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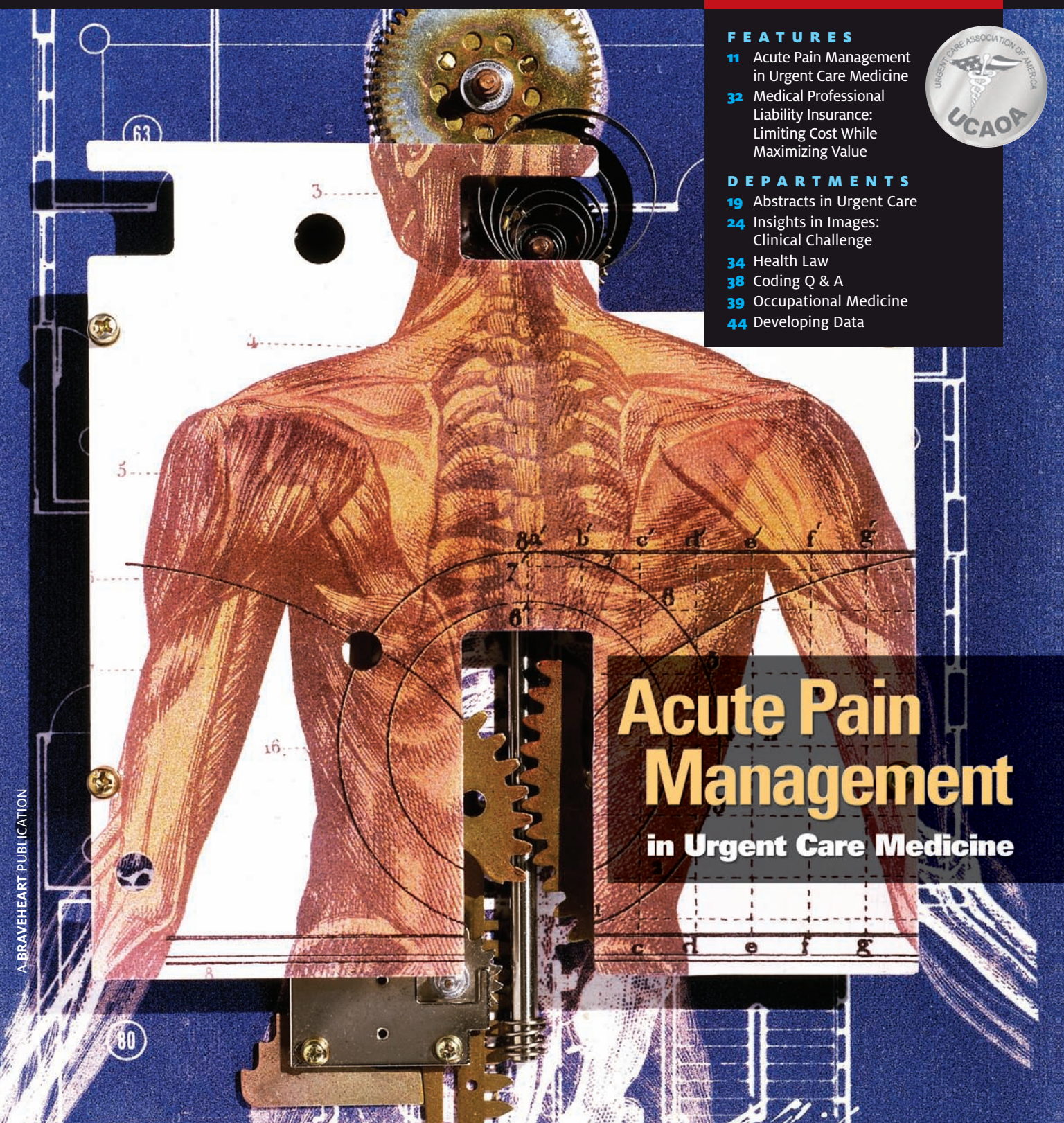
IN THIS ISSUE



Acute Pain Management in Urgent Care Medicine

A BRAVEHEART PUBLICATION

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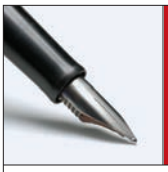

LETTER FROM THE EDITOR-IN-CHIEF

Filling Your Emotional Tank

Nothing like a frigid winter day to inspire a discussion on emotional well-being; the final reserves of endorphins and serotonin that I stored away for the winter are almost depleted, flu season is upon us, wait-times are long, and everyone is cranky.

Times like these remind me of the importance of refueling the emotional tank

This is not just a matter of feeling good, though that's important, too. But physical and emotional fatigue are major contributors to burnout, medical mistakes, and lost productivity. As acute care practitioners, we are especially vulnerable to the ravages of job-related stress. Many of us are also loathe to admit we're susceptible to its effects, however.

Ask yourself the following questions:

- Do you have a shorter temper than you used to?
- Do you feel the need to self-medicate after a shift?
- Do you have chronic pain or depression?
- Do feel energized in the morning?
- Are you still excited about medicine?
- Are you argumentative with patients?
- Do you have healthy hobbies?
- Do you get regular exercise?
- Do you carry a lot of physical tension in your body?
- Do you feel like you don't know your spouse or children well enough?

If these signs of emotional fatigue and burnout apply to you, take action. So what can we do to improve?

Admit that you have a problem, even though acknowledging stress is affecting you can be the hardest thing to do.

Take a break! This is the most obvious thing to do, but it can be the hardest to validate. Start by giving yourself permission to take a break. If you can't be away from your practice for long stretches, take at least one long weekend per month, with no phone calls, no patients, and no Blackberry. Choose calming activities, get outdoors as much as possible, and sleep as much as you can, day and night. Urgent care work is a cortisol binge, and we all know that cortisol binges are followed by cortisol crashes.

Reserve 30 minutes of "me" time daily. Physicians spend most of their time caring for others—on the order of 30-40 "others" per day, in fact. Add to that a spouse and kids who need your care, daily financial management, and home maintenance, and you'll be lucky to have any time left for you. Your time is limited, but if you have no "me" time you will not have anything available to give to others.

Exercise! Sounds like mundane advice, but 30-40 minutes of exercise is the fastest way to boost endorphins, reduce tension, and temper chronic pain.

Breathe! Diaphragmatic breathing exercises are the method of stress reduction most supported by the literature. Try it once and you'll be convinced. It's simple to learn.

Keep humor in your life! Laughter has more scientifically proven health benefits than almost anything other than exercise. Seek out humor in your daily interactions with your staff, your family, your patients, the cashier at the grocery store.... In a grumpy world, nothing has a bigger impact than making someone laugh!

Choose your battles. For some reason, stressed out doctors like to argue with people. Remember that anger is a notoriously bad motivator. Keep your eye on the prize; if your goal is to motivate change, find ways to recruit people. "Sell" them on your ideas, and you will have much less to stress out about.

Stress is a physiologic process governed by neurohormonal regulation; it has no shortcuts and accepts no excuses. Over time, the body becomes resistant to cortisol, requiring ever-greater amounts of stress hormone to fight everyday battles. Couple this with the cortisol crash associated with withdrawal and you have the physiologic recipe for burnout.

Managing your stress more effectively will help you moderate the peaks and valleys of cortisol, which in turn will help mitigate withdrawal symptoms and promote a long and happy career in urgent care medicine. ■

Lee A. Resnick, MD
Editor-in-Chief
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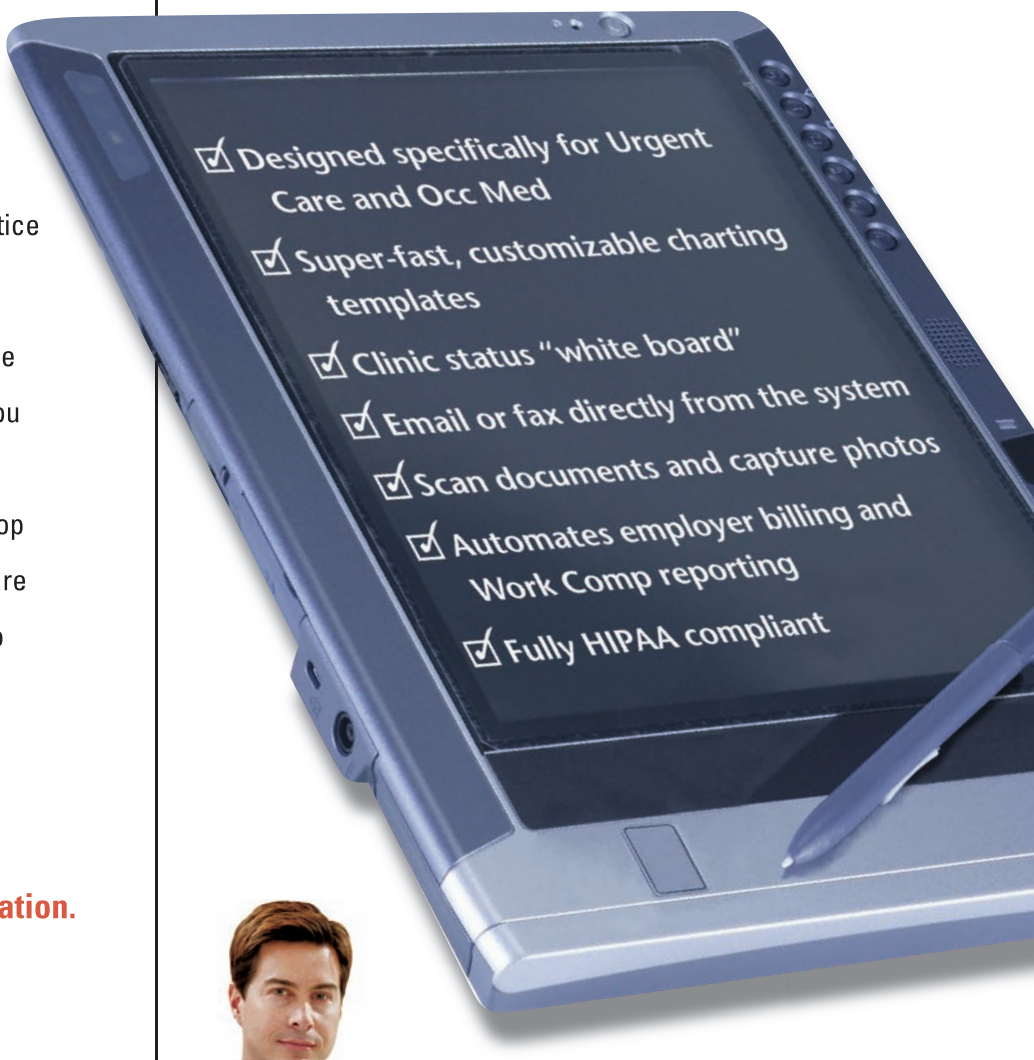

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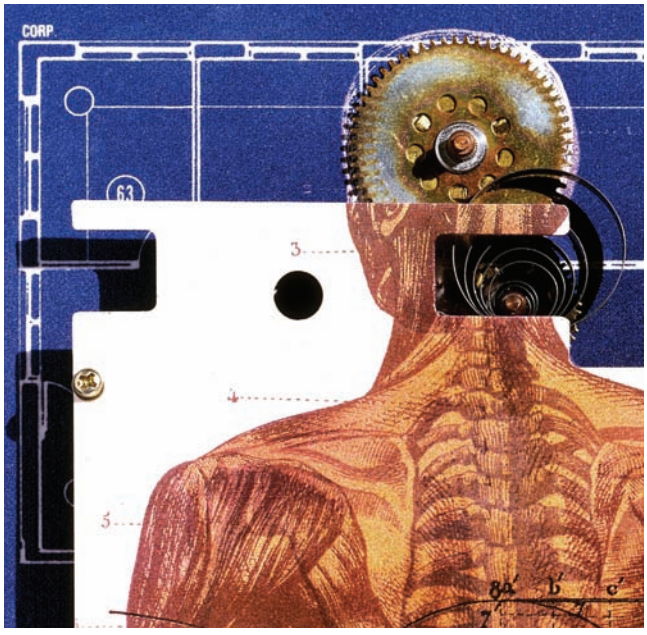


CLINICAL

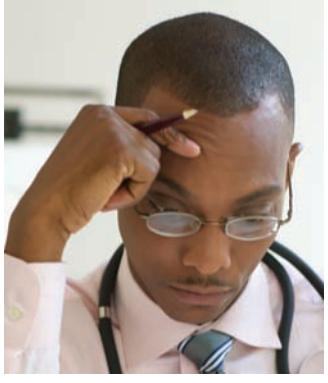
11 Acute Pain Management *in Urgent Care Medicine*

Understanding of various pain syndromes and the pharmacology and analgesic potencies of the proper medications is needed to effectively—and responsibly—treat patients seeking relief.

By Marc R. Salzberg, MD, FACEP and Paolo T. Coppola, MD, FACEP

PRACTICE MANAGEMENT

32 Medical Professional Liability Insurance: Limiting Cost While Maximizing Value



As premiums continue to rise, liability insurance is likely to remain a very costly necessity in urgent care. How can urgent care practitioners get the most value out of every premium dollar spent?

By Terrence P. Coughlin, CPCU, ARM, AIC

DEPARTMENTS

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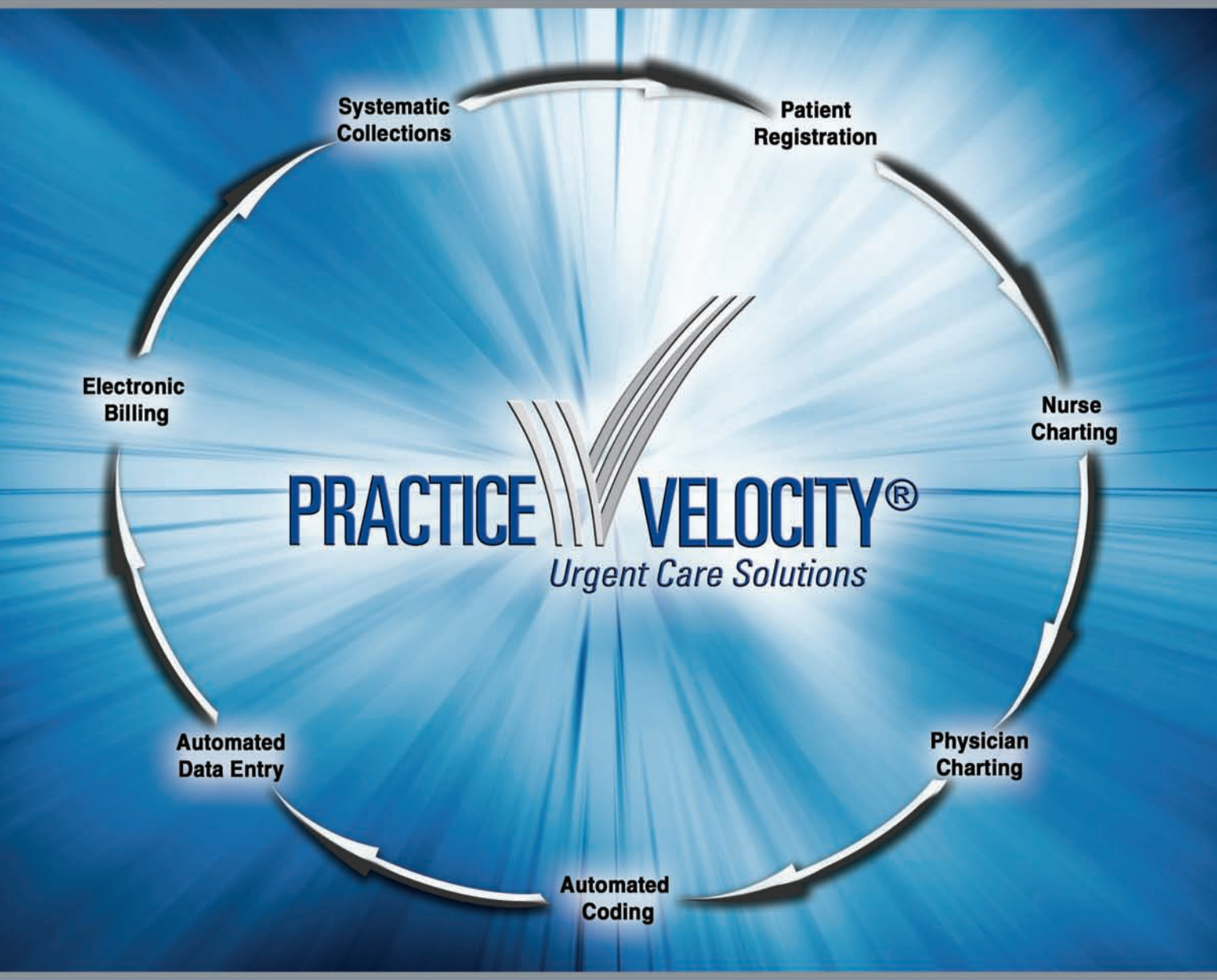
Mission Statement

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.

Software Designed Just For Urgent Care



"We have experienced a dramatic improvement in E&M coding as a result of using Practice Velocity PiVoTs. This case mix shift has significantly softened the impact of the new Illinois Workers' Compensation Fee Schedule as of 2/1/2006."

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"Hands down the best program out there for Urgent Care clinics! This is by far the most user friendly software I have ever used."

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As March's cover article reasons, "pain, either chronic or acute, is the main reason patients seek medical care." Certainly it's a complaint heard commonly in urgent care, as attested to by **Marc R. Salzberg, MD, FACEP** and **Paolo T. Coppola, MD, FACEP**, the co-authors of that article and founding partners of Stat Health Immediate Medical Care, PC, in Smithtown, NY. Dr. Salzberg is also a member of the *JUCM* Editorial Board. Acute Pain Management in Urgent Care Medicine (page 11) offers strategies on how to effectively and correctly address the patient's pain, and how to deal with the fact that the patient's expectations may not always be in line with the physician's clinical judgment of what's best for that patient.

Figuratively speaking, physicians are also familiar with the pain of wrestling with liability insurance issues. Medical Professional Liability Insurance: Limiting Cost While Maximizing Value (page 32), by **Terrence P. Coughlin, CPCU, ARM, AIC**, offers advice on how to tackle this vexing issue. Mr. Coughlin is president of ACC Risk Management, LLC, in Wyckoff, NJ and a member of the Society of Risk Management Consultants and the Chartered Property Casualty Underwriters Society.

Several *JUCM* contributors will speak at the Urgent Care Association of America's Annual Urgent Care Conference, May 9-12 in Daytona Beach, FL—**Frank Leone, MBA** (Occupational Medicine), **John Shufeldt MD, JD, MBA, FACEP** (Health Law), and **David Stern, MD, CPC** (Coding Q & A)—as will **Kevin Ralofsky, MBA**, whose writing has been featured in *JUCM*.

As always, we're very appreciative of the contributions made by **Nahum Kovalski, BSc, MDCM** in Abstracts in Urgent Care and Insights in Images.

Finally, we are also very proud to introduce new members of our Editorial Board and Advisory Board, as follows:

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Led by Editor-in-Chief **Lee A. Resnick, MD**, our Editorial Board and Advisory Board help ensure that *JUCM* speaks with an urgent care voice about challenges that urgent care practitioners face in the real world. We'd like all our readers to be part of that effort, too. Please e-mail us any time with thoughts or suggestions at *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*. 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*.

To Subscribe to *JUCM*

JUCM is distributed on a complimentary basis to medical practitioners—physicians, physician assistants, and nurse practitioners—working in urgent care practice settings in the United States. If you would like to subscribe, please log on to *www.jucm.com* and click on "Free Subcription."

The Promise of Spring

LOU ELLEN HORWITZ, MA

I am a Southerner, born and raised. We didn't get many snow days when I was going to school. And yet, outside my window today it has been snowing for 10 hours, with no sign of stopping.

When we are transplanted—into a new home, a new job, a new relationship, a new challenge—we have some choices to make. We can hold onto the past or to our outdated vision of what the future should have been, or we can embrace our reality and start shoveling the car out of the snow.

In dealing with change, it helps to have some small victories early and often; they can provide enough encouragement to "stick it out" through the transition. I think we all have had that feeling of needing a win, even a small one, just as a symbol for ourselves that everything is going to be OK.

As managers and leaders (regardless of our formal place on the organizational chart), it is important for us to help our colleagues find those small victories when they are going through a transitional period.

For instance, are you...

- bringing in an electronic medical record system?
- expanding your hours or services?
- adding new staff?
- adding a new location?
- reorganizing the supply closet?

Even the little changes can completely throw your urgent care center's smooth operations off track for a while.

While most of us have been educated in some level of change management strategy (e.g., include all stakeholders in the planning, communicate well and often, deal with cultural as well as process issues, etc.), we also know that the hardest part is that murky period after the change has been announced and implemented, but before it is fully integrated. This is the time when leadership is truly needed, and where you can start planting the small victories.

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

How do you do this? By making sure the ground is fertile (you have created a safe environment for people to learn new things, ask questions, and have failures and learn from them) and the gardener (yep, that's you and the rest of your leadership team) is attentive. When that first person (or 21st person) finally "gets it," make sure they are getting recognition and celebration from you. Over time, your small victory plantings will start to flower and then bear fruit.

"When that person finally 'gets it,' make sure they are getting recognition and celebration from you."

Our Own 'Small Victories'

We have been very lucky here at UCAOA. We have had lots of small victories, and we have all of you to thank for that. Your great feedback on the new website, the overwhelming success of the first-ever Fall Conference, the launch of this increasingly excellent journal, and our rapidly expanding membership are all very exciting for the UCAOA staff and board.

So, we're having a little celebration of our own this spring; perhaps you've heard about it.

If you haven't already registered (and we are looking forward to seeing the hundreds of you who have!), please consider yourself invited to join us May 9-12 in Daytona Beach, FL for a grand event full of fellowship and learning and celebration of all that we have accomplished together—plus some glimpses of all of the new things that we are working toward for the future. Full details and registration information are available on the UCAOA website (*www.ucaoa.org*).

More to come!■

PROFESSIONAL BRIEF SUMMARY-CONSULT PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION.
03-5435-Rev. July, 2005
(Nos. 3769, 3771, 6151)

Omnicef® (cefdinir) capsules
Omnicef® (cefdinir) for oral suspension

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INDICATIONS AND USAGE

To reduce the development of drug-resistant bacteria and maintain the effectiveness of OMNICEF and other antibacterial drugs, OMNICEF should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

OMNICEF (cefdinir) capsules and OMNICEF (cefdinir) for oral suspension are indicated for the treatment of patients with mild to moderate infections caused by susceptible strains of the designated microorganisms in the conditions listed below.

Adults and Adolescents

Community-Acquired Pneumonia caused by *Haemophilus influenzae* (including β-lactamase producing strains), *Haemophilus parainfluenzae* (including β-lactamase producing strains), *Streptococcus pneumoniae* (penicillin-susceptible strains only), and *Moraxella catarrhalis* (including β-lactamase producing strains).

Acute Exacerbations of Chronic Bronchitis caused by *Haemophilus influenzae* (including β-lactamase producing strains), *Haemophilus parainfluenzae* (including β-lactamase producing strains), *Streptococcus pneumoniae* (penicillin-susceptible strains only), and *Moraxella catarrhalis* (including β-lactamase producing strains).

Acute Maxillary Sinusitis caused by *Haemophilus influenzae* (including β-lactamase producing strains), *Streptococcus pneumoniae* (penicillin-susceptible strains only), and *Moraxella catarrhalis* (including β-lactamase producing strains).

NOTE: For information on use in pediatric patients, see **Pediatric Use** and **DOSAGE AND ADMINISTRATION**.

Pharyngitis/Tonsillitis caused by *Streptococcus pyogenes*.

NOTE: Cefdinir is effective in the eradication of *S. pyogenes* from the oropharynx. Cefdinir has not, however, been studied for the prevention of rheumatic fever following *S. pyogenes* pharyngitis/tonsillitis. Only intramuscular penicillin has been demonstrated to be effective for the prevention of rheumatic fever.

Uncomplicated Skin and Skin Structure Infections caused by *Staphylococcus aureus* (including β-lactamase producing strains) and *Streptococcus pyogenes*.

Pediatric Patients

Acute Bacterial Otitis Media caused by *Haemophilus influenzae* (including β-lactamase producing strains), *Streptococcus pneumoniae* (penicillin-susceptible strains only), and *Moraxella catarrhalis* (including β-lactamase producing strains).

Pharyngitis/Tonsillitis caused by *Streptococcus pyogenes*.

NOTE: Cefdinir is effective in the eradication of *S. pyogenes* from the oropharynx. Cefdinir has not, however, been studied for the prevention of rheumatic fever following *S. pyogenes* pharyngitis/tonsillitis. Only intramuscular penicillin has been demonstrated to be effective for the prevention of rheumatic fever.

Uncomplicated Skin and Skin Structure Infections caused by *Staphylococcus aureus* (including β-lactamase producing strains) and *Streptococcus pyogenes*.

CONTRAINDICATIONS

OMNICEF (cefdinir) is contraindicated in patients with known allergy to the cephalosporin class of antibiotics.

WARNINGS

BEFORE THERAPY WITH OMNICEF (CEFDINIR) IS INSTITUTED, CAREFUL INQUIRY SHOULD BE MADE TO DETERMINE WHETHER THE PATIENT HAS HAD PREVIOUS HYPERSENSITIVITY REACTIONS TO CEFDINIR, OTHER CEPHALOSPORINS, PENICILLINS, OR OTHER DRUGS. IF CEFDINIR IS TO BE GIVEN TO PENICILLIN-SENSITIVE PATIENTS, CAUTION SHOULD BE EXERCISED BECAUSE CROSS-HYPERSENSITIVITY AMONG β-LACTAM ANTIBIOTICS HAS BEEN CLEARLY DOCUMENTED AND MAY OCCUR IN UP TO 10% OF PATIENTS WITH A HISTORY OF PENICILLIN ALLERGY. IF AN ALLERGIC REACTION TO CEFDINIR OCCURS, THE DRUG SHOULD BE DISCONTINUED. SERIOUS ACUTE HYPERSENSITIVITY REACTIONS MAY REQUIRE TREATMENT WITH EPINEPHRINE AND OTHER EMERGENCY MEASURES, INCLUDING OXYGEN, INTRAVENOUS FLUIDS, INTRAVENOUS ANTIHISTAMINES, CORTICOSTEROIDS, PRESSOR AMINES, AND AIRWAY MANAGEMENT, AS CLINICALLY INDICATED.

Pseudomembranous colitis has been reported with nearly all antibacterial agents, including cefdinir, and may range in severity from mild- to life-threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of antibacterial agents.

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

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

PRECAUTIONS

General

Prescribing OMNICEF in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

As with other broad-spectrum antibiotics, prolonged treatment may result in the possible emergence and overgrowth of resistant organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate alternative therapy should be administered.

Cefdinir, as with other broad-spectrum antimicrobials (antibiotics), should be prescribed with caution in individuals with a history of colitis.

In patients with transient or persistent renal insufficiency (creatinine clearance <30 mL/min), the total daily dose of OMNICEF should be reduced because high and prolonged plasma concentrations of cefdinir can result following recommended doses.

Information for Patients

Patients should be counseled that antibacterial drugs including OMNICEF should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When OMNICEF is prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by OMNICEF or other antibacterial drugs in the future.

Antacids containing magnesium or aluminum interfere with the absorption of cefdinir. If this type of antacid is required during OMNICEF therapy, OMNICEF should be taken at least 2 hours before or after the antacid.

Iron supplements, including multivitamins that contain iron, interfere with the absorption of cefdinir. If iron supplements are required during OMNICEF therapy, OMNICEF should be taken at least 2 hours before or after the supplement.

Iron-fortified infant formula does not significantly interfere with the absorption of cefdinir. Therefore, OMNICEF for Oral Suspension can be administered with iron-fortified infant formula.

Diabetic patients and caregivers should be aware that the oral suspension contains 2.86 g of sucrose per teaspoon.

Drug Interactions

Antacids: (aluminum- or magnesium-containing): Concomitant administration of 300-mg cefdinir capsules with 30 mL Maalox® TC suspension reduces the rate (C_{max}) and extent (AUC) of absorption by approximately 40%. Time to reach C_{max} is also prolonged by 1 hour. There are no significant effects on cefdinir pharmacokinetics if the antacid is administered 2 hours before or 2 hours after cefdinir. If antacids are required during OMNICEF therapy, OMNICEF should be taken at least 2 hours before or after the antacid.

Probenecid: As with other β-lactam antibiotics, probenecid inhibits the renal excretion of cefdinir, resulting in an approximate doubling in AUC, a 54% increase in peak cefdinir plasma levels, and a 50% prolongation in the apparent elimination $t_{1/2}$.

Iron Supplements and Foods Fortified With Iron: Concomitant administration of cefdinir with a therapeutic iron supplement containing 60 mg of elemental iron (as $FeSO_4$) or vitamins supplemented with 10 mg of elemental iron reduced extent of absorption by 80% and 31%, respectively. If iron supplements are required during OMNICEF therapy, OMNICEF should be taken at least 2 hours before or after the supplement.

The effect of foods highly fortified with elemental iron (primarily iron-fortified breakfast cereals) on cefdinir absorption has not been studied.

Concomitantly administered iron-fortified infant formula (2.2 mg elemental iron/6 oz) has no significant effect on cefdinir pharmacokinetics. Therefore, OMNICEF for Oral Suspension can be administered with iron-fortified infant formula.

There have been reports of reddish stools in patients receiving cefdinir. In many cases, patients were also receiving iron-containing products. The reddish color is due to the formation of a nonabsorbable complex between cefdinir or its breakdown products and iron in the gastrointestinal tract.

Drug/Laboratory Test Interactions

A false-positive reaction for ketones in the urine may occur with tests using nitroprusside, but not with those using nitroferricyanide. The administration of cefdinir may result in a false-positive reaction for glucose in urine using Clinitest®, Benedict's solution, or Fehling's solution. It is recommended that glucose tests based on enzymatic glucose oxidase reactions (such as Clinistix® or Tes-Tape®) be used. Cephalosporins are known to occasionally induce a positive direct Coombs' test.

Carcinogenesis, Mutagenesis, Impairment of Fertility

The carcinogenic potential of cefdinir has not been evaluated. No mutagenic effects were seen in the bacterial reverse mutation assay (Ames) or point mutation assay at the hypoxanthine-guanine phosphoribosyltransferase locus (HGPRT) in V79 Chinese hamster lung cells. No clastogenic effects were observed *in vitro* in the structural chromosome aberration assay in V79 Chinese hamster lung cells or *in vivo* in the micronucleus assay in mouse bone marrow. In rats, fertility and reproductive performance were not affected by cefdinir at oral doses up to 1000 mg/kg/day (70 times the human dose based on mg/kg/day, 11 times based on mg/m^2/day).

Pregnancy - Teratogenic Effects

Pregnancy Category B: Cefdinir was not teratogenic in rats at oral doses up to 1000 mg/kg/day (70 times the human dose based on mg/kg/day, 11 times based on mg/m^2/day) or in rabbits at oral doses up to 10 mg/kg/day (0.7 times the human dose based on mg/kg/day, 0.23 times based on mg/m^2/day). Maternal toxicity (decreased body weight gain) was observed in rabbits at the maximum tolerated dose of 10 mg/kg/day without adverse effects on offspring. Decreased body weight occurred in rat fetuses at ≥ 100 mg/kg/day, and in rat offspring at ≥ 32 mg/kg/day. No effects were observed on maternal reproductive parameters or offspring survival, development, behavior, or reproductive function.

There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Labor and Delivery

Cefdinir has not been studied for use during labor and delivery.

Nursing Mothers

Following administration of single 600-mg doses, cefdinir was not detected in human breast milk.

Pediatric Use

Safety and efficacy in neonates and infants less than 6 months of age have not been established. Use of cefdinir for the treatment of acute maxillary sinusitis in pediatric patients (age 6 months through 12 years) is supported by evidence from adequate and well-controlled studies in adults and adolescents, the similar pathophysiology of acute sinusitis in adult and pediatric patients, and comparative pharmacokinetic data in the pediatric population.

Geriatric Use

Efficacy is comparable in geriatric patients and younger adults. While cefdinir has been well-tolerated in all age groups, in clinical trials geriatric patients experienced a lower rate of adverse events, including diarrhea, than younger adults. Dose adjustment in elderly patients is not necessary unless renal function is markedly compromised.

ADVERSE EVENTS

Clinical Trials - OMNICEF Capsules (Adult and Adolescent Patients):

In clinical trials, 5093 adult and adolescent patients (3841 US and 1252 non-US) were treated with the recommended dose of cefdinir capsules (600 mg/day). Most adverse events were mild and self-limiting. No deaths or permanent disabilities were attributed to cefdinir. One hundred forty-seven of 5093 (3%) patients discontinued medication due to adverse events thought by the investigators to be possibly, probably, or definitely associated with cefdinir therapy. The discontinuations were primarily for gastrointestinal disturbances, usually diarrhea or nausea. Nineteen of 5093 (0.4%) patients were discontinued due to rash thought related to cefdinir administration.

In the US, the following adverse events were thought by investigators to be possibly, probably, or definitely related to cefdinir capsules in multiple-dose clinical trials (N = 3841 cefdinir-treated patients):

ADVERSE EVENTS ASSOCIATED WITH CEFDINIR CAPSULES US TRIALS IN ADULT AND ADOLESCENT PATIENTS (N=3841)[a]

Incidence ≥ 1%	Diarrhea	15%
	Vaginal moniliasis	4% of women
	Nausea	3%
	Headache	2%
	Abdominal pain	1%
	Vaginitis	1% of women
Incidence <1% but >0.1%	Rash	0.9%
	Dyspepsia	0.7%
	Flatulence	0.7%
	Vomiting	0.7%
	Abnormal stools	0.3%
	Anorexia	0.3%
	Constipation	0.3%
	Dizziness	0.3%
	Dry mouth	0.3%
	Asthenia	0.2%
	Insomnia	0.2%
	Leukorrhea	0.2% of women
	Moniliasis	0.2%
	Pruritus	0.2%
	Somnolence	0.2%

[a] 1733 males, 2108 females

The following laboratory value changes of possible clinical significance, irrespective of relationship to therapy with cefdinir, were seen during clinical trials conducted in the US:

LABORATORY VALUE CHANGES OBSERVED WITH CEFDINIR CAPSULES US TRIALS IN ADULT AND ADOLESCENT PATIENTS (N=3841)

Incidence ≥ 1%	↑ Urine leukocytes	2%
	↑ Urine protein	2%
	↑ Gamma-glutamyltransferase[a]	1%
	↓ Lymphocytes, ↑ Lymphocytes	1%, 0.2%
	↑ Microhematuria	1%
Incidence <1% but >0.1%	↑ Glucose[a]	0.9%
	↑ Urine glucose	0.9%
	↑ White blood cells, ↓ White blood cells	0.9%, 0.7%
	↑ Alanine aminotransferase (ALT)	0.7%
	↑ Eosinophils	0.7%
	↑ Urine specific gravity, ↓ Urine specific gravity[a]	0.6%, 0.2%
	↓ Bicarbonate[a]	0.6%
	↑ Phosphorus, ↓ Phosphorus[a]	0.6%, 0.3%
	↑ Aspartate aminotransferase (AST)	0.4%
	↑ Alkaline phosphatase	0.3%
	↑ Blood urea nitrogen (BUN)	0.3%
	↓ Hemoglobin	0.3%
	↑ Polymorphonuclear neutrophils (PMNs), ↓ PMNs	0.3%, 0.2%
	↑ Bilirubin	0.2%
	↑ Lactate dehydrogenase[a]	0.2%
	↑ Platelets	0.2%
	↑ Potassium[a]	0.2%
	↑ Urine pH[a]	0.2%

[a] N<3841 for these parameters

Clinical Trials - OMNICEF for Oral Suspension (Pediatric Patients):

In clinical trials, 2289 pediatric patients (1783 US and 506 non-US) were treated with the recommended dose of cefdinir suspension (14 mg/kg/day). Most adverse events were mild and self-limiting. No deaths or permanent disabilities were attributed to cefdinir. Forty of 2289 (2%) patients discontinued medication due to adverse events considered by the investigators to be possibly, probably, or definitely associated with cefdinir therapy. Discontinuations were primarily for gastrointestinal disturbances, usually diarrhea. Five of 2289 (0.2%) patients were discontinued due to rash thought related to cefdinir administration.

In the US, the following adverse events were thought by investigators to be possibly, probably, or definitely related to cefdinir suspension in multiple-dose clinical trials (N=1783 cefdinir-treated patients):

ADVERSE EVENTS ASSOCIATED WITH CEFDINIR SUSPENSION US TRIALS IN PEDIATRIC PATIENTS (N=1783)[a]

Incidence ≥ 1%	Diarrhea	8%
	Rash	3%
	Vomiting	1%
Incidence <1% but >0.1%	Cutaneous moniliasis	0.9%
	Abdominal pain	0.8%
	Leukopenia[b]	0.3%
	Vaginal moniliasis	0.3% of girls
	Vaginitis	0.3% of girls
	Abnormal stools	0.2%
	Dyspepsia	0.2%
	Hyperkinesia	0.2%
	Increased AST[b]	0.2%
	Maculopapular rash	0.2%
	Nausea	0.2%

[a] 977 males, 806 females

[b] Laboratory changes were occasionally reported as adverse events.

NOTE: In both cefdinir- and control-treated patients, rates of diarrhea and rash were higher in the youngest pediatric patients. The incidence of diarrhea in cefdinir-treated patients ≤2 years of age was 17% (95/557) compared with 4% (51/1226) in those >2 years old. The incidence of rash (primarily diaper rash in the younger patients) was 8% (43/557) in patients ≤2 years of age compared with 1% (8/1226) in those >2 years old.

The following laboratory value changes of possible clinical significance, irrespective of relationship to therapy with cefdinir, were seen during clinical trials conducted in the US:

LABORATORY VALUE CHANGES OF POSSIBLE CLINICAL SIGNIFICANCE OBSERVED WITH CEFDINIR SUSPENSION US TRIALS IN PEDIATRIC PATIENTS (N=1783)

Incidence ≥ 1%	↑ Lymphocytes, ↓ Lymphocytes	2%, 0.8%
	↑ Alkaline phosphatase	1%
	↓ Bicarbonate[a]	1%
	↑ Eosinophils	1%
	↑ Lactate dehydrogenase	1%
	↑ Platelets	1%
	↑ PMNs, ↓ PMNs	1%, 1%
	↑ Urine protein	1%
Incidence <1% but >0.1%	↑ Phosphorus, ↓ Phosphorus	0.9%, 0.4%
	↑ Urine pH	0.8%
	↓ White blood cells, ↑ White blood cells	0.7%, 0.3%
	↓ Calcium[a]	0.5%
	↓ Hemoglobin	0.5%
	↑ Urine leukocytes	0.5%
	↑ Monocytes	0.4%
	↑ AST	0.3%
	↑ Potassium[a]	0.3%
	↑ Urine specific gravity, ↓ Urine specific gravity	0.3%, 0.1%
	↓ Hematocrit[a]	0.2%

[a] N=1387 for these parameters

Postmarketing Experience

The following adverse experiences and altered laboratory tests, regardless of their relationship to cefdinir, have been reported during extensive postmarketing experience, beginning with approval in Japan in 1991: Stevens-Johnson syndrome, toxic epidermal necrolysis, exfoliative dermatitis, erythema multiforme, erythema nodosum, serum sickness-like reactions, conjunctivitis, stomatitis, acute hepatitis, cholestasis, fulminant hepatitis, hepatic failure, jaundice, increased amylase, shock, anaphylaxis, facial and laryngeal edema, feeling of suffocation, acute enterocolitis, bloody diarrhea, hemorrhagic colitis, melena, pseudomembranous colitis, pancytopenia, granulocytopenia, leukopenia, thrombocytopenia, idiopathic thrombocytopenic purpura, hemolytic anemia, acute respiratory failure, asthmatic attack, drug-induced pneumonia, eosinophilic pneumonia, idiopathic interstitial pneumonia, fever, acute renal failure, nephropathy, bleeding tendency, coagulation disorder, disseminated intravascular coagulation, upper GI bleed, peptic ulcer, ileus, loss of consciousness, allergic vasculitis, possible cefdinir-diclofenac interaction, cardiac failure, chest pain, myocardial infarction, hypertension, involuntary movements, and rhabdomyolysis.

Cephalosporin Class Adverse Events

The following adverse events and altered laboratory tests have been reported for cephalosporin-class antibiotics in general:

Allergic reactions, anaphylaxis, Stevens-Johnson syndrome, erythema multiforme, toxic epidermal necrolysis, renal dysfunction, toxic nephropathy, hepatic dysfunction including cholestasis, aplastic anemia, hemolytic anemia, hemorrhage, false-positive test for urinary glucose, neutropenia, pancytopenia, and agranulocytosis. Pseudomembranous colitis symptoms may begin during or after antibiotic treatment (see **WARNINGS**).

Several cephalosporins have been implicated in triggering seizures, particularly in patients with renal impairment when the dosage was not reduced (see **OVERDOSAGE**). If seizures associated with drug therapy occur, the drug should be discontinued. Anticonvulsant therapy can be given if clinically indicated.

OVERDOSAGE

Information on cefdinir overdosage in humans is not available. In acute rodent toxicity studies, a single oral 5600-mg/kg dose produced no adverse effects. Toxic signs and symptoms following overdosage with other β-lactam antibiotics have included nausea, vomiting, epigastric distress, diarrhea, and convulsions. Hemodialysis removes cefdinir from the body. This may be useful in the event of a serious toxic reaction from overdosage, particularly if renal function is compromised.

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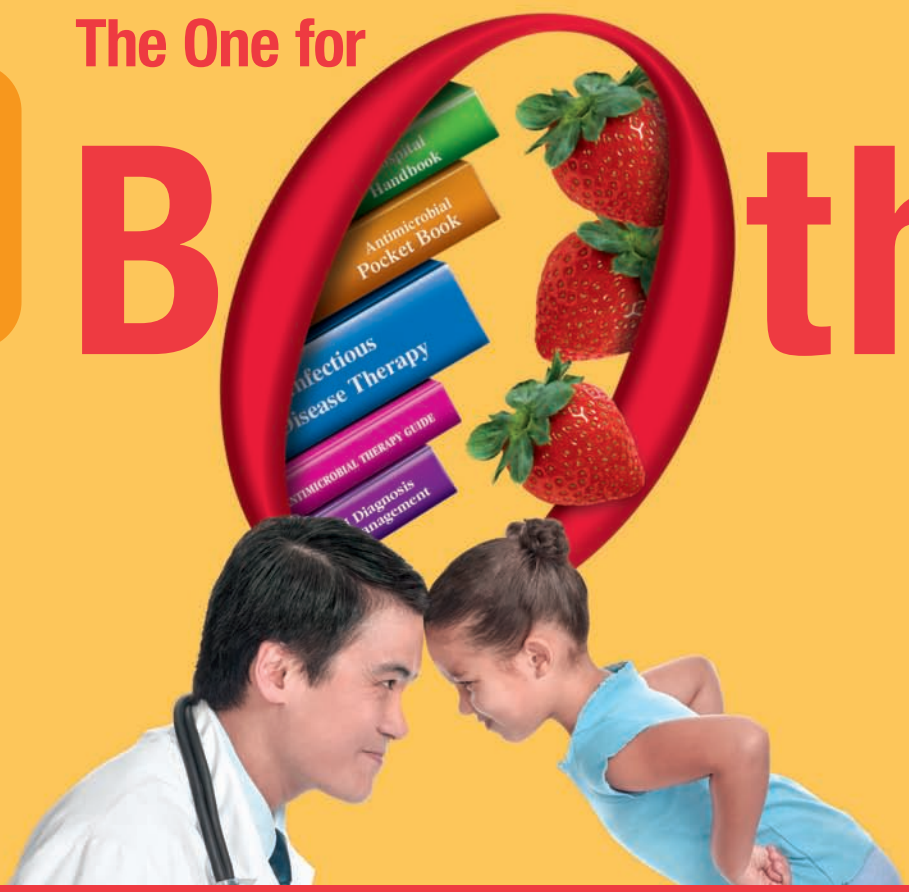

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According to published peer-reviewed literature,[1-3] compliance factors that make an antibiotic easy to take include:

- **Taste (palatability)**
- **Tolerability**
- **Short duration of treatment**
- **Number of daily doses**

Indications (mild to moderate infections caused by susceptible microorganisms in pediatric patients 6 months through 12 years).[4]

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Important Safety Information[4]

- To reduce the development of drug-resistant bacteria and maintain the effectiveness of OMNICEF and other antibacterial drugs, OMNICEF should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria
- OMNICEF is contraindicated in patients with known allergy to the cephalosporin class of antibiotics
- For patients with previous hypersensitivity reaction to penicillins, caution should be exercised because cross-hypersensitivity among ß-lactam antibiotics has been clearly documented. If an allergic reaction to cefdinir occurs, the drug should be discontinued
- Safety and efficacy in neonates and infants less than 6 months of age have not been established
- 2% of 2,289 pediatric patients discontinued medication due to adverse events in US and non-US clinical trials. Discontinuations were primarily for gastrointestinal disturbance, usually diarrhea
- The most common reported adverse events occurring in ≥1% of pediatric patients in US clinical trials (N=1,783) were diarrhea (8%), rash (3%), and vomiting (1%)

References: 1. Brixner DI. Improving acute otitis media outcomes through proper antibiotic use and adherence. *Am J Manag Care.* 2005;11(6 suppl):S202-S210. **2.** Kardas P. Patient compliance with antibiotic treatment for respiratory tract infections. *J Antimicrob Chemother.* 2002;49:897-903. **3.** Ramgoolam A, Steele R. Formulations of antibiotics for children in primary care. *Pediatr Drugs.* 2002;4:323-333. **4.** OMNICEF (cefdinir) Capsules and for Oral Suspension Prescribing Information, Abbott Laboratories.

Please see adjacent brief summary of full prescribing information.

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Acute Pain Management
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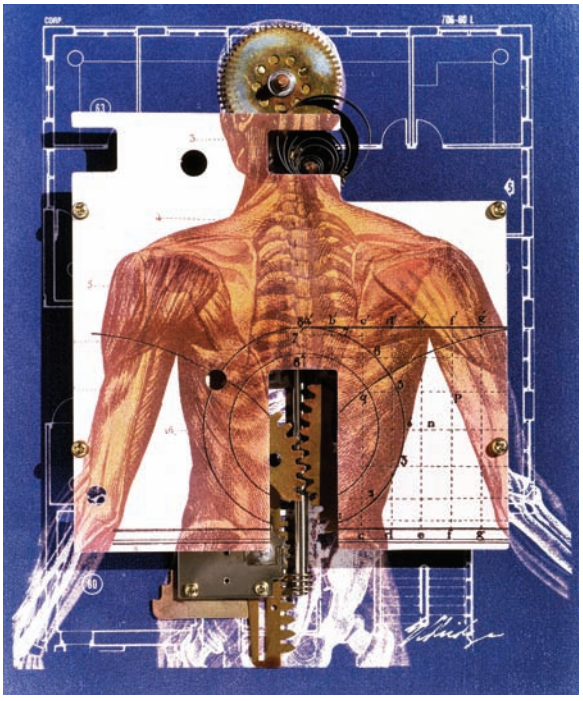
Urgent message: Urgent care practitioners are called upon daily to alleviate pain. A thorough understanding of the various pain syndromes and the pharmacology and analgesic potencies of various medications will aid in their safe and appropriate use.

Marc R. Salzberg, MD, FACEP and Paolo T. Coppola, MD, FACEP

Introduction

Pain, either chronic or acute, is the main reason patients seek medical care. In this article, we will discuss acute pain management in an urgent care setting, calling on over 30 years of collective experience in community emergency medicine and urgent care.

For the purpose of this article, we will assume that the urgent care physician (UCP) has ordered and interpreted the correct labs and radiological studies, made the correct diagnosis, and has reviewed the patient's allergy history and current medication usage.



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It is not the purpose of this article to address every possible pain syndrome. We will offer our strategies to effectively and correctly address the patient's pain and expectations, while being mindful that meeting *patients'* demand for pain medication may actually not be in the patient's—nor the physician's—best interest.

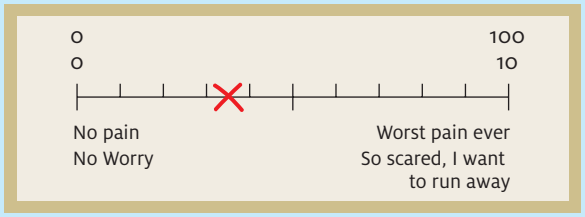
Rather, we will discuss analgesic equivalents, the appropriate and limited use of opioid medication, drug-seeking behavior (how to recognize it and what to do about it), and, finally, give several real-case scenarios that occur frequently in an urgent care setting. (It should be noted that many "pain management" physicians often prefer the term *opioid* to *narcotic*, as it has less of a negative connotation. Technically, the terms are interchangeable, however.)

Generally, it is the UCP's responsibility to:

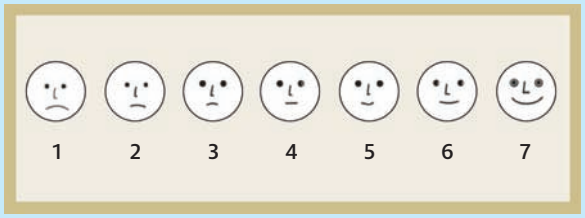
- Assess the quality and severity of pain.
- Identify pain that may represent a medical or surgical emergency.
- Differentiate acute vs. chronic pain.
- Assess pain that is the normal part of an injury or illness.
- Assess pain that may be the result of opioid dependence and its associated withdrawal symptoms.
- Identify drug-seeking behavior.

Figure 1.

Numerical rating scale (adults)



Faces scale (children)



- Carefully document findings. (Remember the maxim, "In God we trust; all others must document.")

Pain

Pain is an unpleasant sensory and emotional experience and is described as either *nociceptive* or *neuropathic*.

Nociceptive pain is the result of noxious stimuli that have the potential to damage normal tissue; it is either somatic or visceral. Neuropathic pain results from nerve lesions or another nervous system dysfunction and is either peripheral or central.

Pain is described by its quality, severity, location, and duration (chronic/acute). Some descriptors used to qualify the quality of pain include:

- sharp
- aching
- throbbing
- pressure
- tight
- electric
- tingling
- crampy
- stabbing
- knife-like
- band-like
- dull
- burning
- squeezing
- burning
- thunderclap
- colicky
- radiating
- numbing

Assessing Pain Severity

In addition to taking clues from the quality of a patient's pain, the UCP must make a determination of its severity, as well. This can usually be done by simply asking a patient to rate his or her pain on a scale of 1-10. There are several pain scale measurement tools that are useful in assessing pain based on the patient's perception. They include the visual analog scale (VAS) or numerical rating scale (NRS) for adults and the faces scale for children (**Figure 1**).

In addition, observation of the patient by the physician, nurses, and medical assistants can add to the clinical assessment. In an urgent care setting, quantifying the patient's level of presenting pain, quality of pain, and response to your intervention should always be clearly documented and used to guide therapy.

Pain That May Represent a Medical/Surgical Emergency

Clearly, pain sometimes is a warning sign of a true medical or surgical emergency. Classic examples in this category include, but are not limited to, the abrupt onset of "the worst headache of my life;" chest/-arm/neck/back pain that may represent an acute vascular process such as an acute MI, pulmonary embolism, or dissecting aneurysm; scrotal pain from testicular torsion; abdominal pain consistent with an intra-abdominal process such as appendicitis or diverticular abscess; abdominal pain out of proportion to physical findings as seen in mesenteric vascular occlusion; and acute eye pain from acute angle glaucoma.

Such presentations should be transported without delay to the nearest emergency department.

Acute Pain

Acute pain is pain that started abruptly or has increased over a short period (minutes to hours) and is ongoing (or intermittent and recurring, such as in renal colic). Examples of acute pain include trauma/burns, visceral/somatic pain such as abdominal pain, chest pain, acute gout, headache, eye pain, etc., and pain associated with an illness such as pharyngitis, urinary tract infections, influenza, and acute otitis media and externa.

Chronic Pain

Chronic pain, as the name implies, is a pain syndrome that has been ongoing. Examples may include discogenic pain, post-herpetic neuralgia lasting at least three months, pain from metastatic disease, chronic/stable angina, and chronic headaches (migraine, tension, etc.). Other chronic pain syndromes such as fibromyalgia and pain from chronic Lyme disease are more difficult to quantify, although often patients will present to urgent care centers with one of these diagnoses.

Fibromyalgia has been considered by some to be a "wastebasket" diagnosis for unexplained pain, and although the American College of Rheumatology established strict criteria for its diagnosis, in our experience only a small percentage of patients who have been so diagnosed actually meet these criteria. These and other chronic pain syndromes require a multidisciplinary approach and are not the purview of this article.

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Table 1. Commonly Used Non-Opioid Analgesics

Drug	Average Adult Dose	Dosing Interval	Maximum Dose in 24 Hours	Side Effects	Comments
Acetaminophen (Tylenol)	500 mg-1000 mg	4-6 hours	4 g (<3 g in patients with liver dysfunction or in the elderly)	Minimal, if any, side effects	Toxic to liver in overdose
Non-steroidal anti-inflammatory drugs (NSAIDs); use with extreme caution in the elderly					
Aspirin	500 mg-1000 mg	4-6 hours	4000 mg	*See below	Caution with hepatic/renal disease
Choline magnesium trisalicylate (Trilisate)	500 mg-1000 mg	8-12 hours	3000 mg	Lower incidence of GI bleeding, minimal anti-platelet activity	Caution with hepatic/renal disease
Ibuprofen (Motrin and others)	200 mg-400 mg	4-6 hours	2400 mg	*See below	Caution with hepatic/renal disease
Naproxen (Naprosyn)	500 mg initial then 250 mg subsequent	6-8 hours	1500 mg	*See below	Caution with hepatic/renal disease
Nabumetone (Relafen)	500 mg-750 mg	8-12 hours	2000 mg	*See below	Caution with hepatic/renal disease
Ketorolac tromethamine (Toradol)	30 mg IV initial, 15 mg-30 mg subsequent	6 hours	150 mg first day, 120 mg thereafter	*See below	In elderly, 30 mg starting dose, 15 mg thereafter. Use caution with hepatic/renal disease. Use restricted to 5 days max. Caution with hepatic/renal disease
Celecoxib (Celebrex)	100 mg-200 mg	12 hours	200 mg-400 mg	Lower incidence of GI effects	Contraindicated in sulfonamide allergy. No platelet effects. Risk of cardiovascular events. Use lowest dose possible.
Tramadol HCl (Ultram)	25 mg-50 mg	4-6 hours	400 mg (300 mg in elderly)	Headache, confusion, sedation	Atypical opioid with additional non-opioid effects. Available combined with non-opioids. Lowers seizure threshold.

*Monitor for common adverse effects: GI ulceration and bleeding, decreased platelet aggregation, and renal toxicity

Pain Medication

Selection of the correct analgesic for a patient is based on the patient's level of pain, the cause of that pain, prior medical history, current medications, other presenting complaints or comorbid conditions, vital signs, and the clinician's assessment of the patient. It is also important to set realistic pain management goals so that someone with fractured ribs, for example, understands that the discomfort will take several weeks to improve.

Although we will not address specific pain-relieving therapies such as trigger point injections or nerve blocks, they should be considered if you are familiar with and have experience in these modalities.

In general, most pain can be effectively managed with acetaminophen or nonsteroidal anti-inflammatory drugs (NSAIDs) or a combination of both, as they act synergistically when combined. Occasionally, a short course of oral opiates is warranted.

Non-Opioid Analgesics

Non-opioid analgesics include aspirin and other salicylates, acetaminophen, and NSAIDs. In general, non-opioid drugs are used to treat mild-to-moderate pain and in combination with opioids for more severe pain. Since opioids and non-opioids have different mechanisms of action, they can be used together to produce a synergistic effect.

Acetaminophen

Acetaminophen produces its analgesic effect by inhibiting central prostaglandin synthesis with minimal inhibition of peripheral prostaglandin synthesis. Prostaglandins are involved in sensitization of peripheral and central nociceptors, as well as in the inflammatory process.

Acetaminophen does not have an anti-inflammatory effect; nor does it have an adverse effect on platelet function or the gastric mucosa. It is rapidly absorbed, with peak plasma levels seen in 30 to 60 minutes, and is metabolized in the liver by conjugation and hydroxylation to inactive metabolites.

Because of the risk of hepatotoxicity, acetaminophen should be used cautiously in patients with liver disease, chronic alcoholism, and malnutrition. As acetaminophen is readily available either alone or in combination with other drugs, recommended doses are often overlooked and must be followed to avoid a toxic overdose.

NSAIDs

NSAIDs act by inhibiting both central and peripheral prostaglandin synthesis. Inhibiting cyclooxygenase activity results in prostaglandin synthesis being blocked, thereby decreasing the inflammatory response.

NSAIDs block the production of prostaglandins but do not inhibit the effects of prostaglandins already present.

Therefore, although anti-inflammatory effects are relatively delayed, the analgesic effects occur more quickly. Responses to various NSAIDs vary among patients, so inadequate pain relief from one NSAID should not preclude the use of other drugs in this class.

NSAIDs are associated with GI effects including nausea, vomiting, and bleeding. Ketorolac has a slightly better profile for GI bleeding, but the risk is increased in elderly patients. Some physicians advocate the concomitant use of proton pump inhibitors or H2 blockers to lessen the GI effects of this class of drugs. Other adverse effects include nephrotoxicity, hepatotoxicity, and cognitive dysfunction.

Cyclooxygenase-2 (COX 2)-selective NSAIDs are effective analgesics, but their role in pain management remains unclear in light of the serious safety issues that led to the withdrawal of rofecoxib and valdecoxib from the U.S. market, leaving only celecoxib available. There are also concerns about the increase in the international normalized ratio of patients being treated with both a COX-2 inhibitor and warfarin. (See **Table 1**.)

Table 2. Opioids Available in the United States

Mu-Receptor Agonists		Kappa-Receptor Agonist/Mu-Receptor Antagonists	Mu-Receptor Antagonists
Alfentanil	Morphine	Buprenorphine	Nalmefene
Codeine	Opium	Butorphanol	Naloxone
Fentanyl	Oxycodone	Nalbuphine	Naltrexone
Hydrocodone	Oxymorphone	Pentazocine	
Hydromorphone	Propoxyphene		
Levorphanol	Remifentanil		
Meperidine	Sufentanil		
Methadone	Tramadol		

Opioids

Opioids and related drugs are classified by their activity at different opioid receptors in the brain. The three main types of receptors that have been described are the mu, kappa, and delta; other receptors are thought to exist as well.

Mu receptor agonists produce analgesia and affect mood and behavior; delta agonists produce analgesia, although none of the currently available opioids are predominantly delta active; kappa-receptor agonists produce analgesia and relatively less respiratory depression but have psychological effects and can produce dysphoria.

Table 2 is a list of opioids by receptor; **Table 3** is an opioid equianalgesic chart.

A few thoughts about narcotics: With very few exceptions, almost no patients presenting to an urgent care center require narcotics. If you feel that a patient does need an opioid drug (to treat renal colic, acute shingles, an acute fracture or burn, etc.), prescribe only one-to-two days worth and then have them switch over to an NSAID and/or acetaminophen. Any pain that requires more than two days of opioid medication must be re-evaluated for another serious underlying cause of the pain.

Some reasons/conditions for which you should not prescribe opiates include:

- "My pain doctor is away and I need a refill of…."
- Low back pain—always assuming that you have made the correct diagnosis and it's not an abdominal aortic aneurysm, etc. Beware the patient who comes to you and says, "Here is my MRI showing my herniated L4/5." In general, if the patient was able to get to you, he or she does not need narcotics. The overprescribing of narcotics for back pain is one of the leading causes of iatrogenic narcotic addiction.
- "I'm in withdrawal and I need something until…."
- "I have fibromyalgia, I'm from out-of-town and I need a refill of…"
- "Here's the prescription from my last doctor. He's in Antarctica now and I need…."

If you feel a short course (i.e., one to three days) of narcotics is appropriate, we recommend starting with the least addictive, such as tramadol (Ultram), and rapidly transitioning the patient to an NSAID and/or acetaminophen.

Because of the epidemic of prescription opiate drug abuse and addiction, we have made it a policy in our center to not write for more than two days of Vicodin, Percocet, or OxyContin, with no refills.

We are aware of some practitioners' philosophy of "write them for the 60 Vicodin they want and get them out." In our view, this is not only bad medicine but may end up costing you a substantial malpractice verdict. There have been numerous successful law suits against physicians for iatrogenic addiction.

An even more sobering thought is the fact that the DEA and other state agencies have been undertaking "sting" operations based on prescribing patterns of physicians.

Table 3. Opioid Equianalgesic Chart

Opioid	Parenteral Route	Oral Route	Starting Dose for Opioid-Naïve
Opioid drugs (no ceiling dose)			
Morphine	10 mg	30 mg	15 mg for both sustained-release and immediate-release
Hydromorphone	1.5 mg	7.5 mg	4 mg
Oxycodone	NA	20 mg	10 mg sustained-release, 5 mg immediate-release
Fentanyl	0.1 mg	NA	25 mcg patch is equal to ~50 mg oral morphine q 24h
Methadone	5 mg	10 mg	3 mg-5 mg po for long-term (can accumulate due to long half-life); consult a pain specialist and the DEA
***Combination opioid drugs (have ceiling dose)**			
Hydrocodone + aspirin, acetaminophen, or ibuprofen (Vicodin, Lortab, Vicoprofen)	NA	30 mg	5 mg, 7.5 mg, or 10 mg hydrocodone with acetaminophen, aspirin, or ibuprofen (4 g/24 h ceiling dose with acetaminophen)
Oxycodone (Percocet, Tylox)	NA	20 mg	5 mg oxycodone with 325 mg or 500 mg acetaminophen (4 g/24 h ceiling dose with acetaminophen)

*Equianalgesic doses are approximate; individual patient response must be observed. Doses and intervals are titrated according to patient's response.

ICDM 304.0: Opioid Dependence and Drug-Seeking Behavior

Patients who are opioid dependent often seek narcotics from urgent care centers, thinking they have more anonymity there than in a primary care office. Often, they are successful for all the wrong reasons. In an upcoming article, we will discuss in detail how you can help these patients treat their addiction with buprenorphine HCl/naloxone HCl (Suboxone), how to become certified by the DEA in its use, and how it can be beneficial to your practice.

Case Studies

Case #1

A 34-year-old female presents to your urgent care center complaining of two days of increasing dysuria, frequency, urgency, and lower abdominal cramps. Vital signs are normal and the patient is afebrile. Physical exam reveals only tenderness over the bladder with deep palpation. A urine analysis is positive for blood, nitrites, and leukocytes.

You prescribe an antibiotic and discharge the patient. A follow-up phone call two days later confirms that the infection is indeed resolved, but the conversation is marred by the patient's complaint, "I went to my own doctor the next morning and he confirmed that I had a urinary tract infection and he shook his head that I was still in pain. He gave me Pyridium (phenazopyridine) and in 15 minutes all my discomfort was gone! What did *you* do for me?"

Although this patient came to you to treat her UTI, she really came to you to treat her symptoms, as well.

Case #2

A 26-year-old male presents a half-hour after sustaining an inversion injury to his left ankle while playing basketball. On examination, he has normal vital signs, and neurovascular exam of his left lower extremity is normal. He has significant swelling over his left lateral malleolus. X-rays show soft-tissue swelling, but no fracture.

This patient's pain and ankle sprain is best treated by:

1. Immobilization of the ankle by an air-cast or other splinting device
2. Non-weight bearing
3. Crutches
4. Ice and elevation of the ankle
5. NSAIDs
6. Referral to an orthopedist for follow-up care

The mainstay of treatment for this patient is immobilization and non-weight bearing. This will alleviate the majority of pain. The rest can be managed with NSAIDs along with acetaminophen. Opiates are not indicated.

Case #3

A 37-year-old woman presents to your office 15 minutes after cutting her left index finger with a knife while cutting a bagel. She is crying and scared.

After reassurance, you assess the wound for neurovascular compromise and tendon involvement and tell the patient she needs stitches and a tetanus booster. She wants to know how much it will hurt. You explain that the Lidocaine stings for a few seconds and that's all. She screams loudly during the Lidocaine injection, after which the rest of your repair is painless.

At discharge she asks for pain medication for "after the Lidocaine wears off." In fact, she mentions Vicodin, which she has been given in the past. Reassure the patient that when the Lidocaine wears off the pain will be minimal and that acetaminophen should take care of any discomfort. Any more severe pain would require a re-evaluation of the finger for infection, etc.

Lēvaquin®
(levofloxacin) Tablets/Injection
(levofloxacin in 5% dextrose) Injection

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DAIICHI

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Case #4

A 27-year-old male presents complaining of severe low back pain for the past two days after helping a friend move furniture. He states that he has a ruptured disc at L4/5 and even has a copy of his last MRI report with him.

On examination, his neurovascular exam is normal except for positive bilateral straight leg raising at 45 degrees. His urine is heme negative. Of note is his pulse of 120, BP of 145/98, and dilated pupils. He is afebrile. When you suggest a course of NSAIDs, he is quick to tell you that only Vicodin or OxyContin, which is "regular doctor" prescribes, works for him.

It's not possible to say he does not have low back pain, but it is clear that he presents a picture of narcotic withdrawal (specifically, tachycardia, dilated pupils, elevated blood pressure, and increasing back pain with his history of a ruptured disc). While these findings—with the exception of dilated pupils—can be consistent with severe pain, increasing bone and joint pain are classic symptoms of narcotic withdrawal.

We would recommend confronting this patient with your findings and suggesting that he needs treatment for his narcotic dependence. You can also do a toxicology screen on his urine, which you already collected.

Be aware that patients like this often become angry, abusive, and dismissive of your findings, then get up and leave. Be satisfied that you have done your job; hopefully, you have planted a seed and he will eventually seek help for his narcotic dependence.

A practical note: In our center, patients presenting with back pain are given a policy statement that states we rarely prescribe narcotics for back pain, and if we do it will be for only one- to two days. We also have these patients pay for their visit prior to being seen.

Case #5

A 37-year-old women presents with two days of increasing right ear pain. Her past medical history is negative. Her vital signs are normal, as is her ENT exam, with the exception of a very red and swollen right external ear canal. The TM is normal. On further questioning, the patient states she uses cotton swabs (e.g., Q-tips) daily.

For this patient, an ear-drop combination of an antibiotic and a steroid, such as ciprofloxacin/dexamethasone (Ciprodex), is indicated. A wick should be placed if the canal is so swollen that the drops would not go all the way in. A one- to two-day course of a combination opioid/NSAID is also appropriate.

In less severe cases, the drops and NSAIDs are usually sufficient. Follow-up is with ENT if there is not significant improvement in 24-36 hours.

Oral antibiotics are reserved for febrile patients *in addition to* the ear drops. And of course, remind the patient that "nothing goes in your ear unless it's smaller than your elbow," so no more cotton swabs.

Case #6

A 22-year-old male presents with two days of increasing throat pain, temperature to 101°F and a mild headache. Acetaminophen has offered no relief. Vital signs are normal, with the exception of an oral temperature of 101.5°F. ENT exam reveals a red pharynx, no exudates, normal tonsils, and no lymphadenopathy. A rapid strep test is positive. Penicillin is prescribed along with acetaminophen/NSAIDS.

Two days later, the patient returns with "unbearable" throat pain in spite of taking all the medication prescribed. He is afebrile and his ENT exam is unchanged. A three-day course of oral prednisone is given and on callback the next day, the patient is significantly improved.

Barring contraindications, a short course of steroids for acute inflammatory conditions like this or acute tendonitis, gout, etc., can offer he significant relief.

Summary

The management of pain is based on the correct diagnosis of the underlying problem and its natural course, a thorough understanding of the different medications available, and the appropriate prescription for each individual patient. This, combined with patient education and open communication, will most often result in appropriate and successful pain management. ■

Resources for Further Information

- American Academy of Pain Management, *www.aapaimmanage.org*
- American Academy of Pain Medicine, *www.painmed.org*
- American Pain Foundation, *www.painfoundation.org*
- American Pain Society, *www.www.ampainsoc*
- DEA, *www.usdoj.gov/dea*
- Mayo Clinic Pain Management, *www.mayoclinic.com/findinformation/diseasesandconditions/index.cfm*
- MedlinePlus Pain, *www.nim.nih.gov/medlineplus/pain.htm*
- National Institutes of Health Pain Consortium, *http://painconsortium.nih.gov*
- Tufts U School of Medicine Masters of Science in Pain Research, *www.Tufts.edu/med/prep*
- Pain.com, *www.pain.com/*

On Asthma in Children, Occult Pneumonia, Elbow X-Rays, Mortality in COPD, and the Risks of Cold Medicine in Babies and Delayed Appendectomy in Adults

NAHUM KOVALSKI, BSc, MDCM

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

Single-Dose Oral Dexamethasone in the Emergency Management of Children with Exacerbations of Mild-to-Moderate Asthma

Citation: Altamimi S, Robertson G, Jastaniah W, et al. *Pediatr Emerg Care*. 2006;22(12):786-793.
URL: *http://www.pec-online.com/pt/re/pec/home.htm*
Key point: Singe-dose dexamethasone is equivalent to five days of oral prednisone for kids with mild/moderate asthma.

The purpose of this study was to compare the efficacy of a single dose of oral dexamethasone (dex) versus five days of twice-daily prednisolone (pred) in the management of mild-to-moderate asthma exacerbations in children.

This was a prospective, randomized, double-blinded trial of children 2-to-16 years of age who presented to the ED with acute mild-to-moderate asthma exacerbations. Subjects received single-dose oral dex (0.6 mg/kg to a maximum of 18 mg) or oral pred (1 mg/kg per dose to a maximum of 30 mg) twice daily for five days. After discharge, subjects were contacted by telephone at 48 hours to assess symptoms, and reevaluated in the ED in five days.

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

The mean number of days needed for the Patient Self Assessment Score to return to baseline was 5.21 in the dex group and 5.22 in the pred group. Pulmonary index scores were similar in both groups at initial presentation, initial ED discharge, and at the day 5 follow-up visit. At the first visit, mean time to discharge was 3.5 hours for dex and 4.3 hours for pred (NS). Initial admission rate was 9% for the dex group and 13.4% in the pred group. There was no significant difference between the number of salbutamol therapies needed in the ED and at home after discharge. For subjects discharged home, the admission rate after initial discharge was 4.9% (dex) versus 1.8% (pred), resulting in overall hospital admission rates of 13.4% in the dex group and 14.9% in the pred group.

The authors conclude that a single dose of oral dexamethasone (0.6 mg/kg) is no worse than five days of twice-daily prednisolone (1 mg/kg per dose) in the management of children with mild-to-moderate asthma exacerbations. ■

Clinical Predictors of Occult Pneumonia in the Febrile Child

Citation: Murphy CG, van de Pol AC, Harper MB, et al. *Acad Emerg Med*. Published online before print January 22, 2007.
URL: *www.aemj.org/cgi/content/abstract/j.aem.2006.08.022v1*
Key point: There is limited utility in obtaining a CXR in febrile children without cough.

The utility of chest radiographs (CXRs) for detecting occult

pneumonia (OP) among pediatric patients without lower respiratory tract signs has been studied previously, but no predictors other than white blood cell count (WBC) and height of fever have been investigated.

"There is limited utility in obtaining a CXR in febrile children without cough."

This was a retrospective cross-sectional study conducted in a large urban pediatric hospital. Physician records of ED patients age 10 years or less who presented with fever (38°C) and had a CXR obtained for suspected pneumonia were reviewed. Patients were classified into two groups: "signs of pneumonia" and "no signs of pneumonia" on the basis of the presence or absence of respiratory distress, tachypnea, or lower respiratory tract findings. Occult pneumonia was defined as radiographic pneumonia in a patient without signs of pneumonia.

All told, 2,128 patients were studied. Among patients categorized as having no signs of pneumonia (n=1,084), 5.3% had OP. Presence of cough and longer duration of cough (>10 days) had positive likelihood ratios (LR+) of 1.24 and 2.25, respectively. Absence of cough had a negative likelihood ratio (LR–) of 0.19. The likelihood of OP increased with increasing duration of fever (LR+ for more than three days and more than five days of fever, respectively: 1.62; and 2.24). When obtained (56% of patients), WBC was a predictor of OP, with an LR+ of 1.76 and 2.17 for WBC of >15,000/mm^3 and >20,000/mm^3, respectively.

Occult pneumonia was found in 5.3% of patients with fever and no lower respiratory tract findings, tachypnea, or respiratory distress. There is limited utility in obtaining a CXR in febrile children without cough. The likelihood of pneumonia increased with longer duration of cough or fever or in the presence of leukocytosis. ■

Can a Normal Range of Elbow Movement Predict a Normal Elbow X-Ray?

Citation: Lennon RI, Rivat MS, Hilliam R, et al. *Emerg Med J*. 2007;24:86-88.
URL: *http://emj.bmj.com/cgi/content/abstract/24/2/86*
Key point: Patients with normal extension, flexion, and supination do not require emergent elbow radiographs.

Elbow injuries account for approximately 2% to 3% of presentations to the emergency department. This is associated not only with a very high rate of x-rays but also with a very high rate of "missed fractures."

This study examines which components of elbow examination have the best correlation with a normal radiograph. Data came from a district general hospital's emergency department seeing 83,000 new attendances per annum (pa; approximately 1,600 elbow injuries pa).

Of the 407 who were entered into the study, 331 received a radiograph of the elbow. Full extension of the elbow had a specificity of 0.916 for detection of a normal radiograph. An equal range of movement (ROM) had a specificity of 0.976. Subgroup analysis of patients aged <16 years showed a specificity of equal ROM of 1 for the detection of a normal x-ray.

Logistic regression analysis showed that best predictive values were achieved by a combination of full extension, flexion, and supination.

A two-tier clinical rule for management of elbow injury is proposed:

- Those patients aged 16 years with an ROM equal to the unaffected side may be safely discharged.
- Those patients with normal extension, flexion, and supination do not require emergent elbow radiographs. ■

Meta-Analysis: Anticholinergics, but not Beta-Agonists, Reduce Severe Exacerbations and Respiratory Mortality in COPD

Citation: Salpeter SR, Buckley NS, Salpeter EE. *J Gen Intern Med*. 2006;21(10):1011-1019.
URL: *http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=16970553&dopt=Abstract*
Key point: Inhaled anticholinergics reduced exacerbations and deaths in COPD patients; beta-2 agonists increased mortality.

Anticholinergics and beta-2 agonists generally have been considered equivalent choices for bronchodilation in chronic obstructive pulmonary disease (COPD). The authors performed a comprehensive search of electronic databases from 1966 to December 2005, clinical trial websites, and references from selected reviews and included randomized controlled trials of at least three months duration that evaluated anticholinergic or beta-2 agonist use compared with placebo or each other in patients with COPD.

Pooled results from 22 trials with 15,276 participants found that anticholinergic use significantly reduced severe exacerbations (RR 0.67) and respiratory deaths (RR 0.27) compared with placebo.

Beta-2 agonist use did not affect severe exacerbations (RR 1.08) but resulted in a significantly *increased* rate of respiratory deaths (RR 2.47) compared with placebo.

There was a twofold increased risk for severe exacerbations associated with beta-2 agonists compared with anticholinergics (RR 1.95). The addition of beta-2 agonist to anticholinergic use did not improve any clinical outcomes. ■

HOW CAN YOU MISS?

This is Equally Impressive: Cure More Otitis Externa Patients than CORTISPORIN* Otic with the #1 Otic Drop Among ENTs and Pediatricians.[1,2]

If you're wedded to more cures, CIPRODEX® Otic is a real gem. Based on 2 clinical trials, CIPRODEX® Otic demonstrated clinical cures in 87% and 94% of per protocol evaluable acute otitis externa (AOE) patients compared to 84% and 89%, respectively, for CORTISPORIN Otic.[1] And, among culture positive patients, clinical cures were 86% and 92% for CIPRODEX® Otic compared to 84% and 89%, respectively, for CORTISPORIN Otic.[1]

CIPRODEX®
(ciprofloxacin 0.3% and dexamethasone 0.1%)
STERILE OTIC SUSPENSION

It all adds up.

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Please see adjacent page for prescribing information.

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CIPRODEX® Otic is indicated in patients 6 months and older for acute otitis externa due to *Staphylococcus aureus* and *Pseudomonas aeruginosa*. CIPRODEX® Otic is contraindicated in patients with a history of hypersensitivity to ciprofloxacin, other quinolones and viral infections. If the infection is not improved after one week of treatment, cultures should be obtained to guide further treatment. Most commonly reported adverse reactions in clinical trials in AOE patients: pruritus (1.5%), ear debris (0.6%), superimposed ear infection (0.6%), ear congestion (0.4%), ear pain (0.4%), and erythema (0.4%).

CIPRODEX®
(ciprofloxacin 0.3% and dexamethasone 0.1%)
STERILE OTIC SUSPENSION

DESCRIPTION

CIPRODEX® (ciprofloxacin 0.3% and dexamethasone 0.1%) Sterile Otic Suspension contains the synthetic broad-spectrum antibacterial agent, ciprofloxacin hydrochloride, combined with the anti-inflammatory corticosteroid, dexamethasone, in a sterile, preserved suspension for otic use. Each mL of CIPRODEX® Otic contains ciprofloxacin hydrochloride (equivalent to 3 mg ciprofloxacin base), 1 mg dexamethasone, and 0.1 mg benzalkonium chloride as a preservative. The inactive ingredients are boric acid, sodium chloride, hydroxyethyl cellulose, tyloxapol, acetic acid, sodium acetate, edetate disodium, and purified water. Sodium hydroxide or hydrochloric acid may be added for adjustment of pH.

Ciprofloxacin, a fluoroquinolone is available as the monohydrochloride monohydrate salt of 1-cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-7-(1-piperazinyl)-3-quinolinecarboxylic acid. The empirical formula is $C_{17}H_{18}FN_3O_3 \cdot HCl \cdot H_2O$. Dexamethasone, 9-fluoro-11(beta),17,21-trihydroxy-16(alpha)-methylpregna-1,4-diene-3,20-dione, is an anti-inflammatory corticosteroid. The empirical formula is $C_{22}H_{29}FO_5$.

CLINICAL PHARMACOLOGY

Pharmacokinetics: Following a single bilateral 4-drop (total dose = 0.28 mL, 0.84 mg ciprofloxacin, 0.28 mg dexamethasone) topical otic dose of CIPRODEX® Otic to pediatric patients after tympanostomy tube insertion, measurable plasma concentrations of ciprofloxacin and dexamethasone were observed at 6 hours following administration in 2 of 9 patients and 5 of 9 patients, respectively.

Mean ± SD peak plasma concentrations of ciprofloxacin were 1.39 ± 0.880 ng/mL (n=9). Peak plasma concentrations ranged from 0.543 ng/mL to 3.45 ng/mL and were on average approximately 0.1% of peak plasma concentrations achieved with an oral dose of 250-mg [3]. Peak plasma concentrations of ciprofloxacin were observed within 15 minutes to 2 hours post dose application. Mean ± SD peak plasma concentrations of dexamethasone were 1.14 ± 1.54 ng/mL (n=9). Peak plasma concentrations ranged from 0.135 ng/mL to 5.10 ng/mL and were on average approximately 14% of peak concentrations reported in the literature following an oral 0.5-mg tablet dose[4]. Peak plasma concentrations of dexamethasone were observed within 15 minutes to 2 hours post dose application. Dexamethasone has been added to aid in the resolution of the inflammatory response accompanying bacterial infection (such as otorrhea in pediatric patients with AOM with tympanostomy tubes).

Microbiology: Ciprofloxacin has *in vitro* activity against a wide range of gram-positive and gram-negative microorganisms. The bactericidal action of ciprofloxacin results from interference with the enzyme, DNA gyrase, which is needed for the synthesis of bacterial DNA. Cross-resistance has been observed between ciprofloxacin and other fluoroquinolones. There is generally no cross-resistance between ciprofloxacin and other classes of antibacterial agents such as beta-lactams or aminoglycosides.

Ciprofloxacin has been shown to be active against most isolates of the following microorganisms, both *in vitro* and clinically in otic infections as described in the **INDICATIONS AND USAGE** section.

Aerobic and facultative gram-positive microorganisms: *Staphylococcus aureus, Streptococcus pneumoniae.* **Aerobic and facultative gram-negative microorganisms:** *Haemophilus influenzae, Moraxella catarrhalis, Pseudomonas aeruginosa.*

INDICATIONS AND USAGE: CIPRODEX® Otic is indicated for the treatment of infections caused by susceptible isolates of the designated microorganisms in the specific conditions listed below: **Acute Otitis Media** in pediatric patients (age 6 months and older) with tympanostomy tubes due to *Staphylococcus aureus, Streptococcus pneumoniae, Haemophilus influenzae, Moraxella catarrhalis,* and *Pseudomonas aeruginosa.* **Acute Otitis Externa** in pediatric (age 6 months and older), adult and elderly patients due to *Staphylococcus aureus* and *Pseudomonas aeruginosa.*

CONTRAINDICATIONS

CIPRODEX® Otic is contraindicated in patients with a history of hypersensitivity to ciprofloxacin, to other quinolones, or to any of the components in this medication. Use of this product is contraindicated in viral infections of the external canal including herpes simplex infections.

WARNINGS

FOR OTIC USE ONLY (This product is not approved for ophthalmic use.) **NOT FOR INJECTION**

CIPRODEX® Otic should be discontinued at the first appearance of a skin rash or any other sign of hypersensitivity. Serious and occasionally fatal hypersensitivity (anaphylactic) reactions, some following the first dose, have been reported in patients receiving systemic quinolones. Serious acute hypersensitivity reactions may require immediate emergency treatment.

PRECAUTIONS

General: As with other antibacterial preparations, use of this product may result in overgrowth of nonsusceptible organisms, including yeast and fungi. If the infection is not improved after one week of treatment, cultures should be obtained to guide further treatment. If otorrhea persists after a full course of therapy, or if two or more episodes of otorrhea occur within six months, further evaluation is recommended to exclude an underlying condition such as cholesteatoma, foreign body, or a tumor. The systemic administration of quinolones, including ciprofloxacin at doses much higher than given or absorbed by the otic route, has led to lesions or erosions of the cartilage in weight-bearing joints and other signs of arthropathy in immature animals of various species. Guinea pigs dosed in the middle ear with CIPRODEX® Otic for one month exhibited no drug-related structural or functional changes of the cochlear hair cells and no lesions in the ossicles. CIPRODEX® Otic was also shown to lack dermal sensitizing potential in the guinea pig when tested according to the method of Buehler. No signs of local irritation were found when CIPRODEX® Otic was applied topically in the rabbit eye. **Information for Patients:** For otic use only. (This product is not approved for use in the eye.) Warm the bottle in your hand for one to two minutes prior to use and shake well immediately before using. Avoid contaminating the tip with material from the ear, fingers, or other sources. Protect from light. If rash or allergic reaction occurs, discontinue use immediately and contact your physician. It is very important to use the ear drops for as long as the doctor has instructed, **even if the symptoms improve**. Discard unused portion after therapy is completed. **Acute Otitis Media in pediatric patients with tympanostomy tubes:** Prior to administration of CIPRODEX® Otic in patients (6 months and older) with acute otitis media through tympanostomy tubes, the solution should be warmed by holding the bottle in the hand for one or two minutes to avoid dizziness which may result from the instillation of a cold solution. The patient should lie with the affected ear upward, and then the drops should be instilled. The tragus should then be pumped 5 times by pushing inward to facilitate penetration of the drops into the middle ear. This position should be maintained for 60 seconds. Repeat, if necessary, for the opposite ear (see **DOSAGE AND ADMINISTRATION**). **Acute Otitis Externa:** Prior to administration of CIPRODEX® Otic in patients with acute otitis externa, the solution should be warmed by holding the bottle in the hand for one or two minutes to avoid dizziness which may result from the instillation of a cold solution. The patient should lie with the affected ear upward, and then the drops should be instilled. This position should be maintained for 60 seconds to facilitate penetration of the drops into the ear canal. Repeat, if necessary, for the opposite ear (see **DOSAGE AND ADMINISTRATION**).

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

Pregnancy

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

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

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

ADVERSE REACTIONS

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

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

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

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

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

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

DOSAGE AND ADMINISTRATION

CIPRODEX® OTIC SHOULD BE SHAKEN WELL IMMEDIATELY BEFORE USE

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

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

HOW SUPPLIED

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

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

References:

1. CIPRODEX® Otic package insert.
2. *Wolters Kluwer*, Health Source® Prescriber; year ending December 2005.
3. Campoli-Richards DM, Monk JP, Price A, Benfield P, Todd PA, Ward A. Ciprofloxacin: a review of its antibacterial activity, pharmacokinetic properties and therapeutic use. *Drugs*. 1988;35:373-447.
4. Loew D, Schuster O, Graul E. Dose-dependent pharmacokinetics of dexamethasone. *Eur J Clin Pharmacol*. 1986;30:225-230.

U.S. Patent Nos. 4,844,902; 6,284,804; 6,359,016
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Pneumonia Severity Index Aids Site-of-Treatment Decisions: The PSI is a Safe and Effective tool.

Diane M. Birnbaumer, MD, FACEP, published in *J Watch Emerg Med*. 2007;105.

Citation: Renaud B et al. Routine use of the Pneumonia Severity Index for guiding the site-of-treatment decision of patients with pneumonia in the emergency department: A multicenter, prospective, observational, controlled cohort study. *Clin Infect Dis*. 2007;44:41-49.

URL: *http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=retrieve&db=pubmed&list_uids=17143813&dopt=Abstract*

Marrie TJ. The Pneumonia Severity Index Score: Time to Move to a Prospective Study of Patients with Community-Acquired Pneumonia Who Are Discharged from Emergency Departments to Be Managed On an Ambulatory Basis. *Clin Infect Dis*. 2007;44:50-52.

URL: *http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=retrieve&db=pubmed&list_uids=17143814&dopt=Abstract*

Key point: Clinician judgment plus PSI is a powerful combination for guiding disposition of patients who present with pneumonia.

The Pneumonia Severity Index (PSI), initially derived to predict prognosis, has been used in emergency departments to guide disposition and treatment of patients presenting with pneumonia. These authors evaluated the utility of the PSI for guiding site-of-treatment decisions and determining patient outcomes.

In a prospective, observational, controlled cohort study, investigators in France compared outcomes for 472 patients treated at eight EDs that used the PSI and 453 patients treated at eight EDs that did not. The primary outcome was the proportion of low-risk (PSI classes I–III) patients who were treated as outpatients.

The authors calculated the PSI for all patients and determined that 48.5% were at low risk. In the EDs that used the PSI, 42.8% of low-risk patients were treated as outpatients, compared with 23.9% in the EDs that did not use the PSI. After adjusting for pneumonia severity, 28-day mortality among all patients was lower in those treated in the EDs that used the PSI (9.1% vs. 12.2%). ■

Cold Medicine Risky for Babies, Toddlers

Citation: *MMWR*. 2007;56(1):1-4.

URL: *http://www.cdc.gov/mmwr/PDF/wk/mm5601.pdf*

Key point: There is a very real risk of even fatal overdosage from OTC decongestants in toddlers and infants.

More than 1,500 toddlers and babies wound up in emergency rooms over a two-year period; three died because of bad reactions to cold or cough medicine, federal health officials reported.

The U.S. Centers for Disease Control and Prevention warned parents not to give common over-the-counter cold remedies to children under 2-years-old without consulting a doctor.

The deaths of three infants 6 months or younger in 2005 led to an investigation that showed the children all had high levels of the nasal decongestant pseudoephedrine, up to 14 times the amount recommended for children ages 2 to 12. The study found 1,519 ER cases from 2004 and 2005 involving young children and cold medicine.

The CDC said it is not known how much cold or cough medicine can cause illness or death in children under 2-years-old, but there are no approved dosing recommendations by the U.S. Food and Drug Administration for that age group.

The American Academy of Pediatrics first advised parents in 1997 about the risks of complications and overdose potential with certain cough suppressants. Last year the American College of Chest Physicians advised doctors not to recommend cough suppressants and over-the-counter cough medications to young children because of the risks. ■

Unsafe to Delay Appendectomy in Adults: Delays Increase Risk for Complications.

Citation: Birnbaumer DM. *J Watch Emerg Med*. 2007;105.

Is it safe to delay appendectomy in adults with acute appendicitis?

Citation: Ditillo MF, Dziura JD, Rabinovici R. *Ann Surg*. 2006;244(5):656-660.

URL:*www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=retrieve&db=pubmed&list_uids=17060754&dopt=Abstract*

Key point: A longer total time from symptom onset to surgery increased the risk for advanced pathology and complications.

Recent literature suggests that delaying appendectomy until daytime surgery is available is safe in children who present with appendicitis. These authors addressed the safety of delaying appendectomy in adults.

They reviewed charts of 1,081 adult patients who underwent appendectomy for acute appendicitis from 1998 to 2004 to determine time from symptom onset to emergency department arrival (patient interval), time from ED admission to surgery (hospital interval), and grade of appendiceal pathology. The authors found that a longer total time from symptom onset to surgery increased the risk for advanced pathology and complications, such as perforation, phlegmon, abscess, and gangrenous appendicitis. For example, the risk for advanced pathology was 13 times greater when the interval was greater than 71 hours than when the interval was less than 12 hours. Delays in the patient interval were more strongly associated with complications than were delays in the hospital interval. ■

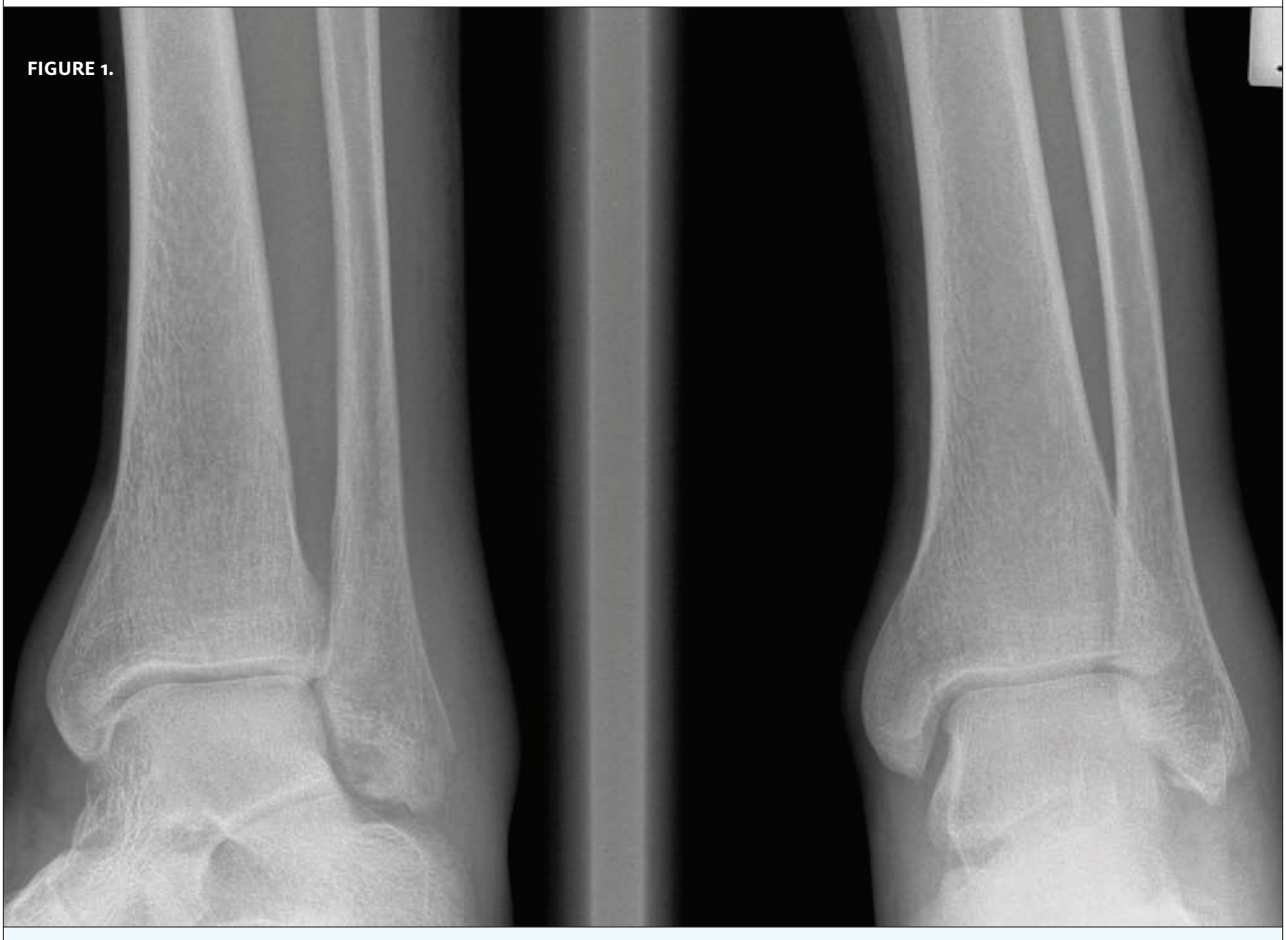
INSIGHTS IN IMAGES

CLINICAL CHALLENGE: CASE 1

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

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

FIGURE 1.

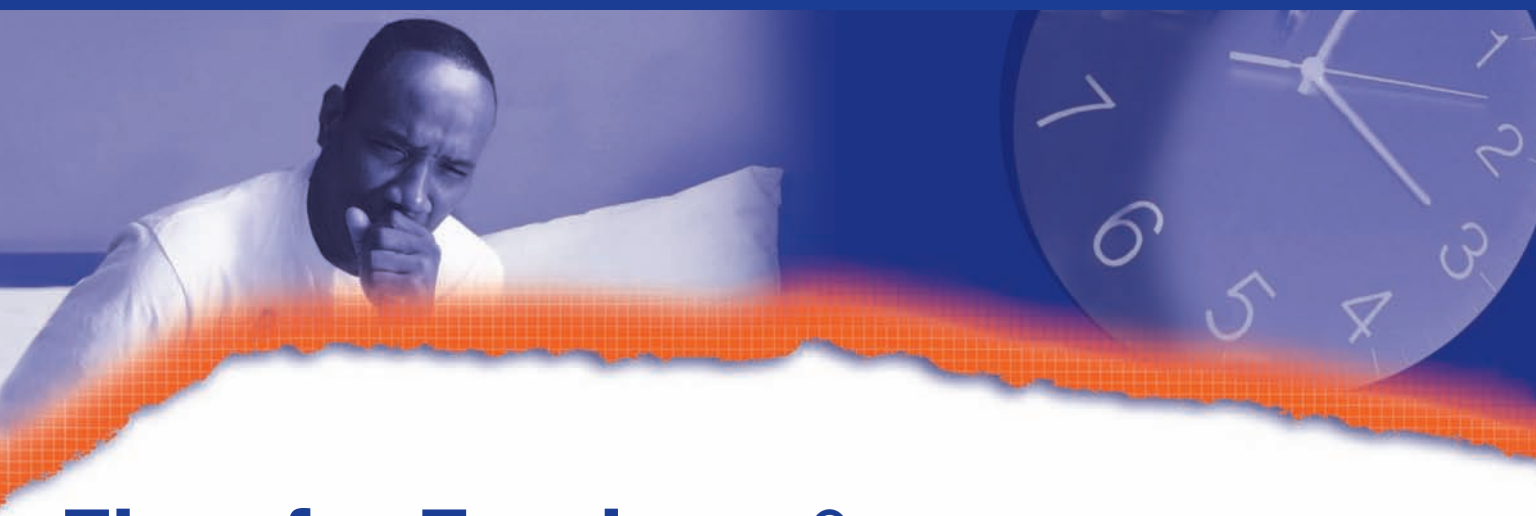


The patient is a healthy 30-year-old male who presents with pain shortly after "twisting" his ankle while playing soccer. Pain is severe enough to prevent him from putting weight on the ankle.

There are no other remarkable findings from exam or patient history.

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

3:00 AM, and his cough won't rest...



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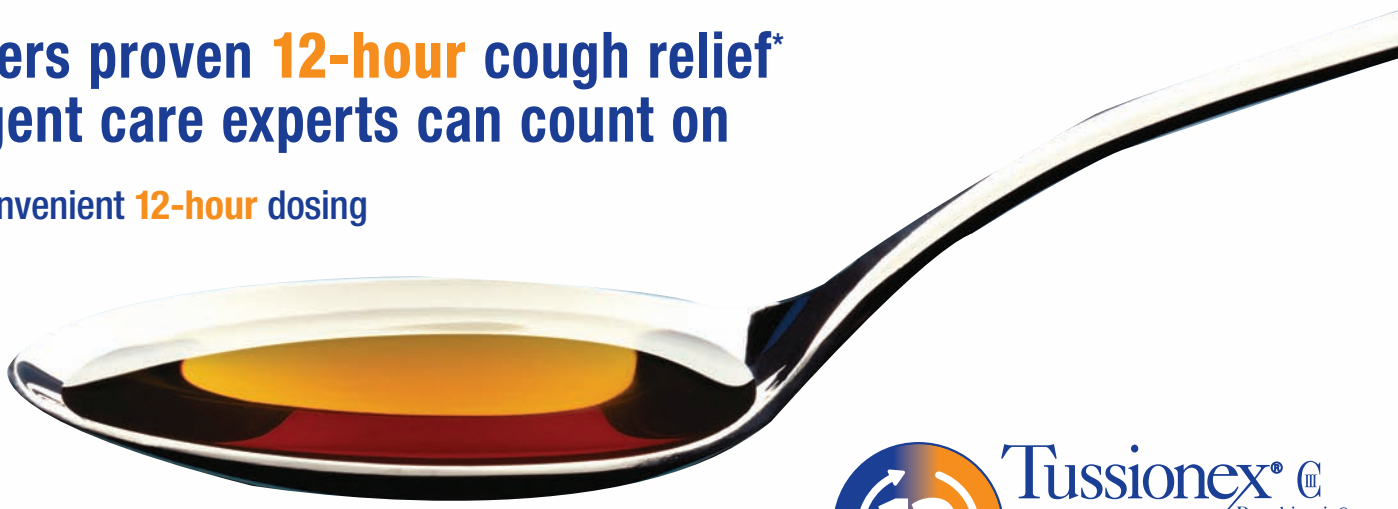
- Convenient 12-hour dosing



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

FDA-APPROVED

Cough relieved. Rest assured.™

IMPORTANT SAFETY INFORMATION

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

TUSSIONEX® is contraindicated in the presence of known allergy to hydrocodone or chlorpheniramine. The most common adverse reactions associated with TUSSIONEX® are sedation, drowsiness, and mental clouding, which may impair the mental and/or physical abilities required for potentially hazardous tasks. As with other drugs in this class, the possibility of tolerance and/or dependence, particularly in patients with a history of drug dependence, should be considered.

Please see full Prescribing Information on reverse.

TUSSIONEX® contains approximately 1.9 g of total carbohydrate (CHO) per 5 mL teaspoonful (1 g from granular sugar, 0.8 g from high fructose corn syrup, and 0.1 g from other CHO). Thus, total daily CHO load from the use of TUSSIONEX® at recommended adult dose (1 tsp every 12 hours) is 3.8 g.[1]

*Based on pharmacokinetic data.[1]

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

Please visit www.tussionex.com

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Manufactured by UCB Manufacturing, Inc.

TU1149-0107

Printed in U.S.A.

Tussionex®

Pennkinetic®

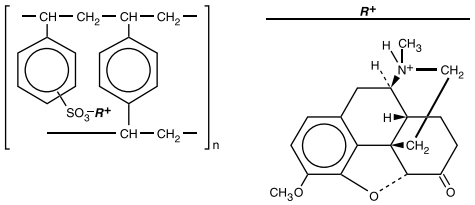
(hydrocodone polistirex and chlorpheniramine polistirex)

Extended-Release Suspension

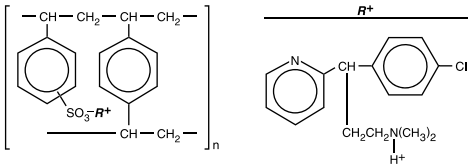
℞ Only
LR242A
Rev. 12/02

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

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



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



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

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

Chlorpheniramine is an antihistamine drug (H_1 receptor antagonist) that also possesses anticholinergic and sedative activity. It prevents released histamine from dilating capillaries and causing edema of the respiratory mucosa.

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

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

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

CONTRAINDICATIONS: Known allergy or sensitivity to hydrocodone or chlorpheniramine.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Dermatologic System: Rash, pruritus.

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

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

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

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

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

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

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

DOSAGE AND ADMINISTRATION: Shake well before using.

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

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

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

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

NDC 53014-548-67 473 mL bottle

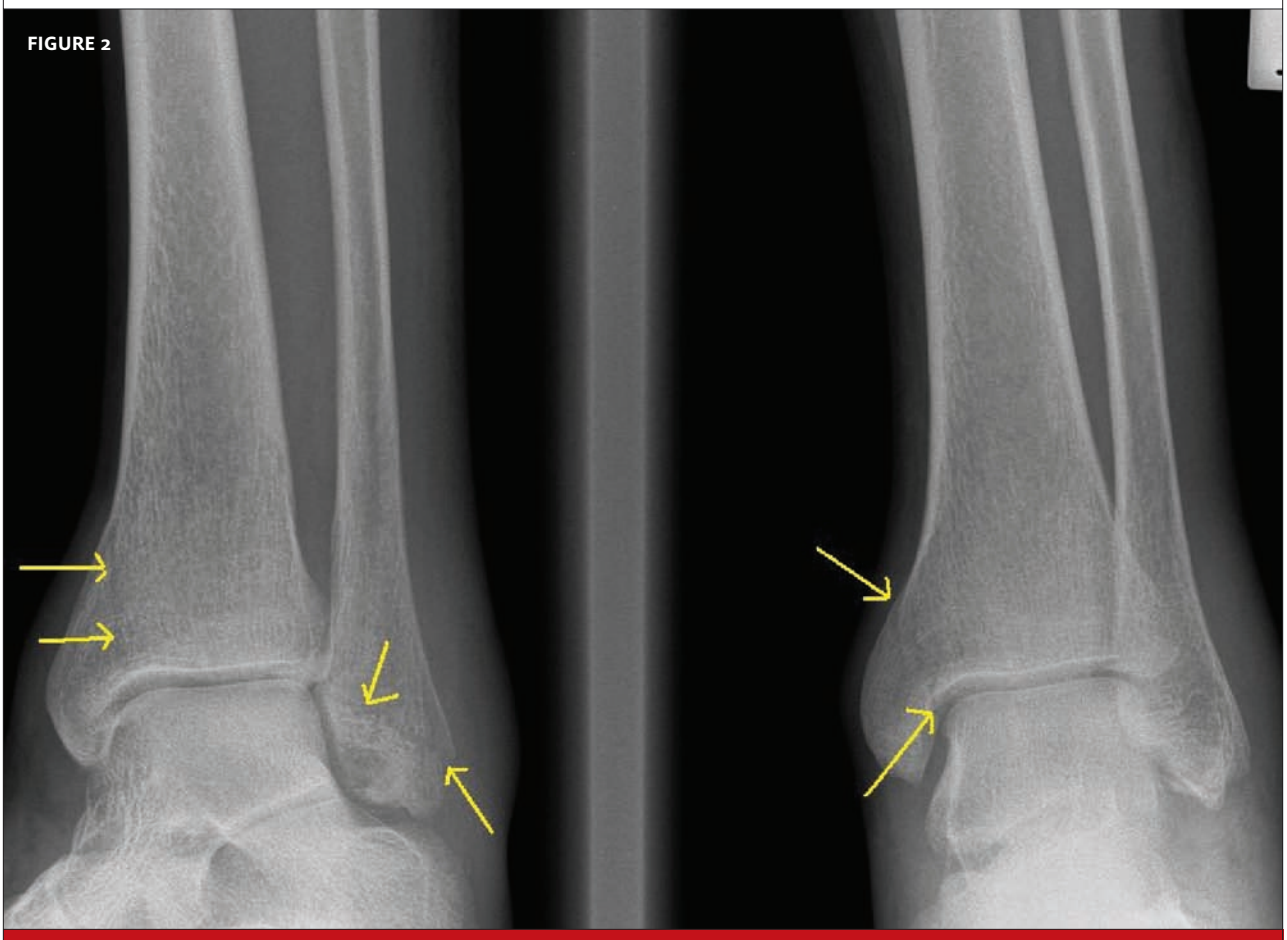
Shake well. Dispense in a well-closed container. Store at 59°-86°F (15°-30°C).

CELLTECH

Celltech Pharmaceuticals, Inc.
Rochester, NY 14623 USA

Rev. 12/02
Tussionex® Pennkinetic® Extended-Release Suspension: US Patent No. 4,762,709.2. LR242A

FIGURE 2

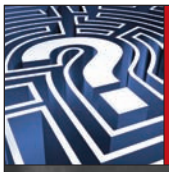


THE RESOLUTION

The patient has a fracture of the distal tibia and fibula, as well as an intra-articular fracture of the tibia. He was referred to the hospital.

Ideally, the patient should be casted by an orthopod; however, one can apply a posterior slab without any weight bearing and direct the patient to follow up the next day with an orthopod.

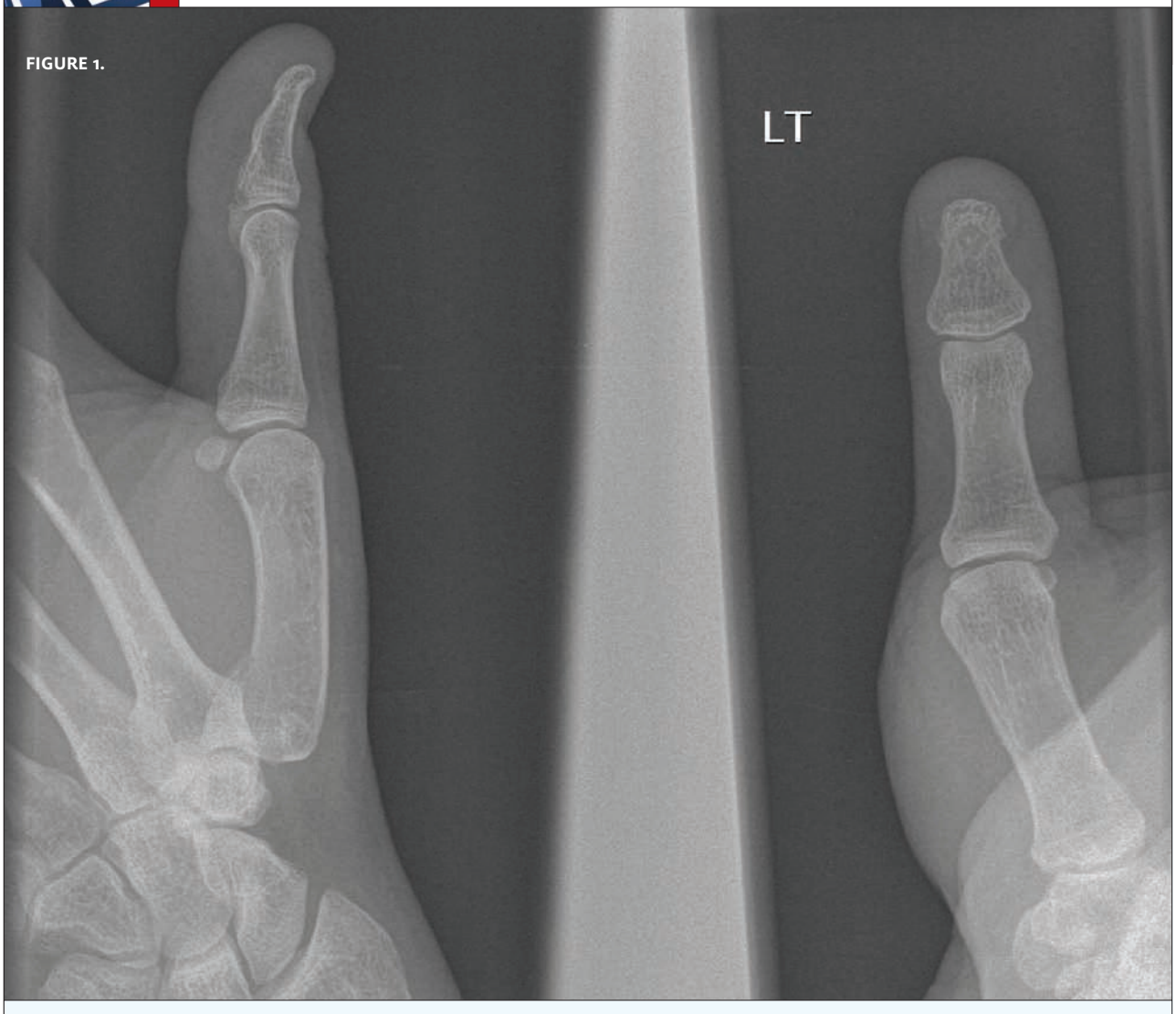
Acknowledgment: X-rays taken and fractures identified by radiologist Scott Fields, MD. Case presented by Nahum Kovalski, BSc, MDCM.



INSIGHTS IN IMAGES

CLINICAL CHALLENGE: CASE 2

FIGURE 1.



The patient is a healthy 37-year-old who reports falling on his hand, with his thumb outstretched.

Upon examination, you find local mild swelling and tenderness and decreased range of motion of the thumb. There is no snuffbox tenderness, however.

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

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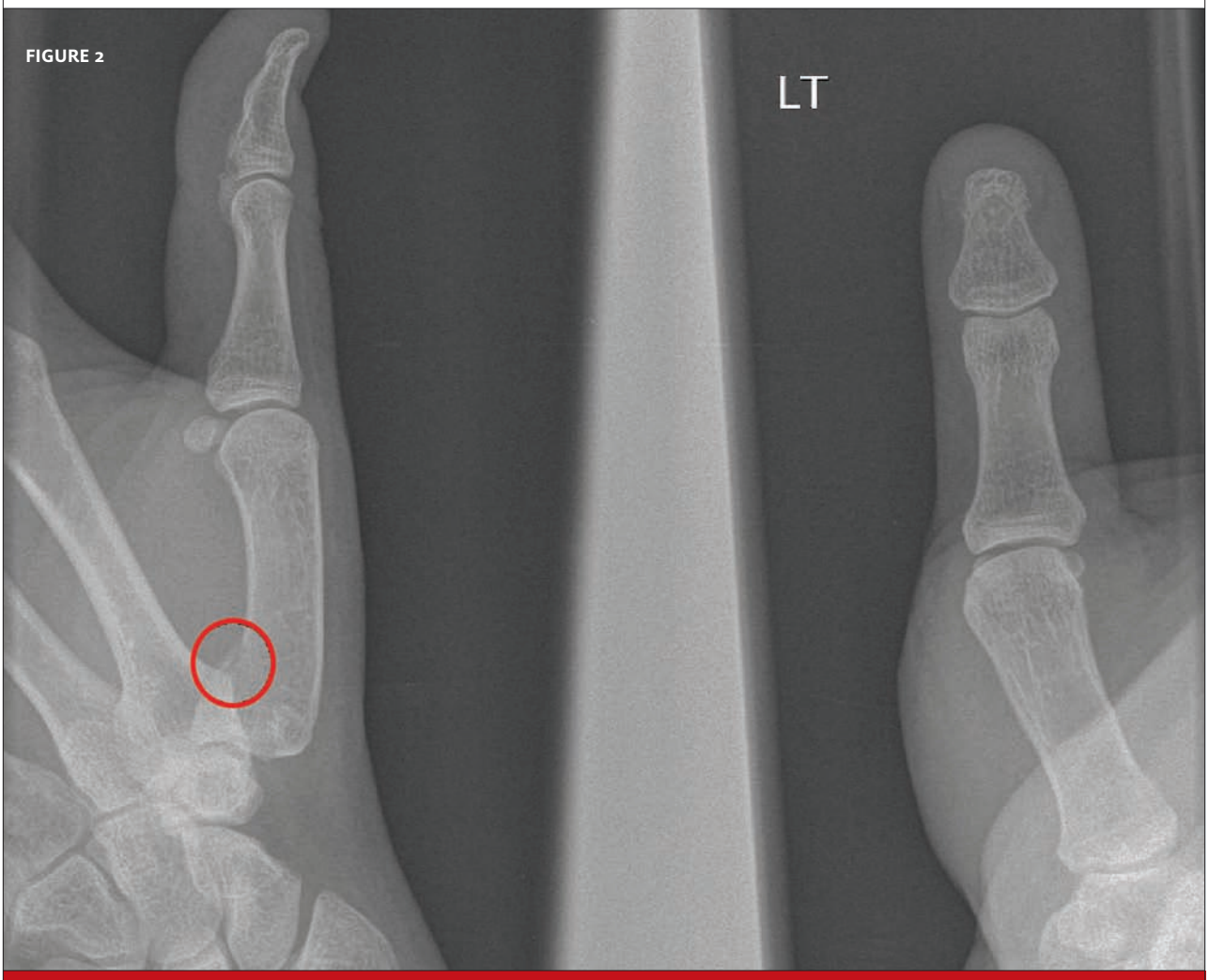
FIGURE 2



THE RESOLUTION

The patient has a fracture at the base of the metacarpal. The decreased range of motion is probably most attributable to pain, as opposed to being indicative of the severity of the injury.

It was important to note the lack of snuffbox tenderness in this patient. Snuffbox tenderness is highly suggestive of scaphoid fracture, especially among patients who experienced a fall like this patient did. Hence, its absence may alleviate clinical suspicion of that particular injury and help guide the clinician to the true injury site.

The patient was casted by the orthopedist and signed out.

Acknowledgment: X-rays taken and fractures identified by radiologist Scott Fields, MD. Case presented by Nahum Kovalski, BSc, MDCM.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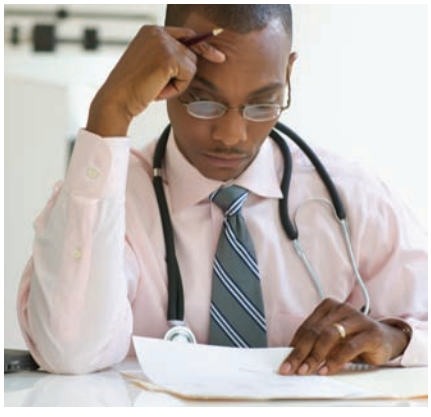
Medical Professional Liability Insurance

Limiting Cost While Maximizing Value

Urgent message: Liability insurance premiums continue to rise across the spectrum of medical practice environments. Urgent care practitioners can maximize the value of every premium dollar spent by understanding whom and what the policy actually covers.

Terrence P. Coughlin, CPCU, ARM, AIC

One of the more important and costly aspects of running an urgent care center is the insurance coverage needed to protect the center and the medical staff working there. In recent years, all medical facilities have been hit hard by rising medical professional liability insurance premiums; in many cases, these higher premiums are coupled with increases in deductibles or self-insured retentions and new restrictive exclusions.



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And yet, how many of these same facilities have actually researched how to minimize those increases; how to transfer the financial responsibility to the correct party; which exclusions apply, and how those exclusions might affect their coverage? And is there a staff member with the expertise to negotiate and understand what the practice is purchasing? Medical professional liability is not just about limits and premiums.

An urgent care practice can maximize the benefit of the premium dollars being spent by carefully examining and fine-tuning the professional liability/medical malpractice insurance program (not just the policy). The importance of knowing whom and what the insurance program is covering cannot be over-emphasized.

Key Questions

There are too many nuances to medical malpractice insurance to address them all here, but this article will take a look at some of the major issues.

First let's look at the key questions regarding the individuals to be insured:

- Are they independent contractors or employees? Full or part time?
- Do they already carry medical liability under their own name, or under a different organization?
- Do they need to be listed (and paid for) under your policy?
- Do you have residents working at the facility?
- Is there a contract with another organization (educational institution, hospital etc.) that requires *them* to insure and indemnify your clinic for those residents?
- Is your current carrier aware of these relationships and any "hold harmless" agreements?
- Have you asked for, saved, and submitted copies of certificates of insurance for those medical profes-

sionals who already carry their own professional liability insurance to your medical liability insurance carrier?

Answers to these questions will help determine the adequacy of the insurance protection afforded to various individuals and will aid in the tailoring of needed insurance coverage.

Carefully examine all employment or independent contractor agreements to see what they stipulate insofar as your responsibility to insure each party. Avoid duplicating coverage or offering coverage unnecessarily, and be sure "Other Insurance" provisions of the various policies work in concert with each other.

Once you have correctly identified who is to be insured under your program, it's time to examine how they should be covered.

Organize each person by job classification and hours. Many insurance carriers will allow you to set a separate per-individual coverage limit for those employees that have a higher degree of responsibility (i.e., risk).

Some employees—especially those make some medical decisions but whose basic responsibilities are administrative in nature—can be covered by a shared limit. The rationale for this approach is simple: By providing the higher-risk employees with their own limits, you are protecting everyone else's coverage. You are not going to dilute the organization's protection with one or two claims associated with a high-risk position. At the same time, those with a lesser degree of risk do not need to have a separate—and more costly—limit in place. A shared limit of liability is often sufficient to cover them and the organization.

By correctly classifying who is to be insured and on what basis, many businesses have been able to maximize the coverage they buy while minimizing the dollars spent to get that coverage.

Deductibles vs. SIRs

Next, let's look at the too infrequently examined but very important role of the deductible or self-insured retention (SIR).

In many states, there is little regulation concerning deductibles and SIRs. In states that do allow them, many insureds do not know the difference between the two and therefore never question it.

With a deductible, the insurance company pays the claim and associated expenses from "dollar one" and then asks you to reimburse them for the amount of the deductible. In effect, they are playing with your money.

With an SIR, the policyholder handles the claims and is responsible for paying any amount under the SIR level (a very simplified explanation). Once that dollar amount has been spent, the insurance company is responsible.

The difference is very important in the handling of lower-valued claims. For example, when the insurance company settles a claim for an amount that is lower than the urgent care facility's deductible, is it out of necessity or because it was less expensive to give away your money than to investigate and fight the claim with their own?

An SIR allows you or your third-party administrator to investigate and fight claims that might otherwise be paid. Obviously this saves you money now; by keeping those claims out of your claims history, however, it can also save you money in subsequent years, as well.

These aspects of your medical professional liability insurance represent just the tip of the iceberg. Some fairly common exclusions include:

- abuse/molestation
- harassment
- unfair discrimination
- wrongful discharge
- license revocation
- liability for acts while under the influence of alcohol or drugs
- punitive damages

If your policy contains some or all of these exclusions, you should be aware that there are policies available that don't. And some conditions and exclusions can be negotiated out of your policy.

Something else to bear in mind: Under some policies, an insured has the right to deny the insurance carrier's move to settle a claim. This can be very important to a medical practitioner who wants (and needs) to safeguard his or her professional reputation.

The topic is complex. If you or your clinic's business administrator is not familiar with these concepts, it may be worthwhile to consult an independent risk management and insurance consultants. Having a professional who understands the "ins and outs" of the risk management and insurance look over your program might be one of the smarter moves you can make. ■

Note: Before you allow someone to work on your behalf, ensure that they have the proper designations or industry affiliations. The Society of Risk Management Consultants lists its members on its website (www.srmcsociety.org/). In addition, the Chartered Property Casualty Underwriters Society, which grants a "CPCU" designation to insurance professionals based on adherence to its ethical and continuing education guidelines, has an Agent and Broker Locator on its website, www.cpcusociety.org. The author, Terrence P. Coughlin, is a member of both and can be reached at coughlin@accriskmanagement.com.

How to Prepare for and Give a Deposition

JOHN SHUFELDT, MD, JD, MBA, FACEP

You are sitting at a long mahogany table in an unfamiliar, yet very well-appointed, office wearing the same dark suit that you last wore at your cousin's funeral. A pale, gaunt man with what looks like a small typewriter scrambles furiously to keep up with your rapid-pressured response to the question, "Doctor, for the record, please state your name and current address."

Is this a bad dream? Only if you are unprepared for what comes next.

Black's Law Dictionary defines *deposition* as "a witness's out of court testimony that is reduced to writing for later use in court or for discovery purposes." Another, more practical, definition might be, "the modern day equivalent of the Spanish Inquisition where the opposing attorney attempts to get you to say something you will forever regret saying."

The deposition can determine the course of the entire trial and mistakes made during the deposition are often very difficult—and sometime impossible—to mitigate. A provider's testimony during the deposition will serve as the foundation for experts' opinions and defense theories. Given the importance of this phase of the litigation, it behooves the provider to be thoroughly prepared.

Preparing for the Deposition

Thoroughly Review the Record

Before taking your deposition, the opposing attorneys have already spent considerable time learning every detail of the record. They typically will have already thoroughly gone over the entire record with one or more experts who have advised them on what to ask you and where the care may have fallen below the standard.

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*.

To be clear: The opposing attorney will be exceptionally well versed on the patient record and will ask questions, not only on your portion of the record, but often times on the entire record.

"Thoroughly review the record from beginning to end."

Take, for example, the case of a 38-year-old female who presents with a cough and cold symptoms. Her x-ray is normal and her oxygen saturation is 95%. You prescribe a Z-PAK and an over-the-counter cough preparation.

Being a very thorough provider, you have documented that you have considered the diagnosis of a pulmonary embolism but have, in your mind, ruled it out given her history, physical exam, and diagnostic findings. You admit, however, that if the patient was on oral birth control medication, smoked, or had a history of hypercoagulability, had hemoptysis, or had just had a prolonged period of being sedentary that you would have pursued the PE diagnosis more aggressively. You further agree that if she in fact had those factors in her history, it would be below the standard of care to not have pursued the diagnosis.

The plaintiff's attorney refers you to a page in the hospital record containing the intensivist's admitting note and asks you to read the following: "*38 y/o intubated female on dopamine is received from the ED. Reportedly, this unfortunate young lady, who just returned from Europe, and who has a remote history of DVT, had quit smoking a week prior the event and was just taken off oral birth control pills, was being treated for URI symptoms with a Z-PAK.*"

His "question" at trial is, "Doctor, you agree of course, after the answer you gave in your deposition, that if you had taken the time to get a better history your care would not have fallen below the standard."

The take-home point is to thoroughly review the record from beginning to end. That way, you won't get tripped up by what other providers have documented, nor will you inad-

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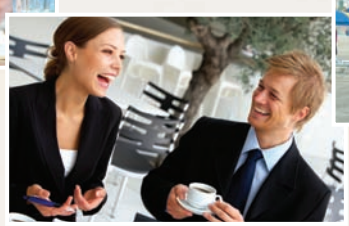

Relaxation

vertently impeach yourself by not knowing exactly what you documented.

Understand the Plaintiff's Case

Understand where the plaintiff is coming from, as opposed to simply discounting it. You will probably have a copy of his or her expert's opinions. If asked, be able to provide a rational explanation of why those opinions are not applicable to the case, or why the facts were different from their analysis. Understand what the opposing experts are basing their analysis upon; is it recent literature, an out-of-date textbook or a practice-pattern nuance specific to their local environment?

To fully prepare for your own deposition, it is important to know the basis for the suit. Think of Sun Tzu, who said, "If you know the enemy and know yourself, your victory will not stand in doubt...."

Giving the Deposition

Attempting to Talk Your Way Out of the Suit

Do not try to rationalize or talk your way out of a suit by explaining the basis for treating the patient the way you did in the hope that the plaintiff's attorneys will see the error of their ways and drop the suit. This approach often stems from not understanding the basis for the suit in the first place and often leads to volunteering information that was not asked for.

As providers, we are very used to explaining things to nearly everybody, often times in great detail. It is a great trait to have and suits us well in almost all aspects of our professional lives. After all, one of our jobs is to educate our patients.

However, for the 120 minutes or so that you will be seated at the mahogany table, lose this trait. The deposition is not the place to educate the opposing attorney. Answer what was asked, honestly and completely, and stop. Give your attorney an opportunity to object to the question before you begin your answer. If you don't completely understand the question, or if it is a two-part or compound question, ask for clarification. Many people giving depositions begin to answer a question before it is completed or without really understanding what was asked.

Like everyone else, attorneys will ask some really poorly worded questions. Don't guess at what they are trying to ask and don't say, "Are you trying to ask...?" Let them do their job, just ask for clarification if you are not 100% sure of where they are going with the question.

Lying, Becoming Argumentative or Overly Defensive

Be on your toes without becoming argumentative or overly defensive. It serves no purpose and may be very damaging to argue with plaintiff's counsel. Attorneys spend their days arguing; consequently, they are very good at it and the majority of physicians will lose an argument with a seasoned lawyer.

This is not to say that you should not disagree. State your disagreement firmly and conclusively and leave it at that. I have seen physicians become overly defensive during a deposition. When this happens, they start disagreeing with even the most obvious statements ("Doctor, would you agree that your role is to treat the patient?"). Many providers start to think that every question is a trick question and, thus, will not agree with anything the opposing counsel says. When this pattern of behavior is woven through the deposition, a provider can lose credibility and the jury may start to doubt the provider's integrity on the important issues in the case.

In documenting, depositions, and trial, the rule of thumb is to simply be honest. Answer questions without expounding or letting your emotions get the best of you. If you are caught lying or have altered the records, you will lose, no matter how good your care was.

Blaming Others

During the discovery portion of the trial, other providers who may be liable for some aspect of the care will be uncovered. It is not your job to expose them, and you should not point fingers at other caregivers during the deposition. This invariably leads the other party to point their finger right back at you. The typical outcome is that you will both lose.

Court is Theater

As providers, we take this very seriously. After all, someone is questioning our ability and livelihood. While the facts and your responses are very important, so too is your demeanor and presentation. You need to remember that the jury will be looking at you in an effort to judge your credibility and competence. Act the part. The impression you want to give is that you are a very caring, honest, competent provider who will accept fault when appropriate and who is not arrogant, uncaring, or detached.

If you follow this, what should be very intuitive advice, you will greatly improve your chances of a favorable outcome at trial. Remember, the cards are already statistically stacked in your favor. ■

TAKE-HOME POINTS

- The opposing attorney may ask questions on the entire patient record, not just your portion; be prepared.
- Understand the plaintiff's perspective and the basis for the suit.
- Answer questions simply, honestly, and directly. Then stop talking.
- Fight the urge to become defensive or argumentative.

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CODING Q&A

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DAVID STERN, MD, CPC

Q. I have been told that I can get credit for a complete review of systems (at least 10 systems) by simply noting positive findings in certain systems and then noting "all other systems negative."

A. This is, indeed, a general CMS "guideline," but two Medicare carriers have issued contradictory guidelines. TrailBlazer Health Enterprises (Medicare carrier for Delaware, the District of Columbia, Maryland, Virginia, and Texas) and Wisconsin Physicians Services (Medicare carrier for Illinois, Michigan, Minnesota, and Wisconsin) have issued directives that the provider must specify the actual systems that are negative (Trailblazer) or that specifically disallow coding credit for use of the phrase "all other systems negative" (Wisconsin Physicians Services).

In mid-November, Wisconsin Physicians Services reverted back to allowing the "all other systems negative" phrase. Since the situation is still in flux, physicians should consider revising their documentation procedures in order to avoid challenges to their E/M claims.

Many payors continue to give credit for the "all other systems negative" notation. It is my opinion, however, that making specific notations on each appropriate system is a better procedure from both a clinical and a compliance standpoint.

Q. When a patient returns to the urgent care center for an injection of an antibiotic a day after being seen by the physician for an infection, can we bill a 99211 for the nursing services?

A. Yes. CPT guidelines allow coding a 99211 for an injection given without direct physician supervision. Medicare's incident-to billing guidelines, however, require direct physician supervision if 99211 is coded. Thus, you may not use this code to bill any payor that follows Medicare's incident-to guidelines for an injection given without direct physician supervision.

If the injection was provided by a midlevel provider following a treatment plan previously documented by a physician who had devised this plan as part of a face-to-face encounter with a patient, then an appropriate E/M may be billed under the physician provider number. If the midlevel provider administers the injection but is *not* following a specific plan outlined by the physician as part of a previous patient encounter, then the E/M must be reported under the midlevel provider's number.

Q. How do we code for patient visits that are limited to gynecological exams and screening Pap smears?

A. The answer varies, based on the payor being billed. If you are billing Medicare, use code G0101 to code a pelvic and breast examination. Medicare will reimburse for this code once every two years for low-risk patients (those with diagnosis V76.2, V76.47, V76.49). For high-risk patients, Medicare will reimburse once per year. To document this high risk, use diagnosis code V15.89.

Likewise, Medicare will pay for Pap smear screening once every two years for low-risk patients and once per year for high-risk patients. For specimen collection and preparation, code with Q0091. Use G0124, G0141, or P3001 for test interpretation. Use V72.31 as the ICD-9 code for a screening Pap and full gynecological exam.

If you are not billing Medicare, the rules may be quite different, and the payor may require codes 99381-99397 for a screening gynecological exam and Pap smear. Some private payors accept code 99000 for specimen preparation and transfer to the lab.

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

Making Employer Advisory Councils Work for You

FRANK H. LEONE, MBA, MPH

Whether you are just now incorporating occupational health into your service mix or have a burgeoning occupational health component, an Employer Advisory Council is an excellent idea.

In general, a council should include at least 12 members (providing a cushion against no-shows) and consist of a mix of owners, company CEOs, and HR personnel that reflect your service area. Be certain to include both high-profile candidates and worker bees from both client and non-client companies.

There are numerous ways in which such a council can be valuable to an urgent care clinic:

- **As an advisory body—**A council can provide your clinic with an ongoing vehicle for insight, advice, spot checks on your clinic's performance, and new ideas.
- **As a publicity vehicle—**In this age of cost consciousness**,** provider-employer "coalitions" can serve as an example that a local business is making every effort to be fiscally responsible—and that you're a key part of that effort. This tends to play well with the media and throughout the community**.**
- **As a reward to high-volume clients—**If particular companies drive your occupational health component (or if you think a client could be such a customer in the future), a "seat" on your council provides a good hedge against losing them to another provider.
- **As an entrée to highly targeted prospects—**Are there some prospect companies that you would like to bring on as clients? A seat on your council is a good place to start.
- **As a credibility enhancer—**Know a "mover and shaker" in the community? A slot on your council would provide added credibility to your clinic.

"A finite term ensures more active interest during the term."

Several guidelines should govern council membership:

- **The "right" number of seats—**An average attendance of six-to-nine council members per meeting is about right. But to get that many at a meeting, you probably need twice as many council members. Therefore, strive for a range of 12-18 members at any one time.
- **Make a council seat a valued commodity—**Capping the number of seats (e.g., 15) and adding new members only to replace previous members guards against devaluation of the privilege.
- **Establish finite council terms—**Establish a finite council term, such as two years. This ensures more active interest during the term, and the council seat appears more "special." If you start from scratch with 15 council members, appoint five members for a one-year term, five members for a two-year term, and five for a three-year term. That way, you will establish a rotation of new members each year, ensuring a continuous supply of new blood and energy.
- **Replace non-participants—**A certain council member misses three meetings in a row? Unless there are mitigating circumstances, his or her membership should be revoked. Again, you are establishing value.
- **Elect a rotating council chair—**Most councils tend to be chaired by a representative of the sponsoring clinic. Yet, the council is really an *employer* council. I suggest that council members elect one of their own as chair every year.

Frank H. 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*.

- **Multiple clinics = multiple councils—**Let's say your organization encompasses several clinics in several communities. Develop a separate council for each community (or clinic) and have one or two members of each council form a "Super Council."

Finally, how should a council function?

- **Give them a charge—**Be careful not to make your council appear self-serving; this breeds disinterest and then disintegration. Position your council as a task force to "provide solutions to significant workplace health and safety challenges."
- **Keep it going—**Councils should meet as often as six times a year in order to create and sustain momentum. Ninety minutes per meeting is about right. The optimal time of day (breakfast, lunch, after work) and day of the week vary; council member preferences should be polled via e-mail.
- **Neutral turf—**Meetings *should not* be held at your clinic, in order to minimize the risk of the dreaded self-serving image. Keep rotating the venue in order to minimize the "same-old, same-old" feeling. Locations that make sense include private rooms at local restaurants and conference rooms at employer workplaces.
- **Publicize your efforts—**Send a press release and updates to local media ("Local provider-employer task force tackles worker absenteeism"). Send e-mail blasts detailing task force progress and findings. Add a section to your website and include a roster of council members, if not their photos and biographies.

An Employer Advisory Council can provide your clinic with new insight concerning employer perspectives, ideas for new services, and a vehicle for taking the marketing "high road." ■

TAKE-HOME POINTS

- Use your council as a publicity vehicle, pointing out that such coalitions look for ways to keep healthcare spending down.
- Remember the council is for employers; members should elect one of their one as chair annually.
- Keep interest among members high by giving the council an objective.

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Career Opportunities

Call for Articles

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

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

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

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

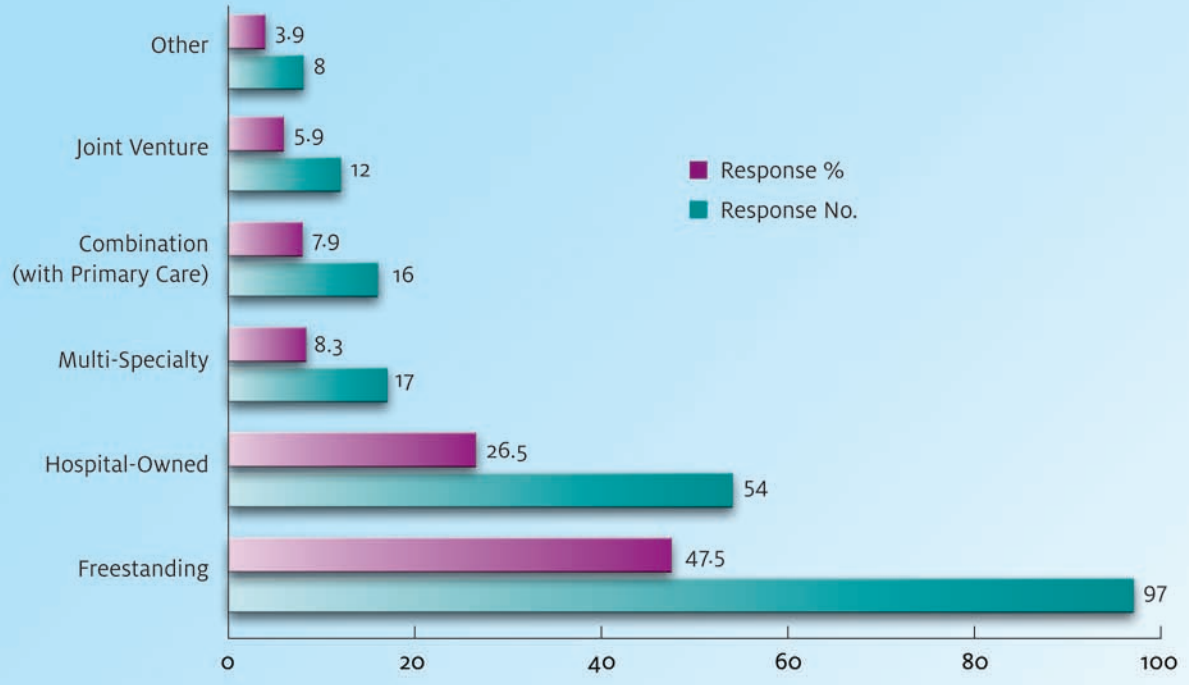
He will be happy to discuss it with you.

DEVELOPING DATA

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

In this issue: Typically, urgent care providers are physicians/entrepreneurs. But they come from a wide variety of practice environments—family practice, emergency medicine, etc.—so what's the breakdown of how urgent care practices are structured, organizationally speaking?

ORGANIZATIONAL STRUCTURE



Bear in mind that how a business defines itself clinically was a separate question. Sixty-two percent of respondents classified their clinical offerings as "traditional urgent care" combined with occupational health; 35% just traditional urgent care; and 3% occupational health only.

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

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

Next month in ***Developing Data****:*

Urgent care medicine is a relatively young practice model. What's the breakdown on how many clinics have been in business for how long?

Urgent Care Association of America

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