

# JUCM™

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# Treating Common Upper Respiratory Tract Infections

in an Era of Increasing Antibiotic Resistance

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## LETTER FROM THE EDITOR-IN-CHIEF

# The Hidden Costs of Medical Liability



The malpractice debate continues, like a rerun of *Quincy, M.E.*—you know the ending, but pretend to be surprised, if only to justify why you would watch the same show twice (or, in this case, many more).

The issue of medical liability, while it has received little attention in the health reform debate, is perhaps the best example of why changing healthcare, no matter where you want it to go, is so difficult to achieve. Indeed, the medical liability debate will forever be just that: a debate, with no end, with watered down reforms at best. We will never address the core issues because they are simply “too hot to handle.” Much like healthcare reform, everybody wants it, and a majority agree on what is broken, but no one can agree on how to fix it.

Here’s why: On complex issues, humans have a natural tendency to polarize into camps based on perceived moral superiority. This protects them from the insecurity of uncertainty and compromise. Compromise sounds weak, and why should I have to compromise on something when I know I am “right?”

We seek moral comfort on issues; we want black and white, right or wrong. We run away from anything with a touch of grey. The consequence of our morality dilemma is polarization and indecision. We huddle into camps with the like-minded. We demonize the disbelievers as immoral or insensitive.

On one side of the medical liability issue, you have those who highlight how the fear of liability destroys the very fabric of the doctor-patient relationship. Every decision is made with the fear of liability looming. This, we argue, results in unnecessary tests, increased costs, and more time spent away from patients while we document everything we can to protect ourselves.

On the other side are those who fear that without penalties for “negligence,” patient safety will suffer, and evil, no-good doctors will leave patients on operating tables to get in a round of golf.

Now, at the risk of oversimplifying, it is true that patients have suffered significant, life-altering harm from preventable medical errors, many that seem grossly negligent in hindsight. I am often befuddled by how my colleagues’ care can at times seem so substandard, so sloppy, and often filled with arrogance. But I am also very cognizant of the immense pressure we work under: the productivity demands, and a payment system that is not only unjust, but breeds poor care. Not to mention the most complex, un-

predictable, and rapidly evolving discipline in the world. No one can be the infallible master of all this.

Now, mistakes are made in every profession, every day. What makes medicine different are the consequences. Life hangs in the balance with every decision. We accepted that when we entered this profession. But punitive liability does nothing to mitigate the very mistakes it is intending to prevent.

Here’s why: When liability hangs over every decision, you simply create an environment of fear. And this has its greatest impact on the most caring, thoughtful, and astute in our profession. The fear of liability significantly changes the practices of the “good,” distracting them from their most critical mission, diluting their potential impact on patient care. All the while, the truly negligent, the arrogant, and the uncaring, are, by nature, oblivious to it all.

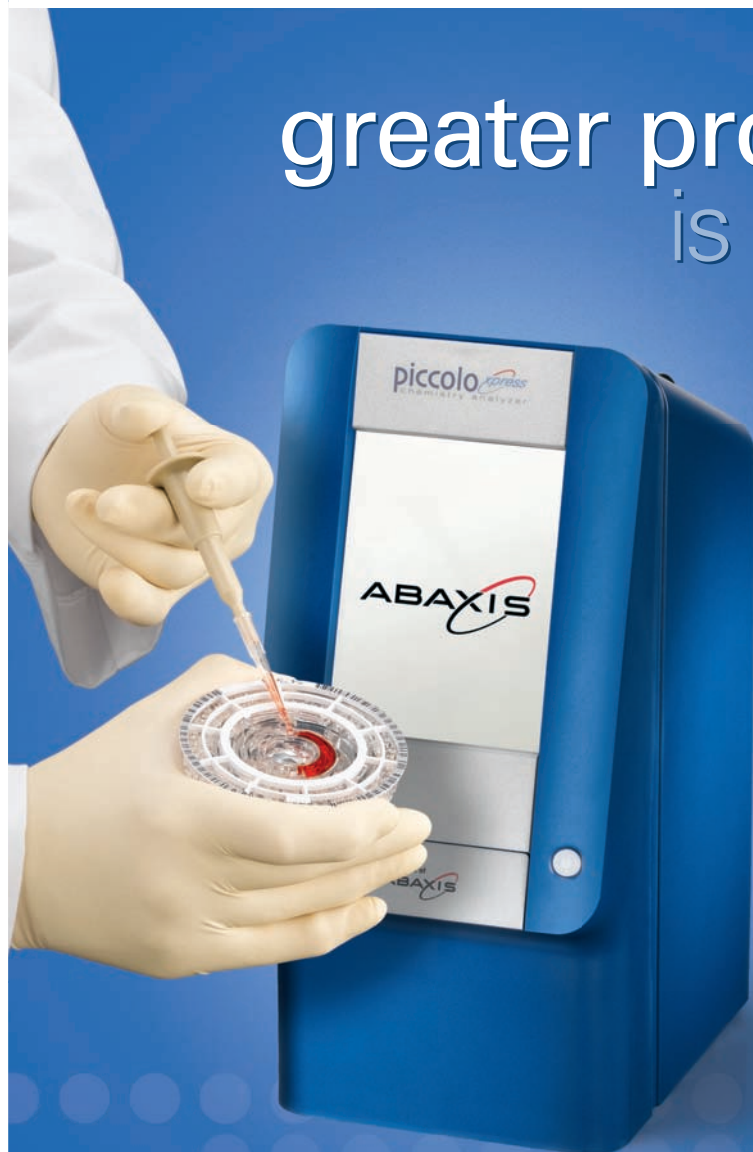
Someone forgot to examine the basic human psychology of a punitive system of liability in a profession littered with uncontrollable land mines. Gross, malicious negligence, of the kind malpractice law should punish, is committed by a tiny minority who often consider themselves untouchable anyway. Fear of liability doesn’t faze them.

Many of those opposed to tort reform will argue that a small minority of cases go to trial, and an even smaller minority of jury verdicts favor the plaintiff. They will argue that the system is, therefore, pretty accurate at identifying gross negligence. What they fail to address are the thousands of cases that don’t go to trial, but inflict an incurable harm on those who have had to endure and the fear they have instilled in all of us. You cannot assign a dollar cost to the impact of fear, but I can assure you it has eroded the quality of care our patients receive and the quality of life our physicians deserve. ■

Lee A. Resnick, MD  
Editor-in-Chief

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## November 2009

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### CLINICAL

## 11 Treating Common Upper Respiratory Tract Infections in an Era of Increasing Antibiotic Resistance

Common complaints can often be treated with common solutions. When it comes to choosing the appropriate therapy for upper respiratory tract infections, however, a healthy view of the big picture is advisable.

*By Joseph Toscano, MD*

### CASE REPORT

## 21 A Child with Constipation and Swollen Abdomen

Often, malignancies in children are discovered only during investigation of a less ominous complaint, highlighting the importance of being vigilant for relevant signs and symptoms.

*By Muhammad Waseem, MD*



### WEB EXCLUSIVE

#### Treatment of Pediatric Community-acquired Pneumonia in an Urgent Care Center

Most cases of community-acquired pneumonia in younger patients can be diagnosed in the urgent care center by non-pediatricians. Subsequent treatment can help reduce the rate of hospitalization. Available only at [www.jucm.com](http://www.jucm.com).

*By Deena R. Zimmerman, MD, MPH, IBCLC, Scott Fields, MD, and Nahum Kovalski, BSc, MDCM*

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### IN THE NEXT ISSUE OF JUCM

*From dermatophytes to Pityrosporum, infectious fungi are likely to walk through your door on a fairly regularly basis, both literally and figuratively. A review of how to identify and treat the more common types.*

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## Mission Statement

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

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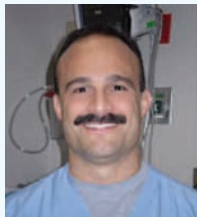


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It's likely that more than a few patients walk into an urgent care center secure in their self-made diagnosis of a respiratory infection, for which they would with equal confidence prescribe themselves the latest super antibiotic.

To which the responsible clinician might respond, respectfully, "Not so fast."

Practitioners who give such patients "what they want" are not doing those patients any favors, of course. And that's the crux of Treating Common Upper Respiratory Tract Infections in an Era of Increasing Antibiotic Resistance (page 11), in which author **Joseph**



**Toscano, MD** argues that clinical diagnosis and testing coupled with judicious use of available treatments—including but not necessarily defined by antibiotics—add up to both appropriate care and patient satisfaction.

Dr. Toscano practices at San Ramon Regional Medical Center and the Palo Alto Medical Foundation in California. He is also a member of the JUCM Editorial Board.

Less common is a child who presents with what is later found to be abdominal tumors. In fact, malignancies in children are often discovered only through evaluation of symptoms presumed to be of a relatively benign nature. This is the lesson of A Child with Constipation and Swollen Abdomen (page 21), a new case report by **Muhammad Waseem, MD**.

Dr. Waseem is associate professor of emergency medicine (clinical pediatrics) at Weill Medical College of Cornell University in New York City and attending physician in emergency medicine at Lincoln Medical & Mental Health Center in the Bronx, NY.

Diagnosing pediatric community-acquired pneumonia is not necessarily a straightforward process, either, but the authors of Treatment of Pediatric Community-acquired Pneumonia in an Urgent Care Center (**Deena R. Zimmerman, MD, MPH, IBCLC, Scott Fields, MD, and Nahum Kovalski, BSc, MDCM**) maintain that diagnosis can often be made, and treatment initiated, by non-pediatricians in the urgent care center. Their belief is supported by research they conducted at Terem Emergency Medical Centers in Jerusalem, Israel. This original article is available exclusively at [www.jucm.com](http://www.jucm.com).

*Also in this issue:*

**Nahum Kovalski, BSc, MDCM** reviews new abstracts on the debate over quality of care at retail clinics, corticosteroids and Bell palsy, and the necessity (or lack thereof) of packing simple abscesses.

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**Frank Leone, MBA, MPH** cautions against viewing national contracts as an insurmountable obstacle when pitching occupational medicine services to larger employers.

**John Shufeldt, MD, JD, MBA, FACEP** casts urgent care's fight for recognition in a historical context.

**David Stern, MD, CPC** responds to questions on billing S9083 to multiple carriers, coding for repair of multiple lacerations, maximizing IV reimbursement, proper use of modifier -59, and how to code for measuring oxygen saturation levels.

Do you have an idea for an article or new feature? Maybe an interesting x-ray case to present? Let us know in an e-mail to **Lee A. Resnick, MD**, JUCM's editor-in-chief, at [editor@jucm.com](mailto:editor@jucm.com).

### To Submit an Article to JUCM

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

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

We prefer submissions by e-mail, sent as Word file attachments (with tables created in Word, in multicolumn format) to [editor@jucm.com](mailto: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](http://www.jucm.com).





## A Note of Thanks to Our Peer Reviewers

**A**s we begin our fourth year of publication, *JUCM* remains committed to publishing articles relevant to the practice of urgent care medicine, told in an urgent care “voice.”

A key factor in achieving that objective is to work with the best and the brightest professionals working in urgent care centers and related companies, as well as academic institutions across the country.

Obviously, this is true of the authors whose work has appeared in the journal. You know their names. But there’s another group of individuals without whom we could not in good conscience call *JUCM* a *peer-reviewed* journal.

The accomplished practitioners who have volunteered to review and comment on articles prior to publication help keep us “honest” and ensure that our content is relevant to the way medicine is practiced in the urgent care setting.

The nature of the peer-review process requires anonymity on a month-to-month basis, but each year we like to collectively thank them for their invaluable contributions.

We are grateful to the following individuals for sharing their time and expertise—some on more than one occasion—in reviewing articles that appeared in Volume 3 (October 2008 through September 2009) of *JUCM*:

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## FROM THE EXECUTIVE DIRECTOR

# What If We Threw a Party and No One Came?

■ LOU ELLEN HORWITZ, MA

An old friend of mine, Caroline Herring, is a musician who is launching her fourth album two days from now as I write this. Even though her reviews have been great, she's still nervous—terrified, in fact.

And who wouldn't be? She's spent countless hours of her life coming up with ideas for songs, exploring different ways to present them, finding her voice (not to mention a record contract), performing those songs in a recording studio...and then she waits to see if anyone is listening.

If you've opened an urgent care center, you know the feeling. Think about it: you've spent countless hours of your life coming up with ideas, researching them, gathering expert feedback, putting all the pieces together, getting finances in order, developing a marketing campaign, making all the final touches...and then you wait to see if anyone comes.

I think we *all* know the feeling. I know that I do.

Every year, about 15 minutes into the start of the annual Urgent Care Convention, we start planning the next one. We make topic lists, we note the great speakers, we start thinking about themes—and for many months after that we narrow down our ideas and choose faculty and put program together. The brochure mails...and we wait to see if anyone registers. It's torture until that first call.

It's the same whether you're opening your first urgent care center or your 31<sup>st</sup>. The seeds may have been planted when you saw the UCAOA booth at the ACEP or AAFP Scientific Assembly in Boston last month, or when a center opened up in your town, or when you heard about an old friend who is opening one.

"Hmmm...", you think to yourself. Then you talk to some trusted advisors, pick a site, get some financing, deal with mountains of paperwork, staffing, build-out, marketing. Opening day

*"What would you pass along to those who are thinking of following in your footsteps?"*

comes...and you wait for that first patient to pull into the parking lot to confirm it wasn't all a crazy fantasy. It's torture!

It may have been five minutes since that first patient walked into your center, or it could be five months or even five years; you probably still remember that feeling of panic that no one would show up—and the tremendous relief when that first person did! It's a common experience we all share, whether we are "selling" albums, conferences, or healthcare.

We want to gather those experiences from you, whether you were the owner, the office manager, the biller, the provider, or the registrar, and share them with others.

What do you remember about your Opening Day and the weeks leading up to it? What do you recall and what would you pass along to those who are thinking of following you?

I think this is a great project, as well as a chance for you to pass along your wisdoms, great and small, and give back to the industry that *you began*. It's a chance for you help others skip the mistakes you made, and build on your successes.

Whether you have one sentence or many pages to share (or simply have a question about the project), I invite you to send those remembrances to me at [lhhorwitz@ucaoa.org](mailto:lhhorwitz@ucaoa.org).

Let's see what we can gather to share with each other and with those who will follow in your footsteps.

By the way, soon we will be able to share some of the details of the 2010 Urgent Care Convention in Orlando, and we hope you will be as excited as we are! If you are not getting the newsletters we e-mail each month, you won't be among the first to hear about early, discounted sign-ups for the convention. This would be a good time to make sure we are on your "safe senders" list and that we have a current e-mail address for you. ■



**Lou Ellen Horwitz** is executive director of the Urgent Care Association of America. She may be contacted at [lhhorwitz@ucaoa.org](mailto:lhhorwitz@ucaoa.org).

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## Treating Common Upper Respiratory Tract Infections in an Era of Increasing Antibiotic Resistance

**Urgent message:** Thorough evaluation and thoughtful prescribing can help ensure responsible, effective care and patient satisfaction.

Joseph Toscano, MD

### Introduction

Upper respiratory tract infections (URTIs) are among the most common reasons patients seek assistance in urgent care practice. The common cold, otitis media, acute sinusitis, and acute pharyngitis are well known to patient and provider alike. Acute bronchitis is a lower respiratory tract infection, with features similar to URTIs. These infections are most often self-limited and uncomplicated, but the approach to evaluating each patient should include examining for complications as well as rarer, more severe diseases that can mimic these simpler, common conditions. Treatment should include patient education, symptom management, and the use of antibiotics *only* if likely to improve the clinical outcome.

Data show a positive correlation between increasing levels of antibiotic use and increasing antibiotic resistance among



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bacteria.<sup>1</sup> Though in the United States there seems to be a gradually decreasing rate of antibiotic prescription for URTIs in general, over-prescription is still common and there is an increasing trend toward the use of broad-spectrum antibiotics for these relatively simple infections.<sup>2,3</sup>

It is intuitive that a strategy of prescribing antibiotics only when necessary and only of the appropriate antimicrobial spectra will minimize the development of antibiotic resistance. Guidelines describing such use have been published by several organizations (see **Table**

**1** for links) and will be the primary subject of this review.

### Clinical Diagnosis, Testing, and Important Complications and Disease Mimics

URTIs are often grouped together because they share a closely related anatomy and pathophysiology. The mu-

**Table 1. Clinical Guidelines for the Treatment of Upper Respiratory Tract Infections**

URTI	Organization	URL for clinical guideline resource (as of July 1, 2009)
<b>Common cold</b>	ACP	<a href="http://www.annals.org/cgi/reprint/134/6/487.pdf">www.annals.org/cgi/reprint/134/6/487.pdf</a> *
	ICSI	<a href="http://www.icsi.org/respiratory_illness_in_children_and_adults_guideline/respiratory_illness_in_children_and_adults_guideline_13116.html">www.icsi.org/respiratory_illness_in_children_and_adults_guideline/respiratory_illness_in_children_and_adults_guideline_13116.html</a>
<b>Acute sinusitis</b>	ACP	<a href="http://www.annals.org/cgi/reprint/134/6/495.pdf">www.annals.org/cgi/reprint/134/6/495.pdf</a> *
	AAP	<a href="http://aappolicy.aappublications.org/cgi/reprint/pediatrics;108/3/798.pdf">http://aappolicy.aappublications.org/cgi/reprint/pediatrics;108/3/798.pdf</a> *
	ICSI	<a href="http://www.icsi.org/respiratory_illness_in_children_and_adults_guideline/respiratory_illness_in_children_and_adults_guideline_13116.html">www.icsi.org/respiratory_illness_in_children_and_adults_guideline/respiratory_illness_in_children_and_adults_guideline_13116.html</a>
	AAO-HNS	<a href="http://www.entnet.org/qualityimprovement/upload/Adult%20Sinusitis%20Guideline.pdf">www.entnet.org/qualityimprovement/upload/Adult%20Sinusitis%20Guideline.pdf</a>
	IDSA	Under development—due out in Fall 2010.
<b>Acute pharyngitis</b>	IDSA	<a href="http://www.journals.uchicago.edu/doi/pdf/10.1086/340949?">www.journals.uchicago.edu/doi/pdf/10.1086/340949?</a>
	ACP	<a href="http://www.annals.org/cgi/reprint/134/6/506.pdf">www.annals.org/cgi/reprint/134/6/506.pdf</a> *
	ICSI	<a href="http://www.icsi.org/respiratory_illness_in_children_and_adults_guideline/respiratory_illness_in_children_and_adults_guideline_13116.html">www.icsi.org/respiratory_illness_in_children_and_adults_guideline/respiratory_illness_in_children_and_adults_guideline_13116.html</a>
<b>Acute bronchitis</b>	ACP	<a href="http://www.annals.org/cgi/reprint/134/6/518.pdf">www.annals.org/cgi/reprint/134/6/518.pdf</a> *
<b>Acute otitis media</b>	AAP	<a href="http://aappolicy.aappublications.org/cgi/reprint/pediatrics;113/5/1451.pdf">http://aappolicy.aappublications.org/cgi/reprint/pediatrics;113/5/1451.pdf</a>
	ICSI	<a href="http://www.icsi.org/otitis_media/diagnosis_and_treatment_of_otitis_media_in_children_2304.html">www.icsi.org/otitis_media/diagnosis_and_treatment_of_otitis_media_in_children_2304.html</a>

ACP, American College of Physicians; ICSI, Institute for Clinical Systems Improvement; AAP, American Academy of Pediatrics; AAO-HNS, American Academy of Otolaryngology-Head and Neck Surgery; IDSA, Infectious Diseases Society of America

Compendia of all relevant clinical practice guidelines for URTIs in adults and children, updated annually, is available for download at:

[www.aware.md/HealthCareProfessionals/ClinicalResources.aspx](http://www.aware.md/HealthCareProfessionals/ClinicalResources.aspx)

\*Certain ACP and AAP Guidelines are over 5 years old and therefore not considered “current” by those organizations; however, pending updates, these are the most recent recommendations.

cosa of the nose, throat, bronchi, middle ear, and paranasal sinuses are essentially contiguous and are exposed to similar organisms.

Typically, the area of the respiratory tract that is *most* involved—indicated either by symptoms or on exam—and the severity of illness yield a clinical diagnosis. The majority of URTIs are viral in nature, with the remainder caused by a narrow-enough range of pathogens that focused-spectrum antibiotics can be used.

- Symptoms of the common cold can include nasal congestion and drainage, sneezing, mild sore throat and cough, and fever. Nasal symptoms usually predominate; otherwise, the widespread nature (sinuses, nose, throat, chest) of generally mild, though often aggravating, symptoms establishes this diagnosis.

- The acute onset of cough and higher fever—typically with associated headache and myalgias—generally distinguishes human, swine, and avian influenza. These particularly viral URTIs have higher rates of associated morbidity and mortality and require a different approach than will be discussed in this article. (An excellent review of the testing, evaluation, and care of patients with swine-origin H1N1 virus appeared in the October 2009 issue of *JUCM*.)
- When cough predominates, bronchitis is usually the diagnosis. Wheezing, even in patients without a history of bronchospastic disease, may be noted on exam. When cough is associated with an inspiratory whoop (usually seen only in children) or post-tussive vomiting or is severe and paroxysmal, clinicians should suspect pertussis, especially when symptoms last longer than 14 days. A higher index of suspicion (e.g. *any* cough illness lasting more than 14 days or severe cough illness of a shorter duration) will apply during an identified pertussis outbreak.<sup>4</sup>
- Prominent ear pain and abnormal otoscopic findings indicate otitis media.

- Sinus pain can suggest sinusitis.

- A chief complaint of sore throat typically indicates pharyngitis.

Sorting through the differential diagnosis of URTIs is largely a clinical exercise. Analyzing a patient's symptomatology and performing a systematic exam are crucial to the process of diagnosis and the exclusion of significant complications or other diseases that can present in ways similar to milder forms of infection (see **Table 2**).

On the other hand, there are no clinical criteria (e.g., the presence of fever, level of discomfort, exam findings, the color or characteristics of any produced sputum or mucous) that can be used to reliably distinguish between bacterial and viral etiologies.

Only a few diagnostic tests are needed when evalu-



Keep influenza under control...

## Make the change— choose RELENZA

- To date, no detectable resistance to RELENZA has been found in CDC surveillance\*
- According to CDC, RELENZA is a preferred treatment for patients with influenza.



**RELENZA®**  
(ZANAMIVIR) INHALATION POWDER  
||| MAKE THE CHANGE |||

\*Clinical significance can not be inferred from surveillance data.

### Important Safety Information

- RELENZA is not recommended for treatment or prophylaxis of influenza in individuals with underlying airways disease (such as asthma or chronic obstructive pulmonary disease)
- Serious cases of bronchospasm, including fatalities, have been reported during treatment with RELENZA in patients with and without underlying airways disease. Many of these cases were reported during postmarketing and causality was difficult to assess
- If use of RELENZA is considered for a patient with underlying airways disease, the potential risks and benefits should be carefully weighed. Use in these patients should be done only under conditions of careful monitoring of respiratory function, close observation, and appropriate supportive care including availability of fast-acting bronchodilators
- Discontinue RELENZA and initiate appropriate treatment if an allergic reaction occurs or is suspected
- Patients with influenza, particularly pediatric patients, may be at an increased risk of seizures, confusion, or abnormal behavior early in their illness. Monitor for signs of abnormal behavior
- Safety and efficacy have not been demonstrated in patients with high-risk underlying medical conditions
- RELENZA has not been proven effective for prophylaxis of influenza in the nursing home setting
- RELENZA is not a substitute for early influenza vaccination on an annual basis as recommended by the Centers for Disease Control's Immunization Practices Advisory Committee
- Influenza viruses change over time. Emergence of resistance mutations could decrease drug effectiveness. Other factors (for example, changes in viral virulence) might also diminish clinical benefit of antiviral drugs. Prescribers should consider available information on influenza drug susceptibility patterns and treatment effects when deciding whether to use RELENZA

For more information on RELENZA visit [www.relenza.com](http://www.relenza.com)

Please see Brief Summary of Prescribing Information on next page.

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# RELENZA®

## (ZANAMIVIR) INHALATION POWDER

### BRIEF SUMMARY

#### RELENZA® (zanamivir) Inhalation Powder

The following is a brief summary only; see full prescribing information for complete product information

#### 1 INDICATIONS AND USAGE

**1.1 Treatment of Influenza:** RELENZA is indicated for treatment of uncomplicated acute illness due to influenza A and B virus in adults and pediatric patients 7 years of age and older who have been symptomatic for no more than 2 days.

**1.2 Prophylaxis of Influenza:** RELENZA is indicated for prophylaxis of influenza in adults and pediatric patients 5 years of age and older.

#### 1.3 Important Limitations on Use of RELENZA

- RELENZA is not recommended for treatment or prophylaxis of influenza in individuals with underlying airways disease (such as asthma or chronic obstructive pulmonary disease) due to risk of serious bronchospasm [see *Warnings and Precautions* (5.1)].
- RELENZA has not been proven effective for treatment of influenza in individuals with underlying airways disease.
- RELENZA has not been proven effective for prophylaxis of influenza in the nursing home setting.
- RELENZA is not a substitute for early influenza vaccination on an annual basis as recommended by the Centers for Disease Control's Immunization Practices Advisory Committee.
- Influenza viruses change over time. Emergence of resistance mutations could decrease drug effectiveness. Other factors (for example, changes in viral virulence) might also diminish clinical benefit of antiviral drugs. Prescribers should consider available information on influenza drug susceptibility patterns and treatment effects when deciding whether to use RELENZA.
- There is no evidence for efficacy of zanamivir in any illness caused by agents other than influenza virus A and B.
- Patients should be advised that the use of RELENZA for treatment of influenza has not been shown to reduce the risk of transmission of influenza to others.

#### 4 CONTRAINDICATIONS

Do not use in patients with history of allergic reaction to any ingredient of RELENZA including lactose (which contains milk proteins) [see *Warnings and Precautions* (5.2) and *Description* (11) of full prescribing information].

#### 5 WARNINGS AND PRECAUTIONS

**5.1 Bronchospasm:** RELENZA is not recommended for treatment or prophylaxis of influenza in individuals with underlying airways disease (such as asthma or chronic obstructive pulmonary disease).

Serious cases of bronchospasm, including fatalities, have been reported during treatment with RELENZA in patients with and without underlying airways disease. Many of these cases were reported during postmarketing and causality was difficult to assess.

RELENZA should be discontinued in any patient who develops bronchospasm or decline in respiratory function; immediate treatment and hospitalization may be required.

Some patients without prior pulmonary disease may also have respiratory abnormalities from acute respiratory infection that could resemble adverse drug reactions or increase patient vulnerability to adverse drug reactions.

Bronchospasm was documented following administration of zanamivir in 1 of 13 patients with mild or moderate asthma (but without acute influenza-like illness) in a Phase I study. In a Phase III study in patients with acute influenza-like illness superimposed on underlying asthma or chronic obstructive pulmonary disease, 10% (24 of 244) of patients on zanamivir and 9% (22 of 237) on placebo experienced a greater than 20% decline in FEV<sub>1</sub> following treatment for 5 days.

If use of RELENZA is considered for a patient with underlying airways disease, the potential risks and benefits should be carefully weighed. If a decision is made to prescribe RELENZA for such a patient, this should be done only under conditions of careful monitoring of respiratory function, close observation, and appropriate supportive care including availability of fast-acting bronchodilators.

**5.2 Allergic Reactions:** Allergic-like reactions, including oropharyngeal edema, serious skin rashes, and anaphylaxis have been reported in postmarketing experience with RELENZA. RELENZA should be stopped and appropriate treatment instituted if an allergic reaction occurs or is suspected.

**5.3 Neuropsychiatric Events:** Influenza can be associated with a variety of neurologic and behavioral symptoms which can include events such as seizures, hallucinations, delirium, and abnormal behavior, in some cases resulting in fatal outcomes. These events may occur in the setting of encephalitis or encephalopathy but can occur without obvious severe disease.

There have been postmarketing reports (mostly from Japan) of delirium and abnormal behavior leading to injury in patients with influenza who were receiving neuraminidase inhibitors, including RELENZA. Because these events were reported voluntarily during clinical practice, estimates of frequency cannot be made, but they appear to be uncommon based on usage data for RELENZA. These events were reported primarily among pediatric patients and often had an abrupt onset and rapid resolution. The contribution of RELENZA to these events has not been established. Patients with influenza should be closely monitored for signs of abnormal behavior. If neuropsychiatric symptoms occur, the risks and benefits of continuing treatment should be evaluated for each patient.

**5.4 Limitations of Populations Studied:** Safety and efficacy have not been demonstrated in patients with high-risk underlying medical conditions. No information is available regarding treatment of influenza in patients with any medical condition sufficiently severe or unstable to be considered at imminent risk of requiring inpatient management.

**5.5 Bacterial Infections:** Serious bacterial infections may begin with influenza-like symptoms or may coexist with or occur as complications during the course of influenza. RELENZA has not been shown to prevent such complications.

**5.6 Importance of Proper Use of DISKHALER:** Effective and safe use of RELENZA requires proper use of the DISKHALER to inhale the drug. Prescribers should carefully evaluate the ability of young children to use the delivery system if use of RELENZA is considered [see *Use in Specific Populations* (8.4)].

#### 6 ADVERSE REACTIONS

**6.1 Clinical Trials Experience:** The placebo used in clinical studies consisted of inhaled lactose powder, which is also the vehicle for the active drug; therefore, some adverse events occurring at similar frequencies in different treatment groups could be related to lactose vehicle inhalation.

*Treatment of Influenza: Clinical Trials in Adults and Adolescents:* Adverse events that occurred with an incidence  $\geq 1.5\%$  in treatment studies (patients  $\geq 12$  years of age) are listed in Table 1.

**Table 1. Summary of Adverse Events  $\geq 1.5\%$  Incidence During Treatment in Adults and Adolescents**

Adverse Event	RELENZA		Placebo (Lactose Vehicle) (n = 1,520)
	10 mg b.i.d. Inhaled (n = 1,132)	All Dosing Regimens (n = 2,289)	
<b>Body as a whole</b>			
Headaches	2%	2%	3%
<b>Digestive</b>			
Diarrhea	3%	3%	4%
Nausea	3%	3%	3%
Vomiting	1%	1%	2%
<b>Respiratory</b>			
Nasal signs and symptoms	2%	3%	3%
Bronchitis	2%	2%	3%
Cough	2%	2%	3%
Sinusitis	3%	2%	2%
Ear, nose, and throat infections	2%	1%	2%
<b>Nervous system</b>			
Dizziness	2%	1%	<1%

\*Includes studies where RELENZA was administered intranasally (6.4 mg 2 to 4 times per day in addition to inhaled preparation) and/or inhaled more frequently (q.i.d.) than the currently recommended dose.

Additional adverse reactions occurring in less than 1.5% of patients receiving RELENZA included malaise, fatigue, fever, abdominal pain, myalgia, arthralgia, and urticaria.

The most frequent laboratory abnormalities in Phase III treatment studies included elevations of liver enzymes and CPK, lymphopenia, and neutropenia. These were reported in similar proportions of zanamivir and lactose vehicle placebo recipients with acute influenza-like illness.

*Clinical Trials in Pediatric Patients:* Adverse events that occurred with an incidence  $\geq 1.5\%$  in patients 5 to 12 years old receiving treatment doses of RELENZA in 2 Phase III studies are listed in Table 2.

**Table 2. Summary of Adverse Events  $\geq 1.5\%$  Incidence During Treatment in Pediatric Patients\***

Adverse Event	RELENZA 10 mg b.i.d. Inhaled (n = 291)	Placebo (Lactose Vehicle) (n = 318)
<b>Respiratory</b>		
Ear, nose, and throat infections	5%	5%
Ear, nose, and throat hemorrhage	<1%	2%
Asthma	<1%	2%
Cough	<1%	2%
<b>Digestive</b>		
Vomiting	2%	3%
Diarrhea	2%	2%
Nausea	<1%	2%

\*Includes a subset of patients receiving RELENZA for treatment of influenza in a prophylaxis study.

In 1 of the 2 studies described in Table 2, some additional information is available from children (5 to 12 years old) without acute influenza-like illness who received an investigational prophylaxis regimen of RELENZA: 132 children received RELENZA and 145 children received placebo. Among these children, nasal signs and symptoms (zanamivir 20%, placebo 9%), cough (zanamivir 16%, placebo 8%), and throat/tonsil discomfort and pain (zanamivir 11%, placebo 6%) were reported more frequently with RELENZA than placebo. In a subset with chronic pulmonary disease, lower respiratory adverse events (described as asthma, cough, or viral respiratory infections which could include influenza-like symptoms) were reported in 7 of 7 zanamivir recipients and 5 of 12 placebo recipients.

*Prophylaxis of Influenza: Family/Household Prophylaxis Studies:*

Adverse events that occurred with an incidence of  $\geq 1.5\%$  in the 2 prophylaxis studies (patients  $\geq 5$  years of age) are listed in Table 3.

**Table 3. Summary of Adverse Events  $\geq 1.5\%$  Incidence During 10-Day Prophylaxis Studies in Adults, Adolescents, and Children\***

Adverse Event	Contact Cases	
	RELENZA 10 mg inhaled once daily (n = 1,068)	Placebo (n = 1,059)
<b>Lower respiratory</b>		
Viral respiratory infections	13%	19%
Cough	7%	9%
<b>Neurologic</b>		
Headaches	13%	14%
<b>Ear, nose, and throat</b>		
Nasal signs and symptoms	12%	12%
Throat and tonsil discomfort and pain	8%	9%
Nasal inflammation	1%	2%
<b>Musculoskeletal</b>		
Muscle pain	3%	3%
<b>Endocrine and metabolic</b>		
Feeding problems (decreased or increased appetite and anorexia)	2%	2%
<b>Gastrointestinal</b>		
Nausea and vomiting	1%	2%
<b>Non-site specific</b>		
Malaise and fatigue	5%	5%
Temperature regulation disturbances (fever and/or chills)	5%	4%

\* In prophylaxis studies, symptoms associated with influenza-like illness were captured as adverse events; subjects were enrolled during a winter respiratory season during which time any symptoms that occurred were captured as adverse events.

*Community Prophylaxis Studies:* Adverse events that occurred with an incidence of  $\geq 1.5\%$  in 2 prophylaxis studies (patients  $\geq 5$  years of age) are listed in Table 4.

**Table 4. Summary of Adverse Events  $\geq 1.5\%$  Incidence During 28-Day Prophylaxis Studies in Adults, Adolescents, and Children\***

Adverse Event	RELENZA 10 mg inhaled once daily (n = 2,231)	Placebo (n = 2,239)
<b>Neurologic</b>		
Headaches	24%	26%
<b>Ear, nose, and throat</b>		
Throat and tonsil discomfort and pain	19%	20%
Nasal signs and symptoms	12%	13%
Ear, nose, and throat infections	2%	2%
<b>Lower respiratory</b>		
Cough	17%	18%
Viral respiratory infections	3%	4%
<b>Musculoskeletal</b>		
Muscle pain	8%	8%
Musculoskeletal pain	6%	6%
Arthralgia and articular rheumatism	2%	<1%
<b>Endocrine and metabolic</b>		
Feeding problems (decreased or increased appetite and anorexia)	4%	4%
<b>Gastrointestinal</b>		
Nausea and vomiting	2%	3%
Diarrhea	2%	2%
<b>Non-site specific</b>		
Temperature regulation disturbances (fever and/or chills)	9%	10%
Malaise and fatigue	8%	8%

\* In prophylaxis studies, symptoms associated with influenza-like illness were captured as adverse events; subjects were enrolled during a winter respiratory season during which time any symptoms that occurred were captured as adverse events.

#### 6.2 Postmarketing Experience:

**Allergic Reactions:** Allergic or allergic-like reaction, including oropharyngeal edema [see *Warnings and Precautions* (5.2)]. **Psychiatric:** Delirium, including symptoms such as altered level of consciousness, confusion, abnormal behavior, delusions, hallucinations, agitation, anxiety, nightmares [see *Warnings and Precautions* (5.3)]. **Cardiac:** Arrhythmias, syncope. **Neurologic:** Seizures. **Respiratory:** Bronchospasm, dyspnea [see *Warnings and Precautions* (5.1)]. **Skin:** Facial edema; rash, including serious cutaneous reactions; urticaria [see *Warnings and Precautions* (5.2)].

#### 7 DRUG INTERACTIONS

The concurrent use of RELENZA with live attenuated influenza vaccine (LAIV) intranasal has not been evaluated. However, because of potential interference between these products, LAIV should not be administered within 2 weeks before or 48 hours after administration of RELENZA, unless medically indicated. The concern about possible interference arises from the potential for antiviral drugs to inhibit replication of live vaccine virus.

Trivalent inactivated influenza vaccine can be administered at any time relative to use of RELENZA [see *Clinical Pharmacology* (12.4) of full prescribing information].

#### 8 USE IN SPECIFIC POPULATIONS

**8.1 Pregnancy: Pregnancy Category C.** There are no adequate and well-controlled studies of zanamivir in pregnant women. Zanamivir should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Zanamivir has been shown to cross the placenta in rats and rabbits. In these animals, fetal blood concentrations of zanamivir were significantly lower than zanamivir concentrations in the maternal blood.



**8.3 Nursing Mothers:** Studies in rats have demonstrated that zanamivir is excreted in milk. However, nursing mothers should be instructed that it is not known whether zanamivir is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when RELENZA is administered to a nursing mother.

**8.4 Pediatric Use:** Treatment of influenza: Safety and effectiveness of RELENZA for treatment of influenza have not been assessed in pediatric patients less than 7 years of age, but were studied in a Phase III treatment study in pediatric patients, where 471 children 5 to 12 years of age received zanamivir or placebo [see Clinical Studies (14.1) of full prescribing information]. Adolescents were included in the 3 principal Phase III adult treatment studies. In these studies, 67 patients were 12 to 16 years of age. No definite differences in safety and efficacy were observed between these adolescent patients and young adults.

In a Phase I study of 16 children ages 6 to 12 years with signs and symptoms of respiratory disease, 4 did not produce a measurable peak inspiratory flow rate (PIFR) through the DISKHALER (3 with no adequate inhalation on request, 1 with missing data), 9 had measurable PIFR on each of 2 inhalations, and 3 achieved measurable PIFR on only 1 of 2 inhalations. Neither of two 6-year-olds and one of two 7-year-olds produced measurable PIFR. Overall, 8 of the 16 children (including all those under 8 years old) either did not produce measurable inspiratory flow through the DISKHALER or produced peak inspiratory flow rates below the 60 L/min considered optimal for the device under standardized in vitro testing; lack of measurable flow rate was related to low or undetectable serum concentrations [see Clinical Pharmacology (12.3), Clinical Studies (14.1) of full prescribing information]. Prescribers should carefully evaluate the ability of young children to use the delivery system if prescription of RELENZA is considered.

**Prophylaxis of Influenza:** The safety and effectiveness of RELENZA for prophylaxis of influenza have been studied in 4 Phase III studies where 273 children 5 to 11 years of age and 239 adolescents 12 to 16 years of age received RELENZA. No differences in safety and effectiveness were observed between pediatric and adult subjects [see Clinical Studies (14.2) of full prescribing information].

**8.5 Geriatric Use:** Of the total number of patients in 6 clinical studies of RELENZA for treatment of influenza, 59 patients were 65 years of age and older, while 24 patients were 75 years of age and older. Of the total number of patients in 4 clinical studies of RELENZA for prophylaxis of influenza in households and community settings, 954 patients were 65 years of age and older, while 347 patients were 75 years of age and older. No overall differences in safety or effectiveness were observed between these patients and younger patients, 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 need assistance with use of the device.

In 2 additional studies of RELENZA for prophylaxis of influenza in the nursing home setting, efficacy was not demonstrated [see Indications and Usage (1.3) of full prescribing information].

#### 10 OVERDOSAGE

There have been no reports of overdosage from administration of RELENZA.

#### 17 PATIENT COUNSELING INFORMATION

See FDA-Approved Patient Labeling (17.6).

**17.1 Bronchospasm:** Patients should be advised of the risk of bronchospasm, especially in the setting of underlying airways disease, and should stop RELENZA and contact their physician if they experience increased respiratory symptoms during treatment such as worsening wheezing, shortness of breath, or other signs or symptoms of bronchospasm [see Warnings and Precautions (5.1)]. If a decision is made to prescribe RELENZA for a patient with asthma or chronic obstructive pulmonary disease, the patient should be made aware of the risks and should have a fast-acting bronchodilator available.

**17.2 Concomitant Bronchodilator Use:** Patients scheduled to take inhaled bronchodilators at the same time as RELENZA should be advised to use their bronchodilators before taking RELENZA.

**17.3 Neuropsychiatric Events:** Patients with influenza (the flu), particularly children and adolescents, may be at an increased risk of seizures, confusion, or abnormal behavior early in their illness. These events may occur after beginning RELENZA or may occur when flu is not treated. These events are uncommon but may result in accidental injury to the patient. Therefore, patients should be observed for signs of unusual behavior and a healthcare professional should be contacted immediately if the patient shows any signs of unusual behavior [see Warnings and Precautions (5.3)].

**17.4 Instructions for Use:** Patients should be instructed in use of the delivery system. Instructions should include a demonstration whenever possible. For the proper use of RELENZA, the patient should read and follow carefully the accompanying Patient Instructions for Use.

**If RELENZA is prescribed for children, it should be used only under adult supervision and instruction, and the supervising adult should first be instructed by a healthcare professional [see Dosage and Administration (2.1)].**

**17.5 Risk of Influenza Transmission to Others:** Patients should be advised that the use of RELENZA for treatment of influenza has not been shown to reduce the risk of transmission of influenza to others.

**17.6 FDA-Approved Patient Labeling and Instructions for Use:** See separate leaflet.

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Research Triangle Park, NC 27709

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**Table 2. Upper Respiratory Tract Infection Complications and Differential Diagnosis**

URTI	Complications	Differential diagnoses and "can't miss" mimics
<b>Common cold</b>	Other URTIs	Other URTIs Allergic or vasomotor rhinitis
<b>Acute bronchitis</b>	CHF, RAD, COPD exacerbation	Pneumonia Exacerbation of RAD, COPD, or CHF Pertussis
<b>Acute otitis media</b>	Mastoiditis, tympanic membrane perforation	Eustachian tube dysfunction Barotrauma Otitis externa Mastoiditis
<b>Acute sinusitis</b>	Intracranial infection, periorbital cellulitis	Common cold Chronic sinusitis Meningitis Wegener's granulomatosis
<b>Acute pharyngitis</b>	Peritonsillar or parapharyngeal space infections (though may be separate disease process); rheumatic fever and acute glomerulonephritis (for <i>Strep</i> )	Peritonsillar or parapharyngeal space infections Epiglottitis HIV primary infection Infectious mononucleosis Gonococcal pharyngitis Kawasaki disease
CHF, congestive heart failure; RAD, reactive airways disease; COPD, chronic obstructive pulmonary disease; HIV, human immunodeficiency virus		

ating patients with URTIs. Each disease mimic, however, may have its own diagnostic test(s), a discussion of which exceeds the scope of this review.

Of course, patients who are toxic-appearing or who are immunosuppressed or have other significant comorbidities should be evaluated very aggressively; the recommendations that follow do not apply to these subsets of patients.

#### Appropriate testing

No diagnostic testing is required for patients with the common cold. However, confirming respiratory syncytial virus (RSV) or influenza infection in febrile pediatric patients with rapid "point-of-care" testing has been shown to reassure clinicians and safely decrease antibiotic prescription and unnecessary further work-ups for other infections.

Complications and mimics of the common cold include any of the other URTIs and allergic and vasomotor rhinitis. Typically, the presence of fever suggests URTI, while ongoing nasal congestion and rhinorrhea in a patient without fever suggest noninfectious rhinitis.

No diagnostic testing is needed to confirm acute bronchitis, though a chest radiograph should be performed if pneumonia is suspected. Pneumonia may be more likely in an older or ill-appearing patient; if there is fever, hypoxemia, tachycardia, or tachypnea; or if abnormalities are present on lung exam.



Those with acute bronchitis symptoms and a history of asthma, chronic obstructive pulmonary disease, or congestive heart failure may be having an exacerbation of chronic disease, either as their primary problem, or triggered by a concomitant chest infection. An assessment of past history and risk factors, as well as physical exam and, when needed, chest radiograph findings can usually establish the diagnosis.

In most situations, for suspected cases of pertussis, the recommended strategy involves both polymerase-chain reaction (PCR) testing and culture, health department reporting, empiric treatment, and close follow-up. A lower threshold for empiric treatment will apply during an identified pertussis outbreak.<sup>4</sup> Local infectious disease specialists, health departments, and the CDC are important resources to consult to balance the need to identify and treat this disease while avoiding treating everyone who has a prolonged cough with antibiotics.

No testing is necessary to make the diagnosis of acute otitis media or sinusitis. There is no proven beneficial role for sinus radiographs in the diagnosis or treatment of sinusitis, and CT scanning of the sinuses should be reserved for refractory or severe cases being treated in conjunction with specialty care.

The diagnosis of otitis media should include acute onset of ear pain and physical exam evidence of tympanic membrane (TM) inflammation and middle-ear effusion (i.e., bulging TM, air-fluid level, otorrhea, or decreased TM mobility on pneumatic otoscopy). Mimics of otitis media are usually distinguishable on exam, and specific palpation of the mastoid process is important in any patient with ear pain.

Features traditionally associated with the clinical diagnosis of sinusitis—nasal obstruction, purulent nasal discharge, pain on bending forward, maxillary toothache, presence of a two-stage illness with sinus symptoms following a URTI—have variable sensitivity and specificity.<sup>5</sup>

One of the more common mimics of acute sinusitis is the exacerbation of chronic sinusitis. There is no specific number, but any patient presenting with his or her “usual sinus infection” three or more times per year probably requires a different approach than just an antibiotic prescription and a pat on the back. For these patients, strongly consider a work-up for chronic sinusitis and its causes (anatomic osteomeatal disease, chronic rhinitis, etc.), typically in conjunction with a specialist. And, though it occurs rarely, patients with sinusitis combined with signs of pulmonary and/or renal disease should be promptly referred for work-up for Wegener’s

granulomatosis.

Diagnostic testing does play a role in the management of acute pharyngitis. Older guidelines presented options for purely clinical diagnosis, emphasizing the cost effectiveness of such an approach, but the most recent recommendations emphasize obtaining positive rapid antigen testing or culture for group A beta-hemolytic *Streptococcus* (GABHS) *before* beginning antibiotic treatment. Some guidelines recommend that, in the face of an initial negative rapid antigen test, patients with a high chance of GABHS (based on age and other risk factors) should have a throat culture obtained before discharge from the clinic. Patients with a prior history of rheumatic fever are at high risk of recurrence and should be followed very closely when they develop pharyngitis or any possible Streptococcal infection.

Any patient with sore throat should be thoroughly examined for swelling or other abnormalities of the uvula and peritonsillar and other parapharyngeal spaces. Drooling, stridor, and trismus are nonspecific but typically indicate severe disease and the need for urgent specialty consultation or ED transfer.

In the absence of such severe symptoms, finding any of these disease mimics at the earliest possible stage requires consideration of the full range of possible diagnoses—maintaining a high index of suspicion—for every patient with a sore throat.

Of the many viral etiologies for pharyngitis, some can result in higher rates of morbidity, including Epstein Barr virus and cytomegalovirus, both of which can cause an acute-mononucleosis-type syndrome of fever, malaise, lymphadenopathy, and frequently splenomegaly and usually mild hepatitis.

Primary infection with human immunodeficiency virus (HIV) can result in a similar clinical picture and should be considered in patients with appropriate risk factors.

Suspicion of gonococcal pharyngitis is also engendered by risk factor assessment.

Kawasaki disease presents more often as stomatitis than as pharyngitis, but it is important to keep this diagnosis in mind due to the potential complication of affected children developing coronary artery aneurysms. Suspect the diagnosis and obtain urgent consultation for children under 10-years-old (particularly under 3 years of age) with fever for five days or more, and a syndrome including conjunctivitis, polymorphous rash or desquamation, cervical lymphadenopathy, and any combination of fissured lips, stomatitis, pharyngitis, and/or strawberry tongue.<sup>6</sup>

### Treatment and Disposition

Toxic-appearing and otherwise unstable patients—those with airway, breathing, and circulatory compromise—require an aggressive approach, with initial rapid evaluation and stabilization (supplemental oxygen and intravenous fluid boluses and airway interventions, if within the scope of the clinic and clinician) and prompt ambulance transport to the emergency department.

Patients who have compromised immunity, significant comorbidities (e.g., chronic obstructive pulmonary disease, pulmonary fibrosis, cystic fibrosis, congestive heart failure, hepatic and renal disease, etc.), or refractory, persistent, or frequently recurrent URTIs require more complex decision-making than that described here.

In general, however, stable, otherwise healthy patients with uncomplicated URTIs who are maintaining their hydration—who will be the overwhelming majority of patients in most practices—can be treated very simply at home.

In every situation, explain to patients what they should expect and discuss precautions for immediate re-evaluation, as well as specific timing for return if not improving. Schedule next-day follow-up for patients for whom the level of illness is unclear. Because every disease has a time course and even uncommon things will occur the longer one practices, use good communication and close clinical follow-up as your safety net for every patient.

### *Common cold, bronchitis, and viral pharyngitis*

Existing clinical practice guidelines emphasize the importance of not prescribing antibiotics for patients with a common cold, acute bronchitis, and viral pharyngitis. Symptomatic care can include acetaminophen or a non-steroidal anti-inflammatory medication (if there are no contraindications) for fever, aches, and pain. Stronger analgesics may be reasonable in patients who fail to get relief with these, e.g., to facilitate oral fluid intake in those with pharyngitis.

Often, patients desire relief from cough; unfortunately, no preparation has consistently shown clinical benefit. A potential limitation in this research, however, is that comparison is often made with a placebo, yet no placebo exists for clinicians to prescribe or recommend! It is probable that, as long as the possible side effects are considered by the patient and provider, prescription of some sort of cough suppressant is reasonable.

In patient with bronchitis, some studies have shown variable benefit for the use of beta-agonist inhalers, like albuterol, to help with cough and chest congestion; the presence of wheezing on exam may indicate a greater chance of benefit in a particular patient.

### *Otitis media and acute sinusitis*

For both acute otitis media and sinusitis, the decision to treat with antibiotics may be based on available guidelines, plus the knowledge that placebo-controlled studies have shown rates of up to 80% resolution without antibiotics for these conditions.<sup>7</sup>

A study published in 2007 in the *British Medical Journal*<sup>8</sup> estimated that over 4,000 patients with otitis media would need to be treated with an-

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**Table 3. Recommended Antibiotic Regimens for Uncomplicated Respiratory Tract Infections**

Respiratory tract infection	First-line antimicrobial therapy	Alternate therapy
Common cold	None	None
Acute sinusitis	None or amoxicillin	Doxycycline Trimethoprim/sulphamethoxazole Cefdinir, cefprozil, cefuroxime, cefpodoxime Amoxicillin/clavulanate Respiratory fluoroquinolones Clarithromycin Azithromycin
Acute pharyngitis	Penicillin, if <i>Strep</i> testing is positive	For penicillin-allergic* patients: Second-generation cephalosporins Erythromycin Clindamycin
Acute bronchitis	None	None
Acute otitis media	Amoxicillin (high-dose) 80-90 mg/kg daily divided BID	Amoxicillin/clavulanate For penicillin-allergic* patients: Cefuroxime Cefdinir Cefpodoxime Azithromycin Clarithromycin Ceftriaxone

\* Some patients who report prior allergy to penicillin also have allergic reactions to cephalosporins; if a person has had anaphylaxis or other severe allergy to penicillin, it is safest to avoid cephalosporins.

tibiotics to prevent a serious complication (e.g., mastoiditis) in one patient; a similar “number needed to treat” of over 4,000 applied to preventing serious complications of URTI and sore throat.

Specifically, antibiotic treatment *is* recommended for all of those under 6 months of age who have a diagnosis of otitis media. There is an option to observe and withhold antibiotics in children between 6 months and 2-years-old if the diagnosis is uncertain or the condition is not severe, and for those 2 years and older unless the diagnosis is certain *and* the disease is severe.

When antibiotics are used, focused-spectrum therapy is recommended (see **Table 3**). Amoxicillin is still first line, although because of the prevalence of drug resistance among pneumococcus, a high-dose regimen (80 mg/kg/day to 90 mg/kg/day, divided BID) is recommended.

For all patients with otitis media, attention to analgesia (oral and topical) is strongly emphasized. Decongestants and antihistamines have not been shown to

be helpful.<sup>9</sup> There are no specific guidelines for adults with otitis media.

For acute sinusitis, existing guidelines recommend using antibiotics in patients with severe symptoms or moderate symptoms that are worsening after five to 10 days or not improved after 10 days. Again, focused-spectrum antibiotics (**Table 3**) are first line for uncomplicated infections if antibiotics are felt to be necessary.

Studies have yielded a range of results regarding the use of nasal steroid sprays, and a *Cochrane Review*<sup>10</sup> of the literature found them to be possibly effective. Antihistamines may cause drying of nasal secretions and impede drainage, and are generally avoided in patients with sinusitis.

Interestingly, some new evidence<sup>11</sup> suggests that, though a specific patient may indeed have sinusitis, there may be no reliable clinical indicators to tell a clinician whether antibiotics might be helpful or harmful to that patient.

#### *GABHS pharyngitis*

Penicillin-resistance among GABHS has been reported to be nonexistent or extremely rare. (In contrast, macrolide resistance is rising.) Concerns have been raised regarding penicillinase activity among other organisms inhabiting the throat at the same time as a GABHS infection, but these seem to impact mostly disease-related outcomes such as culture-proven eradication of the pathogen, rather than patient-oriented outcomes such as duration of illness or the development of complications.

For all of these reasons, guidelines continue to recommend penicillin as first-line antimicrobial therapy for GABHS pharyngitis in patients who are not allergic to it. For penicillin-allergic patients, a narrow-spectrum alternative antibiotic should be used (**Table 3**).

Adjunctive systemic corticosteroids for one to three days (at most) may help decrease pain associated with GABHS pharyngitis.

*Continued on page 28*



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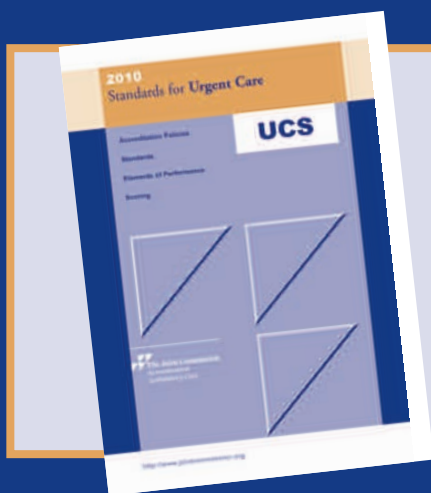




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# Case Report

## A Child with Constipation and Swollen Abdomen

**Urgent message:** Malignancies in children are often discovered only inadvertently, in conjunction with seemingly less dire presentations. Awareness of relevant signs and symptoms by the urgent care clinician can be invaluable in identifying tumors that might otherwise escape notice until they are at an advanced stage.

Muhammad Waseem, MD

### Introduction

The identification of a palpable abdominal mass in an urgent care center or emergency department is quite concerning, as it represents a serious underlying disorder. Any abdominal mass in a child is usually considered malignant until proven otherwise. Abdominal tumors are uncommon in children and can present with pain, vomiting, or abdominal mass.

Here, we report on a child who presented with history of constipation and an abdominal mass that was identified on physical examination and subsequently diagnosed as neuroblastoma.

### Case Study

A 15-month-old female presented with a two-day history of constipation. There was no vomiting, fever, or abdominal pain. She previously had been in good



© iStockphoto/Sean Locke

health and had seen her pediatrician regularly. Her parent also noted her to have a swollen abdomen, which they attributed to “constipation.” She had been evaluated for this by her pediatrician and was taking stool softeners.

### Findings

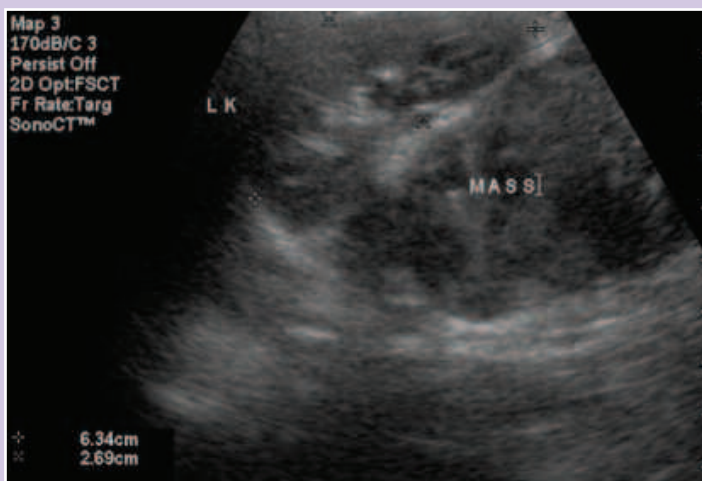
Physical examination revealed a well-developed, comfortable child with:

- temperature 99°F (36.9°C)
- pulse 108 beats per min
- BP 99/62 mmHg
- respiration 20 per minute.

The patient’s abdomen was mildly distended, with fullness on the left side and flank. A somewhat firm, nontender, nonmobile mass with rounded margins was palpable in the left lower quadrant and left lumbar regions. No guarding, rigidity, or tenderness was noted. Bowel sounds were audible. Rectal examination

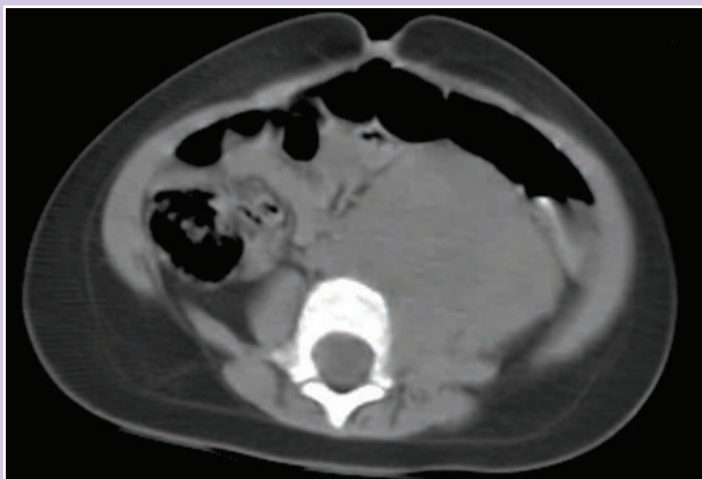


**Figure 1.**



Renal ultrasound showing a retroperitoneal mass in the left flank.

**Figure 2.**



A contrast computed tomography (CT) scan of abdomen showing a left retroperitoneal mass between the left kidney and upper lumbar spine, with some displacement of the left kidney.

revealed no tenderness or masses; rectal vault was empty. The remainder of the physical examination was unremarkable.

Other findings included:

- white blood cell count  $9.3 \times 10^3/\text{mcL}$  ( $11.1 \times 10^9/\text{L}$ )
- 29.1% neutrophils

- 56.4% lymphocytes
- 12.7% monocytes
- 1.2% eosinophils
- 0.6% basophils
- hemoglobin 11.3 g/dL
- platelet count was  $733 \times 10^3/\text{mcL}$  ( $733 \times 10^9/\text{L}$ )
- serum electrolytes were normal
- aspartate aminotransferase 43 U/L
- alanine aminotransferase 16 U/L
- albumin 3.8 g/dL
- bilirubin 0.3 mg/dL
- alkaline phosphatase 188 U/L
- lactic dehydrogenase 317 U/L (105-215).
- Urinalysis yielded normal findings.

The initial renal ultrasound showed a retroperitoneal mass in the left flank without hydronephrosis or intrinsic renal mass (**Figure 1**). Subsequently, a contrast computed tomography (CT) scan of the abdomen revealed a left retroperitoneal mass between the left kidney and upper lumbar spine, with some displacement of the left kidney (**Figure 2**). The urinary catecholamine metabolites, homovanillic acid (HVA), and vanillylmandelic acid (VMA) were also elevated.

The patient was referred to an affiliated tertiary care center for sub-specialty care.

### Discussion

The child with an abdominal mass presents a unique challenge. A palpable mass in the abdomen of a child is a serious finding, with a fairly extensive differential diagnosis.

Abdominal masses may occur at any age, and may have a wide variety of clinical presentations. It is the urgent care clinician's role to differentiate between benign conditions such as constipation and more serious causes of abdominal mass (**Table 1**).

When an abdominal mass is discovered on physical examination, the immediate goal is to determine its nature and extent. A tentative diagnosis can often be made from the presenting symptoms, age of the child, and the site of mass. Physical examination should focus on the location, size, and mobility of the mass, as well as other



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<sup>†</sup>*In vitro* data are not always indicative of clinical success or microbiological eradication in a clinical setting.

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VIGAMOX® solution is indicated for the treatment of bacterial conjunctivitis caused by susceptible strains of the following organisms: *Corynebacterium* species<sup>†</sup>, *Micrococcus luteus*<sup>†</sup>, *Staphylococcus aureus*, *S. epidermidis*, *S. haemolyticus*, *S. hominis*, *S. warneri*<sup>†</sup>, *Streptococcus pneumoniae*, *Streptococcus viridans* group, *Acinetobacter lwoffii*<sup>†</sup>, *Haemophilus influenzae*, *Haemophilus parainfluenzae*<sup>†</sup>, *Chlamydia trachomatis* (<sup>†</sup>efficacy for this organism was studied in fewer than 10 infections). VIGAMOX® solution is contraindicated in patients with a history of hypersensitivity to moxifloxacin, to other fluoroquinolones, or to any of the components in this medication. NOT FOR INJECTION. VIGAMOX® solution should not be injected subconjunctivally, nor should it be introduced directly into the anterior chamber of the eye. In patients receiving systemically administered quinolones, including moxifloxacin, serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported, some following the first dose. As with other anti-infectives, prolonged use of VIGAMOX® solution may result in overgrowth of non-susceptible organisms, including fungi. The safety and effectiveness of VIGAMOX® solution in infants below 1 year of age have not been established. The most frequently reported ocular adverse events were conjunctivitis, decreased visual acuity, dry eye, keratitis, ocular discomfort, ocular hyperemia, ocular pain, ocular pruritus, subconjunctival hemorrhage, and tearing. These events occurred in approximately 1%–6% of patients.

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

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#### Microbiology:

The following *in vitro* data are also available, but their clinical significance in ophthalmic infections is unknown. The safety and effectiveness of VIGAMOX® solution in treating ophthalmological infections due to these microorganisms have not been established in adequate and well-controlled trials.

The following organisms are considered susceptible when evaluated using systemic breakpoints. However, a correlation between the *in vitro* systemic breakpoint and ophthalmological efficacy has not been established. The list of organisms is provided as guidance only in assessing the potential treatment of conjunctival infections. Moxifloxacin exhibits *in vitro* minimal inhibitory concentrations (MICs) of 2 µg/ml or less (systemic susceptible breakpoint) against most (≥ 90%) strains of the following ocular pathogens.

#### Aerobic Gram-positive microorganisms:

*Listeria monocytogenes*  
*Staphylococcus saprophyticus*  
*Streptococcus agalactiae*  
*Streptococcus mitis*  
*Streptococcus pyogenes*  
*Streptococcus Group C, G and F*

#### Aerobic Gram-negative microorganisms:

*Acinetobacter baumannii*  
*Acinetobacter calcoaceticus*  
*Citrobacter freundii*  
*Citrobacter koseri*  
*Enterobacter aerogenes*  
*Enterobacter cloacae*  
*Escherichia coli*  
*Klebsiella oxytoca*  
*Klebsiella pneumoniae*  
*Moraxella catarrhalis*  
*Morganella morganii*  
*Neisseria gonorrhoeae*  
*Proteus mirabilis*  
*Proteus vulgaris*  
*Pseudomonas stutzeri*

#### Anaerobic microorganisms:

*Clostridium perfringens*  
*Fusobacterium species*  
*Prevotella species*  
*Propionibacterium acnes*

#### Other microorganisms:

*Chlamydia pneumoniae*  
*Legionella pneumophila*  
*Mycobacterium avium*  
*Mycobacterium marinum*  
*Mycoplasma pneumoniae*

#### Clinical Studies:

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

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

#### Aerobic Gram-positive microorganisms:

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

#### Aerobic Gram-negative microorganisms:

*Acinetobacter lwoffii*  
*Haemophilus influenzae*  
*Haemophilus parainfluenzae\**

#### Other microorganisms:

*Chlamydia trachomatis*

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

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

#### WARNINGS:

NOT FOR INJECTION.

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

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

#### PRECAUTIONS:

**General:** As with other anti-infectives, prolonged use may result in overgrowth of non-susceptible organisms, including fungi. If superinfection occurs, discontinue use and institute alternative therapy. Whenever clinical judgment dictates, the patient should be examined with the aid of magnification, such as slit-lamp biomicroscopy,

and, where appropriate, fluorescein staining. Patients should be advised not to wear contact lenses if they have signs and symptoms of bacterial conjunctivitis.

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

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

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

**Carcinogenesis, Mutagenesis, Impairment of Fertility:** Long term studies in animals to determine the carcinogenic potential of moxifloxacin have not been performed. However, in an accelerated study with initiators and promoters, moxifloxacin was not carcinogenic in rats following up to 38 weeks of oral dosing at 500 mg/kg/day (approximately 21,700 times the highest recommended total daily human ophthalmic dose for a 50 kg person, on a mg/kg basis).

Moxifloxacin was not mutagenic in four bacterial strains used in the Ames *Salmonella* reversion assay. As with other quinolones, the positive response observed with moxifloxacin in strain TA 102 using the same assay may be due to the inhibition of DNA gyrase. Moxifloxacin was not mutagenic in the CHO/HGPRT mammalian cell gene mutation assay. An equivocal result was obtained in the same assay when v79 cells were used. Moxifloxacin was clastogenic in the v79 chromosome aberration assay, but it did not induce unscheduled DNA synthesis in cultured rat hepatocytes. There was no evidence of genotoxicity *in vivo* in a micronucleus test or a dominant lethal test in mice.

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

#### Pregnancy: Teratogenic Effects.

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

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

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

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

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

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

#### ADVERSE REACTIONS:

The most frequently reported ocular adverse events were conjunctivitis, decreased visual acuity, dry eye, keratitis, ocular discomfort, ocular hyperemia, ocular pain, ocular pruritus, subconjunctival hemorrhage, and tearing. These events occurred in approximately 1-6% of patients.

Nonocular adverse events reported at a rate of 1-4% were fever, increased cough, infection, otitis media, pharyngitis, rash, and rhinitis.

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## CASE REPORT

### Table 1. Common Causes of Abdominal Mass in Children

- Wilms' tumor
- Neuroblastoma
- Lymphoma
- Polycystic or dysplastic kidney
- Hydronephrosis
- Hepatoblastoma
- Teratoma
- Ovarian cyst
- Constipation/fecal mass

Source: Ruddy RM. emergency presentations of cancer in childhood. *Clin Ped Emerg Med*. 2005;6(3):184-191.

abnormalities on examination. The examination should also include measurement of serial blood pressures and a complete neurological assessment.

The presence of an abdominal mass may indicate the existence of colonic stools or tumors. In constipation, a mass can be palpated, which is usually associated with fecal impaction on rectal examination. Wilms' tumor and neuroblastoma (NB) are the two common intra-abdominal masses in children. These are more prevalent in children younger than 4 years.

NB is the most common extracranial tumor in children,<sup>1</sup> accounting for 10% of pediatric malignancies. After tumors of the central nervous system, it is the most common solid tumor in children.<sup>2</sup> It is also the most common malignant tumor of infancy, with 50% of cases occurring in children younger than 2 years of age and 75% diagnosed by the fourth year of life.

The median age at diagnosis is 2 years, but the tumor may present in the neonate or even in adolescents and adults.<sup>3</sup> NB occurs most commonly in the abdomen (65%), either in the sympathetic chain or more commonly in the adrenal gland.<sup>4,5</sup> After the abdomen, the thorax is the second most common location of NB (15%) followed by the neck (1% to 5%) and the pelvis (2% to 3%).<sup>6</sup>

### Clinical Presentation

NB may have diverse clinical features because of its variable sites of origin, propensity to metastasize, and secretion of hormones. Clinical features at presentation depend on the size and location of the primary tumor, and on whether the tumor has



metastasized. Between 50% and 70% of patients with NB may have metastasis at the time of their presentation.<sup>7</sup> Large masses may cause respiratory distress. The common sites for distant metastasis include the bone marrow, liver, and skin.<sup>8</sup>

The signs and symptoms of this tumor are dependent on the location of the primary tumor, which may occur anywhere along the peripheral sympathetic nervous system, and the sites of metastatic disease. Typically the initial symptoms are nonspecific (general malaise, weight loss, unexplained fever), as in most patients the tumor is either retroperitoneal or in posterior mediastinum.<sup>9</sup>

#### Common symptoms

The common symptoms are:

- abdominal pain or discomfort
- sensation of fullness
- fever
- weight loss.

Although most children present with abdominal pain or a palpable mass, many present with manifestations of their metastatic disease, including bone or joint pain and periorbital ecchymosis.

#### Diagnostic Evaluation

An abdominal mass in a child must be considered malignant until proven otherwise. As such, any studies described here but not feasible for the urgent care setting should be facilitated via referral. They are included here for the sake of presenting as complete a picture of the diagnostic process as possible.

When an abdominal mass is detected in a child, imaging studies should be performed. Ultrasound is helpful in the initial evaluation of a child with an abdominal mass, as it is useful in determining the origin of the mass. It will also help determine whether the mass is cystic or solid.

Abdominal CT scan is a commonly used imaging modality for the assessment of a child with abdominal mass. It offers several advantages in the differential diagnosis of a possible Wilms' tumor, such as confirmation of the intrarenal origin of the tumor, detection of multiple masses, determination of the extent of tumor, and evaluation of the opposite kidney.

Initial laboratory studies should include a complete blood count to identify anemia or thrombocytopenia suggestive of bone marrow invasion. NB produces catecholamine metabolites, which are used as tumor markers; therefore, a search for specific tumor markers se-

creted by the suspected tumor should also be made.

Elevation of urinary catecholamine metabolites, homovanillic acid (HVA), and vanillylmandelic acid (VMA) is used as a diagnostic screen,<sup>10,11</sup> as this is present in 75% to 90% of patients with NB.<sup>12</sup>

#### Differential Diagnosis

Most abdominal masses in infants are due to problems of the urinary tract. Hydronephrosis and multicystic kidney are common causes of flank masses at this age.<sup>13</sup> If a mass appears to be in the flank in an older infant or child, Wilms' tumor and NB should be considered.

Additional features suggestive of Wilms' tumor include fever, abdominal pain, or hematuria.

Hepatoblastoma is the most common primary hepatic tumor in young children. A high serum alpha-fetoprotein is often noted.

Lymphoproliferative conditions can also present with an abdominal mass. A suprapubic mass may be due to a distended bladder, which in turn may be secondary to urinary tract obstruction.

#### Conclusion

The presence of an abdominal mass in children includes a wide spectrum of diseases. This case emphasizes the value of performing a careful and thorough physical examination upon presentation. The presence of an abdominal mass should generate the suspicion for the possibility of tumor. ■

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# On Retail Clinics, Bell Palsy, and Abscesses: to Pack or Not to Pack?

■ NAHUM KOVALSKI, BSc, MDCM

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

### Cost and Quality of Care at Retail Clinics

**Key point:** *Quality scores at retail clinics rivaled those at urgent care centers, physician offices, and EDs.*

**Citation:** Mehrotra A, Liu H, Adams JL, et al. Comparing costs and quality of care at retail clinics with that of other medical settings for 3 common illnesses. *Ann Intern Med.* 2009;151(5):321-328.

Professional organizations have raised concerns about the quality of care that is delivered at store-based retail clinics. Using claims data from a Minnesota health insurer, investigators searched for episodes of initial care for pharyngitis, otitis media, and urinary tract infections; they identified 2,100 episodes that occurred in retail clinics and matched them with 13,070 episodes that occurred in urgent care centers, physician offices, or emergency departments (EDs). In addition to location and ailment, cases were matched by age, sex, comorbidities, and income.

Aggregate quality scores (proportion that met indicators specific for each condition) were similar for retail clinics, physician offices, and urgent care centers (64%, 61%, and 63%, respectively) and lower at EDs (55%). Urine cultures for high-risk patients were ordered less often at retail clinics than in other settings (30% vs. 55%–58%). Costs per episode

(health plan reimbursements plus copayments) were lower for retail clinics (\$110) than for physician offices (\$166), urgent care centers (\$156), and EDs (\$570).

Many physicians smirk when they hear about care that is delivered at a retail clinic or at a freestanding “doc-in-the-box.” This study won’t settle questions about quality of care in such settings, in part because all settings scored low and measures were obtained exclusively from claims data. But, clearly, these services have arisen in response to perceived needs.

[Published in *J Watch Gen Med*, September 17, 2009—Richard Saitz, MD, MPH, FACP, FASAM.]■

### Do Corticosteroids and Antiviral Agents Have Benefits for Patients with Bell Palsy?

**Key point:** *New evidence has emerged regarding the use of corticosteroids and antiviral agents in Bell palsy.*

**Citation:** Almeida JR, Khabori MA, Guyatt GH, et al. Combined corticosteroid and antiviral treatment for bell palsy: A systematic review and meta-analysis. *JAMA.* 2009;302(9):985-993.

Eligible studies were randomized controlled trials comparing treatment with either corticosteroids or antiviral agents with a control and measuring at least one of the following outcomes: unsatisfactory facial recovery (four months), unsatisfactory short-term recovery (six week to less than four months), synkinesis and autonomic dysfunction, or adverse effects. Eighteen trials involving 2,786 patients were eligible.

Regression analysis identified a synergistic effect when



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

## ABSTRACTS IN URGENT CARE

corticosteroids and antiviral agents were administered in combination compared with alone.

Meta-analysis using a random-effects model showed corticosteroids alone were associated with:

- a reduced risk of unsatisfactory recover
- a reduced risk of synkinesis and autonomic dysfunction
- no increase in adverse effects.

In addition:

- Antiviral agents alone were not associated with a reduced risk of unsatisfactory recovery.
- When combined with antiviral agents, corticosteroids were associated with greater benefit than antiviral agents alone.
- When combined with corticosteroids, antiviral agents were associated with greater risk reduction of borderline significance compared with corticosteroids alone. ■

### Simple Abscesses—Can We Poke without the Pack?

**Key point:** *Packing is not necessary.*

Citations: Taira BR, Singer AJ, Thode HC Jr, et al. National epidemiology of cutaneous abscesses. *J Emerg Med.* 2009;27:289-292.

O'Malley GF, Dominici P, Giraldo P, et al. Routine packing of simple cutaneous abscesses is painful and probably unnecessary. *Acad Emerg Med.* 2009;16:470-473.

Visits to the emergency department for cutaneous abscesses more than doubled between 1996 and 2005. Incision and drainage are the mainstay of treatment. The authors of these articles challenge the common wisdom that packing is critical to the care and healing of cutaneous abscesses.

Researchers conducted a prospective, randomized, single-blinded study of 48 adult subjects presenting to a single emergency department with simple cutaneous abscesses. All adult patients with cutaneous abscesses on the trunk or extremities that required I&D were eligible. Exclusion criteria included abscesses greater than 5 cm in diameter, pregnancy, comorbid medical conditions with possible immunosuppression including diabetes, HIV, malignancy, and chronic steroid use, as well as abscesses on other areas of the body and head, and a sulfa allergy.

Standard incision, drainage, and irrigation were performed on each abscess. Subjects were then randomized to packing with ¼ inch plain gauze or no packing. Pain scores were measured in the ED using a standard 100-point visual analog scale (VAS); subjects were asked to record their VAS pain score twice daily until they were seen in a return visit in 48 hours. All subjects were prescribed trimethoprim-sulfamethoxazole (TMP-SMX), ibuprofen, and oxycodone/acetaminophen.

A physician blinded to the study examined each wound at



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the 48-hour visit and determined the need for further intervention and measured wound erythema, induration, and fluctuance. Measurements were repeated by a second, similarly blinded physician. All patients were contacted by phone 10-15 days after the initial visit to determine if their abscesses had required additional interventions.

Patients were randomized to the packing group (n=23) or the non-packed group (n=25). Only 34 subjects (66%) returned for the 48-hour follow-up visit. Thirteen were from the non-packed group and 21 from the packed group. Four of the patients in the packed group and five of the patients in the non-packed group required intervention at follow-up.

Ten of the 11 patients in the non-packed group who did not return for follow-up and were contacted by phone reported that they did not think the abscess required re-evaluation and that they were pain free. Only one of the three patients in the packed group who did not follow up was reached and reported moderate pain but did not return to the ED.

There was no difference between the groups in pre-procedural pain scores. Subjects in the packed group reported higher pain scores in both the immediate post-procedural period and at the 48-hour follow up visit. There was no significant difference in the amount of ibuprofen taken, but patients in the packing group took a mean of 3.1 narcotic pain pills, compared with a mean of 0.91 pills in the non-packed group.

Given the prevalence of community acquired methicillin-resistant *Staph aureus*, it is unlikely that we will see a reduction in the prevalence of cutaneous abscesses. However, if the evidence bears out, elimination of packing of simple abscesses will save time and money and reduce patient discomfort. ■

## A note on dehydration

A complication of any of the URTIs in children, and sometimes adults, is dehydration. Fever and other mechanisms can increase insensible fluid loss, and malaise and sore throat can decrease fluid intake. Discuss fever control, analgesia, and appropriate oral hydration with each patient; occasionally providing intravenous fluid rehydration may be necessary.

## Patient Satisfaction

There is no evidence that patient satisfaction is related to getting an antibiotic prescription for a URTI. In addition, data show that clinicians are not able to determine whether any particular patient expects such a prescription or not.

Studies do link patients' satisfaction to their receiving discussions of their diagnoses, as well as attention to alleviation of their symptoms.

Several years ago, the concept of a delayed or "safety net" prescription was introduced. This strategy involved giving a patient an antibiotic prescription, along with instructions to wait for several days of no improvement before filling and beginning to take it. This approach was shown in several studies to be safe, to reduce antibiotic use, and to be satisfactory to patients. However, a recent review<sup>12</sup> combining many studies showed that prescribing no antibiotic, rather than giving a safety net prescription, resulted in similar clinical and patient satisfaction outcomes, assuming clinicians felt that it was safe not to prescribe antibiotics for a URTI.

## Conclusion

Antibiotic prescribing has a direct impact on the development of antimicrobial resistance. URTIs are a common chief complaint in urgent care practice, and the tendency to overprescribe antibiotics exists. A variety of guidelines and data from the medical literature can assure the clinician that antibiotics are not necessary for the majority of uncomplicated URTIs in most patients. ■

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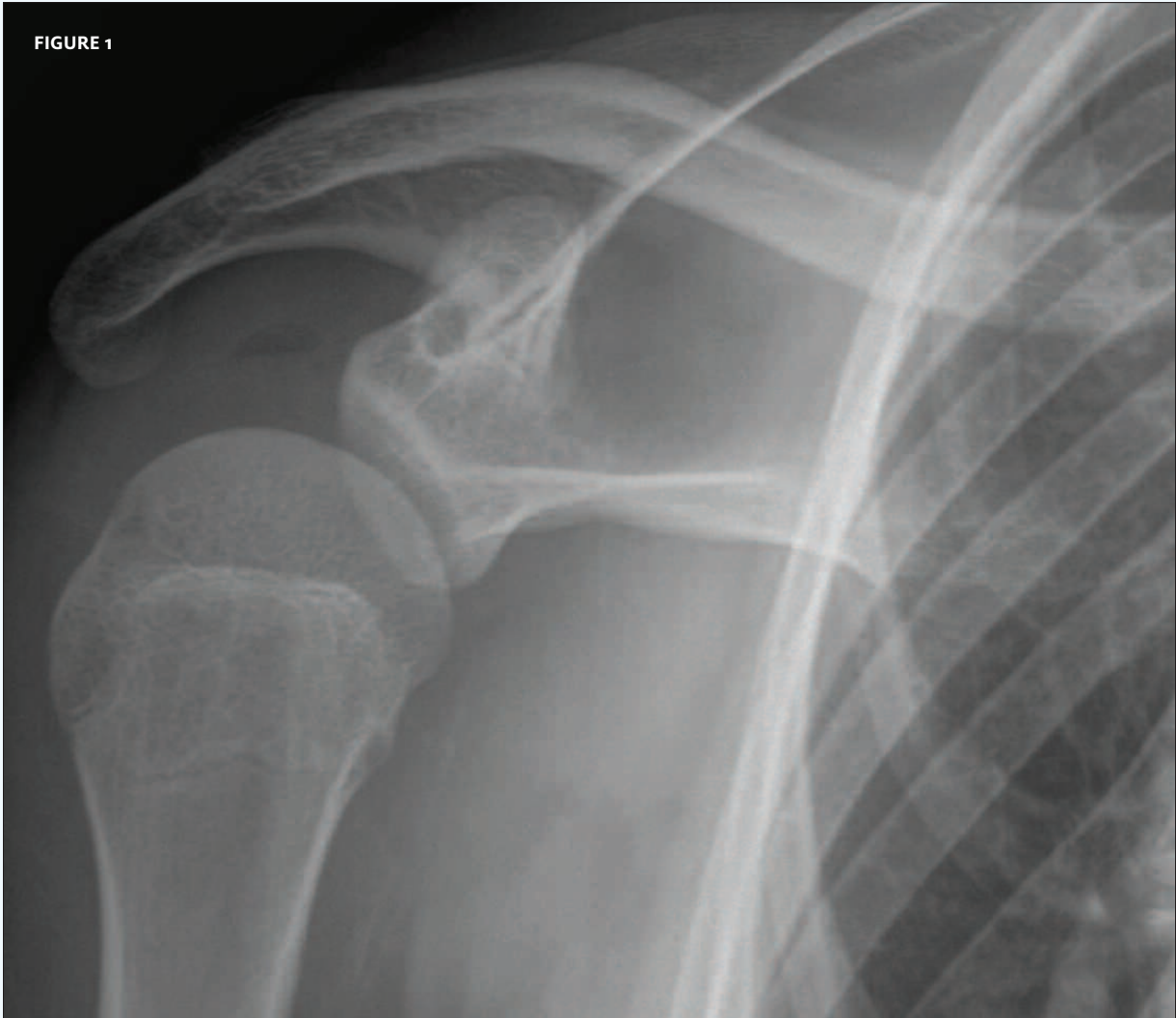
## INSIGHTS IN IMAGES

# CLINICAL CHALLENGE

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

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

FIGURE 1



The patient is a 19-year-old male who complains of pain after receiving a blow to the shoulder.

Range of motion is limited due to pain. The patient is otherwise healthy.

View the x-ray taken (**Figure 1**) and consider what your diagnosis and next steps would be.

Resolution of the case is described on the next page.

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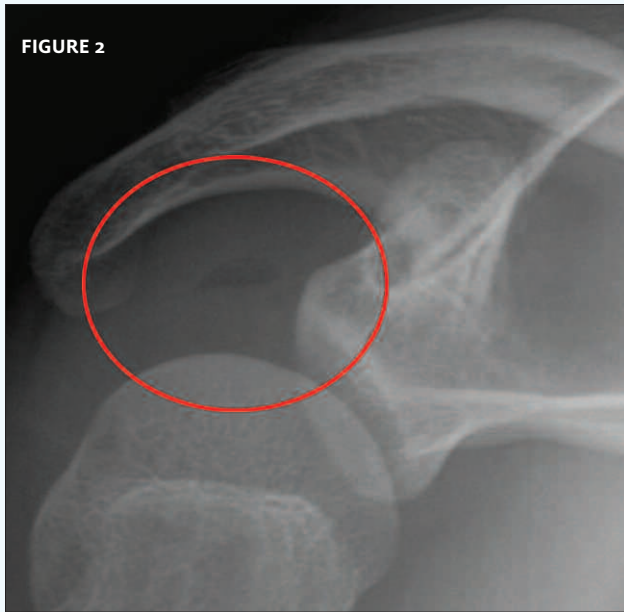
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THE RESOLUTION

FIGURE 2



The correct reading of the image is pseudosubluxation of the shoulder, which refers to inferior displacement of the humeral head relative to the glenoid by fluid in the joint cavity, either hemarthrosis or lipohemarthrosis. This is not a true dislocation.

The radiograph demonstrates a crescent-shaped, low density region representing fat layering above blood within the joint space. The humeral head is inferiorly displaced—but not dislocated—due to distension of the joint.

No fracture line was seen on this film.

Early follow-up with an orthopedist is important. Immediate management is a sling and ice.

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

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## Persistence

■ JOHN SHUFELDT, MD, JD, MBA, FACEP

I just returned from Boston, where the American College of Emergency Physicians held its national conference. While there, along with learning (and relearning) some emergency medicine, I had the chance to walk along the Freedom Trail and enhance my understanding of our battle for independence. What continually amazes me is how fortunate we were to actually succeed. Many times the only thing which turned the tide and saved the day was the persistence of our founders.

Many historians consider the Siege of Boston (starting after the battles of Lexington and Concord) to be the beginning of the Revolutionary War. During the siege, militiamen surrounded Boston, attempting to prevent the British Army, which was garrisoned within Boston, from receiving supplies. To fortify his army's position and prevent the British Navy from supplying the British Army, General Washington sent a 25-year-old bookseller named Henry Knox to bring heavy cannons that had been captured at Fort Ticonderoga in New York all the way to Dorchester Heights, MA, which overlooked Boston's harbor.

Over a wet and freezing winter, Knox and his small group moved 60 tons of artillery by boat, horse-drawn sledges (which they built), and sheer persistence 300 miles along snow-packed trails, across two semi-frozen rivers, and through forests and swamps to the Boston area in 56 days.

Historian Victor Brooks called Knox's feat "one of the most stupendous feats of logistics" of the entire war. Ultimately, the effectiveness of these cannons marked the turning point which eventually forced the British out of Boston.

One of my favorite quotes comes from Calvin Coolidge:

"Nothing in this world can take the place of persistence. Talent will not; nothing is more common than unsuccessful people with talent. Genius will not; unrewarded genius is almost a proverb. Education will not; the world is full of educated derelicts. Persistence and determination alone are omnipotent. The slogan 'press on' has solved and always will

solve the problems of the human race."

You may be asking yourself, how is this relevant to urgent care medicine? More and more I am realizing the "secret sauce" which separates the failing (or, at best, marginally successful) business from the highly profitable endeavor is simply the persistence of the leadership team.

Urgent care medicine is engaged in our own Siege of Boston. There are a number of unknowns which will influence the eventual outcome of our new speciality. Retail clinics will eventually figure out how to turn a profit for their investors. When this happens, how much more of our current patient volume will be usurped by these groups? How will healthcare reform impact our business?

It seems logical that under any plan to reduce healthcare costs, urgent care should fair well. However, will we survive until that happens? How will our rates be affected? We are already at the low end of the reimbursement continuum and even trivial rate cuts could erase our already thin margins.

When will the malpractice insurers realize that urgent care medicine is a risky proposition and raise our premiums?

When will emergency departments improve their throughput and lower their cost to compete with urgent care centers and retail clinics?

So Mr. Knox, what's the game plan? How are we going to move the cannons and protect our already besieged turf? Here are some strategies to consider:

■ **Don't settle.** Health plans are in business to make a profit for their shareholders. To accomplish this, they have three options:

1. Charge higher rates.
2. Reduce utilization.
3. Pay providers less.

Out of those three, guess which one is the easiest? You guessed it, pit the providers against each other, and contract with the urgent care who will accept the least amount of reimbursement. Ever hear of divide and conquer? It is happening to us. How do we combat it without being accused of price fixing? Educate the plans on the value of contracting with urgent care centers and hold the line on reimbursement.



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





# 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 of UCAOA 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](mailto:editor@jucm.com). We will credit all whose submissions are accepted for publication.

**JUCM**  
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## HEALTH LAW

- **Practice quality medicine.** What influences our malpractice rates? The collective industry malpractice experience. Therefore, if our industry has a disproportionate amount of adverse events, it will affect all of our rates, no matter our own center's malpractice history.

I have the “benefit” of reviewing a large number of malpractice cases brought against urgent care centers all across the U.S. The vast majority are very preventable by following a few simple ideas: Urgent care centers (like emergency departments) typically have “one-off” encounters where the tolerance for error is low. Therefore, protect yourself—and most importantly, the patient—by ruling out the things that will kill them.

I advocate using a liberal number of diagnostic tests. No one ever died from getting an unnecessary EKG, CXR, D-dimer, troponin, etc. We typically have one shot to get it right, so do what is necessary to assure yourself that the patient does not have an unusual presentation of a deadly condition.

- **Use standing orders.** Important tasks and tests must not be overlooked during high volume times. Every malpractice case I have reviewed could have been easily prevented by using rational standing orders.
- **Use informed consent and document the conversation.** Engage patients in their own healthcare. Appropriately documented informed consent is medicine's equivalent to *Monopoly's* “Get out of Jail Free” card.
- **Invest in a state-of-the-art electronic health records system.** This will allow the provider to accurately record the patient's treatment, discharge instructions, and informed consent. Let the patient take home an electronic or paper copy of the record so that they can share it with their personal physicians.
- **Stick together.** Don't denigrate your competitors despite what they may be saying. There will be enough people criticizing urgent care centers without us trash-talking our own. As Ben Franklin said, “We must hang together, gentlemen...else, we shall most assuredly hang separately.”

As a discipline, if we simply hold the line on reimbursement, practice quality medicine, and stick together we will enjoy the longevity that our specialty and our patient's deserve.

In other words, we have to persist *and thrive* in the face of a myriad of challenges.

So what happened to Henry Knox? He was repeatedly promoted and was eventually named the first Secretary of War. He went on to champion rights for Native Americans and later retired to Maine. Most importantly, his extraordinary accomplishments paved the way for our eventual independence. ■



# S9083 & Secondary Insurance, Laceration Repair, and More

■ DAVID STERN, MD, CPC

**Q. We bill S9083 to several carriers. Occasionally, a patient will have secondary insurance. If the primary insurance is contracted to pay the S9083 code but transfers the balance to the deductible, how do we bill the secondary carrier if they do not accept the code?**

- Question submitted by Paula Seify, Back Office MD

**A.** Many secondary payors do not accept S9083, but these payors still will often cover the actual services that were rendered under this code if you bill them using typical fee-for-service codes.

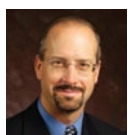
To my knowledge, there is no official CMS or AMA guideline for appropriate coding to a secondary payor under this situation. Most coders would suggest that you recode the services using standard coding methods, i.e., E/M, CPT, and HCPCS codes as appropriate.

In order to avoid compliance issues, the total dollars billed for the aggregate of these codes, however, should not exceed the initial amount billed to the primary insurance under the S9083 code. ■

**Q. A 25-year-old new patient presented to our urgent care center with two lacerations—a 2 cm laceration on the face and a 2.2 cm on the leg. He was otherwise healthy.**

**Can I code an E/M code since I spent 45 minutes for both suture repairs, then add 12011 for the facial laceration repair and 12001 for the leg with modifier -51, as there are more than one laceration? I know that we can add the two cuts into one and use 12004, but I wonder if billing this way you would get less reimbursement since there are two different sites.**

- Physician, Name withheld, California



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

**A.** Let me answer in several parts. First, the time spent repairing the laceration should not count toward an E/M code, as this time is already accounted for in the code(s) for the laceration repair.

Second, is it appropriate to code an E/M code? You say that he was “otherwise healthy,” so I assume that you took an appropriate history and performed an appropriate physical exam. Is this information documented and separately identifiable in the chart? If so, then you may code for the E/M that is appropriate for this documentation and medical complexity. You need to add modifier -25 to the E/M code to indicate that the E/M was performed in addition to the procedure(s).

Third, the coding method that gets more reimbursement should not determine code selection. Instead, use the compliant method per CPT, CMS, or other applicable payor.

Fourth, if the laceration repairs are of the same complexity and if the laceration repairs are located in anatomic regions that are grouped together under the same general heading in the code descriptors for that complexity of laceration repair, then the coder should add the lengths of the two lacerations together to determine the appropriate CPT code. In your example, however, the anatomic locations (face and left leg) are *not* grouped under the same general heading for simple laceration repairs. Thus, you should *not* add the lengths of the lacerations together. Instead, you should *code each laceration separately*, with **12001** (Simple repair of superficial wounds of scalp, neck, axillae, external genitalia, trunk, and/or **extremities** (including hands and feet), 2.5 cm or less) and **12011** (Simple repair of small wound of **facial** area, 2.5 cm or less).

Remember to measure the lacerations after the repair is completed. ■

**Q. We had a patient who needed intravenous fluids and monitoring for five hours. We found the CPT codes 96360-96361 to use for the intravenous hydration therapy. However, the doctor cannot believe the paltry reimbursement for these codes is correct. We did bill an office visit**



# Overcoming the National Contract Barriers

■ FRANK H. LEONE, MBA, MPH

Dealing with prospective client companies such as Walmart that are theoretically wed to a national contract is a relatively common obstacle that may seem virtually impossible to overcome.

Do not, however, view such contracts as impenetrable walls; they can be dealt with in many ways.

### All Contracts are Not Created Equal

When an employer cites a contractual obligation, much may be left unsaid. Indeed, contracts come in various sizes and shapes. A contract can be:

- local, regional, or national
- prospect-specific (relevant only to that company in that locale) or part of a contract that affects an entire national chain (e.g., Home Depot)
- limited in scope or all-inclusive
- binding to the prospect company or discretionary
- simply a price discount that can be matched or sold over by another provider.

Given these variants, there are many ways that an urgent care clinic can approach a contractually bound prospect. You must first, however, ferret out the nature of the contract or perceived obligation. You should pose questions such as:

- Is the contract for a specific time period?
- Do you or your local office have unilateral authority in arriving at a contractual relationship? If not, who is responsible for a final decision?
- Exactly what services does the contract cover?
- What other types of occupational health-related services does your company use that are not specifically

bound to the contract?

- To what degree is the contract binding to your company?
- In what way, if any, might another provider bid for your company's business?
- (If the contract is merely a guaranteed price discount): Beside price, what other things does your company consider when valuating the return on your investment for health and safety support?

In sum, probe to get the facts, look for openings when they occur, and learn to separate opportunities from closed doors.

### Remember: You Have Other Things to Sell

Your urgent care center's occupational health strategy should include product expansion, rather than simply maintaining a static, narrow program. A portfolio-expanding strategy also provides your clinic with a series of fallbacks if and when you are unable to overcome a contractually bound objection.

### Existing Contracts Can Mean Opportunity

Assume for a moment that a national player makes even greater inroads with national contracts and that many of your best prospects become wed to such contracts. Such a theoretical crisis should be viewed as an opportunity.

As provision of core occupational health services becomes less cost effective and as national obligations potentially erode relationships with your clients or prime prospects, it becomes necessary to develop and offer supplemental services (specialized screenings, wellness services, executive health, travel medicine, etc.).

### You Don't Have to Bat 1.000

At .365, the Minnesota Twins' Joe Mauer had the highest batting average in the major leagues in 2009. Accolades aside, Mr. Mauer's .365 batting average also indicates that he

*Continued on page 37*



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



## "Outright resignation negates opportunity that may be a question or two away."

failed to get a hit 63.5% of the time. So it is with a sales professional in almost any industry. You have to anticipate a mix of home runs, base hits, walks, and strikeouts.

A company's national contract obligation may in fact close the door on your clinic—at least for the time being. It is inevitable and part of your sales management function. However, remember to ask questions and probe to seek opportunities when dealing with such companies. Nowadays, outright resignation seems to be the norm, thus negating opportunities that may be only a question or two away.

National contracts suggest that occupational health services are a commodity, when in fact they should be seen in terms of a relationship. Armed with such an understanding, the national contract roadblock should be viewed as less onerous than it is in many cases.

The accompanying table presents a series of appropriate responses to common contract scenarios. ■

Condition	Strategy
Long-term contract	Probe for other service needs
Short-term contract	Position to bid for business at conclusion of contract
Contract with actual company	Stay in touch with decision maker
Contract with national office	Identify contact and correspond with national office
Meeting with decision maker	Learn hot buttons; stay in touch
Decision maker in home office	Identify contact and correspond with national office
Contract covers limited scope of services	Tout value of your broad, integrated services
All, or nearly all, exclusive contract	Look for missing pieces
Contract compliance is mandatory	Look for missing pieces
Contract compliance is discretionary	Treat as traditional prospect; emphasize ROI
Contract involves price discount	Emphasize ROI issues
Contract involves vague obligation	Treat as traditional prospect

**in addition to the intravenous hydration. Is this all we can bill? Does this seem right to you?**

- Question submitted by Nicole, First Health Medical, Fresno, CA

**A.** You are using the correct codes. Don't forget, however, to list the 96361 multiple times (once for each additional hour after the first hour) when appropriate. If the visit in question is properly documented, for example, you would code an E/M code (e.g., 99203), 96360, 96361 x 4. ■

**Q. Is it appropriate to add modifier -59 to after-hour codes?**

- Question submitted by Sharon Dear

**A.** Using modifiers on these codes is *not* helpful for compliance or reimbursement. Modifier -59 is for pointing out to a payor that you are referring to a service that might otherwise be bundled into another code, but because of special circumstances, they are really distinct. For the NCCI edits, the primary purpose of modifier "-59" is to indicate that two or more procedures are performed at *different anatomic sites* or during *different patient encounters*. ■

**Q. Can 94760 (Non-invasive ear or pulse oximetry for oxygen saturation; single determination) be reimbursed in addition to an E/M code?**

- Question submitted by Linda, Keith & Co., El Cajon, CA

**A.** The code 94760 should be used only when the physician orders a single measurement of oxygen saturation (O<sub>2</sub>sat) level. Do not use this code when the clinic is documenting pulse oximetry as a routine part of patient intake.

Some basic guidelines for coding 94760 (per Medicare) include:

1. It is only covered if the patient exhibits any signs or symptoms that may be suggestive of oxygen desaturation.
2. A physician order for the pulse oximetry must be documented in the medical record.
3. When pulse oximetry for oxygen saturation is utilized to monitor a patient's respiratory status, oxygen saturation (during a surgical procedure or conscious sedation) oximetry is considered included in the primary service and not separately reimbursable.

Many, but not all, payors follow similar guidelines. If you are following these guidelines but a payor is denying payment for this code, you should consider an appeal. As always, however, any individual payor may have a policy to deny payment for any particular service. ■

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# Career Opportunities

**URGENT CARE OPPORTUNITY** - Seeking BC/BE primary care physician for urgent care in Bryan/College Station Texas. 8 hour shifts, flexible schedule, paid malpractice. For more information contact Lauren with Emergency Service Partners at 888-800-8237, or Lauren@eddcs.com.

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**Gail Paschall, Sixteenth Street Community Health Center,**  
1032 S. Cesar E. Chavez Dr., Milwaukee, WI 53204

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# Career Opportunities



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For further information on these positions, please contact Faith O'Sullivan at [fosullivan@locumotion.com](mailto:fosullivan@locumotion.com) or on +353 1 299 3550.

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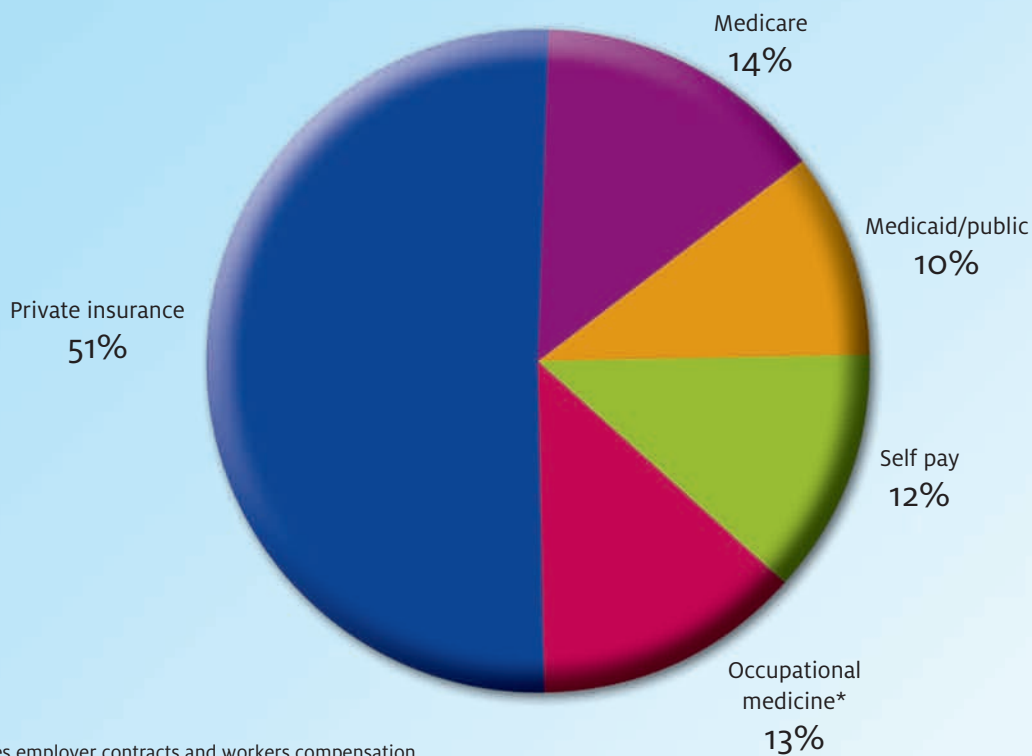
## DEVELOPING DATA

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

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

*In this issue:* Which payors foot the biggest portion of the bill among responding urgent care centers?

### DISTRIBUTION OF PRIMARY PAYORS



The results are not dramatically different from the last time the question was asked on a UCAOA benchmarking survey (2006); slightly higher percentages are coming from Medicaid and Medicare, a slightly lower percentage of patients are paying out-of-pocket, and private insurance is covering exactly the same proportion, according to the current report.

The current UCAOA survey report also offered comparison data with primary care and emergency medicine. The portion of payments coming from the occupational medicine segment was dramatically higher in urgent care than in either primary or emergency care, while Medicaid paid a much higher percentage in emergency care than in either urgent care or primary care. Other categories saw less variation among the three settings.

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

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

# Certified Urgent Care Centers

The Urgent Care Association of America® congratulates the following centers who were recently presented their Certified Urgent Care designation.

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Vernon Hills, IL

***Armistice Urgent Care and  
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Pawtucket, RI

***Bee Caves Urgent Care***

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***Covenant Clinic***

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Romeo, Chesterfield, Clinton, MI

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***MD Urgent Care***

Albuquerque, NM

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***Newport Urgent Care***

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***Staten Island Physicians Practice***

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***Urgent Care of Green Country***

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***Valley FirstCare***

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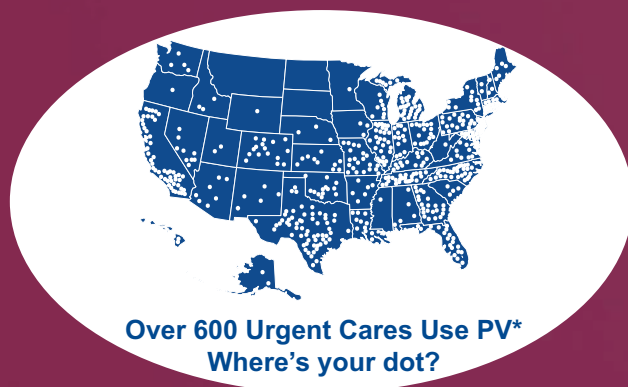
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\* Map: Numbers per state are accurate, but specific locations not designated.



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