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Management of Erythema Multiforme
in the Urgent Care Setting

A **BRAVEHEART** PUBLICATION

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®
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STERILE OTIC SUSPENSION

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 1/07 CDX07501JA

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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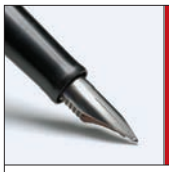

LETTER FROM THE EDITOR-IN-CHIEF

The Road to Recognition

The recent announcement that the American Board of Medical Specialties approved Hospice and Palliative Care as a new subspecialty appears to ring in a new era of subspecialty acceptance.

It was once thought that subspecialties found their homes with one sponsor; Cardiology, Gastroenterology, and Pulmonology were all within the realm of Internal Medicine. Pediatrics followed suit with its own versions of these subspecialties.

There was no con-joint sponsorship from multiple boards until Nuclear Medicine, with Sports Medicine and Pain Medicine being more recent examples. This con-joint sponsorship has opened the door for physicians of multiple specialties to be boarded in one subspecialty.

To be clear, there is a big difference between "specialty" and "subspecialty" recognition. There has not been recognition of a new specialty since Emergency Medicine in 1979 and Medical Genetics in 1991. Several applications for specialty recognition have been rejected since then, most recently Vascular Surgery.

Specialty designation for Urgent Care Medicine is highly unlikely. Subspecialty designation is easier to obtain, however, and con-joint sponsorship has ensured that no one specialty board can control the identity of the new board. This is the model that worked for Sports Medicine, Pain Medicine, and Palliative Care.

Furthermore, the Accreditation Council for Graduate Medical Education (ACGME) has been playing a more critical role in recognizing developing subspecialties and lays out clear criteria for provisional approval. These criteria were presented at the UCAOA Annual Convention this month in Daytona.

According to these criteria, the establishment of qualified training programs and peer-reviewed journals is essential to recognition. UCAOA prides itself on its accomplishments in these fundamental areas, and continues to explore ways to improve the quality of care delivered by those practicing urgent care medicine

Peer-reviewed journals like *JUCM* represent a pivotal step toward official recognition. Publishing some of the first original research in our field (Emergencies in the Office: Why Are 911 Calls Placed from Family Medicine and Urgent Care Offices?, *JUCM*, January 2007) was a defining moment for our discipline, and a source of great pride at *JUCM*.

"By following in the footsteps of other successful organizations, UCAOA is well positioned for success."

Furthermore, the strength of our training programs is highlighted by the recent announcement that UCAOA has launched its second Fellowship in Urgent Care Medicine, at the University of Illinois, Rockford College of Medicine, Department of Family Medicine in collaboration with Physicians Immediate Care, Inc.

The U of I program follows the same model developed for the Department of Family Medicine, Case Western Reserve University and mirrors the model established by ACGME. Candidates are being interviewed for the 2007-2008 Fellowship year.

It remains UCAOA's highest priority to lay the groundwork for successful specialty recognition through proven means and established criteria. By following in the footsteps of other successful organizations that came before, UCAOA is well positioned for success.

I welcome your comments and encourage your participation in this journal and in the continuing growth of urgent care medicine. Feel free to share your thoughts in an e-mail to me at *editor@jucm.com*. ■

Lee A. Resnick, MD
Editor-in-Chief
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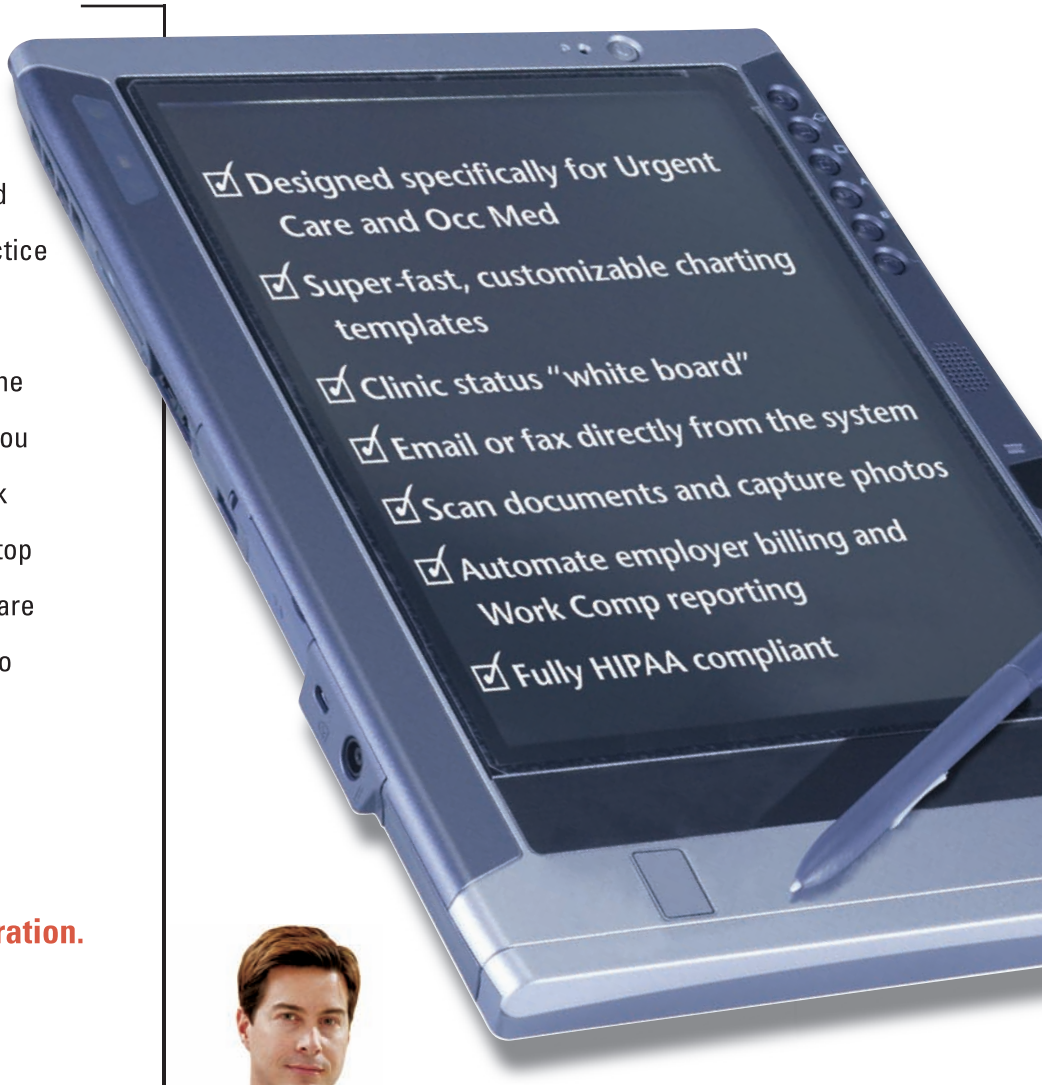

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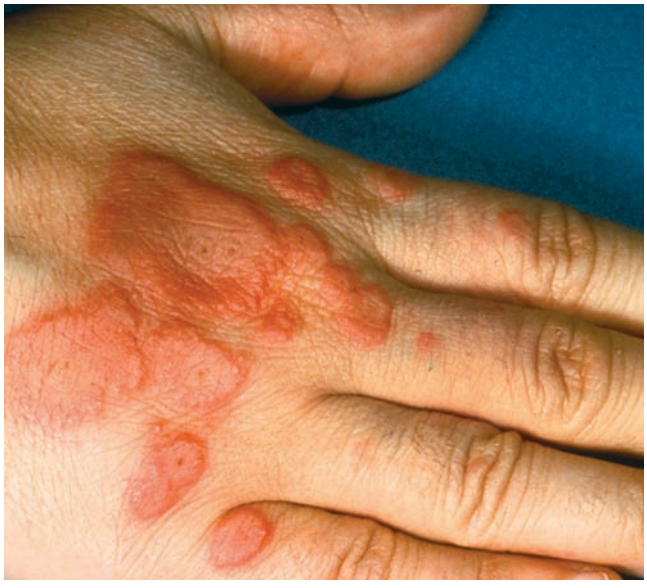

CLINICAL

11 Management of Erythema Multiforme *in the Urgent Care Setting*

Increasing use of medications—particularly antibiotics—is thought to be a contributor to an influx of patients presenting with erythema multiforme. What's the best route to quick clinical resolution of the lesions?

By Shailendra Kapoor, MD

PRACTICE MANAGEMENT

31 Are DNA Relationship Testing Services a Good Match for Urgent Care?

Is there an opportunity for urgent care providers to facilitate ethical and clinically reliable access to DNA parentage testing, while receiving direct and immediate payment for services rendered?

By Elizabeth Panke, MD, PhD

28 Commentary: Quality of Care

Clinicians, patients, and other interested parties all have their own reasonable expectations of what constitutes "quality" medical care. An analysis from a practitioner and academician.

By Kenneth Iserson, MD, MBA, FACEP, FAAEM

9 From the Executive Director

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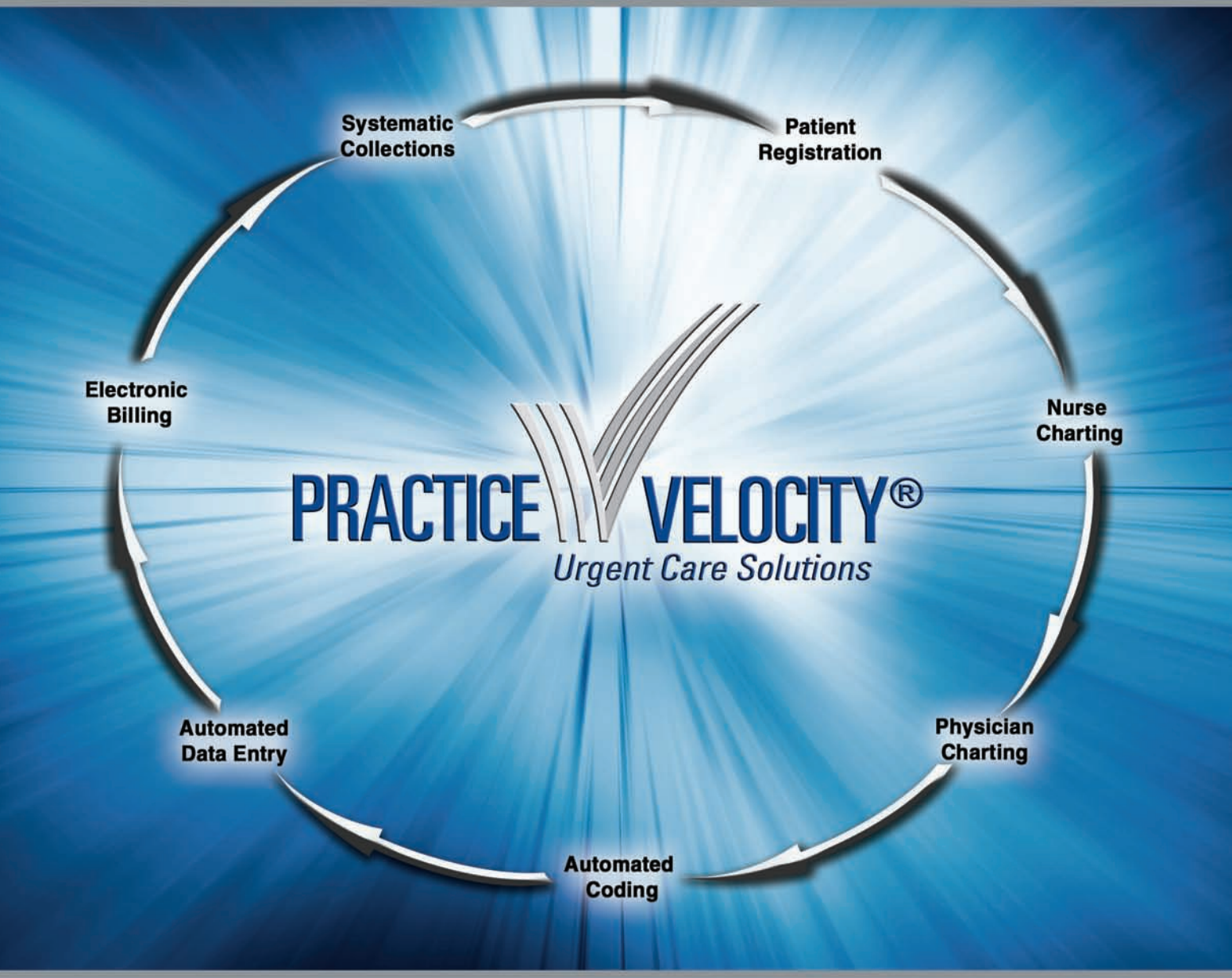
Mission Statement

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 Specifically for Urgent Care



"Practice Velocity has provided a wonderful service to our clinic. Coding and billing is taken care of in a timely and professional manner. I would recommend Practice Velocity to any clinic."

Betty Walsh, Office Manager
Martinsville Urgent Care
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JUCM CONTRIBUTORS

We've been fortunate to publish articles written by a wide range of authors in these first seven issues of *JUCM, The Journal of Urgent Care Medicine*. The May issue is an excellent example.

This month, we're pleased to feature original contributions that came to us unsolicited from a medical resident, an MD/PhD who took her expertise to private industry, and a well-established clinician/academician whose works have graced these pages on more than one occasion.

In that order:

Shailendra Kapoor, MD, a resident physician at the University of Illinois at Chicago is the author of our lead clinical article, Management of Erythema Multiforme in the Urgent Care Setting (page 11). In addition to his clinical duties, Dr. Kapoor has had commentaries published in the likes of *The New England Journal of Medicine*, *Hypertension*, and *BMJ*.

Elizabeth S. Panke, MD, PhD is director, Genetica DNA Laboratories, Inc. and a nationally recognized expert in the field of DNA identity, parentage, and biological family relationship testing. One of her key professional interests is the development of accreditation standards for DNA testing laboratories in the United States and Canada, a subject touched on in her article, Are DNA Relationship Testing Services a Good Match for Urgent Care? (page 31). Dr. Panke has been a member of the Molecular Pathology Resource Committee of the College of the American Pathologists and served for over 10 years on a Committee on Human Research at the University of Cincinnati College of Medicine, at Good Samaritan Hospital in Cincinnati, and as a DNA expert witness in multiple court cases.

Finally, **Kenneth V. Iserson, MD, MBA, FAAEM, FACEP** has been a frequent contributor to *JUCM*, starting with his authorship of the lead clinical article for our inaugural issue. In addition, he is professor of Emergency Medicine and director of the Arizona Bioethics Program at The University of Arizona, and a member of the State of Arizona's Disaster Medical Assistance Team. We're proud to have him as a member of the *JUCM* Advisory Board, as well. This month he has contributed a commentary on Quality of Care (page 28).

We also continue to be most fortunate to count on the expertise of regular contributors **Nahum Kovalski, BSc, MDCM**; **Frank Leone, MBA, MPH**; **John Shufeldt, MD, JD, MBA, FACEP**; and **David Stern, MD, CPC**, and the leadership of our editor-in-chief, **Lee Resnick, MD**.

If you'd like to contribute to our growing list of authors, put forth an idea in an e-mail to us at *editor@jucm.com*. If you're stuck for an idea, send us an e-mail anyway and we'll suggest a topic.

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*.

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Cloudy Crystal Balls

LOU ELLEN HORWITZ, MA

"Dewey Defeats Truman!"

CHICAGO TRIBUNE, 1948

"Prediction is very difficult, especially about the future."

NIELS BOHR

"The empires of the future are the empires of the mind."

SIR WINSTON CHURCHILL

If any of you have ever written for publication, you know that little twinge of fear that by the time your words are published they will be completely outdated.

By the time this is in your hands, you will probably either be standing outside a ballroom in the Daytona Beach Hilton during our annual conference, or in your own urgent care center just after our conference is over. I wish that I could see into the future and be able to give you exciting details on the conference attendance and our plans for next year, but this column will have to wait for that until July.

What we *will* be doing is bringing you daily updates from the meeting via e-mail and the UCAOA website, so if you are not already on our e-newsletter list, quickly visit us at *www.ucaoa.org* and click "Join Mailing List". We'll be sharing some of our benchmarking survey results, tidbits from some courses, the 2008 conference site, and much more.

What We Do Know

Recently, I took a call from someone who was considering opening a new urgent care center (we get three to five of these *per week*). They wanted to know if this was a good time to get into healthcare since it looked like a certain person was going to end up in the White House in 2008.

While I was unable to make any specific predictions, of course, we did discuss that it is very likely that urgent care will not be able to fly under the radar too much longer—which may be a good thing or a bad thing, but likely somewhere in between. We may make some strides in some of the issues you are all facing (reimbursement), but those strides will probably come at a price. It's hard to predict.

Trust Winston Churchill to get it right—what we do know about the future is that it will be conceived and created by us, *but only if we choose to participate in that creation*. If we don't, it will be created by others, and we will be in the unenviable position of living and working in a world we may not have wanted.

Remember the old adage that if you don't vote, you shouldn't complain? I think that we need to start voting. It's time for us to make progress on participating in the creation of the urgent care world that we want—the urgent care world that we believe is the best for patients and for providers. And that progress is going to take work from *all* of us.

"While one person can make a difference, a thousand people can make a bigger difference."

Keeping our business successful and growing and developing requires so much of our attention day-to-day that we may need to remind ourselves that that business takes place within an industry. And it's an industry that requires a very big, very firm, very sustained push to get moving in any particular direction.

We need your involvement, knowledge, time, and energy to make those moves begin. I can assure you, while one person can make a difference, a thousand people can make a bigger difference.

If you have something to say about what you see in urgent care's future, and what we collectively can do about it, say it in an e-mail message to me—*lhorwitz@ucaoa.org*—and help us start planning for your future. ■

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

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Management of Erythema Multiforme *in the Urgent Care Setting*

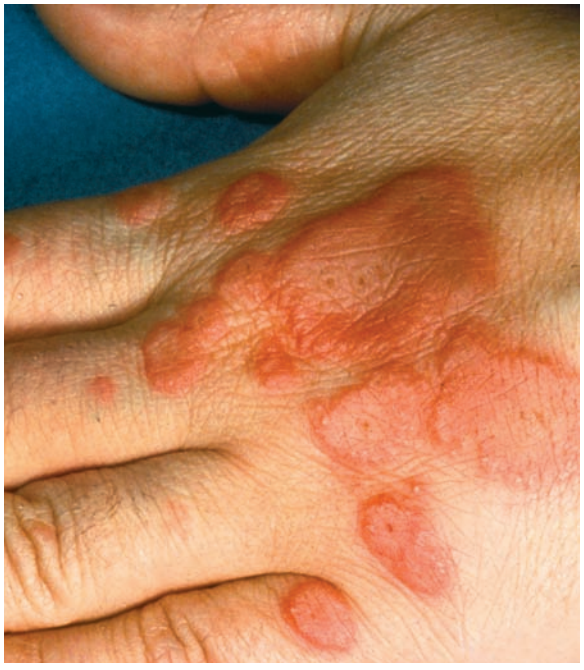
Urgent message: With the increasing use of medications, especially antibiotics, more and more patients are presenting to urgent care with erythema multiforme. Correct diagnosis and identification of the underlying cause can result in rapid clinical resolution of the lesions.

Shailendra Kapoor, MD

Introduction

Descriptions of erythema multiforme (EM) first appeared in the work of Albert and Bazin in 1822, but it was not until 1866 that von Hebra categorized these erythematous eruptions and labeled them "erythema exudativum multiforme." Today, we know that EM is more common in younger adults, especially men.

There are two types of EM: EM minor and EM major. EM minor comprises nearly 70% of the cases. Most cases of EM minor resolve in one to three weeks, while EM major might take three to six weeks to resolve. Recurrences are more commonly seen in EM minor, but are rare in EM major. Traditionally, Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) were included in the same spectrum as EM.



However, the recent tendency has been to categorize SJS and TEN in a different category from EM.[1] SJS and TEN usually involve the torso, and the Nikolsky's sign is usually positive; in EM, the torso is usually spared and the Nikolsky's sign is usually negative.[2] The body surface area involved in TEN is greater than 30%, while in SJS and EM less than 10% of body area is involved.

Etiology and Pathogenesis

Even though the exact pathogenesis of EM is not completely understood, it is thought to be caused by viral, bacterial, or chemical triggers that initiate a hypersensitivity reaction. It may represent a type III immune complex-mediated hypersensitivity reaction, with a portion of the pathology arising from a type IV de-

layed hypersensitivity reaction. A majority of the patients with EM have deposits of complement 3, immunoglobulin M, and fibrin around the dermal blood vessels.

In early stages, a lymphocytic infiltrate is characteristically seen at the dermo-epidermal junction. The pathognomic finding in later stages is dermal edema along with lymphocytic infiltration (predominantly CD-4 cells) accompanied by epidermal necrosis (which may involve the entire epidermal thickness but is usually predominant in the stratum basale). Satellite cell necrosis (i.e., lymphocytes surrounding necrotic keratinocytes) is another characteristic histological feature. Studies have shown that individuals with HLA-DQB1 are especially susceptible to the disease; HLA-B62, HLA-B35, and HLA-DQ3 are commonly seen in patients with recurrent EM.

Many different etiologies have been proposed in the pathogenesis of EM. Currently, herpes simplex virus (HSV) is thought to be the trigger in nearly 100% of cases of EM minor and nearly 50% of cases of EM major.[3,4] Other viral causes include adenovirus, hepatitis, coxsackievirus, and echoviruses. Mycoplasma pneumoniae infection is the most common bacterial trigger.[5] Other bacterial causes include pneumococcus, *Proteus*, *Neisseria,* and *Salmonella*.

Drugs, especially sulfonamides, have been implicated in EM major. Some of the other drugs commonly implicated include NSAIDs, aspirin, barbiturates, phenytoin, and penicillin. (See **Table 1**.) Often, the etiology remains unknown.

Clinical Diagnosis

Symptoms

Most patients with EM minor present with new-onset mucocutaneous lesions which are usually symmetrical and rapidly progressing in nature. These lesions may be pruritic or may be associated with a burning sensation.

Skin involvement in EM major is usually preceded by prodromal symptoms such as fatigue, fever, headaches, and myalgias. These symptoms can appear up to two weeks prior to the mucocutaneous manifestations. Oral mucosal involvement may lead to difficulty in drinking and eating. Ocular involvement may lead to complaints of redness, discharge and ocular pain.

Signs

The initial skin lesion is an erythematous macule or papule, usually less than 3 cm. The hallmark of EM is a typical "target" or "iris" or "bull's eye" lesion which consists of a dusky red center surrounded by an intermediate pale and edematous ring[6] (**Figure 1**). The periphery of the lesion gradually becomes violaceous giving rise to a concentric appearance. The greatest damage occurs at the center, with the peripheral rings showing lesser damage. Atypical "target" lesions consist of two rings instead of the usual three rings. These lesions are usually symmetrical and usually involve the palms, extensor surfaces of extremities, backs of hand, and feet, face, and neck. Involvement of the palms and soles is a characteristic feature of EM.

TABLE 1.
Medications Usually Associated with Erythema Multiforme

Antibiotics	**Anti-Epileptics**	**Anti-Tuberculosis**
Sulfonamides	Barbiturates	Isoniazid
Penicillins	Carbamazepine	Rifampicin
Amoxicillin	Phenytoin	Pyrazinamide
Ampicillin	Valproic acid	
Cephalexin		**Anti-Cancer**
Minocycline	**Antihypertensives**	Thiouracil
Ciprofloxacin	Hydralazine	Dideoxycytidine
	Nifedipine	Didanosine
Antifungals	Verapamil	Methotrexate
Fluconazole		
Griseofulvin	**Analgesics**	**Vaccines**[15]
	NSAIDs	BCG
	ASA	DT
		OPV

EM Minor

EM minor may be episodic or recurrent and is usually self limiting. Less than 10% of the body surface area (BSA) is involved in EM minor. Typically, Nikolsky's sign is negative. Lesions last for one to three weeks and heal without scarring.

EM Major

Less than 10% of the body surface area (BSA) is involved in EM major. Nikolsky's sign is negative. Lesions last for three to six weeks. The skin lesions are more severe, confluent, and vesiculo-bullous compared with EM minor. Mucosal lesions are

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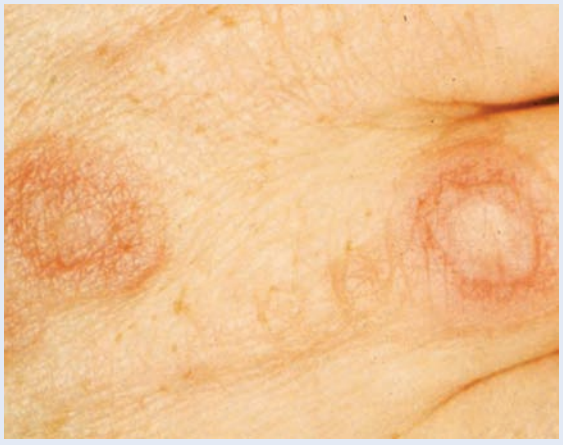
FIGURE 1.
Typical target lesions of erythema multiforme.



Source:Elena Pope, Bernice R. Krafchik In Atlas of Pediatrics: Pediatrics. Edited by Ronald M. Laxer, Elizabeth Lee N. Ford-Jones, Jeremy N. Friedman, J. Ted Gerstle. Current Medicine, Inc. 2000.

TABLE 2.
Differential Diagnosis of Erythema Multiforme

Behçet's syndrome	Kawasaki disease
Herpes simplex	Apthous ulcers
Pemphigus	Viral exanthems
Drug eruptions	Dermatitis herpetiformis
Urticaria	
Stevens-Johnson syndrome	

seen in 40% to 60% of EM major cases. At least two mucosal surfaces must be involved to make a diagnosis of EM major. Mucosal involvement usually involves the lips and buccal mucosa and may present as bullae, ulcerations with or without a pseudomembrane, or hyperkeratotic plaques interspersed with erythematous changes.[7] Ocular involvement may present as redness, discharge, swelling, corneal ulcers, anterior uveitis, and panophthalmitis. Usually, patients with EM major also have fever and generalized lymphadenopathy. Rarely, the genitourinary, gastrointestinal, and respiratory tracts may be involved.

Laboratory Tests

Usually, no laboratory tests are required for diagnosing EM minor. In EM major, elevated white blood cell counts, elevated erythrocyte sedimentation rate, and elevated acute phase reactants may occur. In severe cases, a basic metabolic panel and blood, skin, and mucosal cultures should be ordered to rule out renal involvement, electrolyte imbalances, and secondary infections.

In patients in whom the diagnosis is uncertain, punch biopsy of the skin lesions should be performed. In early stages, a lymphocytic infiltrate is seen at the dermoepidermal junction; later stages are characterized by dermal lymphocytic infiltrates, epidermal necrosis, and satellite cell necrosis.

Complications

Most cases of EM minor resolve without any complications. Some of the complications that might occur include hyperpigmentation, hypopigmentation, or secondary bacterial infection. EM major is more likely to be associated with complications, especially in immunocompromised patients. Corneal ulcers, corneal opacities, anterior uveitis, panophthalmitis, conjunctival scarring, and blindness have been reported with ocular involvement. Severe systemic disease can lead to dehydration and electrolyte imbalances. Rarely, scarring may lead to stricture formation in bronchi, esophagus, urethra, and vagina. Besides the above-mentioned complications, myocarditis, nephritis, and respiratory failure can also occur rarely.

Differential Diagnosis

The differential diagnosis includes herpes simplex, which usually presents with predominantly vesicular lesions and other dermatological conditions which might resemble EM, such as dermatitis herpetiformis, urticaria, drug eruptions, pemphigus, and Behçet's syndrome (**Table 2**). Behçet's syndrome manifests as recurrent aphthous ulcers, genital ulcerations, and uveitis.

Systemic diseases that may present with similar lesions include viral exanthems, septicemia, Kawasaki disease, and serum sickness.

EM may also occur in patients with tuberculosis; in such a case, chest x-rays are helpful in establishing the diagnosis. Target lesions may also be seen in Lyme disease. However, the target lesions in Lyme disease are usually limited to the site of the tick bite.

In questionable cases, punch-skin biopsies are diagnostic.

Treatment

Treatment for EM minor and EM major is basically sim-

ilar (**Table 3**). However, oral and ocular care may be an additional necessity if mucous membranes are involved in EM major.

An emergency dermatologic consultation is indicated if it is unclear whether a patient has TEN, SJS, or EM. A dermatologic consultation, and possibly a subsequent skin biopsy, may also be necessary.

The underlying cause, if identified, should be treated. If a medication is suspected, then it should be discontinued. Generally, mild cases are not treated. Symptomatic treatment involving oral antihistamines and analgesics is usually affective.

Patients with mild symptoms are usually treated as outpatients.

Patients with severe cases should be admitted to a burn unit. Dehydration may also be severe. The clinician should be vigilant in monitoring electrolyte imbalances. Antibiotics may be necessary if secondary infection of lesions is suspected.

TABLE 3.
Treatment of Patients with Erythema Multiforme

Type of Erythema Multiforme	Management
EM minor	■ Treatment of underlying cause ■ Withdrawal of any causative drugs ■ Symptomatic treatment–antihistaminic, analgesic ■ Topical steroids ■ Burow solution dressings
EM major	■ Treatment of underlying cause ■ Withdrawal of any causative drugs ■ Symptomatic treatment ■ Burow solution dressings for severe skin lesions ■ Xylocaine and diphenydramine elixir for oral ulcers ■ Consider dermatology consultation ■ Consider ophthalmology consultation if eyes involved ■ Consider medicine consult if systemic organ involvement ■ Liquid diet ■ Intravenous fluid therapy and electrolyte replacement ■ Antibiotics if secondary infection suspected ■ Acyclovir 400 mg bid x 10 days or children 10 mg/kg/day for recurrences ■ Consider systemic steroid use

Skin Care

In mild cases, cold compresses and topical steroids can be used. Severe skin lesions should be treated as heat burns; 5% aluminum subacetate (Domeboro) solutions should be used and nonadherent dressings should be applied.

Oral Care

Viscous lidocaine or lidocaine gel can be used for pain relief in oral lesions. Diphenhydramine elixir may also be useful for oral lesions. Antibiotics may be necessary if secondary infections are suspected. A bland liquid diet may be necessary if eating and drinking are compromised by pain.

Systemic Steroids

Systemic corticosteroids may be considered in severe cases, though their use remains controversial. A one- to three-week course of prednisone is usually used. Prednisone (40 mg/day to 80 mg/day) is continued until control is achieved and is then tapered rapidly over a week.[8,9] Treatment with prednisone may be successful in aborting a recurrence.

Antivirals

Acyclovir may be considered for prophylaxis for patients with more than five episodes per year. Doses are 400 mg twice a day, usually for six months. In children, a dose of 10 mg/kg/day is used. Herpes-associated EM is not prevented if oral acyclovir is administered after a herpes simplex recurrence is evident, and it is of no value after EM has occurred. Famciclovir and valacyclovir may be considered in patients resistant to acyclovir.

Alternative Treatments

If all the above treatments fail, thalidomide (100 mg/day), cyclosporine,[10] immunoglobulins (0.75 g/kg/d for four days),[11] azathioprine (100 to 150 mg/day), dapsone (100 to 150 mg/day),[12] or interferon alpha[13] can be tried.

Summary

Erythema multiforme is a hypersensitivity reaction usually occurring one to two weeks after exposure to a drug or antigenic stimulus. Typically, it presents as a symmetrical, expanding, erythematous, maculopapular

rash usually affecting the palms and the acral extensor surfaces. The typical lesion is described as the "target" or "iris" or "bull's eye" lesion. The spectrum of the disease ranges from EM minor, which is characterized by skin involvement usually sparing mucosa, to EM major, in which the lesions are larger and more confluent and the mucosa are usually involved. Most mild cases of erythema multiforme resolve without treatment; however, more severe cases may require hospital admission.[14] ■

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TAKE-HOME POINTS

- The hallmark of erythema multiforme is the "target" or "iris" lesion.
- Antibiotics such as sulfonamides and penicillins are common cause of erythema multiforme.
- Treatment of erythema multiforme involves treatment of underlying cause and withdrawal of any causative drugs.
- Acyclovir may be considered for prophylaxis for patients with more than five episodes per year.

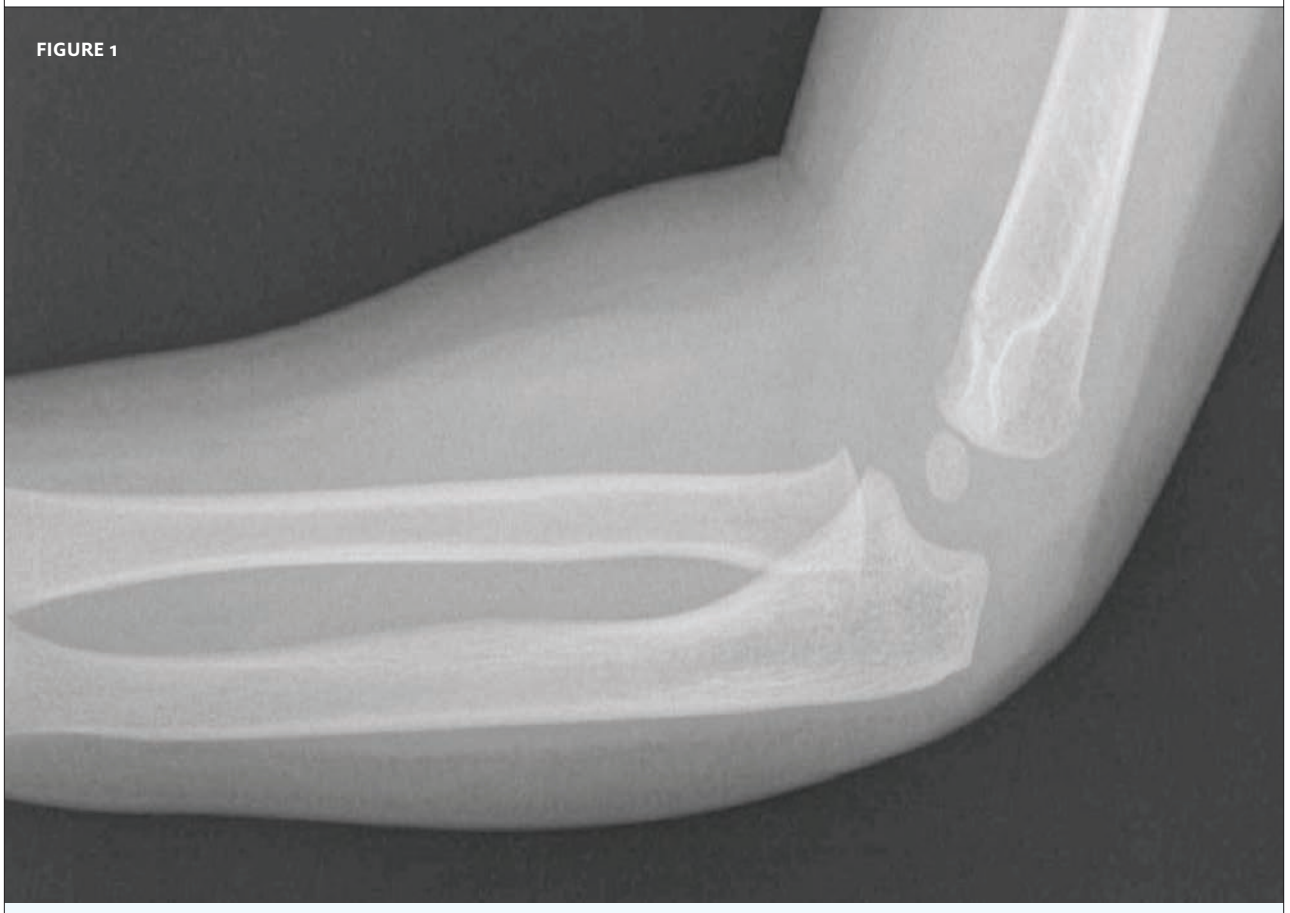
INSIGHTS IN IMAGES

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



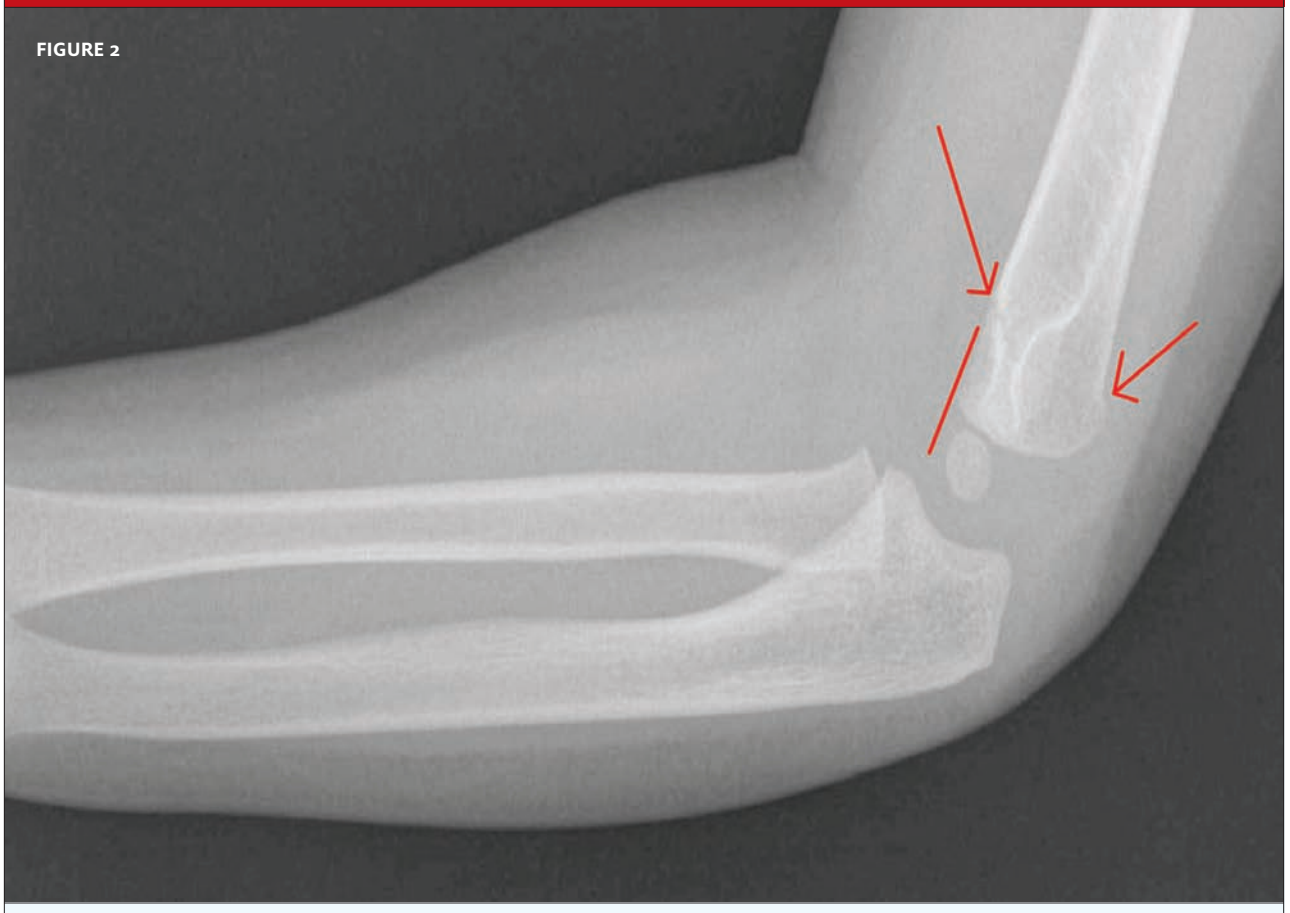
The patient is a 2½-year-old female who presented after falling, unobserved, from an unknown height with tenderness and swelling around the elbow.

Neurovascular exam was normal.

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

THE RESOLUTION

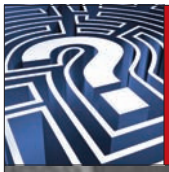
FIGURE 2



The correct diagnosis is a supracondylar fracture; note the loss of the normal angle at the distal humerus.

The injury was managed with a posterior splint in flexion, with follow-up the next day with an orthopedist.

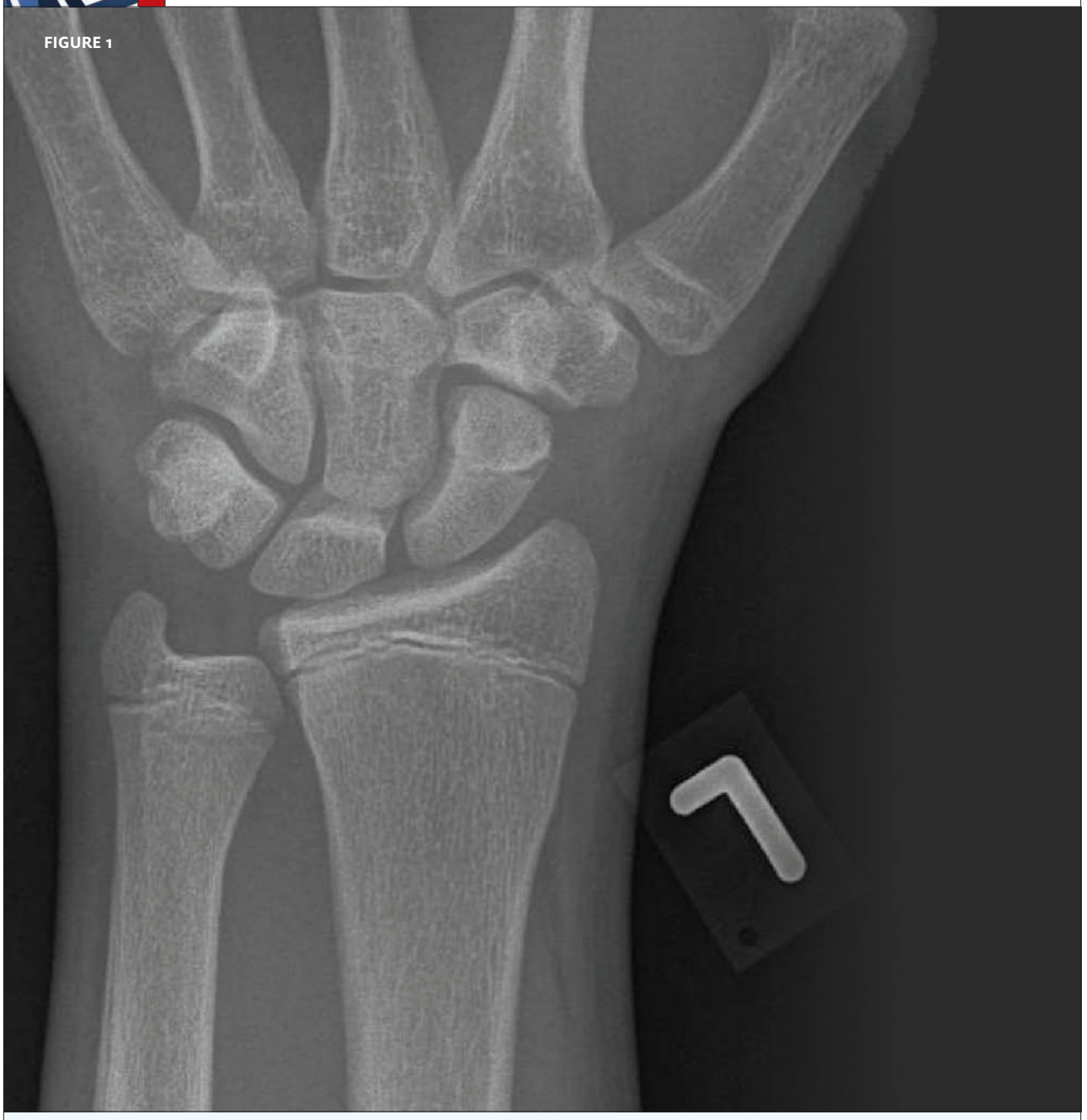
Acknowledgment: Case presented by Nahum Kovalski, BSc, MDCM; the patient was treated by Dr. Elinor Vandermarva.



INSIGHTS IN IMAGES

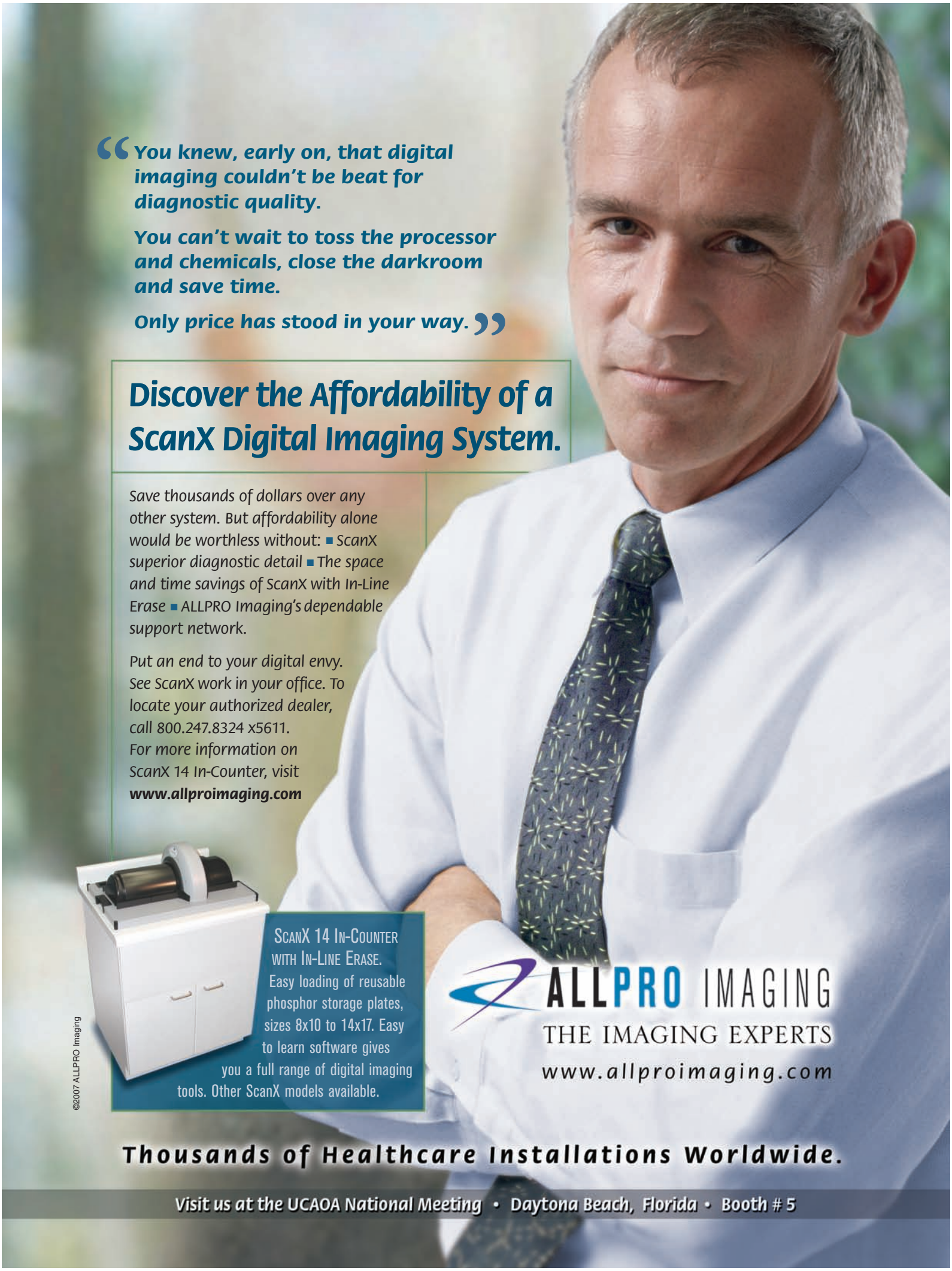
CLINICAL CHALLENGE: CASE 2

FIGURE 1



The patient is a 13-year-old male who presented to urgent care after taking a fall while running; he landed on his outstretched left hand. Upon examination, you find tenderness in the snuff box and observe swelling around the wrist.

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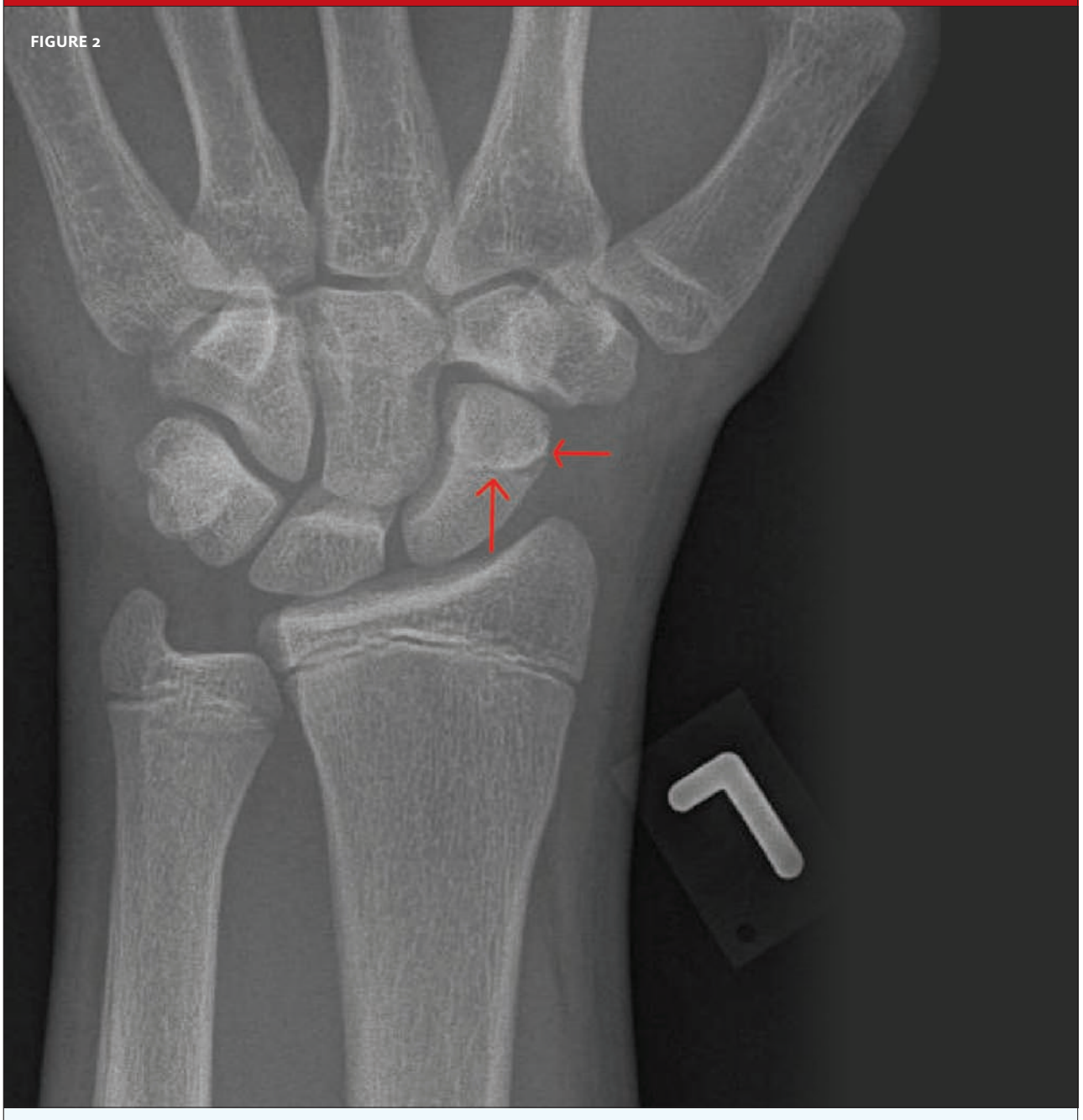
THE RESOLUTION

FIGURE 2



The patient experienced a scaphoid fracture. A spika case was applied, with follow-up with an orthopedist the following day.

Acknowledgment: Case presented by Nahum Kovalski, BSc, MDCM; the patient was treated by Dr. Dan Frimerman.

ABSTRACTS IN URGENT CARE

On the Value of Cardiac Risk Factors, Pediatric vs. General EDs, Diagnosing Appendicitis in Children, Detecting Coronary Vascular Disease, Peripheral Blood Cultures, and Comparing Walk-in Centers and EDs

■ 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.

Are Cardiac Risk Factors of Value in ED Diagnosis of ACS?

Citation: Zane RD. *J Watch Emerg Med*. March 9, 2007.
URL: *http://emergency-medicine.jwatch.org/cgi/content/full/2007/309/3?q=etoc*

The Role of Cardiac Risk Factor Burden in Diagnosing Acute Coronary Syndromes in the Emergency Department Setting

Citation: Han JH, Lindsell CJ, Storrow AB, et al. *Ann Emerg Med*. 2007;(2):145-152. Epub Dec 4, 2006.
URL: *http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=retrieve&db=pubmed&list_uids=17145112&dopt=Abstract*
Key point: Cardiac risk factors are of no discriminatory value in emergent evaluation of patients >40 with suspected ACS.

Population-based studies have shown that diabetes, hypertension, smoking, hypercholesterolemia, and family history of coronary vascular disease are correlated with an increased lifetime risk for cardiovascular disease. Clinicians often use cardiac risk factors in the assessment of patients with suspected acute coronary syndrome (ACS), but Bayesian theory dictates that the diagnostic value of the risk factors would not apply to individual patients. In a retrospective analysis of nearly 11,000 emergency department (ED) patients with suspected ACS, researchers evaluated the association between risk factor burden (number of factors) and ACS.

Patients were considered to have ACS if they underwent revascularization within 30 days, had a discharge diagnosis within one of the diagnostic-related groups for ACS, or had positive cardiac markers at admission and died within 30 days. Researchers divided patients into three groups based on age (<40, 40–65, and >65) and calculated positive and negative likelihood ratios by age group and by number of risk factors.

Overall, ACS was diagnosed in 8.1% of patients. In patients younger than 40, those with four or five risk factors were 22.5 times more likely to have ACS than those with no risk factors. ■

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

Emergency Care for Children in Pediatric and General Emergency Departments

Citation: Bourgeois FT, Shannon MW. *Pediatr Emerg Care*. 2007;23(2):94-102.
URL: *http://www.pec-online.com/pt/re/pec/abstract.00006565-200702000-00006.htm;jsessionid=FxrSPB035PjbqJJ3MhhylTND3tLFWd9Smn21WhGLB2x7fQHXLW7Q!315358234!-949856145!8091!-1*

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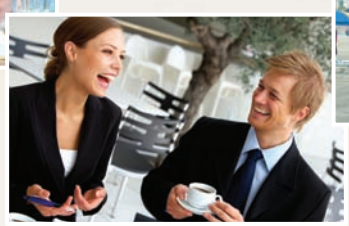

Relaxation

Key point: Significant differences exist between pediatric visits to pediatric and general EDs.

The authors examined the pediatric ED population and their clinical course in pediatric versus general EDs and identified potential factors contributing to differences in performance metrics between the two ED settings.

This was a retrospective analysis of pediatric visits to nationally representative EDs participating in the National Hospital Ambulatory Medical Care Survey from 1995 to 2002. Differences between pediatric and general EDs were examined in terms of patient characteristics and clinical course.

Pediatric EDs treated more children with medical problems than general EDs, which treated more children with injuries. Visits by children to pediatric EDs were associated with longer wait times to see a physician (median, 40 vs. 25 minutes; $P<0.001$) and longer stays in the ED (median, 130 vs. 98 minutes; $P=0.006$).

In multivariate analysis, the type of ED treating a pediatric patient was a significant determinant of wait time (percent change for pediatric EDs, 23.1), length of stay (percent change for pediatric EDs, 23.0), and rate of discharge (odds ratio for pediatric EDs, 0.75). Children in pediatric EDs seemed to be sicker than those in general EDs. ■

The Use of White Blood Cell Count and Left Shift in the Diagnosis of Appendicitis in Children.

Citation: Wang LT, Prentiss KA, Simon JZ, et al. *Pediatr Emerg Care*. 2007;23(2):69-76.

URL: *http://www.pec-online.com/pt/re/pec/abstract.00006565-200702000-00001.htm;jsessionid=F1hLjyrnJ8RFCMTh6vJ1KQGVGmNdrx1mMgh1V2PwnRpMzWp5h7nJ!-1081107103!-949856145!8091!-1*

Key point: The presence of both high WBC count and left shift has the highest specificity (94%).

The use of white blood cell (WBC) count and left shift in the diagnosis of appendicitis in pediatric patients is unproven. It is commonly thought that children with appendicitis have an elevated WBC count with a left shift; however, most data supporting this belief stem from studies conducted on appendicitis in adults, not children. The purpose of this investigation was to determine the value of WBC count and differential in the diagnosis of appendicitis in children presenting to the ED with acute abdominal pain.

Seven hundred twenty-two pediatric ED patients with a primary complaint of nontraumatic abdominal pain were identified by prospective and retrospective methods. White blood cell count with differential was performed on patients with history and physical examination findings that were felt to warrant laboratory investigation. Results of WBC counts were determined as low, normal, or high, with or without a left shift, based on normal age-related values per laboratory protocol for pediatric patients.

The diagnosis of appendicitis was made in 10.2% of all patients presenting to the ED with acute abdominal pain.

- Thirty percent of toddlers (1- to 3.9-years-old) with high WBC counts had appendicitis, whereas 0% of toddlers with low WBC counts and 4.8% of toddlers with normal WBC counts had appendicitis. A normal WBC count did not rule out appendicitis in toddlers; however, the negative predictive value (NPV) for normal or low WBC count was high (NPV=95.6%).
- In the child age group (4- to 11.9-years-old), high WBC count was both sensitive and specific for the diagnosis of appendicitis in children (sensitivity=71%, specificity=72%), and the NPV for normal or low WBC count was high (NPV=89.5%).
- Lastly, 43.9% of adolescents (12- to 19-years-old) with high WBC counts had appendicitis, whereas 0% of adolescents with low WBC counts and 8.3% of adolescents with normal WBC counts had appendicitis. The NPV for a low or normal WBC count was also high in the adolescent group (NPV=91.9%).

Left shift was also strongly associated with appendicitis.

- Among toddlers, 40% of patients with a left shift had appendicitis, whereas 1.8% of toddlers without a left shift had appendicitis (NPV=98.2%).
- Similarly, left shift was strongly associated with appendicitis in children and adolescents. Among children, 54.3% with a left shift had appendicitis, whereas 5.4% without a left shift had appendicitis (NPV = 90.5%).
- Among adolescents, 53.5% of patients with a left shift had appendicitis, whereas 6.1% of adolescents without a left shift had appendicitis (NPV=93.9%).
- In patients with a left shift, 51.2% had appendicitis, whereas 3.7% of patients without a left shift had appendicitis (NPV=96.3%).

The determination of WBC count and differential is useful in the diagnosis of appendicitis in children presenting to the ED with nontraumatic acute abdominal pain, regardless of age. High WBC counts and left shift are independently, strongly associated with appendicitis in children aged 1 to 19 years. In fact, for this subset of patients older than 4 years, the most common diagnosis in the setting of an elevated WBC count was appendicitis.

The presence of an increased WBC count or left shift carries with it a high sensitivity (79%), and the presence of both high WBC count and left shift has the highest specificity (94%). Although not absolute, the WBC count and left shift can be helpful in the diagnosis and exclusion of appendicitis. ■

CT Scan vs. Nuclear Stress Test for Low-Risk Chest Pain

Citation: Zane RD. *J Watch Emerg Med.* March 16, 2007.
URL: *http://emergency-medicine.jwatch.org/cgi/content/full/2007/316/1*

The Diagnostic Accuracy of 64-Slice Computed Tomography Coronary Angiography Compared with Stress Nuclear Imaging in Emergency Department Low-Risk Chest Pain Patients

Citation: Gallagher MJ, Ross MA, Raff GL, et al. *Ann Emerg Med.* 2007;49:125-136.
URL: *http://emergency-medicine.jwatch.org/cgi/external_ref?access_num=16978738&link_type=MED*
Key point: The two tests have similar diagnostic accuracy for detecting coronary vascular disease.

Patients with low-risk chest pain often undergo provocative testing in the ED or in an ED observation unit before discharge. Recent studies have demonstrated that computed tomography (CT) coronary angiography correlates highly with cardiac catheterization in detecting coronary artery stenosis, and that CT results predict future cardiac events. In this prospective study, researchers compared the diagnostic accuracy of CT coronary angiography with nuclear sestamibi stress testing.

A convenience sample of 85 patients who were admitted to an ED observation unit for evaluation of low-risk chest pain and who had negative serial ECGs and negative cardiac markers underwent both tests. Patients with positive stress test results (reversible deficits) and positive CT coronary angiography results (>50% stenosis or calcium score >400) underwent cardiac catheterization.

Overall, seven patients had coronary artery stenosis. Stress testing was negative in 85% of patients, and CT was negative in 86%. Sensitivity was 71% for stress testing and 86% for CT, and specificity was 90% and 92%, respectively. Negative predictive values for stress testing and CT were 97% and 99%, and positive predictive values were 38% and 50%, respectively. None of the differences reached statistical significance.

This small study suggests that CT angiography is as good as nuclear stress testing at detecting coronary vascular disease, but was not powered to differentiate ability to predict cardiac events within 30 days of presentation. CT angiography offers much more rapid results than nuclear testing, which takes several hours. ■

Do Peripheral Blood Cultures Taken in the Emergency Department Influence Clinical Management?

Citation: Howie N, Gerstenmaier JF, Munro PT. *Emerg Med J.* 2007;24:213-214.
URL: *http://emj.bmj.com/cgi/content/abstract/24/3/213*
Key point: Blood cultures rarely directly influenced patient management.

Blood cultures are used routinely to investigate suspected sepsis in the ED, despite several studies demonstrating their limited influence on patient management.

This was a retrospective study of blood cultures taken in the ED between January 1, 2003 and December 31, 2004. Microbiology results and patient records were reviewed to determine the influence of positive cultures on subsequent patient management.

Over the study period, 2,213 blood cultures were taken in the ED. Of those, 132 (6%) yielded a positive result. Three positive cultures cases had incomplete information. Of the remaining 129 positive cultures, 30 (1.4% of all cultures) were "true positives" and four (0.18%) influenced subsequent patient management.

Blood cultures taken in our ED rarely yield bacterial growth and over two years, only four seemed to directly influence patient management. ■

Comparing Care at Walk-in Centres and at Accident and Emergency Departments: An Exploration of Patient Choice, Preference and Satisfaction

Citation: Chalder M, Montgomery A, Hollinghurst S, et al. *Emerg Med J.* 2007;24:260-264.
URL: *http://emj.bmj.com/cgi/content/abstract/24/4/260*
Key point: Patients attending walk-in centers were just as likely to be satisfied overall with the care they received as their counterparts who were treated in the ED facility.

The purpose of this study, which was conducted in the United Kingdom, was to explore the impact of establishing walk-in centers alongside EDs on patient choice, preference and satisfaction. This was a controlled, mixed-method study comparing eight EDs with co-located walk-in centers with the same number of "traditional" EDs. This paper focuses on the results of a cross-sectional questionnaire survey of users.

Survey data demonstrated that patients were frequently unable to distinguish between being treated at a walk-in center or at an accident and emergency (A&E) department and, even where this was the case, opportunities to exercise choice about their preferred care provider were often limited. Few made an active choice to attend a co-located walk-in center. Patients attending walk-in centers were just as likely to be satisfied overall with the care they received as their counterparts who were treated in the co-located A&E facility, although walk-in center users reported greater satisfaction with some specific aspects of their care and consultation. ■

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COMMENTARY

Quality of Care

KENNETH V. ISERSON, MD, MBA, FAAEM, FACEP

"Quality of care," due to both its nebulous nature and its vital importance, has always been a much-discussed issue in medical ethics. For example, the Codes of Hammurabi, the Hippocratic writings, and other early medical treatises discuss quality of care.

Today, the changing goals and priorities within healthcare systems and the ongoing attempts to restructure local, state, and national health treatment delivery systems have increased the importance of defining the term "quality."

Healthcare professionals commonly face conflicts between what they see as their obligations to their patients and the legal-economic constraints imposed upon them by legislators and healthcare administrators. Yet with increasing pressure for greater cost-containment, and with the advent of alternative healthcare delivery systems, it has become more difficult for healthcare professionals always to act in the best interests of their patients.

"Quality" refers to the essential character or nature of medical care. It is an elusive concept. The definition, in part, relies upon the perspective of those applying the term—healthcare providers, patients, or those who regulate the profession:

- Medical professionals often view quality of care as encompassing the best method of practicing medicine. However, they use their own "process standards," sometimes called clinical protocols, as their true yardstick.
- Patients view quality medical care as including appropriate, rapid, and caring treatment—at a low cost.
- Regulators increasingly see quality care as the delivery of measurably improved outcomes using limited resources.

Each of these perspectives has some validity.

Ken Iserson is a professor of emergency medicine and director of the Arizona Bioethics Program at the University of Arizona in Tucson, as well as the author of several books and a member of the *JUCM* Advisory Board. He is a frequent contributor to *JUCM*.

Urgent Care Medicine and Quality of Care

The medical practitioner's goal has always been to benefit the patient whenever possible. Echoing comments from physicians throughout the ages, the American Medical Association defines quality of care as "the degree to which care services influence the probability of optimal patient outcomes."[1] Many other physician organizations use the term "quality" without defining it—assuming, incorrectly, that there is a commonly understood meaning.

"A breakdown in any part of the team can adversely affect the quality of care delivery."

Patients expect quality care from their healthcare providers; providers expect this from themselves. Yet, in our beeping, buzzing, and flashing medical environment, the goal of providing quality care can be lost as the urgent care medical practitioner is inundated with brief visits from new patients with serious and not-so-serious problems, continually short on time and personnel, necessarily focused on a single patient complaint, and harried by constantly changing administrative constraints.

Since urgent care medicine relies on teams of individuals working together to achieve optimal patient care, a breakdown in any part of the team can adversely affect the quality of care delivered.

In arranging their schedules, for instance, urgent care providers frequently make difficult decisions affecting their quality of life and patient care: working multiple sequential shifts (perhaps due to staffing problems) and the resulting lack of sleep, for instance, may result in differing practices and abilities at different spots in the schedule.

Quality may also suffer due to distress after conflict-laden interactions with other healthcare practitioners (re-

garding, for example, transfers to an ED or referrals for consultation) or with patients, since many drug abusers see urgent care centers as an "easy mark."

Personal issues always have the potential to affect the quality of care. Some urgent care staff may be so overwhelmed by their personal problems that they are unable to concentrate on the patients. Any urgent care staff member may compromise quality care due to deteriorating technical skills, substance abuse, incompetence, or consistently poor interpersonal relations with other staff or patients. In each case, the system would fail to provide quality care.

Yet, despite these potential problems, most urgent care centers provide what clinicians and their patients consider is quality care.

Patient/Societal View

Generally, patients recognize the intrinsic limitations of urgent care, and will tolerate brief clinician encounters as the tradeoff for faster service than they would receive in emergency departments.

Understandably, the patient's view of quality care includes receiving an accurate diagnosis with subsequent appropriate treatment or, if necessary, referral. Coming to an urgent care center, they expect to be seen promptly and hope that minimal pain or discomfort is required. They also expect the costs, at least to them, to be low.

Above all, they expect to encounter a caring attitude. In fact, patients' views of quality care may place caring above curing. Studies of malpractice litigation, for example, suggest that many patients view caring practitioners as delivering quality care, even when they have poor outcomes.

Unfortunately, the nature of illness and medicine mean that not every patient will receive exactly the type of care they desire. Hopefully, each will receive the thoughtful attention that he or she deserves.

Standards, Competence, and Quality Care

The various regulators of medical practice use the term "quality" to imply that medical care is somehow rated against a "gold standard" of optimal medical care. Yet systems to measure the quality of medical care remain elusive. Delivering "quality care" implies clinician competence; patients, healthcare professionals, and quality assurance organizations, however, have differing views of what those standards should look like.

Moreover, clinical standards of urgent care medical treatment change constantly. This makes acceptable "quality of care" even more difficult to define. For one, medical technology and knowledge change so rapidly that new standards of care are being introduced constantly.

Second, different facilities and areas of the country are able to offer different levels of care; a patient cannot expect a small community in a very rural area to have the same type of expedited urgent care service as a large metropolitan area, for example.

"Systems to measure the quality of medical care remain elusive."

In addition, the clinical parameters that healthcare providers use to measure "quality" are themselves a matter of debate. Physicians frequently disagree over what specific therapies should be used in particular cases and, when confronted with the same symptoms, will advocate contrasting therapies such as rapid ambulation versus bed rest for low back pain.

Even standards developed by consensus, and in many cases widely promulgated by national organizations, may represent only the "point at which all the errors, oversimplifications, and biases converge; it does not necessarily identify what is best."[2]

What is 'Quality'?

What, then, is "quality" urgent care medicine? Following the verbose lead of the World Health Organization, the American Academy of Family Physicians says that "Quality healthcare . . . is the achievement of optimal physical and mental health through accessible, safe, cost-effective care that is based on best evidence, responsive to the needs and preferences of patients and populations, and respectful of patients' families, personal values, and beliefs." [3]

On the succinct end of the spectrum, Dr. Otis Bowen, former U.S. Secretary of Health and Human Services, said, "Quality is about people." That, however, seems a bit too simplistic.

Perhaps it is easier to think of quality medical care as patient-centered, elegant care—optimizing patient-desired outcomes delivered with the least expenditure, discomfort, and delay. This description accepts that healthcare professionals are not god-like creatures who never make mistakes or fall short. Rather, they are individuals expected to provide acceptable, reasonable care that does more good than harm. ■

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Are DNA Relationship Testing Services a Good Match for Urgent Care?

Urgent message: The last 10 years have seen a dramatic increase in DNA parentage testing. Yet, the DNA testing industry remains, in essence, unregulated. Can urgent care providers fulfill a need for ethical and clinically reliable access, while receiving direct and immediate payment for your services?

Elizabeth Panke, MD, PhD

Introduction

For many generations, defining the parent-child relationship was easy. The woman who gave birth to the child was the child's legal mother; to a large extent, fatherhood was assigned on a social basis.

With the advent of DNA testing, however, the social definition of fatherhood is increasingly being replaced by a genetic test. Advances in the technology employed in DNA testing have pushed the issue of fatherhood into the public spotlight—witness the tabloid-fed frenzy surrounding the paternity of the late Anna Nicole Smith's child—and forced many to re-evaluate the definition of "family."

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The American Association of Blood Banks reports that more than 1 million persons undergo DNA parentage testing each year, with double-digit growth each year.[1] The growth of commercial DNA-based parentage testing has been further spurred by our social and legal systems.

The federal Child Support Enforcement and Paternity Establishment Program was created in 1975 to help establish paternity for a growing number of non-marital children and to support collection of child support payments.[2] The Family Support Act of 1988 requires states to have all parties in a contested paternity case take a genetic test upon the request of any concerned party.[3]

More recently, the states of Ohio and Georgia, among others, have passed legislation that relieves a man of all parental obligations if a DNA test can prove that he is not the child's biological father, regardless of the age of the child or the number of years the man previously was acknowledged and considered the child's father. A growing list of U.S. court systems allowing such disestablishment of paternity is tracked by the National Conference of State Legislatures and can be viewed on their web site (*www.ncsl.org/programs/cyf/paternitylegis.htm*).[4]

Recent years have also seen the creation of the fathers' rights groups.[5] These groups have garnered attention on the Internet and on television shows hosted by the likes of Sally Jessy Raphael, Montel Williams, Jenny Jones, Maury Povich, Ricki Lake, and others. Marketing efforts by some DNA testing laboratories also have contributed to the reinforcement of the belief that DNA testing is a natural method for determination of the essence of identity.

Reasons Patients Seek DNA Paternity or Family Relationship Testing

Patients may seek genetic family relationship testing for any number of reasons (**Table 1**). However, highly accurate and reliable prenatal DNA paternity tests may also be conducted using fetal cells from amniotic fluid (5 ml to 10 ml) or chorionic villus sampling (CVS) if a woman is undergoing amniocentesis or CVS for medical reasons. Patients who have no medical indication for those procedures should receive information on the risks associated with amniocentesis and CVS and should be given the option of having paternity testing performed after birth, which is just as accurate as prenatal testing.

The DNA paternity testing laboratory can utilize the cultured fetal cells from the chromosomal lab to conduct the testing. Typically, samples from the mother and from the alleged father are collected with a buccal swab.

TABLE 1.
Reasons Patients Seek DNA Family Relationship Testing

DNA Test Type	Situation
DNA paternity and maternity test of minors	• Determines the identity of the child's biological parent • Documents the identity of the child's biological parent for: – child support – child custody – social security benefits – insurance benefits – inheritance benefits – visitation rights – consent for adoption – immigration rights – knowledge of health/medical history of child's biological parents
Prenatal DNA paternity test	• Prepares both parents for the birth of the child • Termination of pregnancy – unwanted pregnancy – sexual assault
DNA grandparentage test of minors	• When the alleged father is deceased or missing, paternal grandparentage DNA test may help decide: – Social Security benefits – insurance benefits – biological identity – inheritance benefits – visitation rights – knowledge of health/medical history of child's biological parents
DNA family reconstruction test of adults DNA sibling test of adults	• Biological identity and a sense of belonging in cases of: – adoption – missing or deceased parents – receiving information suggesting different parents – seeking potential siblings • Legal and financial benefits in cases of: – immigration – inheritance
DNA zygosity test	Determines if twins are identical or fraternal

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The Role of Healthcare Providers

A national consensus for the choice providers of DNA testing services to the public has not yet been established. Federal regulation of laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) does not extend to DNA family relationship testing, since such testing is not considered medical testing.[6]

In contrast, the New York State Department of Health mandates that all DNA specimen collections and DNA family relationship tests on New York residents must be authorized by a licensed physician, and that DNA parentage test results must be released only to the ordering physician.[7]

This lack of consensus leaves most patients unable to identify reliable providers of these services. When seeking DNA testing services, some patients turn to physicians or family law attorneys for a referral to a DNA testing laboratory. Other patients consult their yellow pages and/or the worldwide web to identify providers of DNA parentage testing services.

Contrary to the common—and naïve—public trust, DNA family relationship testing is largely an unregulated industry. Government regulation of parentage testing is limited, and DNA paternity laboratory inspections and accreditation are voluntary. There is no mandatory oversight of DNA parentage testing facilities.

In fact, many businesses market DNA paternity testing services and collect specimens, but outsource the actual testing to various laboratories (often, simply the lowest bidder), unbeknownst to the patients.

Recently, the Food and Drug Administration, Federal Trade Commission, and the Centers for Disease Control and Prevention developed a consumer alert that encourages consumers to consult their healthcare provider before using direct-to-consumer genetic tests.[8]

It is reasonable to suggest that patients would be well served by having their initial contact for the delivery of DNA testing services be with their physicians and healthcare providers. Given the breadth of services they provide, it is reasonable to suggest that urgent care clinicians may be well suited to fulfill such a need.

A Partnership Model

How might such a partnership between the clinician and DNA testing laboratory work? It could be reasoned that healthcare providers should serve as the patients' first contact for the provision of these services and be able to help patients decide whether DNA family relationship testing is needed, the type of genetic test that may best be suited to their situation, and the selection of a competent DNA testing facility.

The healthcare provider could then collect DNA specimens and ship the specimens to the DNA testing laboratory for processing. The DNA testing laboratory performs the testing, releases the results per instructions of the healthcare provider, and provides 24-hour physician consultations on the interpretation of the results to the healthcare provider and/or the patient. The clinician may also be able to help patients understand the test results and offer guidance on the availability of qualified counseling in cases where such counseling is needed.

In such a model, the patients pay healthcare providers directly for the clinical consultations and DNA specimen collections at the time they initiate these services. The DNA testing facility receives payment for the laboratory service they perform. The average national cost to the patient for legally admissible DNA paternity test results ranges from $350 to $500.

Thus, delivery of DNA family relationship services in a partnership between a healthcare provider and a reliable DNA testing laboratory is a win-win situation for the patient, the healthcare provider, and the laboratory: The patient receives competent, professional clinical care, reliable DNA test results, and a referral to professional counseling assistance, if needed; the testing laboratory gains patient specimens while knowing that their services are delivered to patients with comprehensive care before, during, and after the DNA test; and the healthcare provider has the satisfaction of providing much needed patient care and receives immediate, direct payment for services rendered.

Selecting a Partner Laboratory

Because there is no regulatory oversight of DNA parentage testing facilities, healthcare providers can be especially helpful in guiding patients in their selection of a qualified DNA testing laboratory. Such DNA testing facility should, at minimum, meet the requirements described in this section and summarized in **Table 2**.

Laboratory Accreditation

A seal of accreditation informs you and your patients that the DNA testing facility, at minimum, meets the established, national testing standards in conducting a DNA test. The most reliable way to determine the accreditation status of a DNA testing laboratory is to contact the national accreditation agencies directly and obtain their list of accredited DNA testing laboratories. Examples of such accreditation agencies include the following:

- The American Association of Blood Banks (AABB) offers a comprehensive list of parentage testing facilities it has accredited at *www.aabb.org*; from the association's homepage, click on *Accreditation*, then on *Parentage Testing Accreditation Program*, and finally on *AABB Accredited Parentage Testing Laboratories*. Alternatively, call the AABB at (301) 215-6584 to determine if a DNA laboratory has been accredited by the AABB.
- If your patients reside in New York, the DNA testing laboratory must be accredited by the New York State Department of Health (NYSDOH). You can determine if the DNA testing laboratory has such accreditation by going to *www.wadsworth.org* and clicking on *Quality Certification*, then on *Clinical Laboratory Evaluation Program*, and *Approved Laboratories*. Last, click on *Parentage/Identity Testing – DNA Testing*.

TABLE 2.
Requirements for DNA Family Relationship Testing Laboratories

DNA Lab Criteria	What to Look For
Laboratory accreditation	• Do not rely on self-acclaimed accreditation statements of DNA test providers since, currently, there is no oversight of DNA testing facilities. • Contact accreditation agencies directly to obtain their list of accredited DNA testing laboratories: – American Association of Blood Banks (*www.aabb.org*) – New York State Department of Health (*www.wardsworth.org*)
Privacy and consent for DNA testing	• Expect a DNA lab to voluntarily be in compliance with HIPAA federal laws and regulations for all DNA tests conducted by the lab. • Expect a DNA lab to provide you with stringently controlled DNA specimen collection materials and forms. • Expect a DNA lab to require that all DNA tests be conducted with properly executed informed consent for DNA testing. At minimum, informed consent forms should: – include the nature and the purpose of the DNA test – list the potential consequences of the DNA test – include the degree of accuracy and the level of confidence of the DNA test – notify the tested child's legal guardian of the precise nature of the representation concerning authority to provide consent on a minor child, and request the disclosure of the legal guardian's identity and full contact information – allow the tested patient to provide the names of specific persons whose DNA profiles may be compared with the patient's DNA profile by the testing laboratory.
Results guarantee	• A DNA lab should guarantee that all direct child-alleged parent DNA results show: – greater than 99.9% probability that the tested man is the biological father, OR – the tested man is not the biological father with a minimum of 3 mismatched genetic sites.
The experience, reputation, and service record of the DNA lab	• How long has the DNA lab been in business? • How many DNA tests did the lab perform on site during the past 10 years? • What are the qualifications of the director and staff? Documented experience as expert witness in courts? • During what hours are doctoral-level staff from the DNA lab available to answer your questions? Is there a charge for such soncultation?
Testing turnaround time	• Request a 48-hour turnaround time for routine DNA parentage tests. • Expect a DNA lab to achieve the most conclusive results and devote expertise, time, and resources to more complicated cases of: – complex DNA family reconstructions – encountered genetic mutations.
Price	• Expect a competitive price for rendered services.

Privacy, Security of Information, and Informed Consent

Federal regulation of laboratories under CLIA does not extend to parentage testing laboratories,[6] and there is a wide variation in the manner with which DNA testing laboratories handle areas such as privacy, confidentiality, and informed consent.[9]

Healthcare providers who enter into business partnerships with DNA testing laboratories need to know if their associate DNA testing laboratory routinely conducts DNA testing on specimens collected from patients without documented consent for such testing. Clearly, it is in the provider's best interest to choose a DNA testing laboratory that has adopted policies that are in compliance with the Health Insurance Portability and Accountability Act (HIPAA) and regulations for all DNA tests performed by the laboratory. This means providing healthcare providers with stringently controlled DNA specimen collection materials and requiring that all DNA testing be conducted with properly executed informed consent.

The informed consent forms provided by the DNA testing laboratory for family relationship testing should, at minimum, describe the nature and the purpose of the DNA test, the potential consequences of the test, and the degree of accuracy and the level of confidence that can be expected. The informed consent form should also allow the tested patient to provide the names of the specific individuals whose DNA profiles may be compared with the patient's DNA profile by the testing laboratory.

In cases where minor children are tested, the form should notify the child's legal guardian of the precise nature of the authority to provide consent for DNA testing on a minor child, and should request disclosure of the legal guardian's identity and full contact information.

Results Guarantee

The general public may have the impression that DNA testing is infallible. However, erroneous DNA test results are not uncommon.

False negative results most commonly arise from human error committed during specimen collection or during the DNA testing process.

False positive results often stem from the limited amount of DNA testing that is conducted by the laboratory. If a DNA testing laboratory tests a limited number of genetic sites in a DNA paternity test, the tested child and man may match many individuals within the population on every tested gene. Such DNA testing may falsely substantiate fatherhood.

The accuracy of DNA testing increases by testing increasing numbers of genetic sites. Some scientists—including the author—may believe that AABB and NYSDOH standards requiring the accredited laboratories to reach a probability of paternity of only 99% during DNA testing is set too low.[9]

To produce the most conclusive DNA results, request that the laboratory not stop testing until they produce one of the following results:

1. a probability of greater than 99.9% that the tested man *is* the biological father of the child; or
2. a minimum of three mismatched genetic sites that prove that the tested man is *not* the biological father of the child.

Request that the laboratory guarantee that you will receive only one of these DNA results.

Experience, Reputation, and Service Record Lab Personnel

Important issues to consider when selecting a DNA testing laboratory also include the experience and qualifications of the laboratory director, staff, and technicians performing the testing. A laboratory that has been performing DNA parentage testing for many years is more likely to have experienced staff and well-validated testing procedures; such a laboratory is also more likely to stay in business for the foreseeable future.

Ask how long the laboratory has been in business, how many DNA paternity tests the laboratory has performed *on site* during the past 10 years, the qualifications of the director and staff, and how much experience they have in providing expert witness testimonies in courts.

It is important to choose a laboratory with an impeccable reputation and a long, error-free service record. A simple, first step to determining how responsive to your needs the laboratory will be is to find out the hours their *doctoral-level* staff is available to speak with you. Be direct; ask, "If I have a question regarding DNA testing, during what hours are doctoral level staff members from your company available to answer my concerns?" It is also a good idea to ask if there is a charge for such consultations.

Turnaround Time

DNA paternity test results are usually obtainable within anywhere from two days to a week, though 24-hour turnaround may also be available. It is important to remember that DNA family relationship testing involves sophisticated genetic analyses.

Occasionally, genetic mutations are encountered in DNA paternity cases, and certain cases of complicated DNA family reconstructions require expert consultations and additional, specialized testing. An efficient, experienced DNA testing laboratory offers quick two-day turnaround results on most DNA tests they perform, and should be willing to devote their expertise, time and additional resources to more complex cases to achieve the most conclusive results.

Summary

Technological, social, and legal developments have fueled more widespread use of DNA family relationship testing services over the past decade. Yet, it remains difficult for both the general public and medical professionals to identify reliable, accredited DNA testing laboratories. As such, partnerships between healthcare providers and reliable DNA testing laboratories may allow patients seeking DNA family relationship testing to simultaneously receive reliable, conclusive DNA test results and competent, professional, clinical care. Due to the entrepreneurial nature of and breadth of services offered in this discipline, urgent care providers may be well positioned to engage in such partnerships. ■

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What do you think?
Let us know your opinion about this topic in an e-mail to *editor@jucm.com*.

Return-on-Investment in Occupational Health Sales

FRANK H. LEONE, MBA, MPH

It began with two cavemen, or even before: Bartering. Fair trade. A transaction where both parties (theoretically) walk away satisfied that they got a positive return on their exchange.

This concept persists to this very day. At a minimum, your urgent care clinic should understand return-on-investment (ROI) for two occupational health staples: work injury management and pre-placement physical examinations.

Work Injury Management

Employers need to get workers back to work as quickly and inexpensively as possible. Thus, you need to decrease the likelihood of a worker getting re-injured. Any discussion concerning the value of your clinic's injury management service must take into account both your injury management proficiency and prevention skills.

When selling such services, you must illustrate your clinic's ability to ensure a rapid return to work at a manageable cost. Sustainable return to work must be more than an idle promise; it requires meaningful justification.

Numerous attributes can lead to a more rapid return to work:

- **Care management software** facilitates faster and tighter control over the care management system.
- **Targeted case management** ensures that the cases most amenable to prompt coordination will get priority attention.
- **Modified duty programs** ensure more rapid integration into the workforce.
- **Continuity with occupational rehabilitation services** provides interventions to reduce lost work time.

The second half of the equation—lower costs—is more challenging because buyers frequently cannot see beyond average fees. Therefore, your clinic must differentiate between price and value (i.e., return on investment).

Next comes the *rationale* used to illustrate why your clinic is the best option. This requires an emphasis on the *likelihood* of your program making a difference, rather than a *guarantee*.

Rationale for a greater likelihood might include your track record, experience, or specific provider training or credentials.

Pre-placement Physicals

Unless your clinic addresses return on investment, you may find it difficult to compete with lower cost providers who offer pre-placement examinations primarily as a low-cost commodity.

Employers may "purchase" pre-placement physical examinations on price alone. They may go one step further and factor in convenience (e.g., availability to provide exams during traditional non-working hours, etc.). Unless prompted, the employer is unlikely to think of ROI when selecting a provider of pre-placement physical exams.

A well-conceived and delivered pre-placement physical exam is usually one that is based on an astute job analysis and performed by a provider who is skilled at matching job requirements to the applicant. Some practitioners do this well; many do not.

Thus, a value statement should stress your clinic's expertise in job analysis.

The rationale in support of this assertion might be physicians with specialized training in job analysis or software that provides the clinician with appropriate parameters and guidelines.

Sell on value, not price, and support the value of your product with meaningful and concrete examples. This is the heart of effective sales.

In summary, remember these four rules in using return-on-investment in occupational health sales:

1. Never be "beaten" on price alone.
2. Advise prospects that ROI is more important than unit price.
3. Ensure that every program provides a unique value.
4. Provide concrete rationale that your clinic's approach provides the greatest likelihood for optimal ROI. ■

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

Overview of a Malpractice Trial (and How to Survive)

JOHN SHUFELDT, MD, JD, MBA, FACEP

It's game day. The trial begins today and your fate will be decided by a jury of your "peers." Never mind the fact that none of them are physicians, only three have been to college, and two did not even graduate from high school; in the eyes of the law, they are your peers and will be the ones to decide if your care met the standard of care.

The typical medical practice trial usually progresses in the following way:

- *Jury selection*: Potential members of the jury are questioned by the judge and the respective attorneys. The attorneys can disqualify a prospective juror "for cause." If the judge determines it is a valid cause, the juror will not sit on the case. Each counsel is also allowed an equal number of *peremptory challenges*, which means the attorney does not need to give a reason to have a juror disqualified.
- *Opening statements by counsel*: The plaintiff's counsel makes the first opening statement, followed by the defense opening statement. The opening statements set the stage for the presentation of the facts and theories of the case. Both attorneys inform the jury about what they will attempt to prove during the course of the trial
- *Presentation of the plaintiff's case*: The accuser goes first, since he has the burden to prove the facts and the essential elements of the case. All the essential elements of the case (duty, breach, causation and damages) must be proved by a preponderance of the evidence (more likely than not, or more than 50% probability). The defense has the opportunity to cross-examine the plaintiff's witnesses in an attempt to point out inconsistencies and to reveal weaknesses or gaps in the testimony.
- *Motion for a directed verdict*: After the completion of the plaintiff's case, the defense attorney may submit a motion for a directed verdict which argues that even if the plaintiff's evidence is taken to be true, no case has been proven against the physician by a preponderance of the evidence. It is basically saying, "That's all you've got?" If the judge agrees, the case is over. If the motion is denied, the defense presents their side of the case.
- *Presentation of the defendant's case*: The defense attorney attempts to establish that some of the essential elements of the plaintiff's case are without substance. Since the burden on the plaintiff is to prove *all* the elements of the case, the defense attorney has put forth an effective defense if he or she can convince the jury that even one element is missing from the plaintiff's case in chief.
- *Closing arguments*: Both attorneys have the opportunity to give a synopsis of their case and why each believes his is the better set of facts. After their initial arguments, both sides are allowed to rebut their opponents' final statements.
- *Jury instructions*: The judge instructs the jury on the applicable laws which define the concepts that the jury will be asked to consider in reaching a verdict. Each side can submit proposed jury instructions. The judge can use part or all of the proposed instructions or can give his or her own instructions. After the jury instructions, the jury adjourns and begins to deliberate.

Despite the fact that the odds may seem stacked against you, they aren't. Physicians win 60% of the cases which make it to trial.

Moreover, most legal scholars believe that juries typically come up with the correct verdict. This means if your care did not, in fact, fall below the standard, or you had no duty to the patient, or your treatment did not cause the damage, you should be in great shape!

So, what else can you do to stack the odds even more in your favor? Read on.

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The Trial is Also a Show

As the defendant, your attire should reflect the appropriate amount of respect due to the court. This means that you should dress neither overly formally or too causally. For men, a conservative dark suit or blazer with a blue or white shirt and understated tie demonstrate a professional demeanor. For women, similar guidelines apply: understated and professional. You should refrain from wearing flashy or expensive jewelry or watches; the last thing you would want to convey is that you have money to burn.

Be Prepared

As with the deposition, it is very important for you to be prepared for the trial. This means being thoroughly familiar with the entire medical record. It may take a number of years for the case to come to trial, so it is imperative to refamiliarize yourself with all of the records and the deposition.

The plaintiff's counsel may attempt to get you to contradict your previous testimony by rephrasing or reordering questions. The best way to prepare for this is to thoroughly review the deposition before the trial. You will only harm your own defense if you allow the plaintiff's council to impeach you with your own prior testimony. If there are inconsistencies in the previous testimony, you may defuse a potentially damaging situation by addressing the inconsistencies upfront and honestly.

Humility Counts

Most people—including the jurors—respect the medical profession; however, the jurors must also find the physician likeable, honest, and genuine. Physicians who come across as pompous or arrogant often don't do well with juries. Sit up straight with your arms at your side, not folded across your chest. Your mannerisms should reflect those of a warm, caring, confident professional.

When speaking, find a balance between directing your comments toward the attorney asking the question and to the jury. Try to make eye contact with both the jury and the attorney. It is important that you not play excessively to the jury, since that may come across as you being "over-coached."

During the direct examination, your attorney will be asking questions. Typically, these questions and their answers are well-rehearsed prior to going into trial. When too much emphasis is placed on direct examination, however, the testimony can come across as "staged."

In other words, if the physician is answering before his or her attorney finishes the question, it may give the appearance of insincerity. It is important to listen to the entire question before speaking. During cross-examination, this will give your attorney a chance to object and provide you with time to actually understand the question before answering it.

Cross-examination

Often, too little time is spent preparing for cross-examination, which is conducted by the opposing attorney who will do his best to trip you up and make you appear incompetent or argumentative. This is why practicing helps; you do not want to respond to blunt questioning about the care you provided by losing your temper or confidence.

Also, if you ponder the question for an excessive period of time before answering, the jury may leave with the impression that you are attempting to deceive them or answer incompletely.

"If care was within the standard, juries typically find for the physician."

Play for Keeps

If the decision was made to not settle the case before the commencement of the trial, the trial is the time to win; do not assume that you will win on appeal before an appellate judge if you lose the jury trial. Occasionally, in a few very specific circumstances, a new trial will be granted; however, it is very rare for an appellate court to grant a new trial on the basis that the "verdict was against the weight of the evidence."

The take home point here is this: The trial is the championship game and there are no trophies for second place.

The best word to describe the right approach to the trial is *balance*. For example: The physician should dress neither too formally (see Tom Hanks' character during the holiday party scene in the movie *Big*) nor too causally (see Tom Hanks' character on the tractor in *Forrest Gump*).

- Answers should be given when the question is finished, not before the question ends or too long after the question ends.
- The physician should practice responses for both the direct and cross-examination.
- Demeanor should be relaxed and confident, not defensive or arrogant.
- Eye contact should shift between the jury and the attorney asking the questions.
- Medical terminology should be kept to a minimum; however, it is OK to use medical terms that are in most people's common vocabulary.

In the end, the odds are on our side. Physicians prevail in the majority of malpractice suits. If their care was within the standard, juries typically come up with the correct verdict and find for the physician. ■

CODING Q&A

Additional Income from After-Hours Codes (99050, 99051, 99053)

DAVID STERN, MD, CPC

Q. A patient with a finger laceration walked into our urgent care center at 8:05 p.m., five minutes after our closing time. Rather than turn the patient away, our team decided to care for the patient. Three of our staff, including the physician, stayed for 50 minutes after our posted closing time.

If we had not stayed after our scheduled closing time, the patient would have been forced to go to the hospital emergency department, where the services would have cost the insurer two to three times more.

Is there a way for our center to receive compensation for providing this service—a cost-saver for the payor but a significant additional expense for our urgent care center?

A. CPT code 99050 ("Services provided in the office at times *other than regularly scheduled* office hours, or days when the office is normally closed, e.g., holidays, Saturday or Sunday, in addition to basic service") has been designated as a code for physicians to obtain reimbursement for services rendered after regularly scheduled office hours.

Q. For code 99050, what determines whether a service is provided "after hours"?

A. The key here is your posted hours. Make sure that your signage, brochures, and website clearly denote the hours of operation for your urgent care center. If the service begins during your posted hours, you should not use this code to denote caring for patients whose visits may last beyond the posted closing time of your clinic.

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

Q. We have a family practice that is open on Saturday mornings for scheduled appointments. Sometimes patients walk in during these hours, and the doctor will see them as an unscheduled, episodic visit.

Since this is essentially an urgent care visit, would it be appropriate to code with 99050?

A. No. Since the patient is being seen when the office is normally open, you should not use code 99050. Some payors, however, may reimburse for code 99051 ("Service(s) provided in the office *during regularly scheduled* evening, weekend, or holiday office hours, in addition to basic service").

Q. Our urgent care center provides services on evenings, weekends and holidays—including Christmas and New Years Day. We have to pay our staff time-and-a-half to work holidays. To hire and retain staff to work these extended hours, we need to pay more than a typical (9 a.m. to 5 p.m., Monday through Friday) family practice.

Is there any code to use to get compensated for providing extended hours services and incurring these additional costs?

A. CPT code 99051 was designed to compensate your practice for these additional costs. Never use this code for Medicare. Some other payors will not reimburse you for this code, so you may want to check the policy of each of your payors.

Q. At what time does "evening" start?

A. Most consultants consider it appropriate to start using this code after 5 p.m. on weekdays. If you are unsure, check with your local payors.

Q. If I code with 99050 or 99051, does this replace the evaluation and management (E/M) code or an-

other code?

A. No. The codes 99050 and 99051 are add-on codes. Thus, it is coded *in addition to* all other codes (E/M, CPT, HCPCS and ICD-9) that you would code for the services rendered.

Q. **Some payors will not reimburse for either code. Do we have any recourse?**

A. Just because a code exists does not mean that any payor is required to reimburse for that code. Unless your contract with the payor specifically states that this code will be reimbursed, you do not have a legal recourse, but you may want to appeal to their sense of reason. If a payor does not reimburse for this code, you may want to lobby and negotiate for policy change.

Note: Medicare will never reimburse for this code, and it is illegal for a participating provider to balance bill a Medicare recipient for this code.

Q. **How can we get payors to start reimbursing for 99051?**

A. It is important to always keep a good relationship with your payors. Urgent care centers have been quite successful (even with large payors) in making their case and obtaining reimbursement for the after-hours code. For example, in 2006 Blue Cross and Blue Shield of North Carolina made the decision to reimburse urgent care centers for 99051.

If you decide to lobby or negotiate for this reimbursement, be sure that you present your case as reasonable and in the payor's best interest. You are merely asking to be compensated for your considerable additional expenses. Remind the payor that if your urgent care center is not providing services during extended hours, then the public will be forced to utilize emergency department services. This will cost the payor two- to three times the cost of care in an urgent care center.

Payment for this code may also provide sufficient added revenues to enable your urgent care center to provide additional hours to help reduce emergency department utilization.

Q. **If a patient is seen after 5 p.m. and also after regularly scheduled closing hours, can we code both 99050 or 99051?**

A. No, it is never appropriate to use both codes for the same patient visit. If the service is *after* your clinic's regularly scheduled hours, use code 99050. If it is *during* your regularly scheduled hours during evenings, weekends, or holidays, use code 99051.

Q. **What constitutes a "holiday" for code 99051? Can we include Jewish, Christian, and Muslim holy days?**

A. Some states have their own significant holidays (such as Casimir Pulaski Day in Illinois), and you may consider asking payors if they will reimburse for services rendered on these state holidays. Choosing multiple additional religious holidays is likely to be seen by payors as abuse of the system and may produce denials or reconsideration of the policy to reimburse for these services. Thus, it is my recommendation that urgent care centers limit the use of this code to Federal holidays.

Check with your payors before using 99051 for any holidays other than Federal holidays.

CODING Q & A

Q. We open at 6 a.m. Can we code with 99051 for services before 9 a.m.?

A. The strict definition of this code is that on weekdays it is for use *only* during "evening" hours. Thus, you should not use this code for early morning services.

Q. Our urgent care center stays open until midnight. We are thinking about using code 99053 for services rendered between 10 p.m. and 8 a.m. We think that payors are more likely to reimburse for 99053 than 99050. Is this a good idea?

A. No. Unless your urgent care center is open for 24 hours on a given day, you should not use code 99053. This CPT code (99053) is reserved for use in centers that operate on a 24-hour schedule. Although it is a growing trend to keep urgent care centers open for 24 hours, the vast majority of urgent care centers do not operate a 24-hour schedule.

If you do operate a 24-hour urgent care, code 99053 is appropriate as an add-on code to obtain reimbursement for these services. If your facility is not open for 24 hours, you should not use 99053. Use 99050 or 99051 instead. ■

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Journal of Urgent Care Medicine
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- 16 centers and rapidly growing with two to four new centers opening in 2007.
- Physicians enjoy working in a fast paced practice with on-site x-ray, lab and electronic medical records.
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Timothy Hendrix, MD at (407) 200-2860

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Phone: 800-638-7021 • Fax: 417-659-6343
Email: ahodkin@stj.com
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- **Marshfield - Urgent Care**
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Please contact: Sandy Heeg,
Physician Recruitment, Marshfield Clinic
1000 N Oak Ave., Marshfield, WI 54449
Phone: 800-782-8581, ext. 19781
Fax: (715) 221-9779
E-mail: heeg.sandra@marshfieldclinic.org
Website: www.marshfieldclinic.org/recruit

Marshfield Clinic is an Affirmative Action/Equal Opportunity employer that values diversity. Minorities, females, individuals with disabilities and veterans are encouraged to apply. Sorry, not a health professional shortage area.

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- Excellent public and private schools
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For more information contact: Deb Packard 800-626-3969
Email: dspackard@freemanhealth.com, or fax CV to 417-347-9316

DEVELOPING DATA

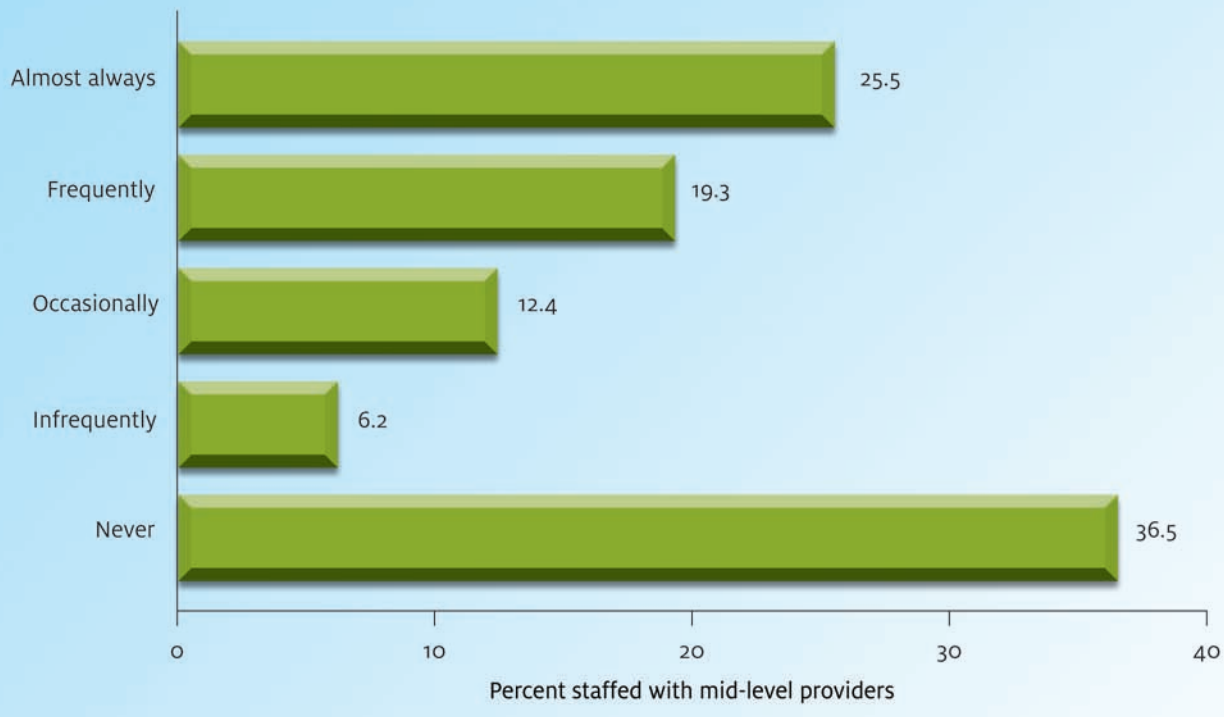
UCAOA's Survey Committee drew two important conclusions from its first industry-wide survey: urgent care is a growing industry nationwide, and those within the industry are hungry for benchmarking data. In each issue of *JUCM*, **Developing Data** will seek to fulfill that need.

In this issue: Who's treating whom?

Physicians are at the forefront of urgent care, both as practitioners and as business owners. They're not the only ones treating patients, however; perhaps more than in any other practice environment, mid-level providers—physician assistants and nurse practitioners, in particular—are charged with administering care to patients.

It's a good thing physicians have well-trained assistance, too, as respondents to the survey reported that their urgent care facilities see 42.3 patients per day, averaged over a seven-day work week of 9.4 hours per day.

MID-LEVEL PROVIDER STAFFING



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****:*

A first look at new data from UCAOA's second benchmarking survey.

Urgent Care Association of America

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