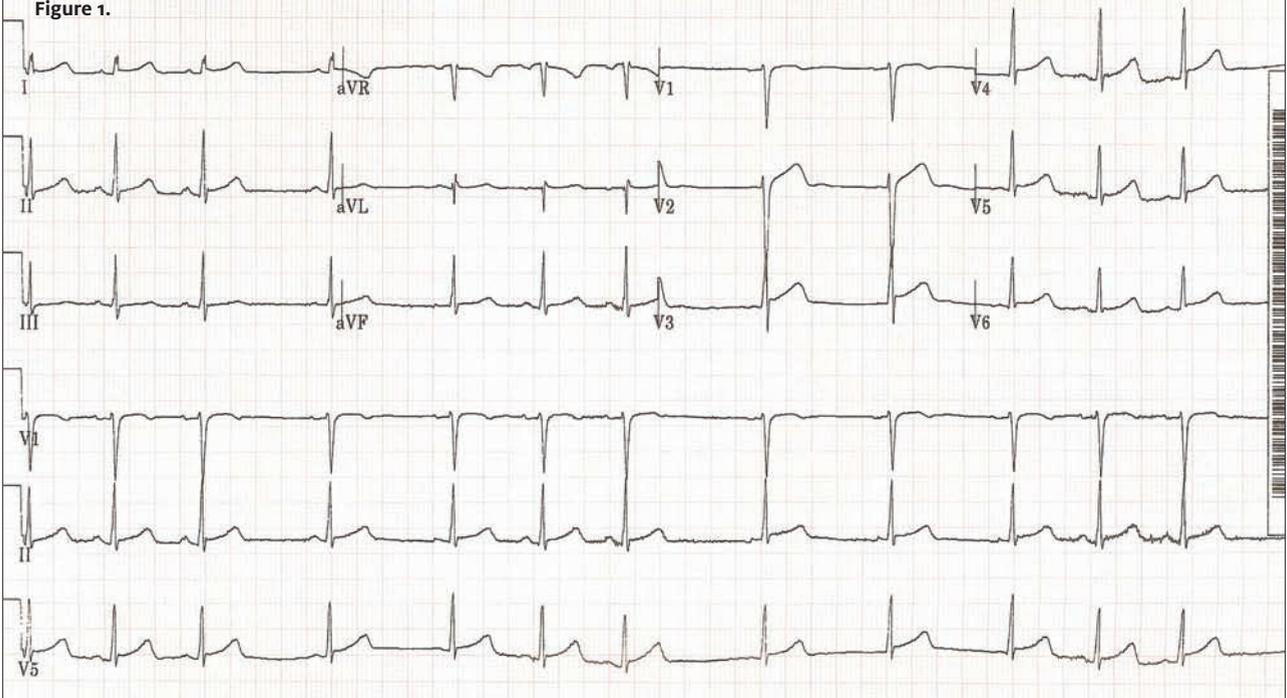
As such, the SHEP tests provided additional information that narrowed the differential diagnosis, and minimized unnecessary blood tests and diagnostic imaging studies.

Comment: The ER physician continues to increase his/her per-
 vue when performing advanced testing in the ER. Today, ER physicians use ultrasonography to identify free fluid in the abdomen, assess pregnancies, look for renal stones, and more. In practical terms, rather than wait for radiological services (or support the extra cost of an onsite radiologist in the ER), an ER physician can personally "wave a wand" over the patient and make a diagnosis. Ultrasonography training is incorporated into most ER residencies today and in a busy ER, the residents and attendings get enough experience to develop clear expertise in ER-appropriate ultrasounds. This trend should reduce time to diagnosis and treatment times. ■



Acute Pericarditis in a 12-Year-Old Girl

Figure 1.



M.J. is a 12-year-old African American female who presented with trouble “taking a breath” which was abrupt in onset, starting two hours prior to presenting and accompanied with abdominal pain and fatigue which resolved prior to her visit. Dyspnea was constant and not related to position. There were no alleviating or aggravating factors.

Observations and Findings

Patient was alert and in no distress and spoke in full sentences.

Pmhx: bronchitis one year prior; no asthma, no cardiac problems, no sickle cell disease

Meds: none

Social hx: no drugs or tobacco

Ros: no fever, lethargy, headaches, chest tightness, cough, wheezing, foreign body aspiration, abd pain, vomiting, back pain, dysuria, polyuria, polydipsia, rashes, swollen glands, extremity pain, falls, or injuries

Physical: t-98.7, p74, rr12, bp 98/60, o2 sat 97% ra

Resp: ctab no crackles or wheezes

Cor: rrr, no m/r/g were appreciated

Diagnostic testing: CXR revealed a normal mediastinal silhouette, clear lung fields with no consolidation, effusion or pneumothorax. All other structures intact. EKG is shown for your review (Figure 1).

Diagnosis

Acute pericarditis was determined by EKG, which reveals sinus rhythm with sinus arrhythmia, and diffuse ST segment elevation in at least two limb leads and all chest leads, especially v3-v6. Lastly, no ST-segment reciprocal changes, no Q-wave features, and T-waves are prominent and upright.

Discussion

Pericarditis is an acute or chronic inflammation of the pericardi-

um. It is more common in males and most common in adolescents and young adults. Causes could include AMI or post-MI (Dressler's syndrome), be viral (coxsackie B, HIV) or bacterial in nature, or be related to collagen vascular disease, radiotherapy, local carcinoma, tuberculosis, uremia, or drugs (e.g., hydralazine, methyldopa, minoxidil, procainamide).

The most common type is fibrous and serofibrous occurring from AMI, uremia, radiation, RA, SLE, or trauma. Other types include serous, purulent, hemorrhagic and caseous.

Clinical signs: Pericardial friction rub: intermittent, positional best heard when sitting forward at the lower left sternal border, louder on inspiration. This can be difficult to detect and is present in approximately 50% of cases. Classical features of pericarditis are pericardial pain, friction rub, and a concordant ST elevation.

Differential diagnosis: Myocardial infarction, angina, aortic dissection, dyspepsia, pneumothorax.

Testing: EKG, CXR (useful to detect pneumothorax and pericardial effusion), PPD, HIV, ESR, CK, troponin (may be elevated in viral), ANA, RF, 2d-echo, CT/MRI.

Symptoms: Sharp, central, retrosternal precordial pain that is worse with deep inspiration, change in position, or exercise. May be sudden or gradual onset. May be relieved with sitting forward, or worse with lying back. Dyspnea is common, as are dry cough and dysphagia. Low-grade fever is a common finding. Patients could present with abdominal pain or just fatigue or malaise.

Treatment

Options range from no treatment with bed rest to anti-inflammatories (e.g., ibuprofen, indocin, prednisone), hospitalization (pericardiocentesis), or surgery (pericardiectomy), depending on age, severity and underlying cause.

Course of illness: Episodes may last one to three weeks; future episodes can occur. One in five people have recurrence within months of original episode. Repeated episodes may be treated with colchicine.

Possible complications include pericardial effusion and cardiac tamponade.

Patient Course

M.J. was sent to the ER for further evaluation. An echo revealed no effusion. Initial workup labs were negative, and the patient was discharged home on NSAIDs with close follow-up. Of note: No instigating cause for this patient's illness was found but a viral source is suspected. ■

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



Share Your Insights

At its core, **JUCM**, *The Journal of Urgent Care Medicine* is a forum for the exchange of ideas and a vehicle to expand on the core competencies of urgent care medicine.

Nothing supports this goal more than **Insights in Images**, where urgent care practitioners can share the details of actual cases, as well as their expertise in resolving those cases. After all, in the words ofUCAOA Executive Director Lou Ellen Horwitz, everyday clinical practice is where “the rubber meets the road.”

Physicians, physician assistants, and nurse practitioners are invited to submit cases, including x-rays, EKGs, or photographic displays relating to an interesting case encountered in the urgent care environment. Submissions should follow the format presented on the preceding pages.

If you have an interesting case to share, please e-mail the relevant images and clinical information to editor@jucm.com. We will credit all whose submissions are accepted for publication.

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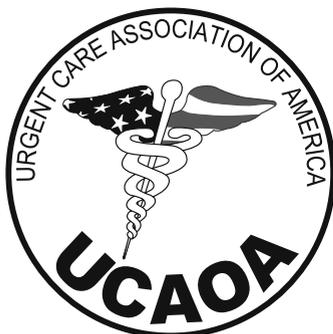
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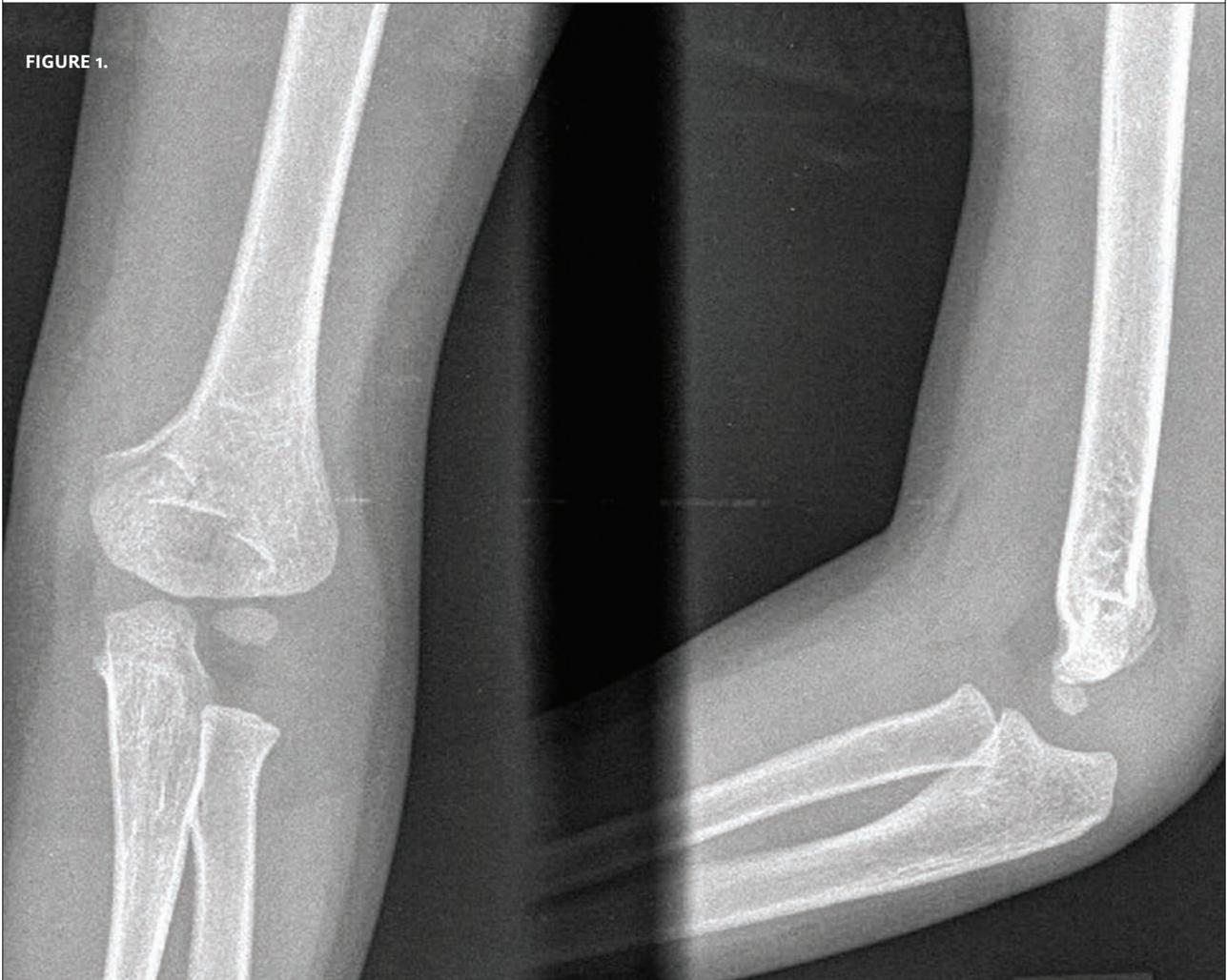


CLINICAL CHALLENGE: CASE 1

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

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

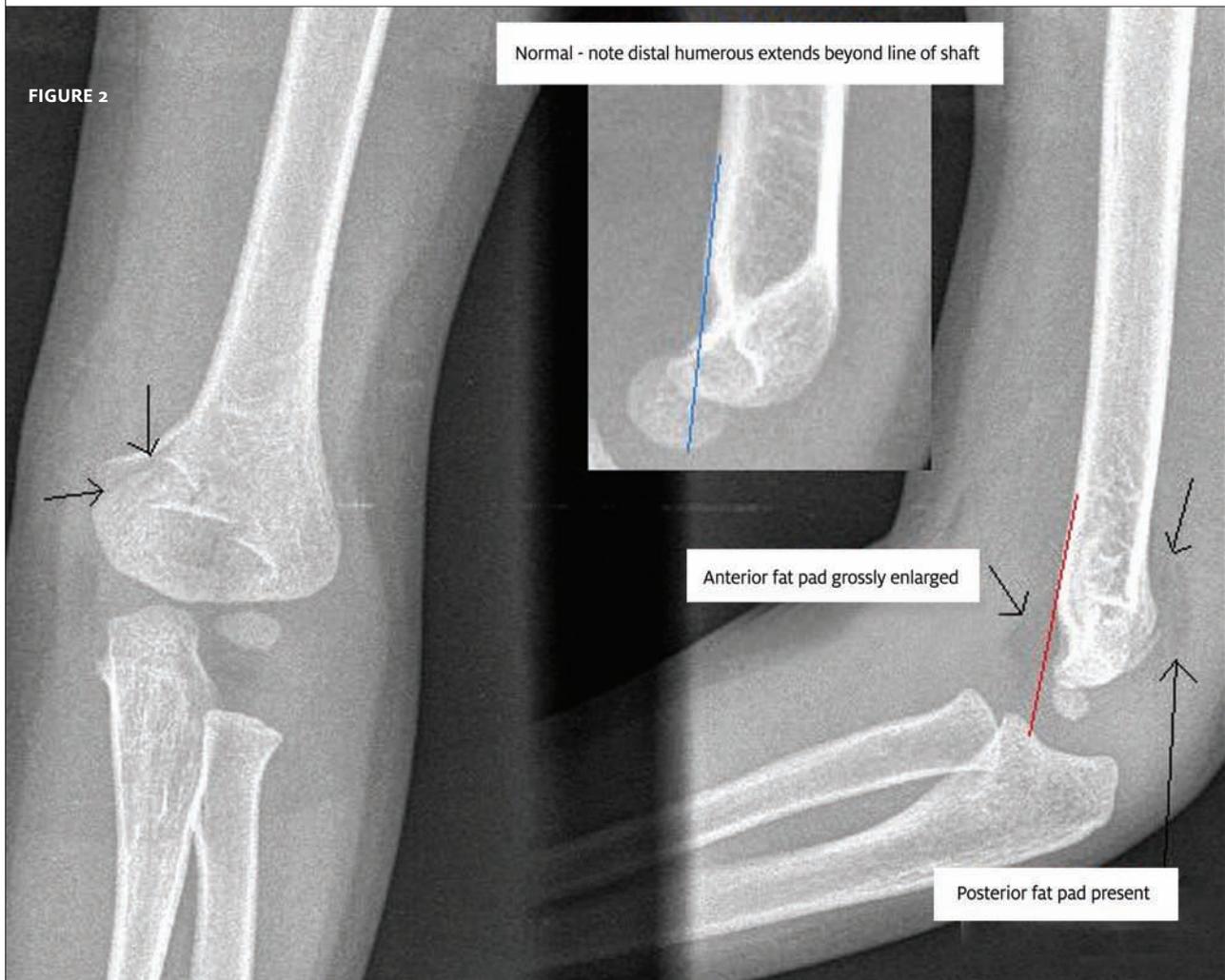
FIGURE 1.



A 3-year-old boy presents to your urgent care center two hours after taking a fall of approximately 1.5 feet. He is experiencing pain in his elbow, which is swollen. Distal pulses and sensation and grip strength are normal.

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

FIGURE 2



THE RESOLUTION

The correct diagnosis is supracondylar fracture, a relatively common elbow fracture in children between 2 and 12 years of age. It is most often the result of a fall.

In the inset in **Figure 2**, note the posterior deviation of the distal humerus as compared with the normal image, and that the anterior fat pad is grossly enlarged.

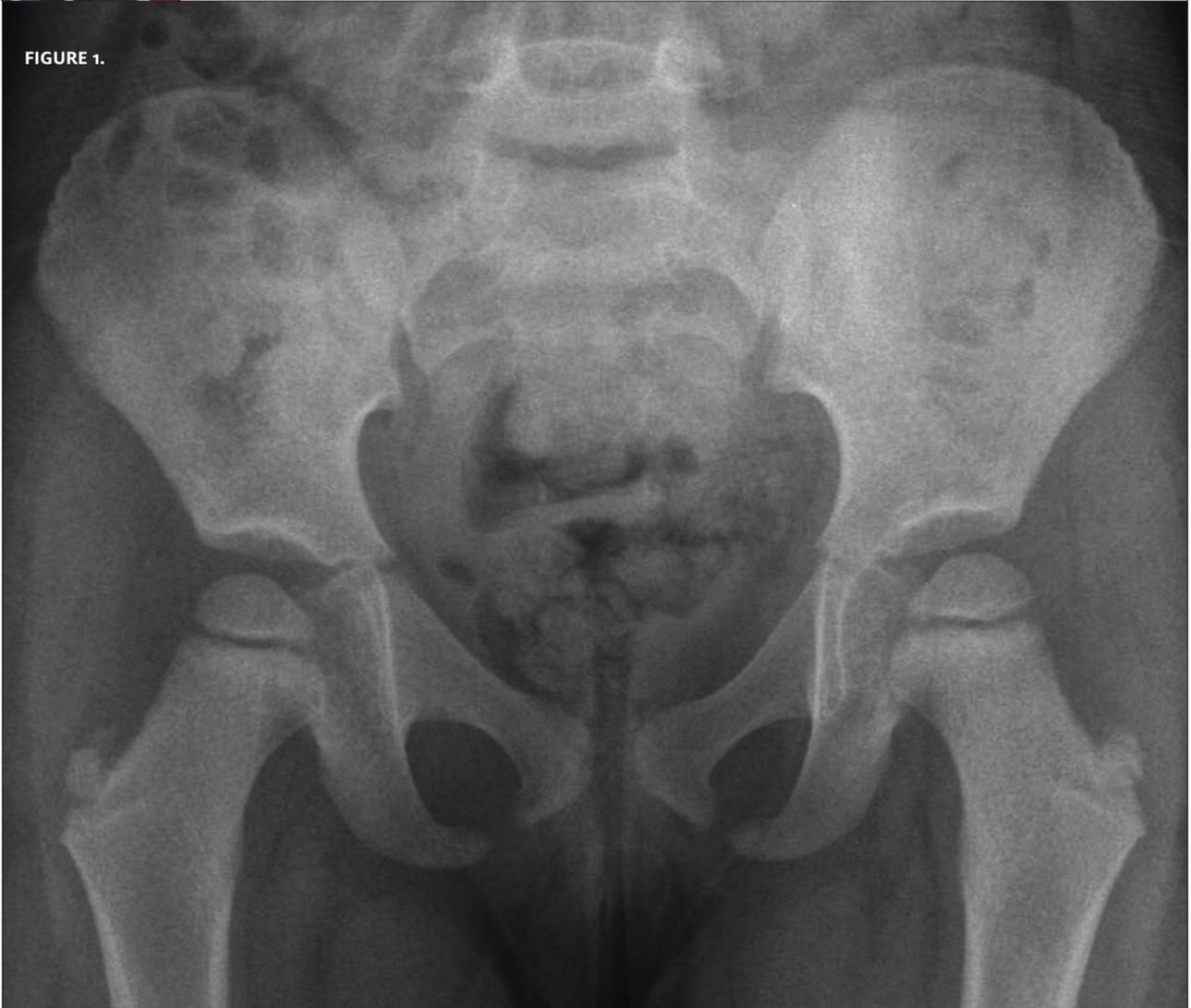
This patient should be referred for immediate orthopedic assessment.

In the absence of displacement of the bone or the fat pads, treatment is usually limited to immobilization of the arm. A splint will probably be used for approximately three weeks. If the fracture is displaced, however, the bones will need to be reduced. Appropriate pain medication may be prescribed depending on the level of the child's pain. Acetaminophen is often given for mild pain.

Acknowledgment: Case presented by Fred Carol, MD, who treated and referred the patient described.



FIGURE 1.



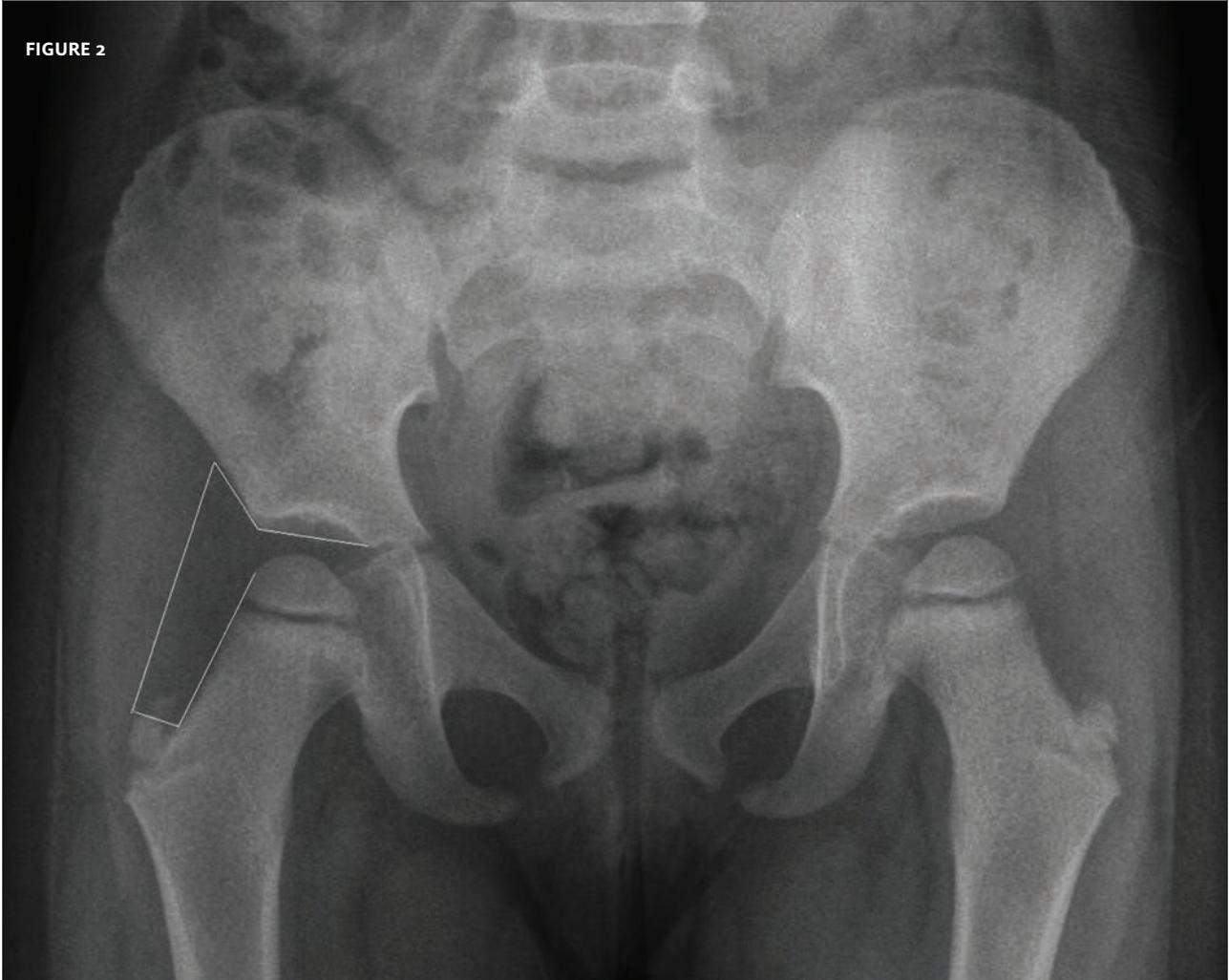
A 3-year-old girl presents to the urgent care center with right hip pain. She has no fever, and the parents report there was no trauma. The child has a limp and reproducible pain on external rotation of the right hip.

White blood count is 11,900 with 40.7% lymphs. The erythrocyte sedimentation rate

(ESR) is 3 mm/hour. The x-ray (**Figure 1**) shows fluid around the right hip joint; this finding was confirmed by ultrasound.

View the x-ray and consider what your next steps would be. Resolution of the case is described on the next page.

FIGURE 2



THE RESOLUTION

The correct diagnosis is transient synovitis. The child was discharged home on ibuprofen with planned follow-up the next day, and clear instructions to return if there was any worsening.

Transient synovitis is a self-limited disease with no expected long-term complications. It tends to occur in children between 2- and 9-years-old. Typically, the patient will complain of hip pain on one side and exhibit a limp. Thigh pain, knee pain, and low-grade fever (<101 degrees F) may also be present.

As indicated on the previous page, appropriate steps for the clinician to take upon presentation include WBC, ESR, x-ray, and ultrasound.

Pain most often resolves within 10 days or less. Treatment may include limiting the child's activity to make him or her more comfortable. However, there is no danger associated with performing normal activities. Nonsteroidal anti-inflammatory medications may be prescribed to reduce pain.

Acknowledgment: Case presented by Scott Field, MD, who treated and referred the patient described.



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Only Tussionex® provides proven 12-hour cough relief*

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

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

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

*Based on pharmacokinetic data.¹

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

Please see adjacent page for full Prescribing Information.

Please visit www.tussionex.com

 Marketed by UCB, Inc.
Manufactured by UCB Manufacturing, Inc.

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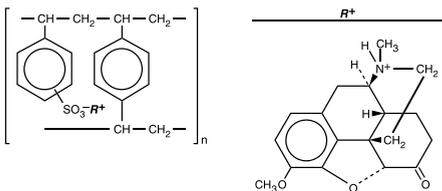
 Tussionex® III
Pennkinetic®
(hydrocodone polistirex/
chlorpheniramine polistirex)
Extended-Release Suspension

Cough relieved. Rest assured.™

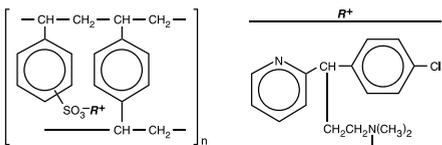


DESCRIPTION: Each teaspoonful (5 mL) of TUSSIONEX Pennkinetic Extended-Release Suspension contains hydrocodone polistirex equivalent to 10 mg of hydrocodone bitartrate and chlorpheniramine polistirex equivalent to 8 mg of chlorpheniramine maleate. TUSSIONEX Pennkinetic Extended-Release Suspension provides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

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



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



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

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

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

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

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

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

CONTRAINDICATIONS: Known allergy or sensitivity to hydrocodone or chlorpheniramine.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from TUSSIONEX Pennkinetic Extended-Release Suspension, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness of TUSSIONEX Pennkinetic Extended-Release Suspension in pediatric patients under six have not been established (see WARNINGS).

Geriatric Use: Clinical studies of TUSSIONEX did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

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

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

Dermatologic System: Rash, pruritus.

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

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

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

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

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

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

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

DOSAGE AND ADMINISTRATION: Shake well before using.

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

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

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

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

NDC 53014-548-67 473 mL bottle

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

CELLTECH

Celltech Pharmaceuticals, Inc.
Rochester, NY 14623 USA

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

Rev. 12/02
LR242A

A Delicate Balance

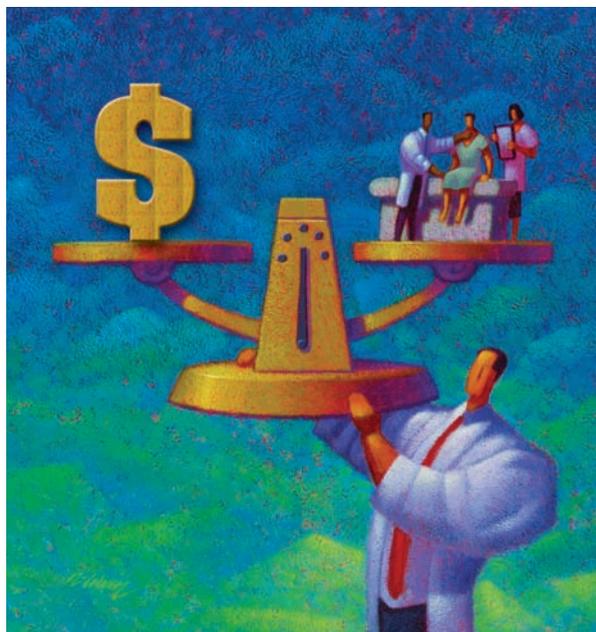
Managing Your Practice, Caring for Your Patients

Urgent message: The challenge of running a successful business can be daunting for any entrepreneur. It's especially tough when your first priority is maintaining excellence as a clinician. The right approach to financial issues can help your business run smoothly—and profitably—while allowing you to focus on caring for patients.

Kevin J. Ralofsky, MBA, Founder of MedCapital and Treasurer of the Urgent Care Association of America

Ask an urgent care physician-owner what the biggest financial obstacle he or she faces is and the answer is likely to be “declining reimbursements.” But what if you found out there is an even bigger challenge to your financial survival—one that is simultaneously global and internal, and one that may be going unnoticed because it's right under our collective noses?

The fact is that this challenge is the very essence of running an urgent care practice: Physician-owners must look at urgent care not only as a clinical practice, but also as a business entity that has the possibility of real loss when neglected and well-deserved profits if managed consistently and carefully. Physicians need to focus on the practice of being an entrepreneur *as well* as a care provider. And the reality is that there are times



when the physician-owner must focus more on the practice of business management in urgent care.

This does not mean devoting less time to your primary mission; there are several ways that physician-owners can be directly involved in the business of urgent care without sacrificing patient care. A constant and gentle balance can be achieved by adopting a few simple practices that will be explained in this article:

- Routinely reviewing flash reports (customized reports that allow you to see the financial health of your business in areas that interest you, packaged as a timely, redundant flow of information)
- Monitoring the payments at the time of service (PATOS) or copays
- Understanding and managing the roller coaster

known as cash flow

- Developing and executing a business marketing plan and business plan
- “Negotiating smart” on lease and loan terms

Keep Your Finger on the Pulse of the Business

Good information will yield good decision-making for your business. I recommend that any business operating for less than six months review flash reports daily; all other businesses should review them weekly.

Key financial indicators in urgent care are comprised of some very basic metrics, as well as more complex ones. At minimum, urgent care owners should be focusing on the following metrics to help build their customized flash report:

Daily Metrics

Patient count – Measures the number of patients who are treated on a daily basis.

Charges – Measures the daily charge volume for all patients seen for a given day.

PATOS – Measures the actual revenue collected from patients at time of service (i.e., copays, generic Rx, ancillary services paid in cash, durable medical equipment, etc.).

Collections – Measures the amount of revenue collected from all other sources (i.e., insurance companies, patient responsibility, occupational medicine revenue from industrial clients, etc.).

Accounts receivable aging – Measures the total revenue that is due your business, broken down into “buckets” (or time).

Weekly Metrics

Procedure count – This can measure the number of specific procedures that are done on a daily or weekly basis.

Checks written – This metric will keep you informed about any money leaving your business.

Other important metrics to monitor are payroll reports, variable expenses, relative value units, personnel costs and benefits, company credit card spending, miscellaneous expenses, employee overtime, and office and medical supply costs. (A relative value unit, or RVU, is a numerical system for describing the value of a medical procedure for the purpose of assigning a

price or a charge. The term “relative value” stems from the idea that each service’s unit value could be measured in relation to the value of other services. A practice can derive its fees by multiplying the unit values by a dollar conversion factor to arrive at a fee or allowable payment.)

Know Every Dollar Collected at Time of Service

Collecting every dollar that you can at time of service helps to expedite cash flow efficiency, in some cases, by 60 days. Additionally, a patient’s copay amount often represents 25% to 40% of the total collected revenue for that visit.

This practice also helps to increase your personnel’s productivity while reducing the burden on the collection staff. Effective collection of copays at the time of service forces your patient to be part of the utilization management. After all, do you want the bill you sent to your patient to compete with the credit card bill or phone bill? Chances are your bill is

one of the last to be paid.

In addition, if the patient does not frequent your facility or if there are other urgent care facilities in your market, the patient may be inclined to go to your competition because they have not settled the bill with your office.

Effective collection of copays takes time and effort. There can be significant hurdles in determining a copay for a patient’s insurance. Insurance companies do not make it easy to verify coverage or copay amounts. There are subscriptions from third-party vendors that you can buy to simplify verifying insurance eligibility and to make it easier for your medical staff to collect copays.

Another hurdle to overcome is largely internal. Some practices I have worked with have had staff that refused to collect copays because (in their view) “asking for money is bad customer service” or because they are “uncomfortable asking for money before the patient is seen.”

This issue is one of culture. Employee concerns can be overcome with training, constant reinforcement, goal setting, education, and in some cases, reorganization. A staff’s positive attitude is paramount to patient service and will set the tone for the whole office visit.

Some offices will not treat patients unless they have paid their copay and settled the balance from past visits.

“A staff’s positive attitude is paramount to patient service and will set the tone for the whole office visit.”

Others will bill patients the copay amount plus a penalty fee for not paying (usually to cover the cost of the bill sent to the patient). Still others do not collect any copays at time of service and bill the patient after the visit.

These decisions are dependent on how you want to operate your business. However, do not be confused about doing what's right for your business and what you or your employees perceive to be good customer service. Executing a strict copay policy takes time and commitment. Set realistic goals (e.g., collect 75% of all potential copays daily the first month this procedure is instituted and work up to a 95% collection rate) and use signs, brochures, and other reminders to help reinforce the policy. Over time, patients will just come to simply expect this as part of the process and you will see a dramatic effect to your accounts receivable balance, as well as a decreased burden on your collection staff.

Understanding the Cash-Flow Roller Coaster

Often, the need for interim, short-term funding comes as a surprise to urgent care owners. Depending on the services provided, most urgent care facilities will experience seasonal ebbs and flows in their business. The billing staff is challenged on an ongoing basis with denials and rejections, forcing accounts receivable farther out on the horizon. Payroll seems to always tighten the purse strings in any business. Quarterly payments for medical malpractice premiums, employee bonuses, and other large expenses can temporarily paralyze an organization.

Understanding cash flow as it pertains to your business is necessary in order to operate on a daily basis, as well as to plan for expansion and growth. If your company does not have access to short-term financing (for example, a business line of credit), you should reconsider if you will be able to weather a financial hiccup in your business. You can usually obtain a small line of credit (under \$100,000) based on your personal credit and signature if you are a single owner/practitioner. For larger organizations, you can usually borrow up to 85% of the total accounts receivable balance.

Offering a wider array of services in addition to episodic sick care can also help you maintain a consistent cash flow in the business. If your facility is in a light-to heavy industrial area, occupational medicine servic-

es such as drug testing (alcohol and blood), breath alcohol testing, employee physicals, hearing tests, and worker injury care can dramatically even out cash flow, as some of these tests can be scheduled in the months during which patient volume typically tapers off.

In order to get a strong hold on cash flow, I recommend that you engage your accounting team in the process. Have regular meetings with your accountant or chief financial officer. Ask them to help you understand what your financial needs are in the short and long term. Challenge them to help you make your business run more smoothly.

In addition, good billing and collection practices, collecting copays at the time of service, and offering pay-for-performance bonuses can help to smooth out cash-flow needs.

Go Through the Motions

Writing a business plan can be one of the most difficult and daunting tasks for any physician owner, CEO, or CFO. However, it is a necessary process in starting, managing,

and growing your business.

Ninety percent of my clients (who were already operating before we engaged in a contract) started their business, be it a single-provider practice or a hospital-based urgent care clinic, without the existence of a business plan. This, in my opinion, is one of the biggest and most crucial mistakes that you can make (the second one being not keeping your business plan up to date with your company's current goals).

You need to think of your business plan as your roadmap for success. When done effectively, you will have a written plan that explains what your business is, where it came from (if already in existence), and where you want to take it. By adding past and projected financials, you have documented data that you can use to make crucial decisions as well as share with prospective investors, partners, or bankers.

If you are not comfortable writing a business plan on your own, there are many resources to assist you. Often, your accountant can help you with parts of the plan; however, some may not want to advise you on certain parts of the financial plan so as not to make any false representations as to future earnings.

You may also get off to a good start by buying business plan software; however, many bankers and investors will know a "canned" business plan when they see

“Offering a wider array of services in addition to episodic sick care can also help you maintain a consistent cash flow.”

one, as the finished product may lack originality and look as though not much thought went into it.

Think of your potential audience and decide from there. You may want to contract with a firm specializing in business plan generation. Keep in mind that it is more important to seek the help of someone who knows the industry of urgent care than it is to understand the process of writing a business plan. When analyzing a business plan, content and realistic expectations are more important than the overall visual presentation of the general components to call it a business plan.

From Pain to Progress

Most often, change is inspired by some degree of “pain.” Pain could manifest itself in many forms: decreased reimbursements, higher malpractice premiums, staffing problems, unwelcome competition, or even lack of capacity for business growth.

A good friend taught me a valuable lesson. He once told me, “*Change happens when the pain of change is less than the pain of doing nothing.*” What he meant is that most businesses will be pushed to make a change when the prospect of changing seems less harmful than if they did not change at all. A business plan will help to prioritize and compartmentalize your businesses goals, strengths, and shortcomings and ultimately guide you through the “pain” of everyday business and make change easier to understand and execute.

“Negotiate Smart” on Leases and Loans

If you speak with any respectable real estate investor, he will tell you that the profit in a deal is made at the time of the purchase, not the sale. That is, you can control many more variables at the time of the purchase than when actually marketing and selling the real estate. This is often true when obtaining financing via a lease or a loan. Smart negotiation and understanding the factors that can affect a business’s overall risk and exposure will ultimately reduce the risk of loss.

When there is a need for business financing, either via a business loan or a lease, negotiating smart up front can save time and money and reduce business risk and uncertainty.

Many companies selling medical equipment can make it very easy to obtain a lease. Often, they require only a personal signature and a quick credit check for the owners and the business, and no historical financial information is necessary. In addition, you can finance 100% of the cost of the equipment, which

means that there is no money out of pocket, except for the leasing fees.

However, as easy as a lease can be to obtain, leasing may not be the wisest choice for your business.

You will first need to decide which type of financing option is most suitable for each acquisition. I will first say that you should always consult your accountant early in the process. Discuss different scenarios (lease vs. buy) and how each will affect the business’s tax position and its owners as it pertains to their personal tax situation. Focus on the overall tax advantages or consequences, and how cash flow will be affected.

Following are a few tips for financing via a traditional bank loan and lease:

Financing with a traditional bank loan

When today’s office or medical equipment is likely to meet long-term needs (say, seven years or more), purchasing is often the most cost-effective acquisition choice. When looking at a bank loan proposal for such a purchase, focus on the term, rate, collateral required, bank fees, and prepayment penalties.

Make sure the term of the loan matches the useful life of the asset that you are purchasing. You do not want to continue to pay a monthly loan payment on a piece of equipment that is obsolete. In addition, the rate of the loan needs to be competitive. You can verify this by obtaining other proposals from other lenders.

Pay attention to whether you are required to personally guarantee the loan or if the equipment itself is enough collateral to satisfy the requirements of the deal. In any case, shoot for not signing a personal guarantee; however, offering one can be a very powerful and useful bargaining tool.

Banks count on fees for a large part of their profit, so do not be surprised if you are asked to pay a fee to finance the deal. Fees are often quoted in terms of “points.” That is, one “point” is equal to 1% of the total amount financed. Points are very common when financing real estate or a larger piece of equipment. Points are often negotiable and can be waived based on your company’s business relationship with the bank or in the midst of a competing bid from another bank. On a larger financing deal, try not to pay for more than one point. For example, if you are financing a new medical office building at a cost of \$1 million, a one-point fee will cost you \$10,000.

Last, obtain a loan that does not have a pre-payment penalty provision. This can be very costly for you but can usually be stricken from the loan very easily.

Obtaining a Lease

If your needs are likely to change within the next few years, leasing may be the smarter alternative. Leasing allows you to acquire the equipment you need today and use it cost-effectively until it no longer meets your needs, then upgrade without dealing with it being outdated and obsolete.

Leasing can be easier on cash flow and allow you to upgrade equipment more easily. However, there are some simple pitfalls to avoid when leasing equipment.

As you would when using traditional financing, make sure the term of the lease matches the expected life of the equipment. You may find yourself wanting to upgrade but still have to pay the lease out through the last payment. Look for leases that have a built-in allowance for periodic upgrades.

Focus on the residual value—defined as the amount for which a company expects to be able to sell the fixed asset (the piece of equipment) at the end of its useful life—which will ultimately dictate how much that asset has depreciated.

That is, the inverse of the residual value is the depreciated value. In a lease, you do not finance and pay for the total equipment cost; rather, you pay only for the actual amount that you use, or the depreciated value. If you compared two leases with different residual values and all the other factors (term, fees, lease rate factor) were equal, your lease payment would be less with the lease that valued the asset more highly at the end of the lease. (See the box above for a more detailed explanation of residual value.)

Pay attention to the “money factor” when evaluating leases, too. Lease payments are computed by amortizing the depreciation amount over the lease term and applying an interest rate (called the money factor) to the obligation.

Since you will not usually see a stated interest rate in the standard lease contract, it must be computed in order to properly evaluate and compare leasing options. Leasing companies must disclose either the money factor or the interest rate for you.

Most leasing companies will try to confuse you by quoting the money factor as a larger decimal such as

Understanding Residual (or Fair Market) Value

Essentially, the leasing company will assign a predetermined maximum amount for the residual value because it mitigates their risk. For example, if you leased a piece of x-ray equipment with an original value of \$80,000, the lessor may state that the fair market value, or residual value, will not be more than 10% of the original cost, or \$8,000. In other words, the depreciation—at minimum—is going to be \$72,000, which basically is what you finance in a lease. Look for leases with higher residual, or fair market, value.

3.04, which really means .00304, because it sounds like a more attractive annual interest rate. Converting this to a standard interest rate in terms more familiar to you can help you avoid excessive interest expense during the term of the lease.

Leasing converters and calculators can be found on the internet and are a good tool in helping you get comfortable with leasing

money factors. Or, you can do the conversion yourself simply by multiplying the money factor by 2400 (it is always 2400 and is not related to the length of the loan in months). For example, a money factor of .00304 multiplied by 2400 converts to a corresponding rate of 7.3%.

Last, inquire as to the buyout options on the lease. If you needed to terminate the lease contract early, what are your options? Leases will have a payoff provision equal to the fair market value of the asset at the time of the payoff, or one that is equal to the remaining payments for the life of the lease.

In the latter case, it would not be wise to pay off the lease because you are essentially accelerating 100% of the principle and interest due through the end of the lease.

Conclusion

While focusing on these issues will allow you to be more in tune with the business of urgent care, this is just a starting point at which the physician-entrepreneur can begin to manage and control the business. As in all endeavors, progress takes time to manifest and only continues to move forward with constant, gentle pressure.

In addition, the “pain” that you experience, be it good or bad, will move you to change and allow you to develop your own set of focused initiatives. These initiatives will be a constant reminder and guide you through the perils of business financial management in the urgent care industry.

In the end, with the financial issues in check, you may be able to more effectively focus on what it is that you do best—care for patients who need your expertise as a clinician. ■

known as cash flow

- Developing and executing a business marketing plan and business plan
- “Negotiating smart” on lease and loan terms

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Key financial indicators in urgent care are comprised of some very basic metrics, as well as more complex ones. At minimum, urgent care owners should be focusing on the following metrics to help build their customized flash report:

Daily Metrics

Patient count – Measures the number of patients who are treated on a daily basis.

Charges – Measures the daily charge volume for all patients seen for a given day.

PATOS – Measures the actual revenue collected from patients at time of service (i.e., copays, generic Rx, ancillary services paid in cash, durable medical equipment, etc.).

Collections – Measures the amount of revenue collected from all other sources (i.e., insurance companies, patient responsibility, occupational medicine revenue from industrial clients, etc.).

Accounts receivable aging – Measures the total revenue that is due your business, broken down into “buckets” (or time).

Weekly Metrics

Procedure count – This can measure the number of specific procedures that are done on a daily or weekly basis.

Checks written – This metric will keep you informed about any money leaving your business.

Other important metrics to monitor are payroll reports, variable expenses, relative value units, personnel costs and benefits, company credit card spending, miscellaneous expenses, employee overtime, and office and medical supply costs. (A relative value unit, or RVU, is a numerical system for describing the value of a medical procedure for the purpose of assigning a

price or a charge. The term “relative value” stems from the idea that each service’s unit value could be measured in relation to the value of other services. A practice can derive its fees by multiplying the unit values by a dollar conversion factor to arrive at a fee or allowable payment.)

Know Every Dollar Collected at Time of Service

Collecting every dollar that you can at time of service helps to expedite cash flow efficiency, in some cases, by 60 days. Additionally, a patient’s copay amount often represents 25% to 40% of the total collected revenue for that visit.

This practice also helps to increase your personnel’s productivity while reducing the burden on the collection staff. Effective collection of copays at the time of service forces your patient to be part of the utilization management. After all, do you want the bill you sent to your patient to compete with the credit card bill or phone bill? Chances are your bill is

one of the last to be paid.

In addition, if the patient does not frequent your facility or if there are other urgent care facilities in your market, the patient may be inclined to go to your competition because they have not settled the bill with your office.

Effective collection of copays takes time and effort. There can be significant hurdles in determining a copay for a patient’s insurance. Insurance companies do not make it easy to verify coverage or copay amounts. There are subscriptions from third-party vendors that you can buy to simplify verifying insurance eligibility and to make it easier for your medical staff to collect copays.

Another hurdle to overcome is largely internal. Some practices I have worked with have had staff that refused to collect copays because (in their view) “asking for money is bad customer service” or because they are “uncomfortable asking for money before the patient is seen.”

This issue is one of culture. Employee concerns can be overcome with training, constant reinforcement, goal setting, education, and in some cases, reorganization. A staff’s positive attitude is paramount to patient service and will set the tone for the whole office visit.

Some offices will not treat patients unless they have paid their copay and settled the balance from past visits.

“A staff’s positive attitude is paramount to patient service and will set the tone for the whole office visit.”

Others will bill patients the copay amount plus a penalty fee for not paying (usually to cover the cost of the bill sent to the patient). Still others do not collect any copays at time of service and bill the patient after the visit.

These decisions are dependent on how you want to operate your business. However, do not be confused about doing what's right for your business and what you or your employees perceive to be good customer service. Executing a strict copay policy takes time and commitment. Set realistic goals (e.g., collect 75% of all potential copays daily the first month this procedure is instituted and work up to a 95% collection rate) and use signs, brochures, and other reminders to help reinforce the policy. Over time, patients will just come to simply expect this as part of the process and you will see a dramatic effect to your accounts receivable balance, as well as a decreased burden on your collection staff.

Understanding the Cash-Flow Roller Coaster

Often, the need for interim, short-term funding comes as a surprise to urgent care owners. Depending on the services provided, most urgent care facilities will experience seasonal ebbs and flows in their business. The billing staff is challenged on an ongoing basis with denials and rejections, forcing accounts receivable farther out on the horizon. Payroll seems to always tighten the purse strings in any business. Quarterly payments for medical malpractice premiums, employee bonuses, and other large expenses can temporarily paralyze an organization.

Understanding cash flow as it pertains to your business is necessary in order to operate on a daily basis, as well as to plan for expansion and growth. If your company does not have access to short-term financing (for example, a business line of credit), you should reconsider if you will be able to weather a financial hiccup in your business. You can usually obtain a small line of credit (under \$100,000) based on your personal credit and signature if you are a single owner/practitioner. For larger organizations, you can usually borrow up to 85% of the total accounts receivable balance.

Offering a wider array of services in addition to episodic sick care can also help you maintain a consistent cash flow in the business. If your facility is in a light-to heavy industrial area, occupational medicine servic-

es such as drug testing (alcohol and blood), breath alcohol testing, employee physicals, hearing tests, and worker injury care can dramatically even out cash flow, as some of these tests can be scheduled in the months during which patient volume typically tapers off.

In order to get a strong hold on cash flow, I recommend that you engage your accounting team in the process. Have regular meetings with your accountant or chief financial officer. Ask them to help you understand what your financial needs are in the short and long term. Challenge them to help you make your business run more smoothly.

In addition, good billing and collection practices, collecting copays at the time of service, and offering pay-for-performance bonuses can help to smooth out cash-flow needs.

Go Through the Motions

Writing a business plan can be one of the most difficult and daunting tasks for any physician owner, CEO, or CFO. However, it is a necessary process in starting, managing,

and growing your business.

Ninety percent of my clients (who were already operating before we engaged in a contract) started their business, be it a single-provider practice or a hospital-based urgent care clinic, without the existence of a business plan. This, in my opinion, is one of the biggest and most crucial mistakes that you can make (the second one being not keeping your business plan up to date with your company's current goals).

You need to think of your business plan as your roadmap for success. When done effectively, you will have a written plan that explains what your business is, where it came from (if already in existence), and where you want to take it. By adding past and projected financials, you have documented data that you can use to make crucial decisions as well as share with prospective investors, partners, or bankers.

If you are not comfortable writing a business plan on your own, there are many resources to assist you. Often, your accountant can help you with parts of the plan; however, some may not want to advise you on certain parts of the financial plan so as not to make any false representations as to future earnings.

You may also get off to a good start by buying business plan software; however, many bankers and investors will know a "canned" business plan when they see

“Offering a wider array of services in addition to episodic sick care can also help you maintain a consistent cash flow.”

one, as the finished product may lack originality and look as though not much thought went into it.

Think of your potential audience and decide from there. You may want to contract with a firm specializing in business plan generation. Keep in mind that it is more important to seek the help of someone who knows the industry of urgent care than it is to understand the process of writing a business plan. When analyzing a business plan, content and realistic expectations are more important than the overall visual presentation of the general components to call it a business plan.

From Pain to Progress

Most often, change is inspired by some degree of “pain.” Pain could manifest itself in many forms: decreased reimbursements, higher malpractice premiums, staffing problems, unwelcome competition, or even lack of capacity for business growth.

A good friend taught me a valuable lesson. He once told me, “*Change happens when the pain of change is less than the pain of doing nothing.*” What he meant is that most businesses will be pushed to make a change when the prospect of changing seems less harmful than if they did not change at all. A business plan will help to prioritize and compartmentalize your businesses goals, strengths, and shortcomings and ultimately guide you through the “pain” of everyday business and make change easier to understand and execute.

“Negotiate Smart” on Leases and Loans

If you speak with any respectable real estate investor, he will tell you that the profit in a deal is made at the time of the purchase, not the sale. That is, you can control many more variables at the time of the purchase than when actually marketing and selling the real estate. This is often true when obtaining financing via a lease or a loan. Smart negotiation and understanding the factors that can affect a business’s overall risk and exposure will ultimately reduce the risk of loss.

When there is a need for business financing, either via a business loan or a lease, negotiating smart up front can save time and money and reduce business risk and uncertainty.

Many companies selling medical equipment can make it very easy to obtain a lease. Often, they require only a personal signature and a quick credit check for the owners and the business, and no historical financial information is necessary. In addition, you can finance 100% of the cost of the equipment, which

means that there is no money out of pocket, except for the leasing fees.

However, as easy as a lease can be to obtain, leasing may not be the wisest choice for your business.

You will first need to decide which type of financing option is most suitable for each acquisition. I will first say that you should always consult your accountant early in the process. Discuss different scenarios (lease vs. buy) and how each will affect the business’s tax position and its owners as it pertains to their personal tax situation. Focus on the overall tax advantages or consequences, and how cash flow will be affected.

Following are a few tips for financing via a traditional bank loan and lease:

Financing with a traditional bank loan

When today’s office or medical equipment is likely to meet long-term needs (say, seven years or more), purchasing is often the most cost-effective acquisition choice. When looking at a bank loan proposal for such a purchase, focus on the term, rate, collateral required, bank fees, and prepayment penalties.

Make sure the term of the loan matches the useful life of the asset that you are purchasing. You do not want to continue to pay a monthly loan payment on a piece of equipment that is obsolete. In addition, the rate of the loan needs to be competitive. You can verify this by obtaining other proposals from other lenders.

Pay attention to whether you are required to personally guarantee the loan or if the equipment itself is enough collateral to satisfy the requirements of the deal. In any case, shoot for not signing a personal guarantee; however, offering one can be a very powerful and useful bargaining tool.

Banks count on fees for a large part of their profit, so do not be surprised if you are asked to pay a fee to finance the deal. Fees are often quoted in terms of “points.” That is, one “point” is equal to 1% of the total amount financed. Points are very common when financing real estate or a larger piece of equipment. Points are often negotiable and can be waived based on your company’s business relationship with the bank or in the midst of a competing bid from another bank. On a larger financing deal, try not to pay for more than one point. For example, if you are financing a new medical office building at a cost of \$1 million, a one-point fee will cost you \$10,000.

Last, obtain a loan that does not have a pre-payment penalty provision. This can be very costly for you but can usually be stricken from the loan very easily.

Obtaining a Lease

If your needs are likely to change within the next few years, leasing may be the smarter alternative. Leasing allows you to acquire the equipment you need today and use it cost-effectively until it no longer meets your needs, then upgrade without dealing with it being outdated and obsolete.

Leasing can be easier on cash flow and allow you to upgrade equipment more easily. However, there are some simple pitfalls to avoid when leasing equipment.

As you would when using traditional financing, make sure the term of the lease matches the expected life of the equipment. You may find yourself wanting to upgrade but still have to pay the lease out through the last payment. Look for leases that have a built-in allowance for periodic upgrades.

Focus on the residual value—defined as the amount for which a company expects to be able to sell the fixed asset (the piece of equipment) at the end of its useful life—which will ultimately dictate how much that asset has depreciated.

That is, the inverse of the residual value is the depreciated value. In a lease, you do not finance and pay for the total equipment cost; rather, you pay only for the actual amount that you use, or the depreciated value. If you compared two leases with different residual values and all the other factors (term, fees, lease rate factor) were equal, your lease payment would be less with the lease that valued the asset more highly at the end of the lease. (See the box above for a more detailed explanation of residual value.)

Pay attention to the “money factor” when evaluating leases, too. Lease payments are computed by amortizing the depreciation amount over the lease term and applying an interest rate (called the money factor) to the obligation.

Since you will not usually see a stated interest rate in the standard lease contract, it must be computed in order to properly evaluate and compare leasing options. Leasing companies must disclose either the money factor or the interest rate for you.

Most leasing companies will try to confuse you by quoting the money factor as a larger decimal such as

Understanding Residual (or Fair Market) Value

Essentially, the leasing company will assign a predetermined maximum amount for the residual value because it mitigates their risk. For example, if you leased a piece of x-ray equipment with an original value of \$80,000, the lessor may state that the fair market value, or residual value, will not be more than 10% of the original cost, or \$8,000. In other words, the depreciation—at minimum—is going to be \$72,000, which basically is what you finance in a lease. Look for leases with higher residual, or fair market, value.

3.04, which really means .00304, because it sounds like a more attractive annual interest rate. Converting this to a standard interest rate in terms more familiar to you can help you avoid excessive interest expense during the term of the lease.

Leasing converters and calculators can be found on the internet and are a good tool in helping you get comfortable with leasing

money factors. Or, you can do the conversion yourself simply by multiplying the money factor by 2400 (it is always 2400 and is not related to the length of the loan in months). For example, a money factor of .00304 multiplied by 2400 converts to a corresponding rate of 7.3%.

Last, inquire as to the buyout options on the lease. If you needed to terminate the lease contract early, what are your options? Leases will have a payoff provision equal to the fair market value of the asset at the time of the payoff, or one that is equal to the remaining payments for the life of the lease.

In the latter case, it would not be wise to pay off the lease because you are essentially accelerating 100% of the principle and interest due through the end of the lease.

Conclusion

While focusing on these issues will allow you to be more in tune with the business of urgent care, this is just a starting point at which the physician-entrepreneur can begin to manage and control the business. As in all endeavors, progress takes time to manifest and only continues to move forward with constant, gentle pressure.

In addition, the “pain” that you experience, be it good or bad, will move you to change and allow you to develop your own set of focused initiatives. These initiatives will be a constant reminder and guide you through the perils of business financial management in the urgent care industry.

In the end, with the financial issues in check, you may be able to more effectively focus on what it is that you do best—care for patients who need your expertise as a clinician. ■



Protecting Yourself Against Medical Malpractice Claims

■ JOHN SHUFELDT, MD, JD, MBA, FACEP

We live and practice medicine in a litigious society. How, then, can providers protect themselves against the threat of financial ruin due to malpractice payouts?

The first and most obvious answer is to not commit malpractice; more about that in a moment. The next most likely answer is for providers to purchase malpractice insurance with limits set high enough to protect their personal assets.

The median medical malpractice award tripled between 1997 and 2004. By 2004, the median award in a malpractice case was \$440,000, and the average was \$607,000. Today, approximately 5% of awards are over \$1 million. Most physicians carry malpractice insurance which is capped at \$1 million per claim and \$3 million in aggregate per year.

When awards exceed that \$1 million per claim cap, however, a physician's personal assets are at risk. And once the threat of catastrophic loss is imminent, it is too late to move money to a safe asset. To that end, it is important to discuss asset protection with your financial advisor *before* those assets are at risk.

Back to solution number one (do not commit malpractice). How is it that some providers manage never to get sued? Clearly, some specialties are lower risk than others. Pathologists, physical medicine specialists, etc., generally skew towards the "better" end of the risk profile.

Unfortunately, for a variety of reasons, urgent care physicians are in the middle of the risk profile. We don't typically have long-term relationships with our patients or their families, we don't respond to their calls in the middle of the night, and our interactions are often "one offs." Moreover, many a serious medical problem starts as a trivial complaint which can be easily missed on first inspection. For example, a middle-aged woman with abdominal pain and a benign abdominal examine may

evolve into a patient whose ischemic bowel took two or three visits to correctly diagnose.

For now, let's focus on how urgent care providers can protect themselves when the odds are stacked against them.

Slow and Steady Wins the Patient's Trust

First and perhaps most obvious is to slow down and spend time with your patients. When a bad outcome is coupled with an interaction with a distracted, harried physician, the result is often litigation. Besides, the most satisfying part of our profession is the time we get to spend caring for others.

Consider the following scene as the patient might view it: Your waiting room is packed, the chairs are close together and uncomfortable, your staff is perceived as uncaring, and the magazines which depict all the things you do in your personal life—travel, fancy cars, and golf—are leftovers from your home. The final nail in the coffin is when the distracted, tired, and overwhelmed provider has one foot out the door during the encounter.

Sound familiar?

Although we recognize that in today's healthcare milieu we are required to do more with less, the patient who is ill should not be forced to carry this burden. Do whatever you can to make the patient more comfortable in your waiting room. Educate your front office staff on customer service and communication skills. Introduce yourself on a first name basis ("Good afternoon; I am very sorry you had to wait to see me. My name is Jim Smith and I am happy to be your doctor.") Shake the patient's hand and sit down in a chair to listen to their story.

Many people who feel ill just want someone to listen to them and validate their concerns. At the end of the encounter, go over your treatment plan for them, allow them to ask questions, and tell them not to hesitate to return if they are not getting better or if they feel worse.

Say "No" without Saying "No"

If the patient demands something that you feel is not in their best

See "Health Law" continued on page 36.



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



Occ Med Programs Need Business Plans, Too

■ FRANK H. LEONE, MBA, MPH

In all likelihood, you wouldn't dream of opening a new urgent care clinic without first putting together a business plan. Doesn't it make sense that key aspects of your overall business would benefit from the same careful planning?

Data from the Urgent Care Association of America indicate that over 60% of urgent care companies offer at least some occupational medicine services; nearly 5% of locations offer occ med exclusively.

Putting a business plan for your occupational health services to paper allows this aspect of your business to move purposefully toward where you want to go, with a cohesive strategy for just how you plan to get there.

The "where you want to go" segment of the plan documents the rationale of your business opportunity, how you plan to respond to that opportunity, and your anticipated financial return. The "how you plan to get there" segment is your sales and marketing plan.

The Rationale

With everything else you have to do, you might be asking "why bother?" The answer is multi-fold:

Developing a plan encourages strategic thinking by you and your team. It is valuable, if not essential, to periodically step away from the fray and re-examine what you are doing, and why and how you are doing it.

The very process of developing a business plan encourages a consensus that gets all parties closer to sitting on the same page.

The back end of a business plan should be a date-specific blue-

print to get your clinic's occ med business from point A to point Z. Without such a timeline, your business may be drifting aimlessly from day to day.

Development of a plan allows you to connect the dots, leading your clinic from simply *wanting* to be at a milestone to actually being there.

Marketing professionals acknowledge there is no foolproof format for a business plan; hence, formats vary widely. But regardless of design/format, every plan should answer the same basic questions:

■ *What do we want to do?*

Define your product and how your clinic will provide this product to the market. Here again, the what-why-how continuum should be tied together; e.g., "We will introduce a line of travel medicine services because our large white collar population uses these services disproportionately more than the general population, no similar program is available in the marketplace, and one of our physicians has special expertise in this area."

■ *Why are we doing this?*

The "why" defines and affirms your intention in doing what you are doing. That is, does your clinic have the wherewithal to offer what you suggest, is there a measurable market need for these services, and do competing entities fall short in meeting this need? If the answer to all three is affirmative and if pro forma projections support the return-on-investment (ROI) viability of moving forward, then, as they say, you've got a plan.

■ *How are we going to get there?*

The marketing plan, basically, is a response to the opportunities that you have identified earlier in the business plan. Although flexibility in writing a plan abounds, certain fundamental rules apply:

- Identify quantifiable goals at the outset. In most cases, these goals should be net-revenue based.
- Segment your market, if appropriate. Whereas segments in an overall clinic business plan are likely to be determined by demographics such as age and socioeconomic



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OCCUPATIONAL MEDICINE

strata, common segments in the context of an occ med business plan might include industry type, employer size, and proximity to the clinic. Marketing tactics may vary within each segment, necessitating one or more sub-plans.

- List as many potential marketing tactics as possible. While the possibilities are almost endless—e-mail blasts, live or web-based seminars, open houses, advertising, etc.—virtually any marketing tactic is valuable in its own right. Some are more valuable than others given their inherent cost in human and actual capital and potential return, however. Therefore, you need to list and then rank each marketing tactic in terms of perceived ROI to your clinic.
- Translate every idea and tactic into a date-specific action plan. This is the heart and soul of any plan—an actionable, day-by-day blueprint that propels a clinic's marketing journey from start to finish.

Keep it Practical

Most business plans are too wordy, too predictable, and too easily ignored and then forgotten. Keeping the following tips in mind may help ensure that creating a business plan for the occ med services your clinic offers won't be an exercise in futility:

- Three words: Brevity is good. Authors need to remember that their business plan is for the real business world, not a project for Future Entrepreneurs of America. The plan needs to be easy to read and painfully pragmatic (i.e., style is optional but usability is essential).
- Avoid reiterating the obvious. Lists of strengths, weaknesses, and opportunities are of minimal value, in and of themselves. Rather, establish a context by noting and linking strengths and weaknesses with a competitive advantage or a specific marketing tactic.
- Create clear and meaningful linkages between a *what* and a *why*. Construct your marketing plan to advise all readers exactly why you are offering a certain product or recommending a specific marketing tactic.
- Avoid being overly mechanical or stuck on a formula. I have reviewed hundreds of marketing plans and frequently note that the plans seem to follow rigid, textbook formulas that result in documents that are as dry as they come.
- Use it! Establish a process in which your business plan becomes central to your weekly program operation. Make it a dynamic, changeable document. Realities change, and the sooner you regroup in reaction to these changes, the better off your business will be. ■

**Next month in Occupational Medicine:
*Keeping Your Ear to the Consumer.***

HEALTH LAW

interest, respond in the affirmative and redirect them to a different treatment option. Often, when patients hear the word "no" they tune out the rest of the message.

Consider, for example, a patient who is demanding Percocet because "that is the only thing" that has worked in the past even though his or her condition doesn't warrant it. My response is usually, "You and I will definitely come up with a plan to treat your pain; however, it seems like Percocet has not been working for you in the past since you continue to require it for pain control...."

In 20 years of practice, the technique of never saying "no" to patients has rarely been unsuccessful.

Document with Care

Another way to ward off malpractice suits is through thorough documentation. Charting is often done while running from room to room. What is charted is typically regarded as everything that was said and done. Things not charted are subject to speculation or memory lapse and are often viewed with suspicion by the plaintiff's bar and jury. Take time to thoroughly document the important aspects of the history and physical. Include the pertinent positives and negatives, as well as your thought process behind the diagnosis you made and the treatment plan you recommended.

For example, the chart of a patient who presents with the signs and symptoms of frontal sinusitis should reflect that consideration was given to the potentially fatal diagnosis of cavernous vein thrombosis (e.g., no diplopia, headache, or funduscopic signs of elevated ICP). It should also reflect that you considered meningitis or subarachnoid bleeding (history inconsistent with either diagnosis, along with normal mental status, no meningeal signs, etc.).

Illegible, handwritten notes and checkbox or template charting often give rise to documentation that is not defensible under the retrospective scrutiny of plaintiff's experts. If your practice is using any variation of the aforementioned, take extra time to slow down and write legibly. Do not fall into the template "slash and check" mentality that fails to adequately tell the story of the encounter and provides you little protection against malpractice claims. ■

TAKE-HOME POINTS

- Build trust by spending time with your patients.
- Do whatever you can to make the patient more comfortable in the waiting room.
- Rather than saying "no," redirect patients to a different treatment option when they request something inappropriate.
- Document all important aspects of the patient encounter.
- Neatness counts; illegible, handwritten notes can make it difficult to defend your actions.

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S Codes (S9088 and S9083) in Urgent Care

■ DAVID STERN, MD, CPC

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

In this issue, he delves into the sometimes confusing realm of the S codes.

Q. What is an S code?

A. S codes are a set of Healthcare Common Procedure Coding System (HCPCS) codes that were originally requested by Blue Cross/Blue Shield. The codes are listed by the Centers for Medicaid & Medicare Services (CMS), but they are never for use on claims filed to Medicare.

Q. Does anyone besides Blue Cross and Blue Shield pay on S codes?

A. Yes, many payors and agencies (including managed care organizations [MCOs] and state workers compensation boards) have found these codes useful for defining specific services that are neither recognized nor reimbursed by Medicare or Medicaid.

S9083: Global Fee for Urgent Care Centers

Q. What is S9083?

A. This is used by payors to bundle all services rendered in an urgent care visit—whether it be for a hangnail or a

heart attack—into a single, one-size-fits-all global code for reimbursement with the same single flat-rate fee. Many MCOs in several states (e.g., Florida, California and Arizona) use this case-rate method to reimburse for urgent care visits. Urgent care administrators should point out to the MCOs that this case-rate reimbursement generally means that the urgent care center can take care of only minor ailments profitably.

“Case-rate coding may force an urgent care center to send higher acuity cases to a hospital emergency department.”

Case-rate coding works well for clinics that are equipped only to care for minor illnesses and injuries, such as colds, insect bites, and minor bruises. Many urgent care centers, however, are equipped to take care of many moderate acuity injuries and illnesses (e.g., dehydration requiring intravenous fluids, fractures, complicated lacerations, corneal rust rings, and others). Urgent care centers should make it clear to the MCO that using case-rate coding may end up forcing an urgent care center to send higher acuity cases to a hospital emergency department, where total fees will be up to 10 times more than if those same services were rendered in the urgent care center.

Q. What should I do if the MCO insists on using S9083 for urgent care visits?

A. Whenever possible, the urgent care center should work with the MCO to show that it is in everyone's best interest to pay for services rendered, rather than resort to one-size-fits-all reimbursement. Some visits take 20 minutes of work; others take three hours of work. But if the MCO insists on only paying for 20 minutes worth of work, then the urgent care provider will need to refer more complicated cases to other



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providers in order to avoid financial losses.

If the MCO insists on case-rate coding, explain that you can save them the cost of ED and specialist referrals by taking x-rays, treating complex lacerations, and caring for simple fractures. Specify that in order to provide these services, however, you will need a modification to case-rate coding. You will want to negotiate a list of “carve-out” codes that the MCO will allow you to use for reimbursement, in addition to the flat-rate code of S9o83. Without carve-outs, you will lose money on any complex care, so you will be forced to refer:

- anything more than simple lacerations to specialists
- even finger tuft fractures to orthopedic surgeons
- any complex care such as IV hydration or other work up to the hospital ED.

This extra care will cost the MCO thousands of dollars for every referral. Suggest that certain codes be carved out (at an appropriate fee schedule) and billed in addition to the S9o83. Try to get the MCO to realize that without carve-outs, a flat-rate billing structure will not allow the urgent care center to provide one of its major benefits to the MCO and its clients—namely, reducing the inconvenience and expense of hospital emergency department visits.

Q. When should I use S9o83?

A. Use this code only when you are required to use this code. An MCO contract may require just that; if so, make sure that you negotiate carve-outs (or an acceptable case-rate) prior to signing the contract. A few Medicaid payors insist that urgent care providers use this code. In Delaware, for example, freestanding emergency departments (high-level urgent care centers that are equipped to handle all medical emergencies that have life-threatening potential) are required to bill S9o83 and receive the exact same reimbursement for any and all visits billed to Medicaid clients through an MCO.

S9o88: Services Provided in an Urgent Care Center

Q. What is S9o88?

A. Some payors recognize that the services rendered in true urgent care centers cost significantly more than the services that are rendered in traditional primary care physician offices. Thus, this is an “add-on” code to allow urgent care centers to be reimbursed for at least a portion of this increased cost of rendering service.

Q. Who can use this code?

A. Any urgent care center can use this code. An urgent care center, as defined by UCAOA, is an ambulatory medical clinic (with x-ray and CLIA-waved lab testing) that is open

to the public for walk-in, unscheduled visits during all open hours and offering significant extended hours, which may include evenings, weekends, and holidays. Some payors may have more specific requirements, including ACLS certified personnel, crash cart with specific supplies, on-site inspections, and others. The State of Colorado has made specific, fairly stringent regulations for an urgent care center to qualify to bill this code for workers compensation cases, and other states may follow suit.

Q. When does S9o88 apply?

A. Your urgent care center can use this code for all unscheduled, walk-in visits to the urgent care center.

Q. Can I add this code to codes for other services?

A. Yes. This is an “add-on” code. Unless restricted by contract or regulations, you should add this code to any and all other billed codes.

Q. How much will payors reimburse for S9o88?

A. Reimbursement for S9o88 is quite variable, ranging from no reimbursement up to \$100. Never use this code for Medicare or Medicaid. The fee schedule for workers compensation in Colorado stipulates \$75 reimbursement for this code.

Q. Many payors deny this code, so isn't it a waste of time?

A. Many payors deny it, but many will pay on it. It still makes sense to bill the code. Some payors will see the light and begin to pay on the code. Keep track of those that continue to not pay, and make sure that you include payment for this code the next time you negotiate a contract with this payor.

Remember, delivering good, quality urgent care services costs more than delivering scheduled primary care services. Your services are worth it. ■

TAKE-HOME POINTS

- Never use S codes on claims filed to Medicare.
- S9o83 is used by payors to bundle all services rendered into a global code for reimbursement with a flat-rate fee.
- Negotiate carve-outs with payors that require you to use S9o83.
- S9o88 allows urgent care centers to be reimbursed for their higher cost of rendering services.
- S9o88 is an “add-on” code that can be used for all unscheduled, walk-in visits.

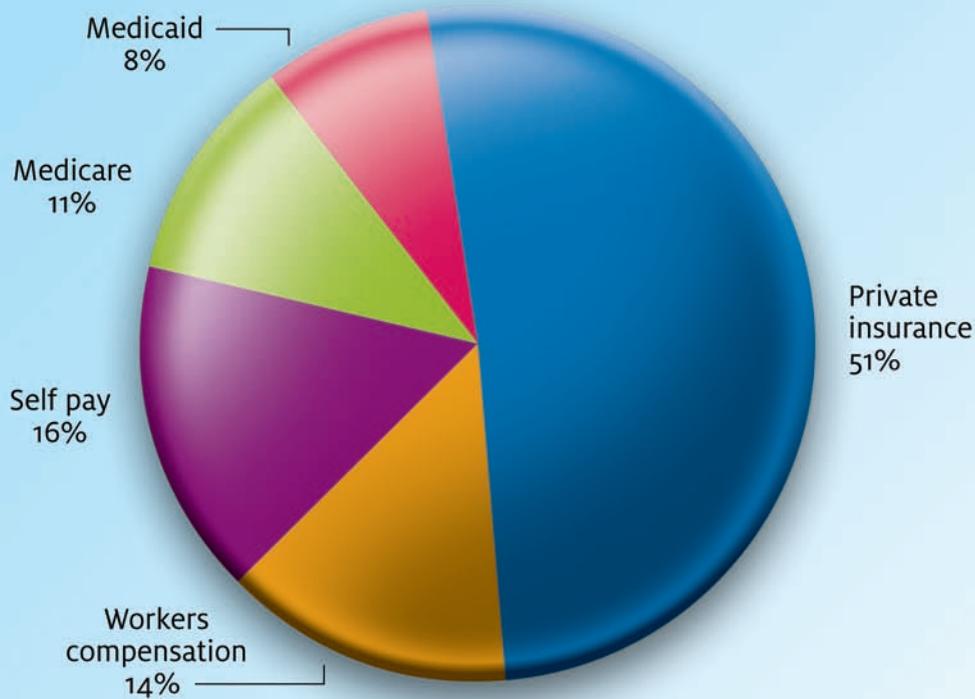


DEVELOPING DATA

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 how patients pay their bills—and how urgent care centers go about getting paid:

HOW PATIENTS PAY THEIR BILLS



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

Of the survey participants, most (78%) manage billing with in-house staff, while the rest contract for their billing services or use other methods. Such billing efforts cost an average amount of \$215.91 per patient—about \$3,336,967 per site and \$8,876,333 per urgent care center. Small wonder, then, that 14% of respondents cannot yet call their business “profitable.”

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:

As the real estate maxim goes, “location, location, location.”

We’ll report on who owns what, and how many locations are operated by the “average” urgent care business.

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

Brief Summary

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

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

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

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

In immature rats and dogs, the oral and intravenous administration of levofloxacin resulted in increased osteochondrosis. Histopathological examination of the weight-bearing joints of immature dogs dosed with levofloxacin revealed persistent lesions of the cartilage. Other findings included similar lesions of the 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, irritability, insomnia, and rarely, suicidal thoughts or acts. These reactions may occur following the first dose. If these reactions occur in patients receiving levofloxacin, the drug should be discontinued and appropriate measures instituted. As with other quinolones, levofloxacin should be used with caution in patients with a known or suspected CNS disorder that may predispose to seizures or lower the seizure threshold (e.g., severe cerebral arteriosclerosis, epilepsy) or in the presence of other risk factors that may predispose to seizures or lower the seizure threshold (e.g., certain drug therapy, renal dysfunction). (See **PRECAUTIONS: General, Information for Patients, Drug Interactions and ADVERSE REACTIONS**.)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Information for Patients

Patients should be advised:

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

Drug Interactions: Antacids, Sucralfate, Metal Cations, Multivitamins

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Nursing Mothers: Levofloxacin has not been measured in human milk. Based upon data from ofloxacin, it can be presumed that levofloxacin will be excreted in human milk. Because of the potential for serious adverse reactions from levofloxacin in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness in pediatric patients and adolescents below the age of 18 years have not been established. Quinolones, including levofloxacin, cause arthropathy and osteochondrosis in juvenile animals of several species. (See **WARNINGS**.)

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

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

The pharmacokinetic properties of levofloxacin in younger adults and elderly adults do not differ significantly when creatinine clearance is taken into consideration. However since the drug is known to be substantially excreted by the kidney, the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

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

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

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

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

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

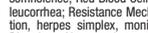
Body as a Whole - General Disorders: Acites, allergic reaction, asthenia, edema, fever, headache, hot flashes, influenza-like symptoms, leg pain, malaise, rigors, substernal chest pain, syncope, multiple organ failure, changed temperature sensation, withdrawal syndrome, Cardiovascular Disorders, General: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

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

Crystalluria and cylindruria have been reported with other quinolones. The following markedly abnormal laboratory values appeared in >2% of patients receiving levofloxacin. It is not known whether this abnormality was caused by the drug or the underlying condition being treated.

Hematology: decreased lymphocytes (2.2%)

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



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U.S. Patent No. 5,053,407.

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Indications:

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

Important Safety Information

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

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

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

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

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

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

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

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

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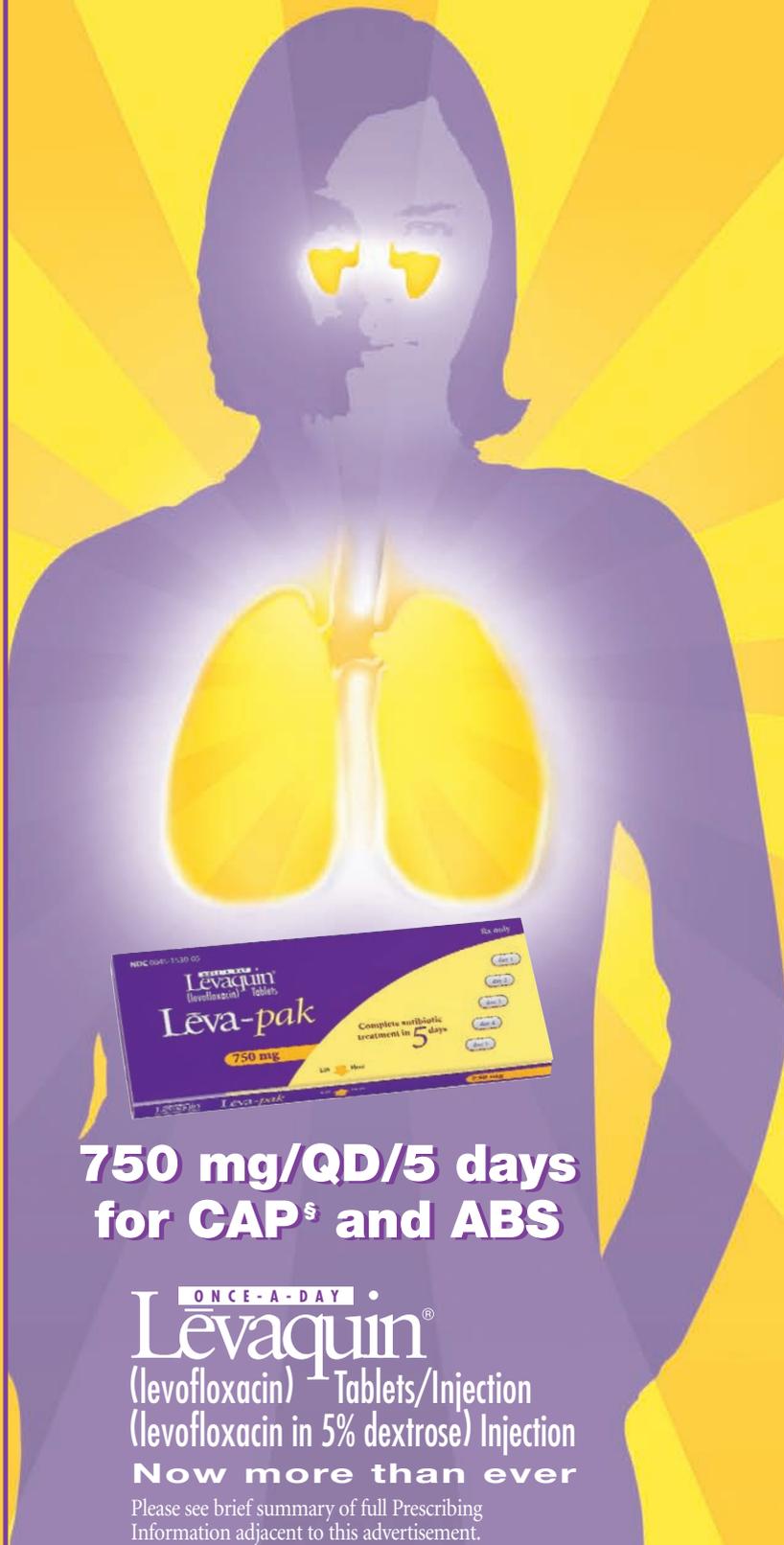
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