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First and Ten: A Decade of JUCM



A s we head into a new year at JUCM, our tenth, it is a natural time to reflect on our journal's history and our goals for the future. Just being able to celebrate a 10th anniversary is nothing short of a miracle. Medical publishing has been in transition

for some time, and the number of traditional journals is decreasing. Information, even complex clinical information, is now available with the click of a button.

Considering the dearth of traditional pharmaceutical advertising dollars flowing into the urgent care space, it is a small wonder that we have managed to produce a high-quality journal month after month for this long. That we have done so is a strong testament to our publisher and editors, our monthly columnists and advertisers, and, of course, our readers and authors, who make *JUCM* a meaningful forum for the urgent care provider, manager, owner, and operator.

It all started in a conference room at O'Hare International Airport. With Dr. David Stern and me representing the Urgent Care Association of America, and Stu Williams and Pete Murphy of the Braveheart Group, the seeds were planted for *JUCM*. Medical publishing veterans Stu and Pete were looking to reach the fledging specialty of urgent care with a high-quality, peerreviewed journal, and David and I were looking to do the same. During that meeting, we all made an immediate connection. Together, we had enough chutzpah to try our crazy plan.

We were very much like a start-up company, working long hours, shamelessly promoting the journal and relentlessly soliciting contributions from our readers and advertisers. Today there are over 100 issues of *JUCM* in print. But like all start-ups, we have come to a point where the original formula must be rejuvenated, nipped here and tucked there for a prosperous future. Over the last year, Braveheart and its editorial leaders created a vision for the next 10 years: delivering more content, with more relevance and with greater value, to our readers and to the urgent care community.

With this vision in mind, we welcomed two new associate editors, one clinical and the other practice management. We feel truly privileged to have engaged with Dr. Michael Weinstock and Alan Ayers, respectively, in those capacities. Though "Over the last year, [we] created a vision for the next 10 years: delivering more content, with more relevance and with greater value, to our readers and to the urgent care community."

neither is an unfamiliar face, their new level of commitment allows for a significant expansion of *JUCM* content. This team is responsible for building a sustainable pipeline of meaningful contributions, adding more content segments like original research, compliance, and finance; for providing editorial oversight to ensure an indispensable and bias-free journal; and for expanding the value of content through offerings like continuing medical education credit for every article we publish.

To support this growth, JUCM enlisted a new managing editor, Katharine O'Moore-Klopf, winner of the 2013 Robinson Prize from the American Copy Editors Society and a board-certified editor in the life sciences, who recently edited the *Textbook* of Urgent Care Medicine. I would be remiss not to mention our long-time art director, Tom DePrenda, who gives JUCM its bestin-class look and has won national awards for his covers and designs for our journal. Finally, to create more innovative and meaningful offerings online, we welcome Brandon Napolitano, our longtime web developer, to an expanded role in our digital initiatives.

We have been very fortunate to represent our passionate urgent care community, and to tell our story in a way that resonates. But this is a transformative time for urgent care, and the seas will be rough. You have our pledge to continue serving as a trusted leader for the discipline and industry as we navigate the next 10 years together.

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



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CLINICAL

8 Urgent Care Evaluation of Diarrhea

In the United States, an estimated 179 million to 375 million cases of acute diarrheal illness occur each year. So many different diseases can cause diarrhea that urgent care providers must take a systematic approach to the patient's medical history and physical examination.

Nathan M. Finnerty, MD, and Michael Weinstock, MD

PRACTICE MANAGEMENT

21 After Signing the Lease: Ensuring a Successful Build-Out of Your Urgent Care Center

How well you handle facility design, permitting, construction, and furnishing will determine for years to come how welcoming and efficient your urgent care center is for the patients you want to keep coming back. A contractor experienced in building out urgent care centers walks you through working with architects and contractors to get what you need for your new center.



IN THE NEXT ISSUE OF JUCM

By the year 2030, a guarter of the U.S. population will be older than 65 years. Rebekah Blickendorf, MD, writes that 30% to 40% of people in that age group fall each year, and that one fall often begets more falls, leading to an increasing loss of function. But the urgent care provider can intervene, preventing future injuries by educating these patients and their families and by seeking out the pathology behind the fall.

Alan A. Ayers, MBA, MAcc

ORIGINAL RESEARCH

27 Impact of a Pharmacist-Provided Comprehensive Medication Review Service for Urgent Care Patients



A small study shows that using a pharmacist-provided comprehensive medication review service in the urgent care setting can optimize medication therapy, helping centers meet best practices for communication during transitions of care.

Jennifer A. Flavin, PharmD, Christopher G. Green, PharmD, Stephanie C. Cook, DO, and Stuart J. Beatty, PharmD, BCACP

CASE REPORT

39 Rocky Mountain Spotted Fever: Dermatologic Manifestation of a Life-Threatening, Systemic Disease

Infection with Rocky Mountain spotted fever may not be detectable on blood work until several days after symptoms appear, and delays in treatment can be life-threatening for patients with the disease. Learn how to make the diagnosis on the basis of clinical findings so that treatment can begin immediately.



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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 and the Urgent Care College of Physicians, 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.

Affiliations

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ven if you have been with us from the beginning, you may not realize that in 2016 we will start our tenth year of serving you. We are as determined as ever to bring you great content that helps you provide a higher level of patient care, remain compliant with changing health-care laws, run your urgent care center efficiently and in a way that is fulfilling for staff members and comforting for patients, and be prepared for the future. We are grateful for your loyalty and for your commitment to helping increase the quality of literature on urgent care medicine by submitting manuscripts to us. We look forward to seeing what great things you and we can do together over the next 10 years.

In our cover article, you will learn that in the United States, an estimated 179 million to 375 million cases of acute diarrheal illness occur each year.



Nathan M. Finnerty, MD, and Michael Weinstock, MD, take you through a systematic approach to diagnosing the cause of illness so that you can quickly provide appropriate therapy to limit disease duration and progression.

Finnerty is a Senior Resident in Emergency Medicine, Department of Emergency Medicine, Ohio State University College of Medicine, Columbus, Ohio; a member of the Research and Social Media Committees for the Society for Academic Emergency Medicine; and a manuscript reviewer for Annals of Emergency Medicine. Weinstock is Associate Clinical Editor for the Journal of Urgent Care Medicine; Adjunct Professor of Emergency Medicine, Department of Emergency Medicine, Ohio State University College of Medicine; Chairman and Director of Medical Education, Mount Carmel St. Ann's Hospital Department of Emergency Medicine, Columbus, Ohio, Immediate Health Associates, Inc.; and Editorin-Chief, UC:RAP.





With the fast pace in urgent care centers, it is vital that medication information be communicated clearly to patients and to their primary-care providers for use in follow-up treatment. A new study conducted by Jennifer A. Flavin, PharmD, Christopher G. Green, PharmD, Stephanie C. Cook,

DO, and Stuart J. Beatty, PharmD, BCACP, shows that instituting a pharmacist-supervised comprehensive medication review service can help optimize medication therapy.

Flavin is Clinical Pharmacist for Memorial Health Medication Therapies Center in Marysville, Ohio; Green is Specialty Practice Pharmacist for University Health Services in Columbus, Ohio; Cook is founder and Medical Director of University Health Services in Columbus, Ohio; and Beatty is Vice Chair of Clinical Affairs and Associate Professor of Clinical Pharmacy at Ohio State University College of Pharmacy in Columbus, Ohio.

You found the perfect location for your new urgent care center and have signed the lease, but what do you do now? Alan A. Ayers, MBA, MAcc, conducts a question-and-answer session with Brent



Johnson, an experienced contractor, to fill you in on dealing with general contractors, time lines, the permit process, and build-out costs and common pitfalls.

Ayers is Practice Management Editor of the *Journal of Urgent Care Medicine*, a member of the board of directors of the Urgent Care Association of America, and Vice President of Strategic Initiatives for Practice Velocity. Johnson is Vice President of Midland General Contractors, a national design-build firm specializing in urgent care centers that is based in Rockford, Illinois.

In our case report, Whitney Cramer, PA-C, details how to diagnose Rocky Mountain Spotted fever, a potentially life-threatening disease, on the basis of clinical findings and recent environmental exposure.



Cramer is a recent graduate of Ohio Dominican University in Columbus, Ohio, and is now working at Arlington Urgent Care in Upper Arlington, Ohio.

Also in this issue:

In *Health Law and Compliance*, **Ron Lebow**, **JD**, transaction and regulatory counsel for Michelman & Robinson, LLP, discusses the legal implications of integrating hospitals and urgent care centers.

Sean M. McNeeley, MD, and the Urgent Care College of Physicians review new reports from the literature on the identity of the most frequent carriers of pertussis, local antibiotic resistance patterns and urinary tract infections, new guidelines for evaluating for pulmonary embolism, single-dose dexamethasone for children with acute asthma, preventing contamination through careful removal of personal protective equipment, renal stones and the need for computed tomography, pulmonary embolism prediction models, and concussion evaluation in teenagers.

In *Coding Q@A*, **David Stern, MD, CPC**, discusses when to use unspecified diagnosis codes and how to code for preoperative examinations and for tuberculosis skin tests.

Our *Developing Data* piece provides statistics on disposition of patients' visits to U.S. urgent care centers in 2014.

To Subscribe to JUCM

JUCM is distributed to medical practitioners—physicians, physician assistants, and nurse practitioners—working in urgent care practice settings in the United States. To subscribe, log on to *www.jucm.com* and click on "Subscription."

Orlando Urgent Care Spring Convention

The 2016 UCAOA Awards Nominations Are Open!

The Urgent care association of America (UCAOA) invites you to recognize the difference we all make in the urgent care industry by nominating a deserving urgent care peer, employee, center, company or even yourself, for a 2016 UCAOA Award. Award recipients will be recognized during a ceremony to be held at the 2016 Spring Convention (April 17-20) in Orlando.

Awards Categories

- **Outstanding Achievement Award:** The highest honor given by UCAOA, this award recognizes significant achievements in the field of urgent care medicine.
- Lifetime Membership Award: Recognizes an individual member's significant contributions to the Urgent Care Association of America.
- Advocacy Award: Honors individuals, organizations or companies for impactful advocacy efforts benefitting patients or the industry on a state or national level.
- **Community Service:** Recognizes an individual or organization for significant volunteer initiatives that result in a positive impact on community health.
- Humanitarian: Recognizes an individual or organization for substantial medical-related volunteer outreach on a national or international level.
- **Innovation (New!):** Recognizes outstanding creativity in products, services or clinical discoveries that advance the urgent care industry.

Submit your nominations at ucaoa.org/?awards_nominations by Monday, February 15, 2016.



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ROGER HICKS, MD

ominate colleagues for a UCAOA award for their achievements or for giving back to the urgent care community and the larger community. The 2016 awards will be presented at our National Urgent Care Convention on April 19 (http://www.ucaoa.org/?2016Spring). All nominations should be submitted online (https://ucaoa.site-ym.com/?Awards) by February 15, 2016. A list of previous award recipients and all award criteria can be found online as well. The UCAOA Awards Committee, chaired by Roger Hicks, MD, will consider nominations in the following categories.

Award Categories

Outstanding Achievement

The Outstanding Achievement Award is the highest honor given by UCAOA in recognition of significant achievements in clinical, managerial, and/or administrative arenas that have advanced urgent care medicine.

Lifetime Membership

Significant contributions of UCAOA members to the association are recognized with lifetime membership.

Advocacy

The Advocacy Award recognizes those who advocate for urgent care medicine and its patients through education and outreach to state or national decision-makers.

Community Service

The Community Service Award recognizes noteworthy medical volunteer contributions that have positively affected the health of the nominee's community.



Roger Hicks, MD, is treasurer of the Urgent Care Association of America and serves as chair of its Awards Committee.



 Cindi Lang, RN, MS, winner of the 2015 Lifetime Membership Award. 2. Laurel Stoimenoff, PT, CHC (left), and Roger Hicks, MD (right), presenting the 2015 Advocacy Award to Radwan Hallaba, MD. 3. Steve Sellars, MBA (left), and Roger Hicks, MD (right), presenting the 2015 Community Service Award to Eric McDonald, chief executive officer of DocuTAP.
 UCAOA board members applaud the recipients of the 2015 UCAOA Awards.

Humanitarian

The Humanitarian Award recognizes substantial and medically related volunteer contributions with a positive impact on a national or international cause or event.

Innovation

Significant advances in the field of urgent care medicine in one or more of the following areas are recognized by the Innovation Award: clinical practice, clinical research, practice management, clinic design, and marketing.

General Criteria for Awards

You may submit a nomination for you and your center or company, or for the work of a colleague or friend. Current directors and Awards Committee members are not eligible for awards. The committee will judge the entries, with its recommendations subject to approval by the board of directors. The board reserves the right to make no award in a given category if there are no nominees with accomplishments of sufficient merit.

Clinical

Urgent Care Evaluation of Diarrhea

Urgent message: Diarrheal illness presents with varying degrees of severity and a broad range of etiologies. The urgent care center provider's ability to gather key information from the medical history and physical examination, determine when laboratory testing is beneficial, and recognize indications for treatment is essential for the effective and efficient treatment of this common symptom.

NATHAN M. FINNERTY, MD, and MICHAEL WEINSTOCK, MD

Introduction

liarrheal illness is a common presenting complaint to all urgent care centers. In the United States, an estimated 179 million to 375 million cases of acute diarrheal illness occur each year (0.6–1.4 bouts per person per year), accounting for more than 900,000 hospitalizations and 6000 deaths annually.^{1,2} Although most episodes are self-limited, understanding critical components of the medical history and physical examination and following a systematic approach to diarrheal illness is crucial for proper treatment.

Diarrhea has traditionally been defined by weight (200–250 g) of unformed stool (i.e., it takes the shape of the container it is in) per day, but it is more practically defined as the passage of three or more unformed stools per day.^{1,3} Diarrhea is further classified by duration of

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illness. Acute diarrheal illness is defined as lasting fewer than 14 days; persistent illness, as lasting 14 to 29 days; and chronic illness, as lasting more than 30 days.²

Presentation of Cases

Case 1

A 4-year-old boy presents with diarrhea. His mother



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reports that he has had 3 days of four or five loose, nonbloody stools. She reports that he also has had fatigue and decreased appetite. His vital signs are within normal limits for his age, and his abdomen is soft and nontender, with increased bowel sounds. He has no significant past medical history, has no history of recent travel or antibiotics, and attends day care three times a week.

Case 2

A 45-year-old woman presents with diarrhea. She reports 2 days of multiple loose stools with associated bright red blood over the preceding 12 hours. She has associated muscle aches, nausea but no vomiting, and abdominal cramping. She has a history of hypertension and no recent changes in medications. She reports that she has not recently traveled or taken antibiotics. Her temperature is 101.9°F (38.8°C), and the remainder of her vital signs are within normal limits. She is in no acute distress, her abdomen is soft and nontender, and findings from her stool sample are positive for occult blood.

Case 3

A 56-year-old man presents with diarrhea. He reports 5 days of eight to 10 large-volume, nonbloody, loose stools per day. He describes a sensation of bloating and abdominal cramping. He has a history of diabetes mellitus and was recently discharged from a hospital after admission for cellulitis of his left foot. His vital signs are within normal limits, and his abdomen is mildly tender throughout.

Case 4

A 26-year-old man presents with diarrhea. He reports 3 days of loose, foul-smelling stool with associated abdominal cramping. He reports that he has not had nausea or vomiting. He recently returned from a hiking trip through the Shenandoah Valley and is unaware of whether his fellow travelers have been ill. Findings on his physical examination are unremarkable.

Initial Assessment

Initial assessment should focus on signs of instability and indications for transfer to an acute-care facility. As always, vital signs are indeed *vital*. Tachycardia, hypotension, or tachypnea alone, in conjunction with each other or with associated fever, are considered overt signs of clinical instability or systemic illness, and the patient would likely benefit from rapid intervention and acute-care treatment. The general appearance of the patient can provide further evidence of instability. Lethargy, lack of verbal or pain response, cachexia, mottled or ashen skin, acute distress from pain, and writhing can all indicate the need for acute-care treatment. As always, extra caution is warranted with the very young (neonates and infants) and the elderly.

Differential Diagnosis

The differential diagnosis for diarrheal illness is broad, but it can be simplified by categorizing to infectious and noninfectious disease, and then subcategorizing infectious into dysenteric and nondysenteric etiologies.

Infectious, Nondysenteric Diarrhea

In general, nondysenteric infectious diarrhea is acute, is self-limiting, and requires no testing or empiric treatment.² Most infectious diarrheal illness is due to viral infections, most commonly with *Norovirus* and *Rotavirus*.¹ These are typically acute and self-limiting. Food poisoning also falls into this category and is typically caused by foods contaminated with bacteria (such as *Staphylococcus aureus, Bacillus cereus,* and *Clostridium perfringens*) that emit a preformed enterotoxin. Food poisoning typically has an acute onset (1–6 hours after ingestion) and is self-limiting, requiring only supportive care.⁴

Special considerations for nondysenteric infectious diarrhea include the following:

- Traveler's diarrhea: Traveler's diarrhea is contracted from contaminated food or water and caused by a variety of noninvasive *Escherichia coli* species. As the disease's name suggests, a recent travel history with nondysenteric diarrhea should increase the clinician's suspicion for the condition.⁵ Stool analysis is not necessary, and the disease course is self-limited. However, empiric treatment with ciprofloxacin (500 mg twice a day for 3–5 days) has been shown to decrease the duration of symptoms.
- Botulism: Caused by *Clostridium botulinum*, botulism is uncommon but can be life-threatening. It is contracted by the consumption of contaminated food products, most commonly home-canned fruits and vegetables. In addition to diarrhea, botulism produces a descending paralysis (a top-to-bottom paralysis). Symptoms may include weakness, dry mouth, diplopia, dysphagia, progressive cranial nerve palsies, and respiratory failure. Treatment includes hospitalization and supportive care, including intubation and ventilation in severe cases.
- Scombroid: Scromboid is caused by the consumption of contaminated fish such as tuna, mackerel,

and mahi-mahi. This produces a histamine-like reaction and, in addition to diarrhea, may present with diffuse flushing of the face, neck, and upper trunk; palpitations; nausea and vomiting; and rarely, bronchospasm. This can be confused with an allergic or anaphylactic reaction. Treatment is with antihistamines.

Giardiasis: Giardiasis is the most common parasitic infection in the United States and is contracted through the consumption of contaminated food or water, typically with a history of recent hiking, backpacking, or other travel. In addition to diarrhea, patients may experience bloating, abdominal cramps, excessive flatus, and weight loss from malabsorption. Stool analysis is indicated, and treatment with metronidazole is needed.¹

Infectious, Dysenteric Diarrhea

Dysentery is defined by the presence of visibly bloody stool, but it also includes fever and tenesmus and is a sign of invasive or inflammatory illness.² Acute, bloody diarrhea is most often infectious in etiology. Most common pathogens include *Salmonella, Shigella, Campylobacter*, and Shiga toxin–producing *E. coli*. Most presentations warrant stool analysis and empiric treatment with antibiotics (ciprofloxacin, 500 mg twice a day for 3–7 days).¹

Special considerations for dysenteric infectious diarrhea include the following:

- Enterohemorrhagic E. coli (EHEC O157:H7): Classically contracted through the consumption of undercooked meats, EHEC causes abdominal pain, vomiting, and grossly bloody diarrhea, but often no fever. Empiric antibiotics are not recommended, because this may increase the risk of complications such as hemolytic-uremic syndrome (HUS).¹
- C. difficile: C. difficile is a common enteric bacterium and does not always cause acute inflammation or colitis. C. difficile colitis is caused by the production of toxin A and/or toxin B; these strains of bacteria typically develop in the setting of recent antibiotic use (clindamycin, penicillin, cephalosporin) or hospitalization for more than 3 days.⁶ Patients may present with fever, abdominal pain, diarrhea, and, in rare cases, vomiting. This may lead to significant illness, especially in the elderly. Stool analysis for C. difficile toxin A and/or toxin B and discontinuation of offending agents are essential. The treatment of choice is metronidazole or oral vancomycin.^{1,6}
- Amebic dysentery: Amebic dysentery is caused by

Entamoeba histolytica and is contracted from contaminated food or water, most commonly in developing countries. Amebic dysentery is difficult to distinguish from the bacterial form. For patients with a history of travel to developing countries, those who are immunocompromised, and those with persistent or chronic dysentery that has not responded to conventional treatment, stool analysis for ova and parasites should be considered.¹

Noninfectious Diarrhea

In the acute phase, noninfectious diarrhea can be hard to distinguish from infectious diarrhea. A thorough medical history and physical examination are essential for accurate diagnosis and treatment. For patients presenting with an isolated chief symptom of diarrhea, the most common noninfectious etiology is drug-induced or iatrogenic. Many commonly prescribed and over-the-counter medications affect the gastrointestinal tract. These include—but are in no way limited to—antibiotics, laxatives, antacids, antihypertensives, antiepileptics, antidepressants, diuretics, nonsteroidal anti-inflammatory drugs, cholinergics, and cholesterol-lowering medications. Evaluating suspected noninfectious diarrhea in the context of associated symptoms can help in making a diagnosis.

- Abdominal pain: Acute or focal abdominal pain as the presenting or associated symptom, along with diarrhea, is very concerning regarding intraabdominal pathology and work-up. The clinician should consider appendicitis, intestinal obstruction, pancreatitis, cholecystitis, diverticulitis, pyelonephritis, pelvic inflammatory disease, hepatitis, volvulus, inflammatory bowel disease (IBD), and mesenteric ischemia according to the patient's age, sex, medical history, and findings on physical examination, because each of those diseases may present with diarrhea.
- Toxidromes: Many acute and chronic intoxications, as well as withdrawals, may present with or have associated diarrhea.

History of Present Illness

The differential diagnosis for diarrheal illness is broad, so obtaining a thorough history of the present illness is the most critical component in the treatment of diarrheal illness. As you interview the patient, consider the following²:

- Diarrheal illness category and duration:
 - Diarrhea is defined as >3 unformed stools per day.



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- Categorize it as acute (<14 days), persistent (14–29 days), or chronic (>30 days). Acute and persistent illness are more frequently infectious, whereas diet and systemic disease states should be considered in chronic illness.
- Stool characteristics:
 - Acute bloody stool is suggestive of infectious diarrhea.
 - Chronic bloody stool can indicate a systemic illness such as IBD.
- Exposures:
 - Living arrangements: Viral illnesses are particularly common in closed populations such as those for cruise ships, nursing homes, dormitories, and hospitals.
 - Food exposure: Just as viral diarrhea occurs in closed populations, food-borne illnesses often occur in groups. Produce is the most common source, and contaminated leafy green vegetables are the most common food type involved. Noroviruses are the most common food-borne pathogens. Poultry is associated with the highest proportion of deaths, most commonly from infection with Salmonella or Listeria.⁴ A recent history of eating raw oysters should prompt consideration and special culture for Vibrio cholerae. Ingestion of undercooked beef should prompt testing for Shiga toxin-producing E. coli.⁴ In addition to food-borne illness, a causal relationship between certain foods and the onset of diarrhea could suggest lactose intolerance or celiac sprue.
 - Foreign travel: Foreign travel increases the likelihood of traveler's diarrhea and should increase suspicion for bacterial or parasitic pathogens.
 - **Domestic travel:** Recent hiking or camping places the patient at risk of giardiasis, particularly if water-purification procedures were not strictly followed, as does well-water consumption in rural environments.
 - Antibiotics or hospitalizations: Recent antibiotic use or hospitalization places the patient at increased risk of infection with *C. difficile*, as does use of proton-pump inhibitors.^{6,7}
- Associated symptoms:
 - **Inflammatory or dysenteric symptoms:** These include fever, bloody stool, and tenesmus and are often indicative of infectious diarrhea, warranting testing and empiric treatment.
 - Nausea or vomiting: When vomiting is the pre-

dominant finding, viral gastroenteritis or food poisoning with a preformed toxin should be considered, though there are many other etiologies with this constellation of symptoms.

- Abdominal pain: Associated abdominal pain may suggest diverticulitis, small bowel obstruction, infectious gastroenteritis, or IBD.
- **Seizures:** Seizures have classically been associated with shigellosis but can also indicate an electrolyte imbalance such as hyponatremia.
- Heat intolerance: Heat intolerance can suggest hyperthyroidism or thyrotoxicosis.
- **Situational:** Situational diarrhea, especially triggered by stress or emotion, can suggest irritable bowel syndrome, though this is typically a diagnosis of exclusion.
- Medical history:
 - Immune state: Malignancy, chemotherapy, sickle cell disease, previous organ transplantation, and human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS) are only a few of the disease states or conditions that lower a host's immunity. If the patient is immunocompromised, the differential diagnosis is broadened to include protozoal infections, *Mycobacterium avium* complex, and intestinal cytomegalovirus infections.⁸
 - Medications: A review of the patient's current medications may reveal an inciting agent. Antibiotics are a common cause of diarrhea.
- Surgical history—abdominal surgery:
 - Previous abdominal surgeries increase the risk of adhesions and small bowel obstruction.
 - Though typically presenting with abdominal pain and constipation, patients may have associated small-volume, unformed stool that passes the site of obstruction.
 - Family history: IBD often has a genetic predisposition.
- Social history—sexual practices:
 - Men who have sex with men might have proctitis or colitis with sexually transmitted pathogens.
 - *Entamoeba* has been detected in higher numbers in men who have sex with men than in other populations.

Physical Examination

The physical examination should begin with a review of the patient's vital signs and general appearance. As

previously mentioned, unstable vital signs, altered mental status, and acute distress from pain are all indications for rapid intervention and transfer to an acute-care setting. Though a complete examination is recommended, here we focus on critical elements most likely to guide treatment:

- Volume status: Important factors indicating moderate to severe volume depletion include tachycardia, hypotension, altered mental status, decreased skin turgor, dry or tacky mucous membranes, sunken eyes (or fontanelles, as appropriate), and postural hypotension.
- Abdominal examination: Important factors include the presence or absence of surgical scars, tenderness to palpation, distention, masses, and peritoneal signs. Peritonitis warrants transfer to an acute-care setting. Focal or severe abdominal pain may suggest acute appendicitis, intestinal obstruction, intussusception, pancreatitis, cholecystitis, diverticulitis, hepatitis, volvulus, IBD, or toxic megacolon, depending on the age of the patient, location of pain, and clinical context. Abdominal pain out of proportion to the findings on physical examination may indicate mesenteric ischemia.
- Rectal examination: Rectal examination is especially critical in the elderly and in patients presenting with bloody stool. Important factors include inspection for hemorrhoids and fissures. Anal fissures, especially outside the typical 6 o'clock and 12 o'clock positions, should raise suspicion for IBD. Digital rectal examination should be performed to evaluate for gross and occult blood. In the elderly, fecal impaction may result in diarrhea as liquid stool passes around the site of impaction.
- Additional findings: Thyroid enlargement, masses, oral ulcers, erythema nodosum, and episcleritis can suggest an autoimmune source of diarrhea such as hyperthyroidism, thyrotoxicosis, adrenal insufficiency, carcinoid syndrome, hypoparathyroidism, and IBD.

Diagnostic Work-Up

Findings on the medical history and physical examination should guide testing and treatment. Because most diarrheal illnesses are self-limited or viral, microbiologic testing is usually unnecessary in the urgent care setting.⁹ In the absence of clinical signs of severe dehydration, instability, or focal physical examination findings (i.e., right lower quadrant abdominal pain or thyroid enlargement), serum studies are usually not indicated. Most diagnostic tests recommended in the work-up of diarrheal illness are rarely immediately helpful in the urgent care setting, but they can be helpful for follow-up treatment. Patients presenting with fever, bloody or purulent stool, tenesmus, or diarrheal illness lasting more than 7 days should be considered for stool analyses, including fecal leukocytes or lactoferrin, stool bacterial culture, ova and parasites, and *C. difficile* toxin assay.^{9,10}

Fecal leukocytes and lactoferrin are markers of inflammatory diarrhea. The presence of leukocytes serves as a fairly specific marker of inflammation, indicating the need for empiric treatment and/or stool culture; the absence of lactoferrin serves as a fairly sensitive marker for the absence of inflammation or the presence of invasive pathogens.9 Neither is perfect, so again, findings on the medical history and physical examination should be considered prior to testing and treatment. Stool cultures will not produce results quickly enough to guide treatment in the outpatient setting, but if they are ordered for follow-up encounters, they should target the most common pathogens (Salmonella, Shigella, Campylobacter, and, especially if there are bloody stools, Shiga toxin-producing E. coli) and uncommon pathogens as indicated by the medical history (hospitalization, being immunocompromised, travel, consumption of problematic foods, etc).⁸

Treatment and Disposition

Supportive Care

In all cases, initial therapy should include hydration. Oral hydration with a glucose-based electrolyte solution is preferred. In pediatric patients, oral rehydration can be accomplished by giving 50 to 100 mL/kg of a glucoseelectrolyte solution over 4 hours. Intravenous hydration with normal saline or lactated Ringer's solution should be reserved for patients with contraindications to oral therapy (e.g., altered mental status, established need for parenteral nutrition or feeding tube), in those who cannot tolerate oral hydration because of persistent vomiting, or in those with severe dehydration.

Antiemetics are indicated for the vomiting patient and can prevent the need for intravenous hydration. Commonly used medications that are safe for both adults and children include ondansetron (Zofran), promethazine (Phenergan), and metoclopramide (Reglan).

Antidiarrheal agents should be used with caution, because they have been implicated with prolonged fever in shigellosis, toxic megacolon in *C. difficile* infection and IBD, and HUS in EHEC infection. Thus, antidiarrheal agents should be avoided in patients with bloody

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diarrhea or suspected inflammatory diarrhea, as well as in children. Loperamide is the agent of choice in adults and may reduce the duration of diarrhea by 1 day. Bismuth subsalicylate is an appropriate second-line option.

Empiric Antibiotic Therapy

Because definitive diagnostic studies are not readily available in the acute-care setting, they have limited utility, so empiric antibiotic therapy should be considered in the appropriate clinical scenario. However, the majority of infectious causes of diarrhea are viral or noninvasive bacteria, and illness tends to be self-limited and to require only supportive therapy. Initiation of empiric antibiotic treatment is recommended in patients with a suspected invasive bacterial process and severe diarrhea and systemic symptoms. Ciprofloxacin (500 mg orally for 3 or 4 days) is the medication of choice, with azithromycin as a secondary option or for children and pregnant women. Antibiotic therapy is considered a contraindication if there is suspicion of EHEC infection, because it has been implicated in increasing the incidence of HUS. Further indications for empiric therapy include the following:

- Traveler's diarrhea:
 - Cause: Noninvasive *E. coli* species, *Campylobacter, Salmonella*, and *Shigella*, with *Cryptosporidium* and *Giardia* in persistent cases
 - Source: Contaminated food and water
 - **Presentation:** Diarrhea with or without abdominal cramps, nausea or vomiting, or fever, with recent travel to endemic areas such as Africa, Central America and South America, and Mexico
 - Empiric treatment: Bismuth subsalicylate reduces the rate of diarrhea; ciprofloxacin has been shown to decrease the length of illness.
- *C. difficile* infection:
 - Cause: C. difficile toxin A and/or toxin B
 - **Source:** Recent antibiotic use (clindamycin, penicillin, cephalosporin) or hospitalization for more than 3 days
 - **Presentation:** Fever, abdominal pain, diarrhea, and, rarely, vomiting, which may cause significant illness especially in the elderly. Suspect it if the patient has been hospitalized for more than 3 days and/or has taken antibiotics in the preceding 2 weeks.
 - Work-up: Stool analysis for *C. difficile* toxin A and/or toxin B
 - Empiric treatment: Discontinue associated antibiotics, metronidazole, or oral vancomycin.

- Giardiasis:
 - Cause: Giardia
 - Source: Contaminated water
 - **Presentation:** Abdominal pain, persistent diarrhea, weight loss, and, rarely, vomiting. Suspect it if there is a history of hiking, camping, or drinking poorly purified water.
 - Work-up: Stool analysis for ova and parasites. Direct immunofluorescence staining can improve the sensitivity for detecting *Giardia* and *Cryptosporidium*. Multiple samples may have to be collected to be sufficient to yield a positive result.
 - Empiric treatment: Metronidazole

Systematic Approach

To assist with decision-making, the clinical approach to diarrheal illness can be categorized as follows:

- Acute diarrhea without dysentery
- Acute diarrhea with dysentery
- Nosocomial diarrhea
- Immunocompromise
- Persistent or chronic diarrhea

Acute Illness Without Dysentery

- Essential features:
 - Symptoms for less than 7 days
 - An appearance of being well, plus either no abdominal pain or mild abdominal pain that is generally cramping and nonfocal
 - Absence of fever, bloody stools, or tenesmus
- Differential diagnosis and common pathogens:
 - Infectious causes include *Norovirus, Rotavirus,* and food poisoning with a preformed toxin.
 - There are many noninfectious causes. Consider medication-induced diarrhea, medication with-drawal, gastrointestinal bleeding, adrenal insufficiency, thyroid storm, toxicologic exposures, and mesenteric ischemia.
- Work-up:
 - In general, neither blood work or stool analysis is required.
 - Consider serum chemistries if there is moderate to severe dehydration.
 - Consider stool analysis for *Giardia* or *Cryptosporidium*.
 - Consider testing for sexually transmitted infections for men who have sex with men.
- Treatment and disposition:
 - Give supportive care only, because the disease is typically self-limited.

URGENT CARE EVALUATION OF DIARRHEA

"The majority of infectious causes of diarrhea are viral or noninvasive bacteria, and illness tends to be self-limited and to require only supportive therapy. [However, initiation] of empiric antibiotic treatment is recommended in patients with a suspected invasive bacterial process and severe diarrhea and systemic symptoms."

- Consider empiric therapy with ciprofloxacin (trimethoprimsulfamethoxazole in children) if there is concern for traveler's diarrhea.
- Consider empiric therapy with metronidazole if there is concern for giardiasis.
- Consider empiric therapy with ceftriaxone, azithromycin, and metronidazole if there is concern for sexually transmitted infectious colitis.
- Discharge if the patient appears well, has normal vital signs, has no underlying disease, tolerates oral intake, and has a healthy social situation at home.

Acute Illness with Dysentery

- Essential features:
 - Symptoms for fewer than 7 days
 - Associated fever, bloody stools, or tenesmus
- Differential diagnosis and common pathogens:
 - Infectious causes include *Campylobacter*, *Salmonella*, *Shigella*, EHEC, and Shiga toxin–producing *E. coli*.
 - Noninfectious causes include gastrointestinal bleeding, toxicologic exposures, and mesenteric ischemia. Cephalosporin use can produce red stools with negative findings on stool guaiac tests that can be mistaken for dysentery.
- Work-up:
 - Obtain a stool culture for the listed common pathogens.
 - Consider a stool leukocyte count and/or lactoferrin test.
 - Consider serum chemistries if there is moderate to severe dehydration.
 - Consider stool analysis for Giardia or Cryptosporidium.
 - Consider testing for sexually transmitted infections for men who have sex with men.
- Treatment and disposition:
 - Provide supportive care.
 - Provide empiric therapy with ciprofloxacin (trimethoprimsulfamethoxazole in children) except if there is suspicion of EHEC infection (bloody stool without fever), because this may increase the risk of complications such as HUS.
 - Consider empiric therapy with metronidazole if there is concern for amebic dysentery.







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- Consider empiric therapy with ceftriaxone, azithromycin, and metronidazole if there is concern for sexually transmitted infectious colitis.
- Hospital admission is necessary for extremes of age (elderly and infants), unstable vital signs, and severe illness.
- Discharge patients who appear well, have normal vital signs, have no underlying disease, tolerate oral intake, and have a healthy social situation at home.

Nosocomial Diarrhea

- Essential features:
 - Recent hospitalization for more than 3 days
 - Or recent antibiotic use
- Differential diagnosis and common pathogens:
 - Infectious causes include *C. difficile, Norovirus, Rotavirus, Campylobacter, Salmonella,* and *Shigella.*
- Drug-induced diarrhea should also be considered.Work-up:
 - Obtain a stool analysis for *C. difficile* toxins.
 - Consider a stool leukocyte count and/or a lactoferrin test.
 - Consider serum chemistries if there is moderate to severe dehydration, plus additional serum studies as indicated.
- Treatment and disposition:
 - Provide supportive care; antidiarrheal agents are contraindicated.
 - Discontinue offending agents.
 - Provide empiric therapy with metronidazole or oral vancomycin if there is a high suspicion for *C. difficile* infection.
 - Consider empiric therapy with metronidazole if there is concern for giardiasis.
 - Hospital admission is necessary for the elderly, when there are unstable vital signs, and in severe illness.
 - Discharge if the patient appears well, has normal vital signs, has no underlying disease, tolerates oral intake, and has a healthy social situation at home.

Immunocompromise

- Essential features—any underlying medical condition or therapy that compromises the patient's immune status:
 - Malignancy
 - Chemotherapy
 - Sickle cell disease
 - Previous organ transplantation

HIV or AIDS

- Differential diagnosis and common pathogens:
 - Infectious causes include protozoal infections, *Mycobacterium avium* complex, fungal infections, and intestinal cytomegalovirus, in addition to those already described.
 - Noninfectious causes include drug-induced diarrhea, malignancy, increased intestinal transit, and graft-versus-host disease
- Work-up:
 - Conduct a stool analysis for common pathogens.
 - Consider stool a leukocyte count and/or a lactoferrin test.
 - Consider serum chemistries if there is moderate to severe dehydration, plus additional serum studies as indicated, including a CD4 count.
- Treatment and disposition:
 - Provide supportive care. Antidiarrheal agents are contraindicated in the presence of dysentery.
 - Discontinue offending agents.
 - Highly active antiretroviral therapy (known as HAART) is the most important treatment in the setting of HIV or AIDS.
 - Findings on stool studies should guide therapy, given the broad range of potential offending agents.
 - Consider empiric therapy with metronidazole if there is concern for giardiasis.
 - Maintain a low threshold for hospital admission, especially for the elderly, when there are unstable vital signs, or in severe illness.

Persistent or Chronic Diarrhea

- Essential features: Symptoms for more than 7 days with or without dysentery
- Common pathogens:
 - Infectious causes include *Giardia*, *Cryptosporidium*, *Entamoeba*, *Campylobacter*, *Salmonella*, and noninvasive *E. coli* strains.
 - Noninfectious causes include drug-induced or iatrogenic diarrhea, postinfection irritable bowel syndrome, and IBD.
- Work-up:
 - Do a stool analysis for common pathogens.
 - Do a stool leukocyte count and/or lactoferrin test.
 - Consider serum chemistries if there is moderate to severe dehydration, plus additional serum studies as indicated.
- Treatment and disposition:
 - Provide supportive care. Antidiarrheal agents are

contraindicated in the presence of dysentery or when there is a high suspicion of IBD.

- Discontinue offending agents.
- Findings on stool studies should guide therapy, given the broad range of potential offending agents.
- Hospital admission is necessary for the elderly, when there are unstable vital signs, and in severe illness.
- Discharge if the patient appears well, has normal vital signs, has no underlying disease, tolerates oral intake, and has a healthy social situation at home.

Discussion of Cases

Case 1

Case 1 involves a well-appearing child with diarrheal illness. Our initial assessment did not indicate the need for emergency transfer to an acute-care setting. This patient would fall into the category of acute diarrhea without dysentery. This child most likely has a viral illness that will resolve without intervention. The primary risk factor is his exposure to other children at day care. Instructions to his mother regarding oral hydration and follow-up are appropriate. Serum or stool studies are not indicated.

Case 2

Case 2 can be categorized as acute diarrhea with dysentery. Though febrile, the patient did not seem to be in extremis, and emergency transfer was not indicated. Stool studies should be considered for this patient, though they will not help in the urgent care treatment of her condition. The medical history did not lead the provider to a causal pathogen, so more information should be elicited. Given the presence of fever and bloody stool, giving empiric antibiotics against the most common pathogens is recommended; ciprofloxacin is the antibiotic of choice. Providing clear instructions for hydration requirements and follow-up is essential to ensure appropriate therapy and resolution of the condition.

Case 3

Case 3 involves a patient with several days of diarrhea after hospitalization and antibiotic use. There is no indication for emergency transfer for acute care. When the clinician applies the algorithm discussed here, this raises concern for nosocomial diarrhea. In addition to common viral and bacterial sources of diarrhea, *C. difficile* infection and drug-induced diarrhea should be high on the differential diagnosis. Discontinuation of the current

"Applying the diagnostic strategies outlined here allows the urgent care provider to rapidly identify critical illness that merits transfer...."

antibiotic regimen is indicated, along with ordering stool studies including *C. difficile* toxins. Empiric therapy with metronidazole is indicated; oral vancomycin is an empiric alternative. Ensuring the availability of appropriate resources for follow-up is essential to ensure appropriate therapy and symptom resolution.

Case 4

Case 4 gives historical clues that are concerning for a protozoal source of infectious diarrhea. These clues include hiking and likely exposure to contaminated water. Stool analysis for ova and parasites and direct immunofluorescence staining, if available, are indicated. Metronidazole should be prescribed, and follow-up should be arranged to ensure resolution, with repeat stool analysis done as needed.

Conclusion

Applying the diagnostic strategies outlined here allows the urgent care provider to rapidly identify critical illness that merits transfer of the patient to an acute-care setting, narrow the differential diagnosis for diarrheal illness, avoid unnecessary testing, and provide appropriate therapy to limit disease duration and progression. It is through algorithms such as these that urgent care centers provide the efficient and rewarding medical care for which they are known.

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Practice Management

After Signing the Lease: Ensuring a Successful Build-Out of Your Urgent Care Center

Urgent message: This exclusive interview with Brent Johnson, Vice President of Midland General Contractors, focuses on dealing with general contractors, time lines, the permit process, build-out costs, and common pitfalls when setting up a new urgent care center.

ALAN A. AYERS, MBA, MAcc

Introduction

II ocation, location, location" has long been the success mantra of the retail and service industries. Because Lurgent care centers are a consumer-facing delivery channel for health care, location is also a key success determinant in that field. High traffic counts, good signage visibility, high density of households with demographics that historically use urgent care, and adjacent food stores, drugstores, and wholesale store drawing consumers to an area are all considerations when selecting a site for an urgent care center. Although a good site is critical, however, many urgent care entrepreneurs skip straight from site selection in their business plans to operational execution, paying little attention to the critical path in between—which is the design, construction, and finishing of the urgent care facility. Brent Johnson, Vice President of Midland General Contractors, provides insights on what happens after the lease is signed.

Alan A. Ayers, MBA, MAcc, is Practice Management Editor of the *Journal* of Urgent Care Medicine, a member of the board of directors of the Urgent Care Association of America, and Vice President of Strategic Initiatives for Practice Velocity. Brent Johnson is Vice President of Midland General Contractors, a national design-build firm specializing in urgent care centers that is based in Rockford, Illinois. Midland General Contractors has teamed with CASCO Diversified Corporation, a national architectural-engineering firm headquartered in St. Louis, Missouri. CASCO is represented by Steve Dahms, Business Development Manager.



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Interview

Alan Ayers: What are the next steps after an urgent care operator signs a lease on a new space? Please describe the high-level process in terms of selecting an architect and contractor, getting permits, building out, and preparing to open the facility. PromptMed Urgent Care in Waukegan, Illinois, occupies a former Blockbuster video store in the end cap of a busy community shopping center anchored by a Jewel-Osco supermarket and near such high-traffic retailers as Starbucks, Walgreens, and Verizon Wireless. Photos courtesy of Midland General Contractors.



Brent Johnson: The process typically entails design of the physical space, including finishes like floor and wall coverings, lighting, and millwork. Furnishings, fixtures, and equipment (FF&E) and signage must be selected and sourced. Before any construction can begin, the plans must be reviewed by the municipality. Once all permits are secured, build-out begins with demolition of the existing space, construction of the new space, and installation of FF&E, computer wiring, and x-ray. Various inspections for building code enforcement and fire safety have to occur before a certificate of occupancy can be issued.

Prior to signing a lease, you should have a pretty good idea who you are going to work with to design and construct your urgent care center, based on referrals, reputation, and experience. You should have a preliminary design and the initial control budget in place. Your contractor will charge a fee to develop these items, and these fees should be part of the control budget, not in addition to the control budget.

Instead of hiring a project manager, an architect, and a contractor separately, consider instead hiring an integrated design-build firm that can offer a complete turnkey project to include preliminary services; complete architectural, mechanical, and interior design; permitting; exterior and interior signs; information technology design; and lead shielding. A good contractor will offer an extended warranty period and lifetime support.

Ayers: How does the start-up urgent care opening its first center go about finding a contractor? What

traits, skills, and capabilities should an urgent care operator look for when hiring a general contractor? *Johnson:* When considering a contractor for an urgent care project, it is wise to partner with a firm in touch with this specific industry and who is knowledgeable about and experienced in the design and construction of urgent care centers. Select a contractor who understands the day-to-day operations of a center, patient comfort and security, clinical workflow, and necessary design features for specialty rooms such as procedure, x-ray, and occupational medicine (including drug testing).

Your selected contractor should understand how an urgent care center is classified by the International Building Code, the National Electrical Code, and the National Fire Protection Association as it pertains to nonambulatory outpatient medical care. This is how the local municipality will look at a plan while reviewing for permits. Classifying an urgent care center incorrectly could have a substantial impact on overall costs and required design standards. Look for recommendations from other urgent care operators and consider value, credentials, and reputation when making your final decision.

Ayers: What is the time line for construction of an urgent care center, and what variables impact that time line? What steps can the urgent care operator take to accelerate the construction time line?

Johnson: The design and permitting process can vary depending on the requirements of the municipality. The building permit process can range from 4 to 12 weeks, and depending on the size of the space, 4 to 8 weeks is also typical for construction. It is possible to decrease these time lines by partnering with a contractor who may have template clinic designs that can easily be adapted to the length and width of a specific tenant space, often allowing for a complete set of plans to be ready for permitting in as few as 10 days.

Product selection and associated lead times of these products can have an effect on the construction time line. Have an idea in mind, a look for your clinic, and if you are comfortable with your contractor and the proposed budget or "not to exceed" contract, submit your plans for permitting and establish your finished-product schedule while waiting for permits. This can save a week or two on the overall time frame. Overtime pay for workers is always an option, if a budget allows.

Ayers: What permits, licenses, reviews, and inspections are generally required when building out space for an urgent care center? What impact does compliPhysicians Urgent Care, known as Physicians Immediate Care in Illinois, operates 33 locations in the Midwest. In December 2013, the company developed a prototype center in Elkhart, Indiana (Figure 5), providing a blueprint with specifications for finishes, furnishings, and fixtures that has been applied to the 12 additional centers that the company has opened since that time. Photos courtesy of Midland General Contractors.



Figure 5. Front entrance of Physicians Urgent Care.



Figure 6. Reception area inside Physicians Urgent Care.



Figure 7. Nurses' station inside Physicians Urgent Care.

ance with local building codes have on the construction time line, and how can an urgent care operator mitigate the risk of delays due to permitting? *Johnson:* In most cases, local county or village or city permitting is all that is required; however, there are

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some states that do require a state design approval and release prior to local approvals, which can add significant time to the permitting process. Reviews and approval by the fire department or an independent agency working with the fire department are usually necessary and will often confirm the need for a firesuppression system and possibly a fire-alarm system, which will impact both schedule and budget. Your contractor should be aware of the requirements and should be capable of navigating this process efficiently—there is no way around it—and should also be capable completing the work and obtaining the necessary inspections to obtain the certificate of occupancy.

Ayers: How much does build-out generally cost? Any recommendations for saving money in the process? *Johnson:* Build-out costs can vary depending on several factors, including geographic location and associated labor rates, size of clinic, interior and or exterior finish levels, and local code requirements. Generally a potential urgent care operator should expect to spend around \$100 to \$120 per square foot depending on those factors and the additional levels of service included in a contractor's proposal.

These additional services could include complete architectural and mechanical design service, installation of information technology infrastructure, exterior and interior signs, installation of owner-provided medical equipment, and x-ray suite construction. These ancillary services should be offered by a qualified urgent care design-build contractor.

Efficient design for construction accompanied by the selection of products readily available can save both time and money when constructing an urgent care center. Establish a reasonable budget that is based on recommendations from industry professionals, and work with your contractor to develop the site to fit your needs and your budget.

Ayers: What are some common pitfalls that urgent care operators encounter when building out a center, and how can these be avoided?

Johnson: First, complete due diligence. If your time frame allows, engage a contractor early, before signing a lease, to confirm that the needed services are in place, as specified in the lease. Landlord-provided items such as size and location of electric service, size and location of water service, and size and location of the rooftop heating and cooling units, if incorrect, could add tens of thousands of dollars to a build-out budget.

Second, do not overbuild. Assuming that the width of the space is adequate, a properly designed 3200- to 4000-square-foot clinic can include 5 or 6 examination rooms, 1 procedure room, 1 occupational medicine and testing room, a full-size x-ray suite, a laboratory, a large center-core nurses' station, and all of the common areas, such as the waiting room, reception area, and break room.

Third, in regard to scheduling, have your contractor develop a schedule to include the delivery dates of the owner-provided items. Delivering furnishings and supplies early will only slow down the completion of the space and risk damage to these items. If there are products that have to be installed by the contractor, set up a separate delivery for them.

Ayers: What other suggestions do you have for urgent care operators to ensure a smooth transition from signing the lease to opening the center?

Johnson: Trust the consultants and professionals in organizations such as the Urgent Care Association of America, as they have a better understanding of the urgent care industry. Establish a relationship with your contractor and encourage open communication through emails, texting, and weekly face-to-face meetings to discuss updated budgeting and scheduling issues. Be upfront about your budget and time line. With a "not to exceed" construction contract, all costs should be shared throughout the process to determine if dollars should be reallocated when a particular line item comes in under or over budget. Using a cloud-based file-sharing site is a good recommendation, as is keeping progress photos and warranty documents available for all team members to view.

The lowest price is not necessarily the best value. Selecting a contractor only on the basis of lowest price increases your risk of project failure and higher potential costs down the road.

Conclusion

A convenient, welcoming, and efficient physical facility determines how well an urgent care center attracts patients through its doors and influences the quality of experience and clinical outcomes that the center delivers. Although facility design, permitting, construction, and furnishing may be one-time activities, they set the stage and impact day-to-day operations for the life of the center. Therefore, before embarking on any urgent care venture, it is important to understand and have a plan for working with architects and contractors to ensure success.

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Impact of a Pharmacist-Provided Comprehensive Medication Review Service for Urgent Care Patients

Urgent message: Urgent care centers are encouraged to meet best practices for communication during transitions of care. Partnering with pharmacists may optimize medication therapy for patients, helping fulfill these best practices.

JENNIFER A. FLAVIN, PharmD, CHRISTOPHER G. GREEN, PharmD, STEPHANIE C. COOK, DO, and STUART J. BEATTY, PharmD, BCACP

Abstract

Objective: This study aimed to (1) evaluate the impact of a pharmacist-provided comprehensive medication review (CMR) service on medication therapy appropriateness, safety, efficacy, and adherence for urgent care patients and (2) identify the workflow considerations required for incorporation of the service in an urgent care practice. *Methods:* In this prospective study of a nonrandomized convenience sample, pharmacists reviewed the electronic medical records of scheduled urgent care patients to identify those with at least 4 chronic medications and 1 chronic disease state. On completion of the

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patients' urgent care visit, clinic staff members recruited eligible patients for a pharmacist-provided CMR within the following 28 days. CMR interventions were communicated to the patient's primary-care provider. A followup phone call to the patient 1 week after the CMR visit and a chart review 1 month after the visit were completed to determine the acceptance of interventions by the patient and provider, respectively. Descriptive statistics were used to report primary and secondary outcomes. *Results:* In the 28-week study, 76 patients accepted the offer for a CMR. Of those, 29 patients (38%) completed their CMR and consented for inclusion in the study. Pharmacists identified a total of 166 interventions. These interventions addressed issues of appropriateness (44%), adherence (23%), efficacy (20%), and safety (13%). *Conclusion:* Results demonstrate optimization of medication therapy for urgent care patients through a pharmacist-provided CMR service. These findings may help support future partnerships between pharmacists and urgent care practices.

Introduction

t is predicted that almost 52,000 additional primarycare providers (PCPs) will be required to serve the health-care needs of the U.S. population in the next 10 years.¹ This shortage, combined with increased demand for emergency department (ED) services, has led to an increase in the use of urgent care centers and retail clinics as cost-effective and time-saving options for care. A 2010 comparison of visits between urgent care, retail clinics, and EDs determined that a significant portion of ED visits were for nonemergency conditions. Researchers estimated that treating these conditions at urgent care centers or retail clinics instead of in an ED could save up to \$4.4 billion in health costs annually.² In response to this opportunity, 50 to 100 new walk-in, stand-alone urgent care centers are opening every year, according to the American Academy of Urgent Care Medicine.¹

With the increase in use of urgent care centers comes a need for quality standards for communication from the urgent care center to the primary-care office during transitions of care. In 2008, a national survey found that one-third of urgent care providers did not send information to their patients' PCPs and that those who communicated did not do so consistently. In the same year, the Centers for Medicare & Medicaid Services (CMS) called for the design of best practices for urgent care communication during patient-care transitions to EDs or back to primary care. This set of standards, the CMS Best Practices for Urgent Care Transitions, was published in July 2014 and requires that at the end of each urgent care visit, as a patient transitions back into primary care, clinical information must be sent to the patient's PCP, medication reconciliation must be completed, and the patient must be provided with effective education about their therapy. To comply with these standards, medication reconciliation should include identification of potential medication errors; explanation of which medications should be stopped, started, or adjusted; and preparation of an accurate list of medications to be given to the patient and provider. Additionally, patients must be educated about the importance of longitudinal care and referred to a PCP if they do not already have one.³

University Health Services is an interprofessional team-based clinic composed of physicians, nursepractitioners, pharmacists, and nurses who provide urgent care services to employees of the Ohio State University (OSU). The urgent care service is a benefit of the OSU health plan used by approximately 80 employees weekly. In addition to diagnosis and triage of acute needs, these urgent care visits serve as a touchpoint for patients with chronic medical conditions and medications who may not have adequate medication management or who may experience fragmented care. Clinical pharmacists at University Health Services offer a comprehensive medication review (CMR) as standard of care to patients prescribed multiple chronic medications, to patients with multiple diagnosed chronic disease states, or on referral from the urgent care physician.

Pharmacist-provided medication reviews have demonstrated positive effects on clinical outcomes, adherence to medication therapy, hospital readmission rates, mortality, patient satisfaction, and cost savings.^{4,5} By definition, a CMR is a component of a medication therapy management service that includes an assessment of all medication therapies with identification of any medication-related problems, preparation of a personal medication record for the patient, a medicationrelated action plan for patient self-management, and documentation of service provided and recommended interventions to the PCP and other providers, as appropriate.⁶ Figure 1 illustrates the overlap in elements of a medication therapy management service and these best practices for care transitions. Although a CMR can lead to improved patient outcomes, there is little information in the literature regarding the impact of CMR in the urgent care setting.

Study Purpose

We conducted a study to evaluate the impact of a pharmacist-provided CMR service on medication therapy appropriateness, safety, efficacy, and adherence for urgent care patients and to identify the workflow considerations required for incorporation of the service in an urgent care practice.

Methods

Ours was a prospective interventional 6-month pilot study of a nonrandomized convenience sample. The project was approved by the OSU institutional review board.

Study investigators screened the electronic health records (EHRs) of all patients scheduled for same-day urgent care appointments in an employeebased clinic to identify those who were eligible for the CMR service. To be eligible for participation, patients were required to take 4 or more chronic medications, have 1 or more chronic disease states, be at least 18 years of age, speak English as their primary language, have OSU health insurance, and have no documentation of a CMR



in their EHR in the preceding year. Eligible patients were flagged on the clinic schedule for recruitment. Clinic staff members offered eligible patients the opportunity to review their medications with a pharmacist on completion of their urgent care visit. Patients who accepted the offer for a CMR were scheduled for the encounter by frontdesk staff members. CMR encounters were encouraged to be completed immediately after the urgent care visit. Patients unable to complete the CMR immediately after the urgent care visit were asked to schedule an appointment for a CMR within the 28 days that followed.

At the time of their CMR encounter, the patient met with a pharmacist to review all of their medications, including any changes made during the urgent care encounter. All medications were screened for a documented indication, effectiveness in treating the indication, potential for safety issues, and patient adherence. At the end of the CMR visit, the patient was provided with a medication-related action plan that included any interventions made directly with the patient and an updated personal medication record. When applicable, documented interventions were routed to the patient's prescriber in addition to the summary of the CMR visit. Sidebar 1 summarizes an example CMR encounter with a pharmacist. Patients received a followup phone call 1 week after their CMR encounter to assess whether interventions made with the patient were accepted. One month after the CMR encounter, researchers reviewed the patient's EHR to determine if interventions made with the provider were accepted.

Interventions were grouped by type of drug-related problem addressed and were categorized into those addressing medication therapy indication, safety, efficacy, and adherence. Interventions categorized as addressing indication for medication included untreated medical condition, unnecessary therapy, suboptimal drug, duplicate therapy, preventative therapy needed, immunization needed, and over-the-counter therapy recommendation. Interventions categorized as addressing safety of medication therapy included adverse drug reaction, drug interaction, contraindication, dose too high, needs monitoring for safety, and duration of therapy too long. Interventions categorized as addressing efficacy of medication therapy included dose too low, needs monitoring for efficacy, and cost-efficacy. Interventions categorized as addressing patient adherence to medication therapy included overuse, underuse, and inappropriate administration. A single researcher categorized interventions for consistency across CMR encounters that were completed by 3 different pharmacists.

The determination of whether a provider was the most appropriate recipient of an intervention was based on the need for a prescription or other order, whether consultation with the prescriber was necessary, and whether it was more suitable for the intervention to be addressed at a future primary-care visit for continuity of care. For example, if an indication for an immunization was identified, patients were given the opportunity to have the vaccine administered during their CMR encounter under a standing protocol with the medical director. Interventions regarding indication for an immunization were made with the PCP if the patient was unable to receive the immunization at the time of

Sidebar 1. Example Comprehensive Medication Review with a Pharmacist

A 58-year-old woman presented to the urgent care center for sinus congestion.

Medications	Past Medical History
Alendronate, 70 mg weekly	Osteoporosis
Lisinopril, 5 mg daily	Hypertension
Saline nasal spray	
Calcium, 500 mg twice daily	
Vitamin D, 400 units twice daily	

While rooming her for the urgent care visit, the nurse offered her a comprehensive medication review (CMR) with a pharmacist. The patient agreed and returned 2 days later for the scheduled appointment with the pharmacist.

During the CMR, the pharmacist completed medication reconciliation, asking open-ended questions to assess how the patient was taking and tolerating her medications. Through this process, the pharmacist found that the patient had stopped taking her alendronate because of heartburn. Further questioning revealed that she had not been taking the medication correctly and that she needed education about the medication's mechanism of action.

Review of the patient's electronic health record indicated that her blood pressure was elevated at the CMR encounter and during the preceding urgent care visit. The patient reported that her blood pressure readings had been elevated on her last several trips to the pharmacy as well.

On completion of the CMR, the pharmacist provided the patient with an updated personal medication list and a medication-related action plan, instructing her to take her alendronate tablets in the morning on an empty stomach with a full glass of water and to remain upright for 30 minutes afterward. The pharmacist sent a summary of clinical information to the patient's primary-care provider, including the recommendation that the provider consider increasing the dose of her lisinopril in response to elevated blood pressure readings.

the CMR encounter. When this occurred, the outcome from the prescriber was recorded rather than the outcome from the patient.

Results

Sample Characteristics and Recruitment

During the 24-week study period, 1546 urgent care visits

Table 1. Baseline Characteristics of Study Participants (n = 29)

Value
48.8 (12.0)
5 (17)
24 (83)
19 (65)
6 (21)
2 (7)
2 (7)

were completed. Of the 274 urgent care patients who met the eligibility criteria for a CMR, 138 patients were offered a CMR. A total of 76 patients agreed to a CMR, and 29 of those completed the CMR within 28 days of their urgent care visit and consented for inclusion in the study.

Table 1 provides an overview of demographic information collected. The majority of participants were female and white and had a mean age of 48.8 years (SD, 12.0 years). Patients who completed a CMR took an average of 8.4 (SD, 3.2) chronic medications and had an average of 3.8 (SD, 1.7) chronic medical conditions. The average time elapsed since the last primary-care visit was 7.6 (SD, 7.1) months. The average time elapsed from urgent care visit to CMR visit was 10.3 (SD, 8.8) days, with only 14% of patients choosing to complete their CMR immediately after their urgent care visit. The average time spent in the CMR visit was 42.4 (SD, 21.6) minutes.

Comprehensive Medication Review Interventions Identified

In the 29 CMR encounters, pharmacists identified a total of 166 interventions, with a mean of 5.7 (SD, 3.4) interventions per patient. These interventions were classified according to type (**Figure 2**) as addressing indication (44%), adherence (23%), efficacy (20%), and safety (13%). The most common interventions made overall were indication for immunization (indication), underuse (adherence), and need for monitoring for efficacy (efficacy).

Outcomes of Comprehensive Medication Review Interventions with Patients

Ninety-four of the 166 total interventions (57%) were made directly with patients (Figure 2), with the most

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Low incidence of adverse events—The most common adverse reactions occurring in patients taking SIVEXTRO® (tedizolid phosphate): nausea (8%), headache (6%), diarrhea (4%), vomiting (3%), and dizziness (2%)

Potency—Consistent antimicrobial activity against susceptible Gram-positive bacteria, including MRSA

Indication: SIVEXTRO is an oxazolidinone-class antibacterial indicated for the treatment of adults with acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following Gram-positive microorganisms: *Staphylococcus aureus* (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus anginosus* group (including *Streptococcus anginosus*, *Streptococcus intermedius* and *Streptococcus constellatus*), and *Enterococcus faecalis*.

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

Selected Important Safety Information

Patients with neutropenia: The safety and efficacy of SIVEXTRO in patients with neutropenia (neutrophil counts <1000 cells/mm³) have not been adequately evaluated. In an animal model of infection, the antibacterial activity of SIVEXTRO was reduced in the absence of granulocytes. Alternative therapies should be considered when treating patients with neutropenia.

Clostridium difficile-associated diarrhea (CDAD), ranging from mild diarrhea to fatal colitis, has been reported with nearly all systemic antibacterial agents, including SIVEXTRO. Evaluate all patients who present with diarrhea following antibiotic use. Careful medical history is necessary because CDAD has been reported to occur more than two months after the administration of antibacterial agents. If CDAD is suspected or confirmed, antibacterial use not directed against *C. difficile* should be discontinued, if possible.

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

Before prescribing SIVEXTRO, please read the accompanying Brief Summary on adjacent pages.



IV=intravenous.



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INDICATIONS AND USAGE

Acute Bacterial Skin and Skin Structure Infections SIVEXTRO[®] is an oxazolidinone-class antibacterial indicated for the treatment of acute bacterial skin and skin structure infections (ABSSSI) in adults caused by susceptible isolates of the following Gram-positive microorganisms: *Staphylococcus aureus* (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), *Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus anginosus* Group (including *Streptococcus anginosus, Streptococcus intermedius,* and *Streptococcus constellatus*), and *Enterococcus faecalis.*

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

CONTRAINDICATIONS None.

WARNINGS AND PRECAUTIONS

Patients with Neutropenia The safety and efficacy of SIVEXTRO in patients with neutropenia (neutrophil counts <1000 cells/mm³) have not been adequately evaluated. In an animal model of infection, the antibacterial activity of SIVEXTRO was reduced in the absence of granulocytes. Alternative therapies should be considered when treating patients with neutropenia and acute bacterial skin and skin structure infection.

Clostridium difficile-Associated Diarrhea Clostridium difficile-associated diarrhea (CDAD) has been reported for nearly all systemic antibacterial agents including SIVEXTRO, with severity ranging from mild diarrhea to fatal colitis. Treatment with antibacterial agents can alter the normal flora of the colon and may permit overgrowth of *C. difficile*. *C. difficile* produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of C. difficile cause increased morbidity and mortality, as these infections can be refractory to antibacterial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary because CDAD has been reported to occur more than two months after the administration of antibacterial agents. If CDAD is suspected or confirmed, antibacterial use not directed against C. difficile should be discontinued, if possible. Appropriate measures such as fluid and electrolyte management, protein supplementation, antibacterial treatment of C. difficile, and surgical evaluation should be instituted as clinically indicated.

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

ADVERSE REACTIONS

Adverse Reactions in Clinical Trials Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in clinical trials of a drug cannot be compared directly to rates from clinical trials of another drug and may not reflect rates observed in practice. Adverse reactions were evaluated for 1050 patients treated with SIVEXTRO and 662 patients treated with the comparator antibacterial drug in two Phase 2 and two Phase 3 clinical trials. The median age of patients treated with SIVEXTRO in the Phase 2 and Phase 3 trials was 42 years, ranging between 17 and 86 years old. Patients treated with SIVEXTRO were predominantly male (65%) and White (82%).

Serious Adverse Reactions and Adverse Reactions Leading to Discontinuation Serious adverse reactions occurred in 12/662 (1.8%) of patients treated with SIVEXTRO and in 13/662 (2.0%) of patients treated with the comparator. SIVEXTRO was discontinued due to an adverse reaction in 3/662 (0.5%) of patients and the comparator was discontinued due to an adverse reaction in 6/662 (0.9%) of patients.

Most Common Adverse Reactions The most common adverse reactions in patients treated with SIVEXTRO were nausea (8%), headache (6%), diarrhea (4%), vomiting (3%), and dizziness (2%). The median time of onset of adverse reactions was 5 days for both SIVEXTRO and linezolid with 12% occurring on the second day of treatment in both treatment groups. The following table lists selected adverse reactions occurring in at least 2% of patients treated with SIVEXTRO in clinical trials.

Selected Adverse Reactions Occurring in $\ge 2\%$ of Patients Receiving SIVEXTRO in the Pooled Phase 3 ABSSSI Clinical Trials

	Pooled Phase 3 ABSSSI Clinical Trials		
Adverse Reactions	SIVEXTRO (200 mg oral/intravenous once daily for 6 days) (N=662)	Linezolid (600 mg oral/intravenous twice daily for 10 days) (N=662)	
Gastrointestinal Disorders			
Nausea	8%	12%	
Diarrhea	4%	5%	
Vomiting	3%	6%	
Nervous System Disorder			
Headache	6%	6%	
Dizziness	2%	2%	

The following selected adverse reactions were reported in SIVEXTRO-treated patients at a rate of less than 2% in these clinical trials: *Blood and Lymphatic System Disorders*: anemia; *Cardiovascular*: palpitations, tachycardia; *Eye Disorders*: asthenopia, vision blurred, visual impairment, vitreous floaters; *General Disorders and Administration Site Conditions*: infusion-related reactions; *Immune System Disorders*: drug hypersensitivity; *Infections and Infestations: Clostridium difficile* colitis, oral candidiasis, vulvovaginal mycotic infection; *Investigations*: hepatic transaminases increased, white blood cell count decreased; *Nervous System Disorders*: hypoesthesia, paresthesia, VIIth nerve paralysis; *Psychiatric Disorders*: insomnia; *Skin and Subcutaneous Tissue Disorders*: pruritus, urticaria, dermatitis; *Vascular Disorders*: flushing, hypertension.

Laboratory Parameters Hematology laboratory abnormalities that were determined to be potentially clinically significant in the pooled Phase 3 ABSSSI clinical trials are provided in the table below.

Potentially Clinically Significant Lowest Laboratory Values in the Pooled Phase 3 ABSSSI Clinical Trials

	Potentially Clinically Significant Values*†	
Laboratory Assay	SIVEXTRO (200 mg oral/intravenous once daily for 6 days) (N=618) [‡]	Linezolid (600 mg oral/intravenous twice daily for 10 days) (N=617)
Hemoglobin (<10.1 g/dL [M]) (<9 g/dL [F])	3.1%	3.7%
Platelet count (<112 × 10 ³ /mm ³)	2.3%	4.9%
Absolute neutrophil count $(<0.8 \times 10^3/\text{mm}^3)$	0.5%	0.6%

M = male; F = female

* <75% (<50% for absolute neutrophil count) of lower limit of normal (LLN) for values normal at baseline

⁺ Represents lowest abnormal post-baseline value through the last dose of active drug

* Number of patients with non-missing laboratory values

Myelosuppression Phase 1 studies conducted in healthy adults exposed to SIVEXTRO for 21 days showed a possible dose and duration effect on hematologic parameters beyond 6 days of treatment. In the Phase 3 trials, clinically significant changes in these parameters were generally similar for both treatment arms (see the table above).

Peripheral and Optic Neuropathy Peripheral and optic neuropathy have been described in patients treated with another member of the oxazolidinone class for longer than 28 days. In Phase 3 trials, reported adverse reactions for peripheral neuropathy and optic nerve disorders were similar between both treatment arms (peripheral neuropathy 1.2% vs. 0.6% for tedizolid phosphate and linezolid, respectively; optic nerve disorders 0.3% vs. 0.2%, respectively). No data are available for patients exposed to SIVEXTRO for longer than 6 days.

USE IN SPECIFIC POPULATIONS

Pregnancy. Pregnancy Category C There are no adequate and wellcontrolled studies of SIVEXTRO in pregnant women. SIVEXTRO should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. In embryo-fetal studies, tedizolid phosphate was shown to produce fetal developmental toxicities in mice, rats, and rabbits. Fetal developmental effects occurring in mice in the absence of maternal toxicity included reduced fetal weights and an increased incidence of costal cartilage anomalies at the high dose of 25 mg/kg/day (4-fold the estimated human exposure level based on AUCs). In rats, decreased fetal weights and increased skeletal variations including reduced ossification of the sternebrae, vertebrae, and skull were observed at the high dose of 15 mg/kg/day (6-fold the estimated human exposure based on AUCs) and were associated with maternal toxicity (reduced maternal body weights). In rabbits, reduced fetal weights but no malformations or variations were observed at doses associated with maternal toxicity. The no observed adverse effect levels (NOAELs) for fetal toxicity in mice (5 mg/kg/day), maternal and fetal toxicity in rats (2.5 mg/kg/day), and rabbits (1 mg/kg/day) were associated with tedizolid plasma area under the curve (AUC) values approximately equivalent to (mice and rats) or 0.04-fold (rabbit) the tedizolid AUC value associated with the oral human therapeutic dose. In a pre-postnatal study, there were no adverse maternal or offspring effects when female rats were treated during pregnancy and lactation with tedizolid phosphate at the highest tested dose of 3.75 mg/kg/day, with plasma tedizolid exposure (AUC) approximately equivalent to the human plasma AUC exposure at the clinical dose of 200 mg/day.

Nursing Mothers Tedizolid is excreted in the breast milk of rats. It is not known whether tedizolid is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when SIVEXTRO is administered to a nursing woman.

Pediatric Use Safety and effectiveness in pediatric patients below the age of 18 have not been established.

Geriatric Use Clinical studies of SIVEXTRO did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. No overall differences in pharmacokinetics were observed between elderly subjects and younger subjects.

OVERDOSAGE

In the event of overdosage, SIVEXTRO should be discontinued and general supportive treatment given. Hemodialysis does not result in meaningful removal of tedizolid from systemic circulation.

CLINICAL PHARMACOLOGY

Drug Interaction Studies

Drug Metabolizing Enzymes Transformation via Phase 1 hepatic oxidative metabolism is not a significant pathway for elimination of SIVEXTRO. Neither SIVEXTRO nor tedizolid detectably inhibited or induced the metabolism of selected CYP enzyme substrates. No potential drug interactions with tedizolid were identified in *in vitro* CYP inhibition or induction studies. These results suggest that drug-drug interactions based on oxidative metabolism are unlikely.



Membrane Transporters The potential for tedizolid or tedizolid phosphate to inhibit transport of probe substrates of important drug uptake (OAT1, OAT3, OATP1B1, OATP1B3, OCT1, and OCT2) and efflux transporters (P-gp and ABCG2 [also known as BCRP]) was tested *in vitro*. No clinically significant inhibition of any transporter was observed at tedizolid circulating plasma concentrations up to the C_{max} .

Monoamine Oxidase Inhibition Tedizolid is a reversible inhibitor of monoamine oxidase (MAO) *in vitro*. The interaction with MAO inhibitors could not be evaluated in Phase 2 and 3 trials, as subjects taking such medications were excluded from the trials.

Adrenergic Agents Two placebo-controlled crossover studies were conducted to assess the potential of 200 mg oral SIVEXTRO at steady state to enhance pressor responses to pseudoephedrine and tyramine in healthy individuals. No meaningful changes in blood pressure or heart rate were seen with pseudoephedrine. The median tyramine dose required to cause an increase in systolic blood pressure of \geq 30 mmHg from pre-dose baseline was 325 mg with SIVEXTRO compared to 425 mg with placebo. Palpitations were reported in 21/29 (72.4%) subjects exposed to SIVEXTRO compared to 13/28 (46.4%) exposed to placebo in the tyramine challenge study.

Serotonergic Agents Serotonergic effects at doses of tedizolid phosphate up to 30-fold above the human equivalent dose did not differ from vehicle control in a mouse model that predicts serotonergic activity. In Phase 3 trials, subjects taking serotonergic agents including antidepressants such as selective serotonin reuptake inhibitors (SSRIs), tricyclic antidepressants, and serotonin 5-hydroxytryptamine (5-HT1) receptor agonists (triptans), meperidine, or buspirone were excluded.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility Long-term carcinogenicity studies have not been conducted with tedizolid phosphate. Tedizolid phosphate was negative for genotoxicity in all in vitro assays (bacterial reverse mutation (Ames), Chinese hamster lung (CHL) cell chromosomal aberration) and in all in vivo tests (mouse bone marrow micronucleus, rat liver unscheduled DNA synthesis). Tedizolid, generated from tedizolid phosphate after metabolic activation (in vitro and in vivo), was also tested for genotoxicity. Tedizolid was positive in an in vitro CHL cell chromosomal aberration assay, but negative for genotoxicity in other in vitro assays (Ames, mouse lymphoma mutagenicity) and in vivo in a mouse bone marrow micronucleus assay. In a fertility study, oral tedizolid phosphate had no adverse effects on the fertility or reproductive performance, including spermatogenesis, of male rats at the maximum tested dose (50 mg/kg/dav) with a plasma tedizolid AUC approximately 5-fold greater than the plasma AUC value in humans at the oral therapeutic dose. Tedizolid phosphate also had no adverse effects on the fertility or reproductive performance of adult female rats at doses up to the maximum tested (15 mg/kg/day). Plasma tedizolid exposure (AUC) at this NOAEL in female rats was approximately 4-fold higher than that in humans at the oral therapeutic dose.

Animal Toxicity and/or Pharmacology Repeated-oral and intravenous dosing of tedizolid phosphate in rats in 1-month and 3-month toxicology studies produced dose- and time-dependent bone marrow hypocellularity (myeloid, erythroid, and megakaryocyte), with associated reduction in circulating RBCs, WBCs, and platelets. These effects showed evidence of reversibility and occurred at plasma tedizolid exposure levels (AUC) \geq 6-fold greater than the plasma exposure associated with the human therapeutic dose. In a 1-month immunotoxicology study in rats, repeated oral dosing of tedizolid phosphate was shown to significantly reduce splenic B cells and T cells and reduce plasma IgG titers. These effects occurred at plasma tedizolid exposure levels (AUC) \geq 3-fold greater than the expected human plasma exposure associated with the therapeutic dose.

For more detailed information, please read the Prescribing Information.

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apy recommendation (indication). One week after the CMR encounter, patients reported accepting 76% of interventions and rejecting 2% of interventions; 22% of interventions had no response or no response could not be determined by a follow-up phone call (Figure 3).

Outcomes of Comprehensive Medication Review Interventions with Providers

Seventy-two of the 166 total interventions (43%) were made with prescribers (Figure 2), with the most common being need for immunization (indication), need for monitoring for efficacy (efficacy), and untreated medical condition (indication). One month after the CMR encounter, EHR review indicated that prescribers accepted 22% of interventions (Figure 3). For the remaining 78% of interventions, there was no response or no response could be determined by a follow-up chart review.

Discussion

Urgent care centers are used by patients with fragmented care who may benefit from medication management with a pharmacist. With an aging population and increasing burden of chronic conditions, prescription medication use has grown since the beginning of the 21st century.⁷ Whether patients have a PCP with limited accessibility or they do not have a PCP at all, some urgent care centers are providing preventative services as well as care for ongoing chronic conditions.⁸ All patients included in this study had a self-identified PCP, with most having consulted their PCP in the preceding 6 to 12 months. Despite this, and despite average of 8.4 chronic medications and 3.8 chronic medical conditions for each patient, pharmacists were able to identify an average of 6 interventions to

common being underuse (adherence), inappropriate administration (adherence), and over-the-counter ther-

optimize medication therapy for each patient included in the study. These interventions indicate an opportunity for optimization of medication therapy in the urgent care population.

More than half of the interventions made during the CMRs were resolved between the patient and pharmacist and communicated to the PCP. The majority of these interventions related to adherence and safety, allowing issues of nonadherence from medication underuse or inappropriate administration and adverse drug reactions to be corrected directly with the patient at the time of the visit. Interventions related to indication for drug therapy were split evenly between providers and patients, with over-the-counter medication therapy recommendations representing the most common intervention made with patients in this category. High acceptance rates for patient-addressed medication-related problems suggest that patients are receptive to pharmacist interventions in the urgent care setting.

The majority of interventions related to efficacy of medication therapy were made with prescribers, because they frequently involved a recommendation for an order to be placed. Documented acceptance rates of interventions made with prescribers were lower than for those made with patients, which may represent a limitation of the chosen follow-up methods. The large percentage of interventions made with providers that had no response suggests that review of the EHR 1 month after the CMR encounter did not often reveal the outcome of the intervention. Prescribers might or might not have been receptive to the recommendations or might have intended to address them at followup, but they did not document their response in the chart within a month of the communication. Although an extension of the follow-up period would impact the extent to which the outcome could be directly related to the intervention made during the CMR encounter, direct communication with prescribers through a phone call, instead of passive communication through the EHR, might have resulted in more documented responses.

The CMS Best Practices for Urgent Care Transitions³ were designed to improve partnerships between urgent care centers and PCPs, but they may also represent an opportunity for partnerships between urgent care practices and pharmacists. The pharmacist-provided CMR service included elements that met the best practice standards, including medication reconciliation and review, patient education and discharge instructions in the form of a medication-related action plan, and a summary of clinical information sent to the patient's PCP. Although recommendations were sent to prescribers directly along with the summary of the encounter, patients were also informed that their prescribers were

being contacted and were encouraged to discuss the issues identified in their medication-related action plan with their prescribers to achieve a resolution. Although the response rates from prescribers were low, some replied with a message of gratitude, indicating appreciation for the service and/or communication. A future direction for study would be to measure provider and patient satisfaction with the service.

Pharmacists complete CMRs in a variety of practice environments, including clinic settings, community pharmacies, long-term-care facilities, and health systems. In the urgent care setting, patients are often seen on a walk-in basis, with little opportunity for workup. The fastpaced nature of an urgent care practice can make incorporation of the CMS best practices for care transitions challenging. Pharmacists are uniquely trained to identify opportunities to optimize medication therapy and can complete a CMR with minimal preparation when necessary. Despite the option to be seen immediately after completion of their urgent care visit, only 4 of 29 patients in our study chose to complete their CMR the same day. Patients might have opted to schedule their CMR visit for another time so that they could return home or to work. Only 18% of the urgent care patients seen during the study period met the criteria of ≥ 4 chronic medications and ≥ 1 chronic disease state, which might be a factor of the age and general health status of the employee population. The single-payer, employee-based model of the clinic was a limitation of the study. Implementation of the CMR service in a more public urgent care setting may result in improved use of the service.

The small sample size was another limitation of the study. Only half of the patients who met eligibility criteria were offered a CMR with the pharmacist. This represents a barrier to incorporation of the service into the normal operations of an urgent care clinic. The pharmacists performing the study have many responsibilities outside of the CMR service. As a result, there was a heavy reliance on the nursing staff to recruit eligible patients for the service. Additionally, flagging of the clinic schedule might not have been the most effective way to signal clinic staff to recruit eligible patients. A contributing factor to the poor recruitment rate was a change in nursing and urgent care provider staff during the study. With consistent staffing and a designated pharmacist managing the service, patients could have been recruited more effectively.

Few urgent care centers have pharmacists on staff, because of the expense associated with employment of an additional health-care provider. Some avenues to help pay for a pharmacist include CMR reimbursement and

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value-based payment models. Completion of a CMR by a credentialed pharmacist is a reimbursable service under some health plans. Association of the interventions made during the CMRs with cost savings to the health plan is another future consideration for this study. Incorporation of pharmacists into the health-care team is further supported by the move toward a value-based payment structure, with pharmacist-provided medication therapy management associated with improved health-care quality and cost savings. Colleges of pharmacy seeking unique practice sites for training of student pharmacists and pharmacy residents may represent opportunities for collaboration. Additionally, urgent care centers and retail clinics are often located in close proximity to community pharmacies to allow for convenient medication dispensing for patients. These pharmacies are potential partners for shared services with the common goal to optimize medication therapy and communication during care transitions.

Conclusion

Urgent care center use by patients with chronic medical conditions and medications provides a unique opportunity for pharmacists to optimize medication therapy. The results of our study demonstrated the impact of a pharmacist-provided CMR service on medication therapy appropriateness, safety, efficacy, and adherence for urgent care patients. The provision of a CMR can help meet CMS standards through inclusion of elements of care coordination through transitions that may help support future partnerships between pharmacists and urgent care practices.

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Case Report

Rocky Mountain Spotted Fever: Dermatologic Manifestation of a Life-Threatening, Systemic Disease

Urgent message: Obtaining a detailed medical history is paramount for the early detection and treatment of Rocky Mountain spotted fever. Failure to acquire adequate patient information can lead to misdiagnosis and delayed treatment of this potentially life-threatening disease.

WHITNEY CRAMER, PA-C

Any dermatologic conditions such as rashes and eczema are encountered by urgent care providers on a daily basis. Often these conditions are diagnosed as contact dermatitis or are misdiagnosed, or the patient is referred to a specialist. There are a vast number of disease processes that include dermatologic symptoms very similar to common ailments such as poison ivy, contact dermatitis, and urticaria. Distribution and characteristics of lesions as well as recent environmental exposure provide valuable insight needed for early diagnosis and treatment of more serious, potentially life-threatening diseases such as Rocky Mountain spotted fever (RMSF). When the rash presents concurrently with fever, chills, and body aches, the presence of systemic disease process must be ruled out and expansion of the differential diagnosis should be considered.

Case Presentation

A 23-year-old man presents to the urgent care center

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with fever, myalgia, and sore throat that he has had for 1 week. The patient has just returned from a 2-week hike through the Appalachian Trail and is concerned, having Figure 1. An American dog tick (Dermacentor variabilis).



Commons. Image available from: https://commons.wikimedia.org/wiki/File: Dermacentor_variabilis,_U,_Back,_MD,_Beltsville_2013-07-08-19.15.11_ZS_PMax.jpg.)

had no reduction or resolution of symptoms. The patient then adds that he developed a mildly pruritic rash on his ankles 3 days earlier and that it has been progressively worsening. He reports that the preceding day, the rash had spread to his wrists and palms and that he awoke that morning with a similar rash on his lower back. The patient has taken Tylenol, Mucinex DM, and Benadryl but gained only minimal relief. He reports that he has had no contact with poison ivy and has sustained no mosquito bites, tick bites, or target lesion. He also reports that he has not experienced coughing, sinus congestion, rhinorrhea, or abdominal pain.

Observation and Findings

- Evaluation of the patient showed the following:
- Temperature: 100.2°F
- Respiratory rate: 14 breaths/min

- Pulse: 92 beats/min
- Blood pressure: 124/72 mm Hg

Physical examination reveals that the patient is aware and oriented and shows no signs of distress. Findings on a dermatologic examination are significant for diffuse, erythematous macules on the ankles, wrists, and palmar aspects of both hands, as well as on the lower back. His throat is mildly erythematous, associated with shotty anterior cervical lymphadenopathy. There are no other abnormal findings on examination.

Diagnostic Studies

A rapid strep test is performed to rule out Streptococcal pharyngitis. Results are negative. Blood work is then performed because of concern for tick-borne illnesses: Lyme antibodies/Western blot reflex test, RMSF immunoglobulin G (IgG) and IgM test, complete blood cell count with differential, and a basic metabolic panel. Findings are positive for RMSF antibody IgG, elevated at 1:342 (normal range, <1:64). Findings for all other laboratory tests are within normal limits.

Diagnosis and Follow-Up

The diagnosis is RMSF. Because of a high suspicion of RMSF, the patient is prescribed doxycycline, 100 mg orally twice daily for 14 days, before leaving the urgent care center. Six days after assessment, his laboratory results are available, and the patient returns to the urgent care center for follow-up. His fever and muscle aches have decreased, but his rash is still present. He is referred to the local hospital's department of infectious diseases for follow-up and monitoring for further complications.

Discussion

Etiology

RMSF is a potentially deadly tick-borne infection caused by the bacteria *Rickettsia rickettsii*. Ticks that may carry the bacteria include the American dog tick (*Dermacentor variabilis*; **Figure 1**), Rocky Mountain wood tick (*D. andersoni*), and brown dog tick (*Rhipicephalus sanguineus*; **Figure 2**). Transmission occurs after at least 24 hours of the tick being attached to a human, with most occurrences in the spring and summer. Although cases have been reported throughout the United States, 60% of all cases occur in North Carolina, Oklahoma, Arkansas, Tennessee, and Missouri^{1–3} (**Figure 3**).

Symptoms

Symptoms begin 2 to 14 days after tick bite and include





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Figure 3. Annual incidence of cases of Rocky Mountain spotted fever in 2010 in the United States, by state, per million persons. NN = not notifiable [in 2010].



fever, headache, nausea, vomiting, abdominal pain, muscle pain, and injection of the conjunctiva. Ninety

percent of people with tick bites also experience some sort of rash, usually appearing 2 to 5 days after they become febrile.¹ The RMSF rash may be atypical or vary depending on the progression of the disease. The most common dermatologic manifestation is erythematous, nonpruritic macules on the wrist, forearms, and ankles that spread to the palms, soles, and trunk. Petechiae, occurring in 35% to 60% of patients with tick bites, may be seen in the same distribution, but they are not usually present until later in the disease process, indicating a more severe infection.

Additional Testing

Early detection and treatment is vital because of the potentially fatal outcomes. If the disease is left untreated, there is a 23% mortality rate.² The bacteria R. rickettsii infects endothelial cells of blood vessels. Disturbance to the vessels potentially results in myocarditis, hepatitis, acute renal failure, and damage to other vital organs.⁴ Infection may not be detectable by blood work for the first few days after the appearance of symptoms, making a definitive diagnosis difficult that is based on laboratory findings at presentation. Therefore, diagnosis should be based on clinical findings. If RMSF is suspected, antibiotics should be started immediately after blood is drawn for laboratory tests. Never delay treatment pending laboratory results. Antibody titers to R. rickettsii are detectable by 7 to 10 days after onset of illness; they are undetectable in the first 7 days in 85% of patients.² The gold standard serologic test for RMSF is indirect immunofluorescence assay with R. rickettsii antigen. Blood for the first set of laboratory tests should be drawn as early in the disease as possible. In many cases, if RMSF is detected early enough, IgG immunofluorescence assay titers are either negative or low. Repeat laboratory tests should be performed 2 to 4 weeks later, when they will typically show a significant elevation in IgG antibody values. IgM antibodies are less specific and will also be elevated and remain elevated for months to years. If treatment is withheld until definitive laboratory results are reported, patients will not receive proper treatment for 2 to 4 weeks after onset of symptoms.²

Treatment

First-line treatment for RMSF is 100 mg of doxycycline every 12 hours for adults; for children, it is weight-based: 2.2 mg/kg twice a day for children weighing <45 kg. The standard duration of treatment is 7 to 14 days, varying with the extent of disease and manifestation of other vascular complications.⁵ In more severe cases, patients must

be hospitalized for treatment and management of complications from the bacteria and the detrimental effects to the vasculature. Treatment of RMSF represents a rare situation in which tetracycline is considered the treatment of choice for children, with benefits outweighing possible side effects. Studies by both the Centers for Disease Control and Prevention and the American Academy of Pediatrics Committee on Infectious Diseases demonstrated that treating children with doxycycline at the recommended dose and duration did not produce permanent teeth discoloration. Other broad-spectrum antibiotics have shown high failure rates, with sulfa drugs actually worsening the infection.⁶

Prevention

Patients should be advised to wear long sleeves and pants when hiking in rural areas. DEET (*N*,*N*-diethyl*meta*-toluamide) should be applied before they spend time outdoors, in order to repel ticks. Adults should also perform a full-body tick checks on themselves, their children, and their pets after spending time outdoors in areas known for RMSF.

Conclusion

When a patient presents with a rash in a distribution similar to that for RMSF (ankles, wrists, palms, or soles) in addition to experiencing a fever, muscle aches, or headache, the physician should suspect RMSF. Antibiotic therapy should begin immediately without waiting for laboratory results, with doxycycline being the first-line treatment. Diagnosis should be based on clinical findings and recent environmental exposure, confirmed by elevated IgG and IgM levels on an indirect immunofluorescence assay with *R. rickettsii* antigen.

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HEALTH LAW AND COMPLIANCE

Legal Implications of Integration of Hospitals and Urgent Care Centers

Ron Lebow, JD

Urgent message: As health systems and payors align their interests in the creation of accountable care organizations, hospitals that acquire or partner with urgent care centers must adopt a legal structure and an operating model that remain compliant with the federal Anti-Kickback Statute and the federal Stark law, and with other federal and state regulations.

Introduction

W ith the advent of the Patient Protection and Affordable Care Act (PPACA), the government recognized that it could not continue to indefinitely pay for a majority of the medical care in the United States without providing sticks and carrots to encourage cost savings, improved outcomes, reduced use of hospital emergency departments as primary-care offices, and reduced hospital readmission rates.

The concept of the *accountable care organization* (ACO) was thus devised at the Medicare level to pay the highest-cost providers a share of the savings they could achieve by addressing these cost drivers, while requiring them to meet certain quality thresholds and qualitative metrics as a precondition to payment. In an ACO, a local network of providers work together to coordinate the full continuum of care for Medicare fee-forservice beneficiaries within their provider network. Providers that meet performance standards or quality benchmarks and reduce per-beneficiary spending below target are entitled to receive a share of the savings (the Shared Savings Program).¹

Naturally, the highest-cost providers—hospitals—have the greatest to gain (and to lose) from ACOs, because they are the primary impetus for spending concerns. Second in cost is the physician fee-for-service payment system, which cannot be sustained indefinitely, given its built-in incentive to perform more and duplicate services across providers. Essentially, health



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care has become about controlling the greatest patient population by controlling the greatest number of physicians serving those patients—off the hospital site. Arguably, insurers led the charge, and states quickly followed suit by providing similar organizational certification as an ACO and incentives for the private insurance market. Among these incentives were limited exceptions to the imposition of Anti-Kickback Statute, the Stark law, and antitrust enforcement.² Nevertheless, because hospitals and health systems have sought to acquire off-site locations *without actually seeking ACO certification*, these laws still affect physician–hospital relationships:

- The Anti-Kickback Statute: The federal Anti-Kickback Statute³ makes it a criminal offense to knowingly offer, solicit, or receive any remuneration—the transfer of value, cash, or otherwise, including payments for equipment and services—directly or indirectly, overtly or covertly, to induce referrals of items or services reimbursable by a federal health-care program. When remuneration is paid to induce or reward referrals of items or services payable by a federal health-care program (i.e., Medicare and Medicaid), the Anti-Kickback Statute is violated. State law equivalents apply to all payors, including insurance and private-pay, as well as to workers' compensation. The workers' injury payment program is increasingly recognized as a viable source of patients for the urgent care market.
- The Stark law: With some exceptions, the Stark law⁴ prohibits physicians who have a financial relationship with an entity from referring certain types of items or services for which payment may be made under Medicare (referred to as Designated Health Services, or DHS), including radiology (e.g., x-rays and positron-emission tomography, computed tomography, and ultrasound images), clinical laboratory services, and inpatient and outpatient hospital services. State law equivalents apply to all payors for these

¹https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavings program/index.html

²https://www.ftc.gov/tips-advice/competition-guidance/industry-guidance/health-care ³http://oig.hhs.gov/compliance/physician-education/o1laws.asp ⁴https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index.html

HEALTH LAW AND COMPLIANCE

types of services, including insurance and private-pay, and further prohibit the submission of claims resulting from such a referral. If the professional entity working out of the center wishes to continue to bill and earn income for DHS conducted on-site at the urgent care center, then the Stark law requires that it qualify as a *true group*, as that term is strictly defined under the Stark law. The definition requires, among other criteria, legal organization under a single tax identification number with common benefits and unified business structure. Additionally, service providers must be primarily physicians constituting bona fide employees or owners of the professional entity, rather than mere independent contractors if used.

Penalties for violation of these laws include large fines, imprisonment, recoupment of past claims' payments, and even triple damages, along with potential for debarment from the Medicare program.

Common Models

The following are examples of mechanisms for control and participation by hospitals in urgent care centers. How they operate varies on the basis on state law, state licensure requirements, and the individual state enforcement environment:

Employment Model

In the straightforward employment model, the hospital employs all of the physicians who operate out of the urgent care center.

Captive Model

As a threshold matter, direct ownership of professional entities by a hospital is prohibited in most states-these entities must be owned by a physician. In a captive model, the professional entity issues all of its ownership interests to a single physician who is also an employee of the hospital. The captive model enables a hospital to work with a friendly entity owned by a physician loyal to the hospital's mission of serving the community. Further, the model ensures that his or her successor is equally aligned with the hospital. It eliminates the licensing and legal uncertainties associated with employment of physicians in private-practice offices who further the hospital's mission and coordinate care but who may not necessarily render clinical services or coverage in licensed hospital facilities. Ultimately, captive models enable the hospital to provide financial support in order to recruit physicians in its community on behalf of the professional entity. The structural, operational, and, to some degree, financial control over the captive entity, its owners, and its managers is then conveyed to the hospital by means of any number of documents and agreements, which can include

An administrative services agreement between the hospital and the captive entity to provide managerial support

- An employment agreement between the hospital and the physician-owner (pursuant to which the ownership of the captive entity can be transferred to another physician at any time, such as through a blank stock power or nominee agreement)
- A professional services agreement
- Staffing and coverage agreements and/or other relevant instruments

A hospital will charge a captive entity for any administrative services, personnel, space, equipment, and financing it provides.

Professional Services Agreement and Medical Directorship Models

The agreements just described can be coupled with any model. The professional services agreement (PSA) may constitute an agreement between the hospital or its captive professional entity and another physician or group providing staffing and services for the center. As a supplement to the PSA or in lieu thereof, the hospital or its captive entity may compensate a group or an individual physician for administrative and clinical oversight services involved in the day-to-day running of the center. The hospital will similarly charge for its own administrative services, personnel, equipment, space, and financing.

Comanagement Model

Under the comanagement model, the assets of the center, including space, leases, equipment, and nonprofessional personnel, will be contributed to a new joint-venture business entity in which the hospital will indirectly take ownership and contribute funds, and the founding members of the center will participate as owners. The purpose of such an arrangement is to recognize (and appropriately reward) medical groups and physicians for their efforts in developing, managing, and improving the quality and efficiency of a service line. Management service, leasing, financing, and other agreements may be entered into by the joint-venture entity, with the professional entity operating out of the center. PSAs and other agreements may also be contracted in accordance with the comanagement model. Comanagement services include

- Service line development
- Budget process management
- Business planning
- Medical director services
- Community relations and education
- Satisfaction surveys
- Clinical protocol development
- Ongoing assessment of the clinical environment
- Physician staffing
- Patient scheduling
- Staff scheduling and supervision

- Human resource management
- Case management
- Inventory management
- Credentialing

Legal Concerns

There is a risk of a finding of violation of the Anti-Kickback Statute by the Office of the Inspector General (within the U.S. Department of Health & Human Services), a determination that the professional entity does not constitute a true group under the Stark law, or an allegation that payments and reallocation of cost responsibility are meant to serve as inducements for referrals to the hospital.

The physicians may enter into an arrangement with the expectation that financial guarantees will be provided by the hospital. For example, if professional entity revenues are insufficient to cover budgeted and unanticipated expenses, the hospital will be expected to fund all necessary cost overruns. Accordingly, payment by the hospital will not be set in advance for the year (and will likely fluctuate in practice, notwithstanding written clauses stating the contrary), so as to cause the arrangement to fall outside of potential federal Anti-Kickback Statute safe-harbor protections. The "as-needed funding" could be alleged to be a kickback for referrals of services to the hospital. Though efforts might be made to qualify the additional funding as a financing arrangement, the issue then becomes whether such financing would be considered excessive or commercially reasonable, absent referrals to the hospital.

If the professional entity is entirely separate from the hospital (i.e., not captive), an agreement to share revenues or profits with such a noncaptive entity can potentially be challenged. The ability to seek or obtain a profit upside (i.e., a path to discrete profitability outside of the admission and referral of patients, services, and testing to the hospital) through the mere funding of the professional entity is threatened (if not nullified). As a catch-22, absent a path to profitability that is irrespective of referrals to the hospital, what would be the purpose of funding independent centers? This raises questions regarding the purpose of the arrangement. Further, any profit obtainable by leasing of personnel (including of physicians employed by the hospital), equipment, and space by a hospital to the professional entity is limited to fair market value (FMV). The profit margin for such business activities is relatively low.

To the extent that a physician or group is compensated for oversight of the center's office operations, rather than administrative functions for the benefit of hospital inpatient department and/or outpatient department, that compensation could be alleged to be a kickback to the professional entity, as a distinct independent entity unrelated to the hospital. Accordingly, any such compensation might instead be the sole burden of the professional entity payable directly out of its revenues, rather than part of the hospital's compensation to the managing physician or group. If the physician is engaged in administrative activities for the benefit of the hospital, FMV considerations still apply, and the conduct of such activities must be carefully documented and tracked. A regular performance review should also be conducted.

Additionally, there is a risk that payments made by the hospital to the physicians could be viewed as a means to offset the loss of Stark DHS, which would otherwise have been conducted on-site at the urgent care center had it not affiliated with the hospital, such as x-rays and clinical laboratory services—which are now farmed out to the hospital or its affiliates.

It is also possible that the government will not consider the physicians to be members of the true group practice if they concurrently hold employment status with the hospital (i.e., they are "leased" to the group as its employees as well). This could destroy the ability of the physicians to meet the group practice definition, such that Stark DHS may not be permitted to be rendered by the professional entity or billed under its tax identification number. Consequently, the physicians are not allowed to receive any DHS revenues or profits from the professional entity, and their DHS referrals (orders) to the professional entity will violate the Stark law. The government could unfavorably view physicians receiving any DHS profits (by claiming group-practice status under the Stark law) when the parties are also taking the position that such physicians are bona fide employees of the hospital in connection with the same or related services. This could also lead the government to challenge the physicians' employment status with the hospital, potentially resulting in significant Stark law penalties associated with hospital facility billings emanating from the physicians' referrals of inpatient and outpatient services and testing to the hospital.

Safe Harbors and Exceptions Protecting from Violation

Note that any agreement entered into should also comply with safe harbors under the Anti-Kickback Statute to the extent possible, as well as exceptions falling under the Stark law. Under these statutory and regulatory exceptions at the federal and state levels, the agreements must meet specific criteria, including that the term of the agreement not be less than 1 year; if an agreement is terminable within the year, the parties must not enter into the same agreement for the remainder of the initial 12 months. Further, services and items provided must clearly be delineated, and the payments associated with them constitute FMV. Additionally, the arrangement must be for a legitimate business purpose, and the compensation must not consider the value or volume of any referrals.

It is paramount that health-care counsel be consulted to ensure that the arrangement complies with legal guidelines and creates synergies through clinical integration, quality improvement, and reduction of hospital utilization, which will further bolster the justification for such a relationship.



ABSTRACTS IN URGENT CARE

- Family Members Are Most Frequent Cause of Pertussis in Children Younger Than 1 Year
- Monitoring Local Antibiotic Resistance
 Patterns Can Assist with Medication
 Choice for Urinary Tract Infections
- New Guidelines Available for Evaluating for Pulmonary Embolism
- Alternative for Children with Acute Asthma: Single-Dose Dexamethasone

- Health-Care Providers Are Not Careful Enough in Removing Personal Protective Equipment
- STONE Score Not Sensitive Enough to Rule Out Need for Computed Tomography Scans
- Five Prediction Models Are Valid for Confirming Pulmonary Embolism
- Preexisting Symptoms Must Be Considered in Teens Being Evaluated for Concussion

SEAN M. MCNEELEY, MD

ach month the Urgent Care College of Physicians (UCCOP) provides a handful of abstracts from or related to urgent care practices or practitioners. Sean McNeeley, MD, leads this effort.

Family Members Are Most Frequent Cause of Pertussis in Children Younger Than 1 Year

Key point: Be sure to suggest adding a pertussis vaccine to tetanus whenever possible.

Citation: Skoff TH, Kenyon C, Cocoros N, et al. Sources of infant pertussis infection in the United States. *Pediatrics*. 2015;136:636–641.

Despite recent efforts to increase the number of U.S. adults whose immunizations are current, pertussis still is a frequent problem for children younger than age 1 year and can be lifethreatening. This multiyear study attempted to determine the cause of pertussis in children in that age group. A total of 1306 cases were reviewed, and 569 likely causes were noted. Of the cases with a determined cause, most involved exposure from immediate family members as follows: siblings, 35.5%; mothers, 20.6%; and fathers 10.0%. Although the largest infectioncausing group is now siblings, parents are close behind. We



Sean M. McNeeley, MD, is an urgent care practitioner and Network Medical Director at University Hospitals of Cleveland, home of the first fellowship in urgent care medicine. Dr. McNeeley is a board member of UCAOA, UCCOP, and the Board of Certification in Urgent Care Medicine. He also sits on the *JUCM* editorial board. urgent care providers can make a real difference in our patients' lives if we recommend a tetanus-pertussis vaccine for patients' family members.

Monitoring Local Antibiotic Resistance Patterns Can Assist with Medication Choice for Urinary Tract Infections

Key point: Know your local antibiotic resistance patterns. Citation: Percival KM, Valenti KM, Schmittling SE, et al. Impact of an antimicrobial stewardship intervention on urinary tract infection treatment in the ED. Am J Emerg Med. 2015;33:1129–1133.

Urinary tract infections (UTIs) are a common presenting complaint in urgent care centers as well as emergency departments. The choice of antibiotic should fit guidelines but also local resistance patterns. In this study, the authors attempted to determine whether an educational intervention about local UTI resistance patterns changed empiric antibiotic choice, looking at data for 174 patients before intervention and for 176 patients afterward. Before the intervention, only 40% of prescriptions complied with recommendations. After education, over 80% did. The intervention focused on the increasing resistance to sulfa and quinolone antibiotics and on recommendations by the Infectious Diseases Society of America (ISDA) to be aware of lo-

ABSTRACTS IN URGENT CARE

"Pertussis still is a frequent problem for children younger than age 1 year and can be life-threatening.... We urgent care providers can make a real difference in our patients' lives if we recommend a tetanus-pertussis vaccine for patients' family members."

cal resistance patterns and increase the use of drugs like nitrofurantoin that are less likely to cause resistance in other flora. Urgent care providers would do well to review the ISDA recommendations and stay updated on local resistance patterns.

New Guidelines Available for Evaluating for Pulmonary Embolism

Key point: New pulmonary embolus evaluation guidelines are available.

Citation: Raja AS, Greenberg JO, Qaseem A, et al; Clinical Guidelines Committee of the American College of Physicians. Evaluation of patients with suspected acute pulmonary embolism: best practice advice from the Clinical Guidelines Committee of the American College of Physicians. *Ann Intern Med.* 2015;163:701–711.

The new guidelines from the American College of Physicians may help the urgent care provider decide whether to transfer the patient with suspected pulmonary embolism (PE) to an emergency department or instead order further tests. Because of the common nature of this problem, a review of the entire article is suggested. Here is a summary of the advice covered by the guidelines:

- Best practice 1 concerns the use of validated clinical prediction rules to estimate pretest probability of PE.
- Best practice 2 advises that p-dimer measurements and imaging studies are unnecessary in patients with a low pretest probability if they meet all pulmonary embolism rule-out criteria.
- Best practice 3 advises using high-sensitivity p-dimer measurement instead of imaging studies in patients with a low or intermediate pretest probability.
- Best practice 4 advises use of age-adjusted p-dimer thresholds rather than a generic threshold in patients older than 50 years to establish the necessity of imaging.
- Best practice 5 advises that imaging studies are not helpful in patients whose D-dimer level is less than the ageadjusted cutoff.
- Best practice 6 advises using computed tomography pulmonary angiography (CTPA), rather than a D-dimer measurement, in patients with a high pretest probability.

Ventilation-perfusion scans can be used for patients in whom CTPA is inadvisable or when CTPA is unavailable.

Alternative for Children with Acute Asthma: Single-Dose Dexamethasone

Key point: Consider dexamethasone for asthma.

Citation: Cronin JJ, McCoy S, Kennedy U, et al. A randomized trial of single-dose oral dexamethasone versus multidose prednisolone for acute exacerbations of asthma in children who attend the emergency department. *Ann Emerg Med.* 2015 October 10. doi: 10.1016/j.annemergmed.2015.08.001. [Epub ahead of print.]

The standard treatment for asthma exacerbation in children is prednisone or prednisolone. Unfortunately the treatment is sometimes not well tolerated. The authors of this study attempted to prove that a single dose of dexamethasone (0.3 mg/kg) was not inferior to prednisolone. The primary outcome was the Pediatric Respiratory Assessment Measure (PRAM) score on day 4 after treatment. A total of 226 children were randomized to one of the steroid treatments, and PRAM scores were obtained for all. There was no difference in PRAM scores, number of hospital admissions, or number of unscheduled physician visits between treatment groups. Urgent care providers who are not already treating patients with dexamethasone may want to consider doing so, because dexamethasone appears to be a good alternative with a reduced risk of poor treatment compliance and reduced need for obtaining further medication.

Health-Care Providers Are Not Careful Enough in Removing Personal Protective Equipment

Key point: To decrease contamination, take care when removing personal protective equipment.

Citation: Tomas ME, Kundrapu S, Thota P, et al. Contamination of health care personnel during removal of personal protective equipment. *JAMA Intern Med*. 2015 October 12. doi: 10.1001/jamainternmed.2015.4535. [Epub ahead of print.]

Appropriate removal of personal protective equipment (PPE) is just as important as using it. This study examined safe removal of PPE by measuring exposure to fluorescent lotion. A concerning 46% of removals resulted in contamination because of improper gown-removal technique and because of glove removal. An intervention involving watching a video on proper technique and then practicing it greatly reduced the contamination rate from 60% to <20%, an effect that lasted at least 6 months. Considering all of the virulent pathogens encountered in urgent care centers, management should consider reinforcing PPE removal techniques for all staff members and health-care providers.

STONE Score Not Sensitive Enough to Rule Out Need for Computed Tomography Scans

Key point: Although it is better than physician gestalt, the STONE score still does not eliminate the need for computed tomography scans.

Citation: Wang RC, Rodriguez RM, Moghadassi M, et al. External validation of the STONE score, a clinical prediction rule for ureteral stone: an observational multi-institutional study. *Ann Emerg Med.* 2015 October 2. doi: 10.1016/j.annemergmed. 2015.08.019. [Epub ahead of print.]

The STONE score was created to categorize patients into low, medium, or high risk of having a renal stone. Its characteristics are as follows: size, topography (stone location), obstruction, number of stones present, and evaluation of Hounsfield units. This study of 845 patients, 331 of whom had renal stones, compared the STONE score to clinical gestalt to determine whether the need for computed tomography (CT) scanning could be eliminated. The STONE score adds points when certain criteria are present: male sex, 2 points; pain duration of <6 hours, 3 points; pain duration of 6 to 24 hours, 1 point; nonblack race, 3 points; nausea alone, 1 point; vomiting, 2 points; hematuria found on urine dipstick testing, 3 points. Patients are then categorized according to score: low, o to 5; moderate, 6 to 9; and high, 10 to 13. It was previously assumed that a high STONE score would allow for skipping a CT scan; however, the score has a sensitivity of only 53% and a moderate specificity of 87%, which the authors believed was not good enough to eliminate the need for a scan. This study does not provide a tool that urgent care providers can use to avoid ordering CT scans, but its findings do help quantify the likelihood that a stone is present. Hopefully additional research will make the STONE score more useful in determining which patients may not need CT scans.

Five Prediction Models Are Valid for Confirming Pulmonary Embolism

Key point: Pulmonary embolism scores appear to be valid in primary care.

Citation: Hendriksen JMT, Geersing G-J, Lucassen WAM, et al. Diagnostic prediction models for suspected pulmonary embolism: systematic review and independent external validation in primary care. *BMJ*. 2015;351:h4438. doi: 10.1136/ bmj.h4438.

Pulmonary embolism is difficult to diagnose or rule out on clinical grounds. This study attempted to validate the criteria that would be available for use in a primary-care setting. The prediction rules using data not normally seen in primary care were excluded. Ten models were reviewed, but only five met the criteria and had available data needed: the original Wells, modified Wells, simplified Wells, revised Geneva, and simplified "Considering all of the virulent pathogens encountered in urgent care centers, management should consider reinforcing PPE removal techniques for all staff members and health-care providers."

revised Geneva models. An independent external review of 598 patients showed that all five decision rules performed well. Sensitivity varied from 88% for the simplified revised Geneva to 96% for the simplified Wells, and specificity ranged from 48% for the revised Geneva to 53% for the simplified revised Geneva. Unfortunately the pulmonary embolism rule-out criteria were not validated because pulse oximetry readings were not available for the cohort used. These findings reassure that the prediction rules may also apply to the urgent care setting, but they are also a reminder that even the best rule misses pulmonary embolism in 4% of patients.

Preexisting Symptoms Must Be Considered in Teens Being Evaluated for Concussion

Key point: Concussion-like symptoms are sometimes present at baseline for teenagers.

Citation: Iverson GL, Silverberg ND, Mannix R, et al. Factors associated with concussion-like symptom reporting in high school athletes. *JAMA Pediatr*. 2015 October 12. doi: 10.1001/jamapediatrics.2015.2374. [Epub ahead of print.]

Concussions have been a hot topic in the news and in the sports world. Most U.S. states have passed laws regarding concussion treatment. However, some concussion symptoms are classic descriptions of adolescence. This study attempted to define baseline concussion-like symptoms in a large cohort of teenagers. Over a 4-year period, almost 32,000 students without a concussion in the preceding 6 months were surveyed for baseline concussion-like symptoms. A large percentage of respondents (60%-82% of boys and 73%-97% of girls) reported one symptom, and 19% of boys and 28% of girls had symptoms that could have been classified as post-concussion syndrome. For the urgent care provider, this is a good reminder of that preexisting symptoms must be considered when diagnosing a concussion or post-concussion syndrome. Student athletes should all be tested before play so that their baseline findings can be used in determining their treatment. This is a proactive service that urgent care centers can provide for their communities. [Editor's note: See our web exclusive "Concussion Care Adds Value to an Urgent Care Sports, Camp, and School Physical Program" at http://www.jucm.com/concussion-care-adds-value-to-anurgent-care-sports-camp-and-school-physical-program/.]



Unspecified Diagnosis Codes, Preoperative Examinations, and Tuberculosis Skin Tests

DAVID STERN, MD, CPC

We are afraid of getting denials for using unspecified ICD-10-CM [International Classification of Diseases, 10th Revision, Clinical Modification] codes. In an urgent care center, we sometimes will see a particular patient only one time for minor illnesses and injuries, and follow-up with their primary-care physician is always advised. Do you have any advice on documenting to get claims paid? Within ICD-10-CM, you may select codes defined as "Not Otherwise Specified" (NOS). Generally, this should be reserved for claims that lack sufficient documentation to select a more specific code. Prior to October 1, 2015, many consultants were warning providers to be prepared for an onslaught of denials for lack of specificity. Although we were skeptical of this advice, we can now confirm that nationally (at least for now). payors are denying almost no claims for NOS ICD-10 codes. In addition, Congress has passed a bill that specifically forbids Medicare carriers from denying a code for lack of specificity.

When sufficient clinical information is not known about a particular condition, it is acceptable to report an unspecified code. For example, in most patients with pneumonia in an urgent care center, the specific organism has not been identified. In these cases, the most accurate code would be J18.9, "Pneumonia, unspecified organism."

Unspecified codes are not the same as ICD-10 codes that are defined as "Not Elsewhere Classifiable" (NEC). These should be used when specific information is documented for the diagnosis but there is not an existing ICD-10-CM code to report. In this case, the documentation on the medical record is suf-



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With ICD-10-CM, is it ever acceptable to use symptoms as a primary diagnosis for an urgent care visit? Yes, many times a sign or symptom is the most specific code available. For example, if the physician sees a patient who has a cough but she is not sure whether the cough is due to bronchitis, asthma, pneumonia, or some other condition, then it would be appropriate to code for cough. It would be inappropriate to code for any of those specific diagnoses. According to the ICD-10-CM Official Guidelines for Coding and Reporting, Section I.B.18:

Signs/symptom, and "unspecified" codes have acceptable, even necessary uses. While specific diagnosis codes should be reported when they are supported by the available medical record documentation and clinical knowledge of the patient's health condition, there are instances when signs/symptoms or unspecified codes are the best choices for accurately reflecting the healthcare encounter....

If a definitive diagnosis has not been established by the end of the encounter, it is appropriate to report codes for sign(s) and/or symptoms....¹

What diagnosis code should we use when a patient just needs a preoperative examination?

For patients receiving a preoperative evaluation, code first the reason for the encounter from ICD-10-CM code set Z01.810 to Z01.818:

1. https://www.cms.gov/Medicare/Coding/ICD10/Downloads/2016-ICD-10-CM-Guidelines.pdf

CODING Q&A

- **Zo1.810:** "Encounter for preprocedural cardiovascular examination"
- **Zo1.811:** "Encounter for preprocedural respiratory examination"
- **Zo1.812:** "Encounter for preprocedural laboratory examination"
- Zo1.818: "Encounter for other preprocedural examination"

Assign a code for the condition to describe the reason for the surgery as an additional diagnosis. For example, a patient presents for a preoperative examination for carpal tunnel surgery on the right wrist and has orders from his surgeon for laboratory tests. You would assign diagnosis code Zo1.812, as already noted, for the primary diagnosis, and G56.01, "Carpal tunnel syndrome, right upper limb" as the additional diagnosis. Code also any findings related to the preoperative evaluation.

When giving a tuberculosis skin test, can we charge for a subcutaneous injection?

Use Current Procedural Terminology (CPT) code 86580 ("Skin test; tuberculosis, intradermal") for purified protein derivative testing in the office. This test is not a vaccine; rather, it is a screening test for the presence of an immune response, indicating the presence of tuberculosis. In addition, code 86580 includes intradermal injection of the substance.

The Resource-Based Relative Value Scale (RBRVS) does not include the work for reading the test. Therefore, you can also use CPT code 99211 for the nurse reading. However, per incident-to regulations, the physician must be in the office at the time of the reading in order to code the 99211.

If the test results are positive, you can code for the additional services rendered during the visit. Typically, the physician will perform a face-to-face encounter with the patient for further evaluation and management (E/M), such as reviewing the diagnosis, conducting a physical examination, assessing risk, dealing with false-positive test results, and deciding among treatment options. You would choose the E/M code appropriately (99212–99214). You would also want to code for any additional testing, such as a chest x-ray.

The appropriate ICD-10-CM code for the initial screening and the reading is Z11.1, "Encounter for screening for respiratory tuberculosis." If the test findings are positive, then you would add another code, such as R76.11, "Nonspecific reaction to tuberculin skin test without active tuberculosis."

Note: CPT codes, descriptions, and other data only are @ 2011, American Medical Association. All Rights Reserved (or such other date of publication of CPT). CPT is a trademark of the American Medical Association (AMA).

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CLINICAL CHALLENGE

This feature will challenge your diagnostic acumen with a glimpse of x-rays, electrocardiograms, and photographs of 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*.



Wrist Pain After a Fall Onto an Outstretched Hand

Case

A 56-year-old woman presents after a fall onto her outstretched hand. She has pain with range of motion of the wrist. She has no associated numbness or weakness and reports no other injuries. View the image taken (**Figure 1**) and consider what your diagnosis would be.

Resolution of the case is described on the next page.

THE RESOLUTION



Differential Diagnoses

- Normal findings on wrist x-ray
- Rolando fracture
- Bennett fracture
- Carpometacarpal dislocation
- Ulnar styloid fracture

Diagnosis

Scaphoid fracture (Figure 2).

Learnings

Most wrist injuries are caused by a fall onto an outstretched hand. If the point of maximal impact is over the thenar eminence, an injury to the scaphoid bone and its associated ligaments is more likely. The scaphoid fracture is the most common carpal bone fracture, with most fractures occurring at the mid aspect of the scaphoid. About a guarter of such fractures occur in the proximal third of the bone, and 10% occur in the distal third. In up to onequarter of suspected scaphoid fractures (even with negative x-ray findings), the suspected diagnosis ultimately turns out to be correct.

A scaphoid fracture should be suspected when there is pain with palpation of the anatomic snuffbox, composed of a triangular depression evident on the dorsal radial aspect of the wrist with extension of the thumb. The scaphoid bone has a tenuous blood supply, which is why the health-care provider should maintain a high index of suspicion for this injury and should splint as if it is a fracture even when x-ray findings are negative. Pain with palpation at the anatomic snuffbox has a 96% sensitivity and a 39% specificity for detecting scaphoid fracture. If there is a proximal fracture that is not adeguately immobilized and treated, avascular necrosis can develop. Complica-

tions also include delayed union or nonunion and onset of degenerative arthritis.

Additional considerations for serious trauma include scapholunate ligament injury, triquetrolunate ligament injury, and perilunate or lunate dislocation.

Treatment includes splinting in slight dorsiflexion with radial deviation, plus referral to orthopedist for follow-up within 1 or 2 days. Of note, most cases of litigation involving scaphoid fractures involve a missed diagnosis, misinterpretation of x-rays, or failure to immobilize.

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DEVELOPING DATA

ata from the 2014 Urgent Care Chart Survey of 1,778,075 blinded visits by patients to more than 800 different urgent care clinics, conducted by the *Journal of Urgent Care Medicine*, reveal that the most frequent disposition of cases at U.S. urgent care centers in 2014 was provision of follow-up care as needed.

The survey's methodology and data abstraction forms were initially designed in 2008 by researcher Robin M. Weinick, PhD, then an assistant professor at Harvard Medical School and a senior scientist at the Institute for Health Policy at Massachusetts General Hospital, and now associate director of RAND Health.





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