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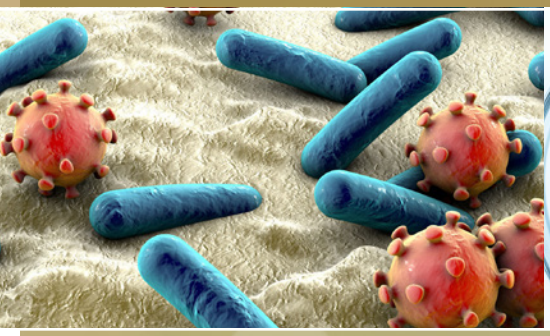
THE JOURNAL OF Legal Nurse Consulting



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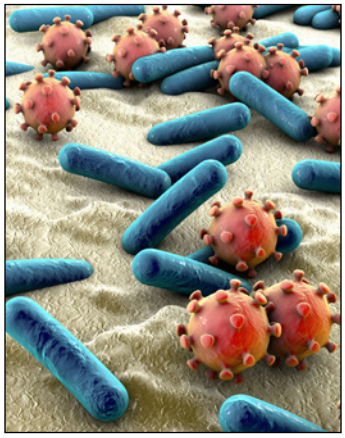
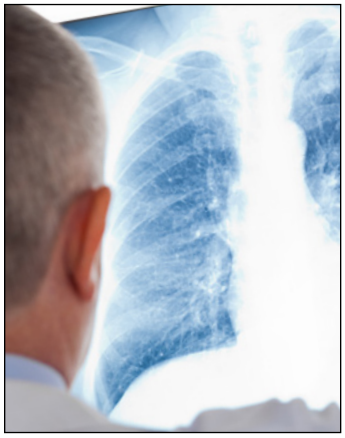
Volume 27 | Number 3 | Fall 2016





AALNC
AMERICAN ASSOCIATION OF LEGAL NURSE CONSULTANTS

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PURPOSE

The purpose of The Journal is to promote legal nurse consulting within the medicallegal community; to provide novice and experienced legal nurse consultants (LNCs) with a quality professional publication; and to teach and inform LNCs about clinical practice, current legal issues, and professional development.

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The Journal accepts original articles, case studies, letters, and research. Query letters are welcomed but not required. Material must be original and never published before. A manuscript should be submitted with the understanding that it is not being sent to any other journal simultaneously. Manuscripts should be addressed to JLNC@aalnc.org. Please see the next page for Information for Authors before submitting.

MANUSCRIPT REVIEW PROCESS

We send all submissions blinded to peer reviewers and return their blinded suggestions to the author. The final version may have minor editing for form and authors will have final approval before publication. Acceptance is based on the quality of the material and its importance to the audience.

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ARTICLE SUBMISSION

The Journal of Legal Nurse Consulting (JLNC), a refereed publication, is the official journal of the American Association of Legal Nurse Consultants (AALNC). We invite interested nurses and allied professionals to submit article queries or manuscripts that educate and inform our readership about current practice methods, professional development, and the promotion of legal nurse consulting within the medical-legal community. Manuscript submissions are peer-reviewed by professional LNCs with diverse professional backgrounds. The JLNC follows the ethical guidelines of COPE, the Committee on Publication Ethics, which may be reviewed at: http://publicationethics.org/resources/code-conduct.

We particularly encourage first-time authors to submit manuscripts. The editor will provide writing and conceptual assistance as needed. Please follow this checklist for articles submitted for consideration.

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- Put title and page number in a header on each page (using the Header feature in Word)
- Place author name, contact information, and article title on a separate title page, so author name can be blinded for peer review
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- Include a 100-word abstract and keywords on the first page
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- All photos, figures, and artwork should be in JPG or PDF format (JPG preferred for photos). Line art should have a minimum resolution of 1000 dpi, halftone art (photos) a minimum of 300 dpi, and combination art (line/tone) a minimum of 500 dpi.
- Each table, figure, photo, or art should be submitted as a separate file attachment, labeled to match its reference in text, with credits if needed (e.g., Table 1, Common nursing diagnoses in SCI; Figure 3, Time to endpoints by intervention, American Cancer Society, 2003)

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Susan Carleo
RN, CAPA, LNCC
President, AALNC

A Message from the President

Dear AALNC Members,

It was a busy summer for AALNC. We presented informative webinars on Critical Concepts in Stroke and a round table on Report Writing. Stay tuned for our exciting Fall lineup of webinars to educate you and improve your practice.

Our Scope & Standards committee has been hard at work reviewing the Scope part of the document and are ready to move on to the Standards section ahead of schedule. Debbie Wipf is our new committee chair.

Shannon Holy, Director of Programs, and I attended the Nursing Alliance Leadership Academy (NALA) in Louisville, Kentucky on August 27-28, 2016. This conference was a great opportunity for us to build relationships and network with leaders of other national nursing specialty organizations. We connected with many nurse leaders to share speakers and promote legal nurse consulting. This was one of our goals for 2016-2017.

Our Nominations Committee has become the Leadership Succession Committee and is now a year round process. Our plan is planning ahead 3-5 years to identify members seriously interested in becoming members of the AALNC Board of Directors. We also added a new member, long time AALNC supporter Beth Diehl, to join Erin Gollogly, Andrea Warner, Debbie Pritts, President-Elect, and myself on the committee.

Our first Chapter Leader meeting organized by Director at Large Beth Murray was informative and successful for our chapter leaders attending and recorded for those who could not.

The Forum Committee has exciting speakers already planned for our Forum next year April 7-8, 2017 in Portland, Oregon. You don't want to miss it.

This *JLNC* edition is dedicated to Infection. Unfortunately, too many patients have succumbed to this illness from a missed or delayed diagnosis and improper treatment. Our journal is full of valuable information to help as you review cases. I presented on Sepsis at the DRI Medical Liability and Healthcare Law conference in March and our AALNC Forum in April. The sepsis article I co-wrote with attorney Bernard Vallejos is reprinted in this issue. It is important to always stay up to date in the latest developments for the diagnosis and treatment of sepsis to assist your attorney clients.

Thank you again for this opportunity to represent and serve AALNC as President. Every day is an exciting adventure towards our continued success.

Please feel comfortable contacting me if you have questions or suggestions about AALNC. Thank you to all our AALNC members, committee volunteers, chapters, and my fellow board members. I appreciate your help and support very much as we move forward.

Sincerely,

Susan Carleo

Susan Carleo, RN, CAPA, LNCC
President AALNC

Editor's Note

Wendie Howland
MN, RN-BC, CRRN, CNLCP, LNCC
Editor, JLNC

Welcome to the September 2016 *Journal of Legal Nurse Consulting*, Infection. We have works on familiar and unfamiliar topics, including emerging infectious diseases, a first-person account by a nurse who was quarantined after returning from caring for Ebola patients, CRE in endoscopy equipment, aspiration pneumonia, dental infections, a reprint on sepsis, and a legal perspective on managing cases on iatrogenic or nosocomial infections, among others.

One of the challenges in putting together your journal is striking a balance between various competing perspectives: clinical information and points in law, formal and accessible language, research and application. Popular, trade, and scholarly publications have different perspectives. Note, though, that the JLNC is not an academic or research journal. We need to present information that working legal nurse consultants can use to guide research, keep up with trends in many fields, run a business, understand complex clinical situations, recognize legal issues, produce demonstrative evidence, and write cogent reports. All this needs to be easy to read without being dumbed-down, comprehensive but not eye-crossing, with adequate resources for you to pursue for more information as you need it. We strive to achieve this balance in every issue.

We need to present information that working legal nurse consultants can use to guide research, keep up with trends in many fields, run a business, understand complex clinical situations, recognize legal issues, produce demonstrative evidence, and write cogent reports.

I've had the opportunity to crystallize my thoughts on this. Over the last few years, I've been asked occasionally whether our journal was insufficiently scholarly, as evidenced by a lack of adherence to standards for scholarly writing. One of my go-to references on this topic is a nifty article by Steven Pinker, written when he was professor of psychology at Harvard, chair of the usage panel of the American Heritage Dictionary, and author of The Sense of Style: The Thinking Person's Guide to Writing in the 21st Century (Viking Press). In his article in the September 26, 2014 Chronicle of Higher Education, "Why Academics Stink at Writing," he makes a very compelling case for consciously rooting out academic writing because it's counterproductive to the very purpose of communication. "Why," he writes, "should a profession that trades in words and dedicates itself to the transmission of knowledge so often turn out prose that is turgid, soggy, wooden, bloated, clumsy, obscure, unpleasant to read, and impossible to understand?" This spoke to my editor's heart.

continued on page 6

Editor's Note

continued from page 5

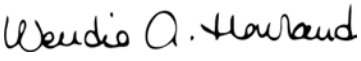
Pinker cites Thomas and Turner, who in their book *Clear and Simple as the Truth* notes that every writing style is an author's effort to produce the "real-time give-and-take of a conversation." They identify several styles, depending on how the author relates to the intended readership and what the author wants to achieve. To avoid getting too deep into writer-nerd territory, I'll cut to the chase: classic and practical styles are the way to go.

> ***Most academic writing, in contrast, is a blend of two styles. The first is practical style, in which the writer's goal is to satisfy a reader's need for a particular kind of information, and the form of the communication falls into a fixed template, such as the five-paragraph student essay or the standardized structure of a scientific article. The second is a style that Thomas and Turner call self-conscious, relativistic, ironic, or postmodern, in which "the writer's chief, if unstated, concern is to escape being convicted of philosophical naïveté about his own enterprise. … Classic style similarly puts aside … philosophical questions about its enterprise. If it took those questions up, it could never get around to treating its subject, and its purpose is exclusively to treat its subject." (emphasis added)***

Those of you for whom this is an intriguing intro to better writing can find the complete piece online (and I believe our readership is able to do that unassisted from the information given).

I look at the JLNC as a kind of conversation with our readers, an extended version of the ones we have when we get together for face-to-face ones to treat our subjects. We do a decent job on citations to the standards of a professional trade journal; the conventions for dissertations do not need to apply here. People really don't need (or want) to open a page (or a conversation) and see at a glance that its most common punctuation mark is the parenthesis. They need to be able learn good information without irritation and to locate the resources the authors identify.

That's our goal: a good conversation about interesting topics in an accessible style. I hope you see us succeeding. You can continue the conversation by emailing me; your comments may appear in the Letters section in December.



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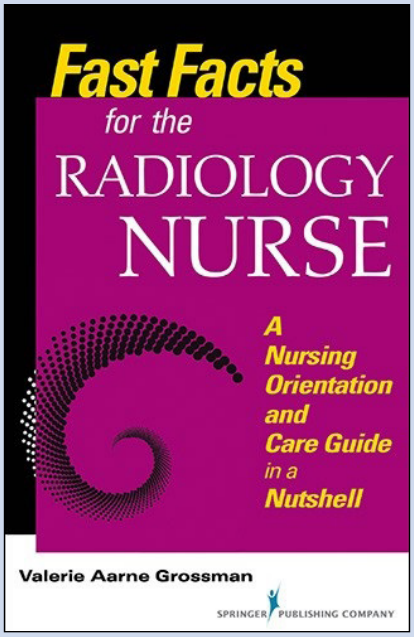
What's in a Picture?

Andrea Perry, RN, MSN, CNL, CEN

"A picture is worth a thousand words."



Fast Facts for the Radiology Nurse (2014)
Valeria Aarne Grossman

Springer Publishing, New York NY.
www.springerpub.com
ISBN-13: 9780826129376 ISBN-10: 0826129374

In radiology, a picture is priceless: images support clinical decision-making and direct care. For a radiology nurse, the picture is only a small fraction of what happens to provide care to a patient having an imaging study. Edited by Valerie Aarne Grossman, 2016 Association for Radiologic and Imaging Nursing (ARIN) Radiology Nurse of the Year, Fast Facts for the Radiology Nurse reviews the wide range of responsibilities and procedures in which a radiology nurse must be proficient. Grossman's expertise in radiology nursing is evidenced by her attention to detail and ability to simplify many ever-changing presentations and procedures. This book includes her own chapter contributions with those of a number of radiology physicians and nurse experts.

Ask any radiology nurse what's in a picture and the answer would undoubtedly be, "the patient!" *Everything in Fast Facts for the Radiology Nurse* drives home this critical point. Steps preceding, during, and following imaging can help determine the final picture's quality and decisions based on it. Patient outcomes can depend on adjusting procedures to achieve the best possible results. Furthermore, communication is vital: radiology nurses often provide the link between the procedure and patient satisfaction.

The book is divided into general sections: teamwork, documentation, a review of procedures done in the radiology suite from simple x-rays to highly complex embolization and ablation therapies, and special issues and trends in radiology nursing. "Fast Facts in a Nutshell" in each chapter highlight essential nursing care, from identifying signs and symptoms of early changes in patient condition to appropriate nurse responses. Easy-to-read tables are packed with details for quick reference. Common medications, sedation levels, and pre-, intra-, and post-procedural tips to promote patient safety and ensure positive patient outcomes are included. In addition, this book offers helpful tips to improve coordination and collaboration with other departments.

This book is an essential resource for any legal nurse consultant looking to understand the diverse and complex responsibilities a radiology nurse has in everyday practice. It's available from the publisher, Springer, at http://www.springerpub.com/fast-facts-for-the-radiology-nurse.html, or at many online retailers at http://tinyurl.com/j3v99cw.

Dawn Friedly Gray MSN, RN, CEN, CCRN is the Clinical Coordinator in the Emergency Department of a Level II Trauma Center. In her three decades of clinical experience in emergency, critical care, and medical-surgical nursing, she has been exposed to a plethora of radiological procedures nurturing her curiosity to review Fast Facts for the Radiology Nurse. Her clinical expertise led her to be a contributing author to Fast Facts for the Triage Nurse which won an American Journal of Nursing Book of the Year Award, 3rd place in the critical-care/emergency category. She can be contacted at RDG1224@verizon.net

MORE ON THE EHR

NORTH BAY BUSINESS JOURNAL STAFF REPORT
July 4, 2016, 5:45AM
Santa Rosa, CA

Editor in Chief and Publisher Brad Bollinger | bbollinger@busjrnl.com

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"Widespread use of electronic health record (EHR) in medical practices may be contributing to more errors and malpractice liability, according to a recent report by The Doctors Company, a Napa-based medical malpractice insurance company.

The Doctor's Company closed almost 100 claims between January 2007 and June 2014 in which EHRs were a contributing factor. The top allegation among the 97 claims was for diagnosis-related errors, followed by medication-related errors, with the wrong medication, the wrong dose, or improper medication management given to the patient.

"It takes 4-5 years from the time a claim is filed until it is resolved one way or another. The study, tracking EHR errors, saw very few claims at the beginning, the speculation being that these kinds of malpractice risks are increasing," said Denise Moore, public relations director at the Company, which is the nation's largest doctor-owned medical malpractice insurer, with 78,000 members and $4.3 billion in assets.

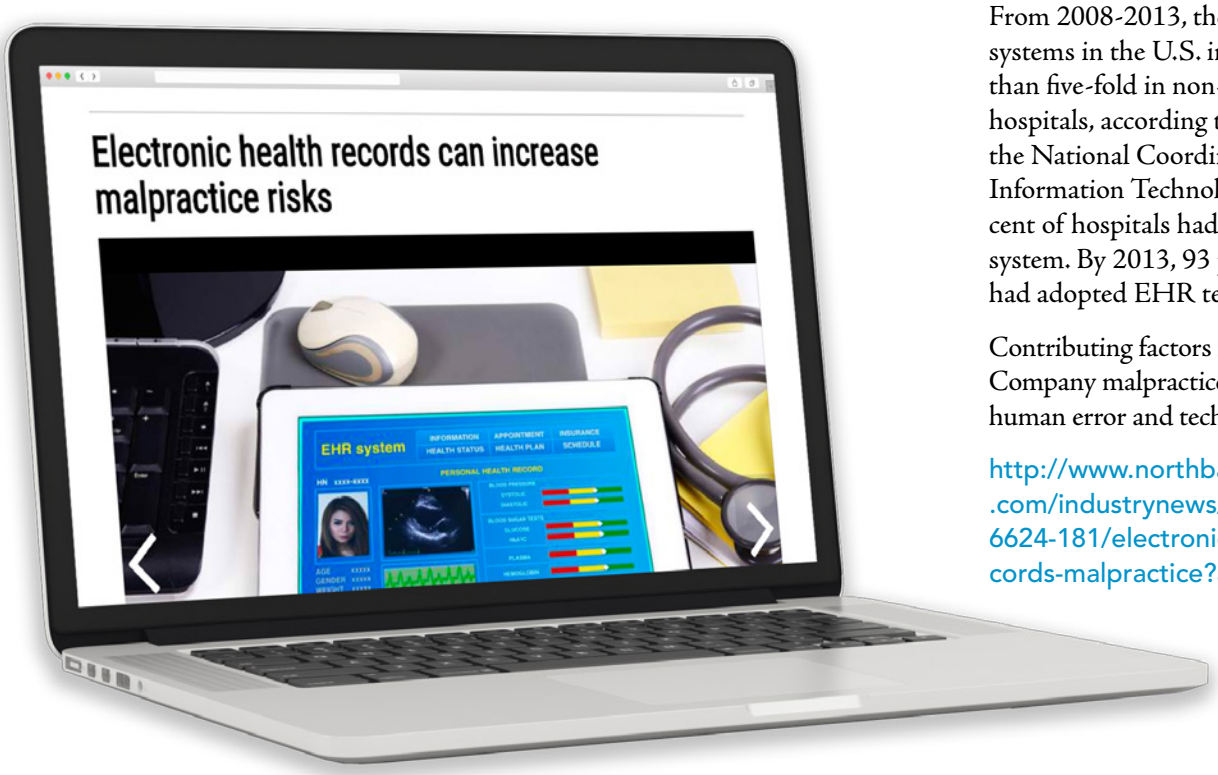
From 2007-2010, two claims were closed in which the EHR was a contributing factor. In 2013 that number had increased to 28, and 26 claims were closed in the first two quarters of 2014.

"Shortly after electronic health records began to be widely adopted, The Doctors Company and other medical professional liability insurers became aware of their potential liability risks. We anticipated that EHRs would become a contributing factor in medical liability claims," Doctor's Group Medical Director David B. Troxel wrote in the report.

From 2008-2013, the adoption of EHR systems in the U.S. increased more than five-fold in non-federal acute care hospitals, according to the Office of the National Coordination for Health Information Technology. In 2008, 9 percent of hospitals had adopted an EHR system. By 2013, 93 percent of hospitals had adopted EHR technology.

Contributing factors in the The Doctor's Company malpractice claims were both human error and technology issues."

http://www.northbaybusinessjournal.com/industrynews/insurance/5776624-181/electronic-health-records-malpractice?artslide=0



From 2007-2010, two claims were closed in which the EHR was a contributing factor. In 2013 that number had increased to 28, and 26 claims were closed in the first two quarters of 2014.

The *JLNC* will be doing reprise of our 2015 EHR issue in 2018, as more and more such news comes to our attention. Related ideas and submissions are welcome at any time.

A Battle of the Nursing Experts

E. Kenneth Snyder, JD, BSN
Editor/Publisher Legal Eagle Eye Newsletter for the Nursing Profession

A battle of the nursing experts determined the outcome of a recent civil healthcare malpractice case in the US District Court for the Eastern District of Pennsylvania. The case was featured in the June 2016 issue of Legal Eagle Eye Newsletter for the Nursing Profession.*

The US District Court accepted the opinion of the defendant hospital's nursing expert and ruled in the hospital's favor. No negligence was committed by a nursing student directly involved in the patient's care or the RN assigned to the patient who was supervising the nursing student.

In its ruling the Court expressly discounted the opinion of the patient's expert, a legal nurse consultant, basically because her opinion that negligence was committed was not credible and did not take into account facts in the patient's medical chart.

THE UNDISPUTED FACTS OF THE CASE

The fifty-three year-old patient fell in her hospital room the day after left total knee replacement surgery.

The night before she fell, hours after surgery, her nurse charted that the patient got up by herself from her recliner chair without assistance, walked over and got into bed. A patient teaching session followed in which the nurse cautioned the patient about the danger of standing up or ambulating on her own without assistance.

DISPUTED FACTS – DEFENDANT HOSPITAL'S VERSION

The day the patient fell a nursing student from the hospital's RN program was caring for her. He had completed classes in patient assessment, safety and bathing. The RN assigned to the

patient was in the nurses' station across from the patient's room.

The nursing student offered the patient a sponge bath in bed. She agreed. He washed her upper body and then offered to wash her perineal area. That she declined. So she could wash herself he removed her leg brace with her still lying in bed and, after twice cautioning her not to get out of bed on her own without asking for help, he stepped behind the privacy curtain.

When the nursing student heard a noise he pulled back the privacy curtain and found the patient on the floor. The RN came from the nurses' station right away when the nursing student called for assistance.

After assessing and helping the patient the RN charted a progress note recounting how patient told her she fell, that is, she fell as she stood up on her own by herself to pull up her pants after she washed her private area.

Under this version of the incident there would be no deviation from the standard of care by the nursing student or the RN and no basis for a judgment in the patient's favor.

DISPUTED FACTS - PLAINTIFF PATIENT'S VERSION

The patient's expert legal nurse consultant based her opinion on the assumption the patient was completely helpless in bed and was therefore incapable of standing up on her own. Nevertheless the student nurse stood the patient up on her feet to try to remove her leg brace. Just as he lifted her to a standing position next to the bed she fell and re-injured her knee.

Under this version of the incident the nursing student would be found negligent. That would also implicate his supervising RN for failing to assess his competency for direct patient care and for failing to watch him more closely. The hospital would be implicated as the RN's employer and the nursing student would also be considered a hospital employee.

COURT FINDS NO NEGLIGENCE

The Court expressly faulted the patient's expert legal nurse consultant for failing to look at the facts. In fact, the patient was not physically helpless in bed. Although it was hazardous and she had been warned not to do so, the patient herself had proven she was physically capable of standing on her own. That pivotal fact was documented in the night nurse's progress note the night before which stated that the patient had stood up from her chair on her own on her new knee and walked over to her bed. The night nurse's progress note fully contradicted a fundamental premise of the patient's legal nurse consultant's flawed review of the facts and resulting flawed legal liability analysis.

Whether the patient was wearing a hospital gown, as stated by the patient and accepted as a fact by her expert legal nurse consultant, or was wearing stretch pants, as the RN testified and the hospital's nursing expert incorporated into her testimony was also an important question for the Court. What the patient was or was not wearing had no direct bearing on liability, but it was highly relevant on credibility, whose version of the facts the Court would believe.

More credible and persuasive for the Court than the patient's testimony and her legal nurse consultant's assumption was the hospital RN's testimony from twenty-six years experience in orthopedics that a patient scheduled for physical therapy that morning more likely would have been wearing stretch pants, not a hospital gown. That was a factual nuance that the Court pointed out the patient's expert legal nurse consultant missed altogether.

The patient's nurse may be allowed to testify both as a fact witness and as an expert witness to fill in gaps in his or her own recollection as to what did happen with an expert opinion as to what probably would have happened.

It was also a difficult hurdle for the plaintiff patient that the RN charted a progress note within two hours of the fall that the patient stated she was wearing pants and stood up on her own. A person's candid initial account of an event carries great weight in court compared to a story possibly doctored at a later time.

*Patient's Fall: Court Says Nurse, Nursing Student Were Not Negligent In Patient's Care, Legal Eagle Eye Newsletter for the Nursing Profession (24)6 Jun. '16 http://www.nursinglaw.com/jun16x7b3.htm See Maria Velez v. Reading Health System, d/b/a Reading Hospital, No. 5:15-cv-1583, US District Court, E.D. Pennsylvania, April 27, 2016, 2016 WL 1696867.

Emerging Infectious Diseases: Global to Local Implications

Mary Lou Manning, PhD, CRNP, CIC, FAAN

Keywords: infectious disease, travel history, public health law

Infectious disease remains among the leading causes of death worldwide. With easy mobility and air travel, pathogens can move quickly and silently to any place around the globe in a matter of days. The recent Ebola crises in West Africa clearly demonstrated the increased risk of emerging infections in our highly connected world. Legal nurse consultants are well-positioned to provide guidance on deciphering public health laws relevant to responding to infectious disease threats.

As the human immunodeficiency virus (HIV) disease pandemic surely should have taught us, in the context of infectious diseases, there is nowhere in the world from which we are remote and no one from whom we are disconnected. Consequently, some infectious diseases that now affect people in other parts of the world represent potential threats to the United States because of global interdependence, modern transportation, trade, and changing social and cultural patterns (Lederberg, Shope, & Oaks, 1992, p.v).

So begins the 1992 Institute of Medicine landmark report, *Emerging Infections: Microbial Threats to Health in the United States*. Today, more than two decades later, despite significant advances in better hygiene, diagnostics, antimicrobials, and vaccines, "the ease of world travel and increased global interdependence have added layers of complexity to containing these infectious diseases that affect not only the health but the economic stability of societies (Morens & Fauci, 2013 p. e1003467)." To find examples of the effect of emerging infectious diseases one need look no further than the recent World Health Organization's (WHO) declarations of "Public Health Emergency of International Concern," one in August 2014 in response to the Ebola crises in West Africa, and another in February 2016 in response to the mosquito-borne Zika virus outbreak in the Americas. Zika virus was introduced into Brazil from the Pacific Islands in early 2015 and has spread rapidly, with most countries in Latin America and the Caribbean reporting local transmission of the virus (Petersen, Jamieson, Powers, & Honein, 2016). Of grave concern is the growing association between prenatal Zika virus infection and adverse pregnancy and birth outcomes, especially fetal microcephaly (Petersen, Jamieson, Powers, & Honein, 2016). Notably, Zika is the first major infectious disease linked to human birth defects to be discovered in more than half a century (Petersen, Jamieson, Powers, & Honein, 2016).

WHAT IS AN EMERGING INFECTIOUS DISEASE?

An emerging infectious disease (EID) is an infectious disease that is newly recognized as occurring in humans (e.g., HIV/AIDS); one that historically has infected humans but is newly appearing in a different population or geographic area than previously affected (e.g., West Nile virus in the US); one that is newly affecting many more individuals; and/or one that has developed new attributes (e.g., drug resistant tuberculosis) (Fauci & Morens, 2012; Morens & Fauci, 2013). The majority of emerging infections in humans are caused by microbes that are established in animals and have crossed the species barrier, highlighting the central role that non-human reservoirs play in human infectious diseases (Fauci & Morens, 2012; van Doorn, 2014).

Such animal to human transmission is termed a zoonotic infection or zoonosis. In humans, for an infectious disease to emerge, something has to change in the relationships among humans, animals, and potential microbial pathogens, and these changes constitute the principal contributing factors to risk emergence (Fineberg & Wilson, 2010). Factors driving this change include: microbial adaptation and change, human susceptibility to infection, climate and weather, environmental change and land use, international travel, migration and commerce, changes in technology and industry, changes in demographics and behavior such as human intrusion into the natural habitats of animals, war and conflict, poverty, and breakdown in public health infrastructure (Lederberg, Shope, & Oaks, 1992; van Doorn, 2014).

In addition to Ebola virus and Zika virus there have been other EIDs that have taken the global community by surprise in the 21st century including, Severe Acute Respiratory Syndrome (SARS) in 2002, the H1N1 influenza pandemic (originally referred to as "swine flu") in 2009 and the Middle East respiratory syndrome coronavirus (MERS-CoV) first reported in Saudi Arabia in 2012 (Sands, Mundaca-Shah, & Dzau, 2016). Each of these has caused "global, societal and economic impact related to unexpected illnesses and deaths, as well as interference with travel, business, and many normal life activities" (Morens & Fauci, 2013 p. e1003467).

Simultaneously, each of these also brought forward a host of legal and ethical issues related to protecting population health and respecting individual rights of privacy, liberty, and freedom of movement (Price, 2015).

Other EIDs are "less catastrophic than these examples; however, they nonetheless may take a significant human toll as well as cause public fear, economic loss, and other adverse outcomes (Morens & Fauci, 2013 p. e1003467)." EIDs can arise anywhere and at any time, Ebola virus disease providing an excellent example of a critical global health issue with significant local implications.

EBOLA VIRUS DISEASE

Ebola virus disease (EVD) is a severe, often fatal disease in humans. It was first recognized in 1976 during 2 unrelated outbreaks in remote villages, near the tropical rainforests, one in southern Sudan, and the other in the Democratic Republic of Congo (WHO, 2016a). The latter occurred in a village near the Ebola River, from which the disease takes its name. Since that time there have been approximately 20 recognized outbreaks of EVD, all occurring in Africa among poor rural residents and the workers caring for them, with fatality rates up to 90% (Myers, Frawley, Goss & Kang, 2015). The Ebola outbreak that began in Guinea in March 2014 was the first to be seen in West Africa, and the first to affect major urban centers. The disease quickly spread across country borders, first to Liberia and then to Sierra Leone, ultimately causing significant loss of life, substantial economic loss and social disruption.

The outbreak became an unprecedented public health crisis with global impact, primarily because the three countries lacked the public health infrastructure, economic stability, and overall gover-

Each of these has caused "global, societal and economic impact related to unexpected illnesses and deaths, as well as interference with travel, business, and many normal life activities."

nance to stem the spread. Public health surveillance was lacking resulting in significant lag time in identifying the outbreak in the community and raising alerts. Local health systems were overwhelmed by large numbers of severely ill patients, medical and non-medical supplies were limited, the numbers of medical personnel and caregivers were insufficient, and there was little regional experience and education about the disease. Additionally, the efforts of the many global governmental, inter-governmental and non-governmental organizations were not well coordinated. Ultimately, the global and local response focused on surveillance, isolation and quarantine, contact tracing, and travel advisories or restrictions. These responses, along with the "courage and commitment of medical staff and communities on the ground and a massive deployment of international resources" succeeding in containing the outbreak (Sands, Mundaca-Shah, & Dzau, 2016, p. 1281). In March 2016 the WHO announced an end of Ebola transmission in Guinea, Liberia, and Sierra Leone, noting that risk for development of sporadic cases remained. As of May 13, 2016 the epidemic in West Africa has resulted in 28,616 reported cases and 11,310 deaths, including numerous healthcare workers (WHO, 2016b).

Seven countries (Italy, Mali, Nigeria, Senegal, Spain, the United Kingdom, and the United States of America) reported a case or cases imported from a country with widespread and intense transmission (WHO, 2016b). In the US four cases of EVD have occurred (CDC, 2016a). The first case was travel-associated, diagnosed on September 30, 2014 in Thomas Eric Duncan who had traveled to Dallas, TX from Liberia. He was initially seen in an Emergency Department (ED) and discharged. Two days later he returned to the same ED and within 48 hours was tested positive for the Ebola virus. On October 8 he died from complications of the disease. Two nurses providing care for the Mr. Duncan subsequently tested positive for Ebola, each hospitalized at a US hospital with a biocontainment unit. Both recovered. The fourth case was diagnosed in New York City in a physician who had returned from Guinea having served with Doctors Without Borders. He also was hospitalized and recovered (CDC, 2016a).

Ebola is transmitted to humans through contact with the blood, secretions, organs, or other body fluids of infected animals in the rainforest (e.g., chimpanzees, gorillas, monkeys). It spreads among people predominately by contact of blood and body fluids with mucosal surfaces or broken skin (CDC, 2016b). The incubation period is 2 to 21 days, although symptoms usually develop 8 to 10 days after infection. Ebola infection is characterized by flu-like symptoms including, fever, severe headache, muscle pain, weakness, fatigue, diarrhea, vomiting, abdominal pain and unexplained bleeding or bruising. During severe illness, blood, sweat, feces, and vomit are highly infectious. People infected with Ebola are contagious only when they are ill and do not transmit the infection during the incubation period. Health care workers and other care providers who come in close contact with infected patients without proper personal protective equipment are at the highest risk for secondary infection. When available, patients with EVD in West Africa received supportive care with oral rehydration solutions, antiemetic agents, analgesics, and antibiotics (Uyeki et al., 2016). Patients with EVD in the US received state-of-the-art clinical care in bio-containment units. Currently there are fifty-five hospitals in the US designated as Ebola treatment centers (CDC, 2016c).

IMPLICATION FOR LEGAL NURSE CONSULTANTS

Legal nurse consultants are well-positioned to provide guidance in deciphering public health law and reviewing EID cases as related to travel history standard of care. Here are some ways to do so.

1. **Advance your EID knowledge.** Increase your EID awareness and knowledge by learning more about the problem. Read articles, subscribe to CDC-EID related scientific journals such as Emerging Infectious Diseases, and participate in educational opportunities (e.g., seminars, webinars). Contact the American Association of Legal Nurse Consultants (AALNC) and other nursing associations and encourage them to offer periodic updates on specific emerging infectious diseases and the associated local, state, national, and global legal challenges (Courtney, Sherman, & Penn, 2013). Learn with your colleagues by starting a journal club and make EIDs a frequent topic.

2. **Advance your knowledge of global and U.S. public health law.** Laws can greatly facilitate responses to public health emergencies, including communicable diseases. Health law includes a "broad array of statutes, regulations, and governmental agencies not traditionally grouped together (Price, 2015, p. 49)." Legal authority for global severe infectious disease threats (such as the Ebola virus outbreak) begins with international law, World Health Organization (WHO) governance, and the International Health Regulations (Price, 2015). The International Health Regulations, adopted in 2007 are "designed to help the international community to prevent and respond to acute public health risks that have the potential to cross borders and threaten people worldwide (Price, 2015, p. 52)." Visit the WHO website (www.who.org) for specific information about the Regulations.

   Countries, including the U.S., used two of the oldest public health tools in response to the Ebola crises, the SARS outbreak, and the H1N1 pandemic: isolation and quarantine. Legal authority to restrict the autonomy or liberty of persons who pose a public health threat can be found at the federal, state, and local levels (Fidler, Gostin, & Markel, 2007). The federal government derives its authority for isolation and quarantine from the Commerce Clause of the U.S. Constitution (CDC, 2016d). Under section 361 of the Public Health Service Act (42 U.S. Code § 264), the Secretary of the Department of Health and Human Services, as the lead for federal public health and medical responses to public health emergencies, is authorized to take measures to prevent the entry and spread of communicable diseases from foreign countries into the U.S. and between states (CDC, 2016d). The authority for carrying out these functions has been delegated to the Centers for Disease Control and Prevention (CDC, 2016d). Under 42 Code of Federal Regulations parts 70 and 71, CDC is authorized to detain, medically examine, and release persons arriving into the U.S. and traveling between states who are suspected of carrying these communicable diseases (CDC, 2016d). Visit the CDC website (www.CDC.org) for further details.

   States have police power functions to protect the health, safety, and welfare of persons within their borders. To control the spread of disease within their borders, states have laws to enforce the use of isolation and quarantine (CDC, 2016d). Visit specific state websites for specific laws and details.

   Until recently, judicial activity in U.S. public health has primarily been driven by the exercise of quarantine powers during epidemics, most notably tuberculosis (Fidler, Gostin, & Markel, 2007). During the recent Ebola crises the governors of New York, Illinois, and New Jersey ordered mandatory, involuntary quarantine of asymptomatic healthcare workers returning from West Africa after caring for Ebola patients, setting off a hailstorm of controversy. (Ed. Note: See Hickox, p. 17)

3. **Obtain and review travel history.** International travel has increased dramatically: from 25 million in 1950; 1.035 billion in 2012; 1.2 billion in 2015 and expected to be 1.8 billion by 2030 (UNWTO, 2016). Global travel on this scale exposes individuals to a range of health risks, including infectious diseases. Therefore, clinicians must obtain a patient's travel history with every clinical encounter. Organizations should have written protocols and a checklist that includes: travel dates, geographic regions visited, nature of travel (e.g., business, pleasure, volunteer), any illness during the journey, exposure to exotic diseases or bites/vectors/animals, and history of chemoprophylaxis (e.g., malaria) and vaccines.

4. **Review "febrile traveler" history.** Of the more than 80 million people who travel from industrialized to developing nations, up to 70% develop a travel-associated illness; between 5% and 19% of those seek medical attention within one month of return (Kotlyar & Rice, 2013). Determining possible infectious exposures and associated incubation periods can be particularly helpful in ruling out causes of fever. Clinicians should ask about

   - timing and sequence of illness/symptoms
   - types of food and water consumed

- places visited
- type/s of transportation
- lay-overs and intermediate stops
- specific activities undertaken during travel (Alp, Erdem, Rello, 2016).

Clinicians should practice standard precautions, with contact and respiratory/droplet precautions for all patients with undifferentiated fever after travel to the tropics, until potentially hazardous diseases are excluded (Kotlyar & Rice, 2013).

Clinicians should verbally communicate significant travel history findings to the health care team. The Dallas hospital caring for Thomas Eric Duncan (who was febrile) learned that the triage nurse collected critical travel information and recorded it in the electronic health record (EHR), but the emergency department staff did not verbally communicate. Viewing the data required the treating physician to look beyond the EHR standard patient assessment screen to access the travel history from the nursing assessment document (Upadhyay, Sittig, & Singh, 2014). This resulted in missing basic but key clinical information.

SUMMARY

History tells us that infectious diseases will continue to emerge and reemerge, leading to unpredictable disease outbreaks and epidemics across the globe. Pathogens can move quickly and silently around the globe in days. International travel has increased dramatically, potentially exposing people to a range of health risks, including exposure to infectious diseases. EID, or mutations of old ones, can have global and devastating consequences. It is important for legal nurse consultants to appreciate the many regulatory aspects of health law, especially as applied to the containment of infectious disease.

REFERENCES

Alp, E., Erdem, H., & Rello, J. (2016). Management of septic shock and severe infections in migrants and returning travelers requiring critical care. Eur J Clin Microbiol Infect Dis, 35:527-533.

Centers for Disease Control and Prevention (2016a). Cases of ebola diagnosed in the United States. http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/united-states-imported-case.html Retrieved May 9, 2016.

Centers for Disease Control and Prevention (2016b). Ebola (Ebola Virus Disease). http://www.cdc.gov/vhf/ebola/pdf/ebola-factsheet.pdf Retrieved May 9, 2016.

Centers for Disease Control and Prevention (2016c). Hospital preparedness: A tiered approach. http://www.cdc.gov/vhf/ebola/healthcare-us/preparing/current-treatment-centers.html Retrieved May 9, 2016.

Centers for Disease Control and Prevention. (2016d). Legal authorities for isolation and quarantine. http://www.cdc.gov/quarantine/AboutLawsRegulationsQuarantineIsolation.html. Retrieved June 22, 2016.

Courtney, B., Sherman, S., & Penn, M. (2013). Federal legal preparedness tools for facilitating medical countermeasures use during public health emergencies. Journal of Law, Medicine & Ethics, Spring, 22-27.

Kotlyar, S., & Rice, B.T. (2013). Fever in the returning traveler. Emerg Med Clin N Am, 927-944.

Fauci, A. S., & Morens, D.M. (2012). The perpetual challenge of infectious diseases. N Engl J Med, 366(5), 454-61.

Fidler, D.P., Gostin, L.O. & Markel, H. (2007). Through the quarantine looking glass: Drug-resistant tuberculosis and public health governance, law and ethics. Journal of Law, Medicine & Ethics. Winter, 616-628.

Fineberg, H.V., & Wilson, M.E. (2010). Emerging infectious diseases. October, 1-13. http://irgc.org/wp-content/uploads/2012/04/Emerging_Infectious_Diseases_Fineberg_and_Wilson-2.pdf

Lederberg, J., Shope, R.E., & Oaks, S.C., Institute of Medicine (U.S.) Committee on emerging microbial threats to health. (1992). Emerging infections: Microbial threats to health in the United States. Washington, D.C.: National Academy Press.

Morens, D.M., & Fauci, A.S. (2013). Emerging infectious diseases: Threats to human health and global stability. PLoS Pathog, 9(7): e1003467.

Meyers, L., Frawley, T., Goss, S., & Kang, C. (2015). Ebola virus outbreak 2014: Clinical review for emergency physicians. Annal of Emergency Medicine, 65(1) 101-108.

Petersen, L.R., Jamieson, D.J., Powers, A.M., & Honein, M.A. (2016). Zika virus. N Engl J Med, 347(16):1552-1563.

Price, P.J. (2015). Public health control measures in response to global pandemics and drug resistance. Journal of Law, Medicine & Ethics, Summer, 49-56.

Sands, P., Mundaca-Shah, C., & Dzau, V.J. (2016). The neglected dimension of globial security - A framework for countering infectious-disease crises. N Engl J Med, 374:(13), 1281-1287

Upadhyay, D.K., Sittig, D.F., & Singh, H. (2014). Ebola US patient zero: Lessons on misdiagnosis and effective use of electronic medical record. Diagnosis, 1:283-288.

Uyeki, T.M., Mehta, A.K., Davey, R.T., Liddell, A.M., Wolf, T., Vetter, P., et. al. (2016). Clinical management of Ebola Virus Disease in the United States and Europe. N Engl J Med, 374(7); 636-646.

van Doorn, H.R. (2014). Emerging infectious diseases. Medicine, 42(1) 60-63.

World Health Organization (WHO).(2016a). http://www.who.int/mediacentre/factsheets/fs103/en/ Retrieved May 9, 2016.

World Health Organization (WHO).(2016b) http://apps.who.int/ebola/ebola-situation-reports. Retrieved May 9, 2016.

World Tourism Organization UNWTO. Tourism market trends. http://cf.cdn.unwto.org/sites/all/files/docpdf/markettrends.pdf. Retrieved May 9, 2016.

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Ebola, Quarantine, and Bike Rides: A Nurse's Reflection on the U.S. Response to Ebola Fighters

Kaci Hickox MSN/MPH, RN

A woman and her daughter were transferred from an Ebola holding facility, a health center that could isolate and test patients for Ebola but one that did not have the ability or capacity to treat patients for the duration of their illness. The daughter was 6 years-old, full of energy with the most radiant smile and sparkling eyes. Her mother tested positive for Ebola four days earlier and her daughter, with no symptoms present, tested negative. Even so, they were kept in the same room together for four days, until our Ebola treatment unit had an open bed. While triaging patients like this mother and daughter, we never had physical contact with our patients. Instead we were separated from our patients by a double fence. The only time we would touch them was when we went into the patient area with full personal protective equipment to cover our entire bodies. So from the other side of the triage fence my colleague explained to the mother that we needed to separate her from her daughter to keep her daughter safe. He said to her, "She may become the president of Sierra Leone one day. We want to keep her safe and that means she cannot be with you in the Ebola unit where positive patients are treated. We will be her aunties and uncles until you are cured." We all celebrated when the mother survived and was reunited with her daughter!

These were some realities that played in my head as I flew home after treating Ebola patients in West Africa. I was soon blindsided by what would become a new reality in my own country.

I am a registered nurse and have worked for Doctors Without Borders in Burma, Sudan, Nigeria, Uganda, and most recently in Sierra Leone in response to the Ebola outbreak. Upon returning to the U.S. from Sierra Leone in 2014, I was quarantined and then isolated by New Jersey officials when I few into Newark International Airport. I was eventually released after having tested negative for Ebola. I was allowed to return to Maine, my home state, where I disputed a home-quarantine order and won my case in court. I personally experienced the impacts of misinformation, misuse of power, and ultimately the justice that our constitution and legal system ensures. In this article, I hope to inform medical and legal professionals of the importance of science-based and legally sound public health decisions related to infectious disease threats and quarantine.

With any infectious disease, understanding the disease is vital to making informed decisions and protecting public health.

EBOLA OVERVIEW

Most people's knowledge of infectious disease outbreaks is from movies like Outbreak or the more recent movie Contagion about an airborne disease that quickly spreads across the world. With any infectious disease, understanding the disease is vital to making informed decisions and protecting public health. Ebola is caused by infection with a virus of the family Filoviridae (Centers for Disease Control and Prevention [CDC], 2016a). It was first discovered in 1976 near the Ebola River in what is now the Democratic Republic of the Congo, and has since caused outbreaks in several African countries (CDC, 2016b). Mortality rates in past outbreaks range from 25% to 90% (World Health Organization [WHO], 2016a). In what is called a spillover event, a human initially becomes infected with Ebola through contact with blood or body fluids of an infected fruit bat or primate such as an ape or a monkey (CDC, 2015). After this spillover event, transmission occurs through contact with the body fluids of an infected person and can result in Ebola outbreaks in humans.

EBOLA IN HUMANS

Ebola's incubation period, the time between initial infection with the virus and onset of symptoms, is 2 to 21 days. A person infected with Ebola typically has a sudden onset of fever, intense weakness, muscle pain, headache, and sore throat (WHO, 2016b). In one of my first days in Sierra Leone, my colleague and I, in full personal protective equipment, went into the area where patients were treated to assist a 10 year-old who was being admitted. As I watched her stand up from a plastic chair, my heart learned what my head already knew. It took all of her energy and determination to push herself up with her arms and legs to a standing position. I watched her shuffle with an unsteady gait and witnessed the extreme weakness Ebola causes. The disease progresses to symptoms including vomiting, diarrhea, rash, impaired organ function, and in some cases bleeding. The level of virus in the body of an Ebola patient increases over time and later in the illness results in highly infectious bodily fluids.

Transmission among humans occurs through direct contact with the blood, secretions, organs or other bodily fluids of infected people, and with surfaces and materials (e.g., bedding, clothing) contaminated with these fluids (WHO, 2016a). A recent analysis of risk factors for transmission of Ebola concluded, "We have shown that risk of acquisition of filovirus infections primarily follows from only close personal contact and generally only in later stages of illness (Brainard, Hooper, Pond, Edmunds & Hunter, 2015)." Ebola is called a "disease of caregivers," because household members, traditional healers, and healthcare workers without protective equipment are most at risk of being infected while caring for those who are infected.

INFECTIOUS DISEASES AND QUARANTINE LAW

During the 2014-2015 Ebola Outbreak in West Africa, public health interventions, including quarantine, quickly surfaced in the U.S. as healthcare workers responding to the outbreak returned home. Quarantine is the restriction of persons who have been exposed to a contagious disease but are not yet ill (Gostin & Berkman, 2007a). Public health and legal experts agree there are circumstances when quarantine is necessary to protect the health of populations. Unfortunately, the understanding of these circumstances during the West African Ebola outbreak became blurred when politicians

decided to ignore public health experts and the law.

The Fourteenth Amendment ensures that no state shall "deprive any person of life, liberty, or property, without due process of law (U.S. Const. amend. XIV)." Because quarantine results in a severe infringement of an individual's life and liberty, quarantine must be applied using a sound legal and scientific framework. Ross Upshur outlines one such framework for quarantine decisions (Upshur, 2003):

- Under the harm principle there must be clear scientific evidence of person-to-person spread of the disease and the necessity of quarantine as a containment measure.
- The least restrictive means should be implemented.
- Upholding the principle of reciprocity points to the community's obligation to provide necessary support services for those in quarantine.
- The obligation of public health authorities is to communicate the reasons for their actions and to allow for a process of appeal.

Ebola is not a disease with presymptomatic shedding of the virus and thus the use of quarantine is not necessary according to the first of the two principles described above. This is precisely why the CDC recommends active and direct/active monitoring of those returning from Ebola-affected countries as being the least restrictive means necessary to protect public health. Speaking of pandemic influenza preparedness, experts reiterate, "Governments should avoid restrictions on individual movement that are arbitrary, unreasonable, or discriminatory. It is vital that individual rights are sacrificed only when necessary to protect the public health. As such, laws must clearly establish the criteria for the exercise of such emergency powers and provide adequate due process to minimize infringements on individual rights (Gostin & Berkman, 2007a)."

STATE GOVERNMENTS AND VOLUNTARY QUARANTINE

The fourth principle in Upshur's framework describes the need for clear communication of reasons for the actions of public health authorities and allowing for an appeal process. State and local governments have the primary responsibility for issuing quarantine orders through either public health orders by a state health officer or court orders by a judge. Many states chose more restrictive measures than those recommended by the CDC for persons returning from Ebola-affected countries in 2014 (CDC, 2015b). Even more concerning, many state officials asked returning Ebola workers to comply with 'voluntary' quarantines, leaving them with no possibility of due process or an appeal.

WHAT DOES A BIKE RIDE HAVE TO DO WITH DUE PROCESS?

I live in Oregon and the first time I tell people my story, they often say, "I remember you! You're the nurse from Maine who went on a bike ride with media following you." In October 2014, officials expected me to voluntarily stay in my home at Fort Kent, Maine. Voluntary in-home quarantine would have meant I could not make an appeal. It would have meant the state answered to no one. What seemed like merely a bike ride forced the state to follow the necessary procedures to quarantine me. The bike ride worked! The Maine Department of Health and Human Services (DHHS) submitted an affidavit to obtain a mandatory court order for quarantine, giving me the chance to argue my case.

The Maine statute, similar to those in many other states, says, "If, based upon clear and convincing evidence, the court finds that a public health threat exists, the court shall issue the requested order for treatment or such other order as may direct the least restrictive measures necessary to effectively protect the public health (22 M.R.S. § 812(1))."

Judge Charles LaVerdiere ruled in my favor and decided against the request by the Maine DHHS to quarantine me in my home. As he explained, "the State has not met its burden at this time to prove by clear and convincing evidence that limiting [Hickox's] movements to the degree requested [home-quarantine] is 'necessary to protect other individuals

Studies have shown that quarantine imposes serious financial and psychological hardships. In one study, about 30 percent of individuals quarantined for SARS suffered from posttraumatic stress disorder and depression.

from the dangers of infection' (Maine v. Hickox, 2014)." I complied with direct/active monitoring for the remainder of the 21 days.

A report by the ACLU Foundation and the Yale Global Health Justice Partnership (2015) tried to quantify the effects of quarantines in the U.S. during the Ebola outbreak and states,

> *"… by December [2015], nearly half the country (at least 23 states) had announced quarantine and movement restriction policies that exceeded the CDC's guidelines. Many of the quarantines were not implemented through official orders, but by coercing individuals to accept "voluntary" quarantines. New Hampshire authorities, for instance, praised two individuals for agreeing to voluntarily quarantine themselves upon their return from West Africa while pointing out that they had the authority to get law enforcement involved if they did not. Many "voluntary" quarantines were based on implied threats to individuals' livelihoods, reputations, and families.*

Indeed, returning health care workers we interviewed often felt as though they had no choice but to accept "voluntary" quarantines, leaving them with no legal recourse and states with no legal obligations to the health care workers or accountability to the public."

POLICIES BASED ON PANIC

As I arrived back into the U.S., the state of New Jersey implemented a policy stating that persons returning from Ebola affected countries would be subject to the NJ Department of Health mandatory quarantine order (2014). This is an example of discrimination against citizens not posing risk to the public. Lawrence Gostin and Benjamin Berkman of Georgetown University Law Center state (2007b), "The individual fear and community panic associated with infectious diseases often leads to rapid, emotionally driven decision making about public health policies needed to protect the community that may be in conflict with current bioethical principles regarding the care of individual patients." We cannot let fear, panic, and politics dictate quarantine policies.

Studies have shown that quarantine imposes serious financial and psychological hardships. In one study, about 30 percent of individuals quarantined for SARS suffered from posttraumatic stress disorder and depression (Hawryluck et al., 2004). This is yet another reason that quarantine must be reserved for only those circumstances where it is necessary to protect the public.

The main objective of my lawsuit against Governor Chris Christie of New Jersey and other state officials was to prevent misuse of quarantine in the future (Hickox v. Christie, 2015). At least one other lawsuit regarding quarantine has been filed against officials in Connecticut (Fink, 2016).

HAVE WE LEARNED ANYTHING?

I am not sure I believe we have learned what we need to learn yet, but there is still time. That is exactly what I and many others have been advocating for the past two years (Drazen et al., 2014; Infectious Diseases Society of America, 2014; Association for Professionals in Infection Control and Epidemiology, 2014; American Nurses Association, 2014; CDC, 2014). It is simple and can be summed up into two points.

- **Infectious disease and state quarantine policies must be based on sound legal and scientific frameworks.** We need to ensure that public health experts are allowed to make public health policy decisions based on epidemiology and medical science. In the case that politicians decide to insert their power, politicians should be held accountable for unlawful decisions in order to protect individual rights and public health principles.

- **There must be due process in quarantine orders; no more voluntary orders.** We must advocate for due process for all quarantines, whether voluntary or mandatory. Due process for those facing quarantine will counteract political overreach and ensure that politics and votes do not motivate state quarantine decisions and policies.

Legal nurse consultants and the medical-legal community can join in this pursuit for protection of our populations through science-based public health policies and legal protection for those facing possible quarantine. In doing this, we can protect populations in the U.S. and around the world by ensuring appropriate public health responses both at home and overseas.

REFERENCES

ACLU Foundation & Yale Global Health Justice Partnership. (2015). Fear, politics, and Ebola: How quarantines hurt the fight against Ebola and violate the constitution. Retrieved from http://media.wix.com/ugd/148599_3c2a77dfa3c84942be9b40efacda1876.pdf

American Nurses Association. (2014, October 29). ANA Supports CDC Guidance, Not Mandatory Quarantine for Health Care Professionals Returning from Treating Ebola Patients in West Africa (news release). Retrieved from http://nursingworld.org/ana-supports-cdc-guidance-not-mandatory-quarantine

Association for Professionals in Infection Control and Epidemiology (APIC). (October 26, 2014). APIC opposes mandatory quarantines for healthcare personnel returning from Ebola care in West Africa. Retrieved from http://www.apic.org/For-Media/Announcements/Article?id=529c5389-b73b-4ae9-8889-e47c-6305c3ea

Brainard, J., Hooper, L., Pond, K, Edmunds, K & Hunter, P.R. (2015). Risk factors for transmission of Ebola or Marburg virus disease: a systematic review and meta-analysis. Int. J. Epidemiol. Retrieved from http://ije.oxfordjournals.org/content/early/2015/11/20/ije.dyv307.full.pdf+html

Centers for Disease Control and Prevention (CDC). (2014, October 27). Update: CDC Ebola Response and Interim Guidance (press briefing transcript). Retrieved from http://www.cdc.gov/media/releases/2014/t1027-ebola-response-interim-guidance.html

Centers for Disease Control and Prevention (CDC). (2015a). Ebola virus disease: Transmission. Updated January 22, 2015. Retrieved from http://www.cdc.gov/vhf/ebola/transmission/

Centers for Disease Control and Prevention (CDC). (2015b). State Ebola protocols. Updated September 4, 2015. Retrieved from http://www.cdc.gov/phlp/publications/topic/ebola.html

Centers for Disease Control and Prevention (CDC). (2016a). Ebola virus disease: About Ebola virus disease. Updated February 18, 2016. Retrieved from http://www.cdc.gov/vhf/ebola/about.html

Centers for Disease Control and Prevention (CDC). (2016b). Outbreaks Chronology: Ebola Virus Disease. Updated April 14, 2016. Retrieved from http://www.cdc.gov/vhf/ebola/outbreaks/history/chronology.html

Drazen, J.M., Kanapathipillai, R., Campion, E.W., Rubin, E.J., Hammer, S.M., Morrissey, S. & Baden, L.R. (2014). Ebola and Quarantine. N Engl J Med. 371, 2029-2030. Retrieved from http://www.nejm.org/doi/full/10.1056/NEJMe1413139

Fink, S. (2016, February 7). Connecticut faces lawsuit over Ebola quarantine policies. New York Times. Retrieved from http://www.nytimes.com/2016/02/08/nyregion/connecticut-faces-lawsuit-over-ebola-quarantine-policies.html?_r=1

Gostin, L. O., & Berkman, B. E. (2007a). Pandemic influenza: Ethics, law, and the public's health. Administrative Law Review, 59(1), 121-175. Retrieved from http://scholarship.law.georgetown.edu/facpub/449

Gostin, L. O., & Berkman, B. E. (2007b). Preparing for pandemic influenza: legal and ethical challenges. In Institute of Medicine (US) Forum on Microbial Threats. Ethical and Legal Considerations in Mitigating Pandemic Disease: Workshop Summary. Washington (DC): National Academies Press (US). 3, Strategies for Disease Containment. Retrieved from http://www.ncbi.nlm.nih.gov/books/NBK54163/

Hawryluck, L., Gold, W.L., Robinson, S., Pogorski, S., Galea, S. & Styra, R. (2004). SARS Control and Psychological Effects of Quarantine, Toronto, Canada. Emerg Infect Dis. 10(7), 1206–1212. Retrieved from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3323345/

Hickox v. Christie, 2015. 42 U.S.C. § 1983. Retrieved from https://www.aclu-nj.org/files/7014/4554/5483/Hickox_v_Christie_Complaint_home_addresses_redacted.pdf

Infectious Diseases Society of America (IDSA). (2014). IDSA Statement on Involuntary Quarantine of Healthcare Workers Returning From Ebola-Affected Countries. Retrieved from http://www.idsociety.org/2014_ebola_quarantine/

Maine Revised Statutes, 22 M.R.S. § 812(1). Retrieved from http://www.mainelegislature.org/legis/statutes/22/title22sec812.html

Maine Department of Health and Human Services v. Hickox. (2014). Retrieved from http://www.courts.maine.gov/news_reference/high_profile/hickox/order_pending_hearing.pdf

New Jersey Department of Health. (2014). New Jersey mandatory quarantine and screening protocols. Retrieved from http://www.state.nj.us/health/news/2014/approved/20141031b.html

U.S. Const. amend. XIV (repealed 1968).

Upshur, R. (2003). The ethics of quarantine. AMA Journal of Ethics. 5(11). Retrieved from http://journalofethics.ama-assn.org/2003/11/msoc1-0311.html

World Health Organization (2016a). Ebola virus disease. Updated January, 2016. Retrieved from http://www.who.int/mediacentre/factsheets/fs103/en/

World Health Organization. (2016b). Frequently asked questions on Ebola virus disease. Updated January, 2016. Retrieved from http://www.who.int/csr/disease/ebola/faq-ebola/en/

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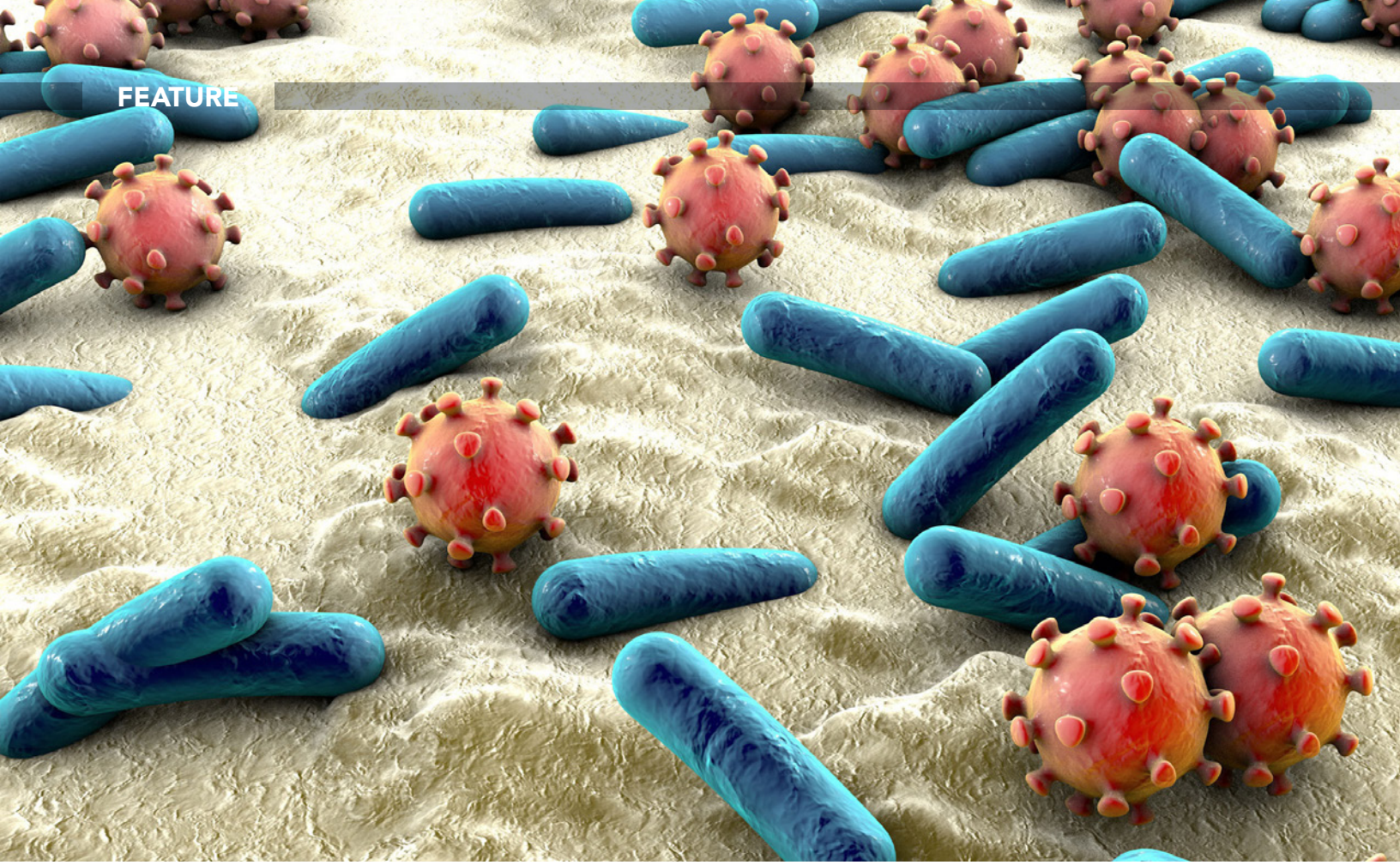

Sepsis: The Medicine, Claims and Defenses

By Susan Carleo and Bernard S. Vallejos

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Sepsis has reached epidemic levels, and even with appropriate interventions, sepsis has associated adverse outcomes, and medical malpractice litigation often will follow.

Sepsis is a serious illness, the hallmarks of which are an overwhelming systemic inflammatory response by the body and widespread tissue injury. It occurs secondary to severe infection and constitutes a medical emergency (as emergent as a heart attack or stroke),because it causes an interruption of oxygen and nutrients to the tissues (i.e., hypoperfusion), including vital organs such as the brain, intestines, liver, kidneys, and lungs. Early identification and restoration of adequate perfusion are critical in preventing irreversible organ dysfunction and death. Management includes recognition and implementation of aggressive interventions aimed at source control and reversal of sepsis-induced tissue hypoperfusion.

The incidence of sepsis is at epidemic levels. From 2000 to 2008, the number of hospitalizations with septicemia or sepsis listed as the first, principal, or secondary diagnoses jumped from 621,000 to 1,141,000. *See Hall et al., Inpatient Care for Septicemia or Sepsis: A Challenge for Patients and Hospitals,* NCHS Data Brief No. 62, Nat'l

Ctr. for Health Statistics (June 2011). While it occurs in just 10 percent of all hospital patients in the United States, it contributes to 33–50 percent of all hospital deaths. Liu *et al., Hospital Deaths in Patients with Sepsis from 2 Independent Cohorts*, JAMA, Vol. 312, No. 1 (July 2, 2014), available at http://jama.jamanetwork.com/article.aspx?articleid=1873131 (last visited Feb. 9, 2016). Sepsis globally is more common than heart attack and claims more lives than any cancer. World Sepsis Day Org., Sepsis Facts, http://www.world-sepsis-day.org/?MET=SEPSISSTART&vPRIMNAVISELECT=3&vCONTAINERID= (last visited Feb. 9, 2016).

In 2011, the United States spent more than 20 billion dollars on the diagnosis and treatment of sepsis, making it the most expensive condition treated in hospitals. *See* Celeste M. Torio & Roxanne M. Andrews, *National Inpatient Hospital Costs: The Most Expensive Conditions by Payer*, HSUP Statistical Brief No. 160, Agency for Healthcare Research and Quality, Aug. 2013, at http://www.hcup-us.ahrq.gov/reports/statbriefs/sb160.pdf. The Agency for Healthcare Research and Quality found that from 1997 through 2008, the inflation-adjusted aggregate costs for treating hospital patients with sepsis increased annually at a rate of 11.9 percent. *See* Hall *et al., supra*. Using that percentage, sepsis can be expected to cost over 30 billion dollars in 2016.

Sepsis and its related conditions—systemic inflammatory response syndrome (SIRS), severe sepsis, and septic shock—can be associated with adverse outcomes, including chronic deficits and death—even with appropriate interventions. As a consequence, claims of medical professional liability often follow. It is important for defense practitioners to understand these medical conditions and their treatments, common plaintiffs' theories, and potential defense themes. This article will address these serious medical conditions and provide practical pointers for consideration, focusing on the diagnosis and treatment issues for individual healthcare providers in medical malpractice litigation rather than environmental (nosocomial) claims against hospitals and other healthcare facilities.

IMPORTANT INTERNATIONAL SEPSIS-RELATED CLINICAL GOALS

In August 1991, the American College of Chest Physicians and the Society of Critical Care Medicine held a consensus conference with the goal of agreeing on a set of definitions for application to patients with sepsis and its sequelae. Bone *et al., ACCP/SCCM Consensus Conference, Definitions for Sepsis and Organ Failure and Guidelines for the Use of Innovative Therapies in Sepsis*, Chest 101:1644–55 (1992). In 2001, a second sepsis conference resulted in modification of the 1992 criteria definitions to reflect the then current understanding of the pathophysiology of sepsis. *Levy et al., 2001 SCCM/SCCP/ATS/SIS International Sepsis Definitions Conference*, Crit. Care Med., 31(4):1250–56 (2003). Five conclusions resulted:

- **Conclusion 1:** Current concepts of sepsis, severe sepsis, and septic shock remain useful to clinicians and researchers.
- **Conclusion 2:** These definitions do not allow precise staging or prognostication of the host response to infection.
- **Conclusion 3:** While SIRS remains a use-ful concept, the diagnostic criteria for SIRS published in 1992 are overly sensitive and nonspecific.
- **Conclusion 4:** An expanded list of signs and symptoms of sepsis may better reflect the clinical response to infection.
- **Conclusion 5:** PIRO, a hypothetical model for staging sepsis, may better characterize the syndrome on the basis of predisposing factors and premorbid conditions, the nature of the underlying infection, the characteristics of the host response, and the extent of the resultant organ dysfunction.

In 2002, relative to the increased awareness of sepsis, the Surviving Sepsis Campaign was formed as a joint collaboration of the Society of Critical Care Medicine, the European Society of Intensive Care Medicine, and the International Sepsis Forum. Its goal was to achieve a 25 percent reduction in mortality from sepsis by 2009 through such things as increasing sepsis awareness, educating healthcare professionals, and developing guidelines of care. In March and April 2004, *Critical Care Medicine and Intensive Care Medicine* published the first guidelines for the management of severe sepsis and septic shock. In 2008, the second edition of the "Surviving Sepsis Campaign Guidelines for Management of Severe Sepsis and Septic Shock" was published. In 2012, the Guide lines again were updated and revised treatment bundles were incorporated. Surviving Sepsis Campaign, *International Guidelines for Management of Severe Sepsis and Septic Shock: 2012*, http://www.sccm.org/Documents/SSC-Guidelines.pdf. The guidelines provided recommendations for clinicians caring for patients with severe sepsis or septic shock. It is critical for defense litigators to understand and emphasize that while "these recommendations are intended to be best practice… [they were] not created to represent standard of care" as that phrase is understood in the legal field. Id. As the document notes: "Recommendations from these guidelines cannot replace the clinician's decision-making capability when he or she is presented with a patient's unique set of clinical variables." *Id.*

The guidelines identify a number of risk factors for sepsis: children younger than one year of age and adults over 65; patients with bacteremia (bacteria in the blood); ICU patients; patients who are immunosuppressed; patients with chronic illness, cancer, diabetes, or renal dysfunction; patients who undergo surgery and other invasive procedures; and patients with cardiac disease, community acquired pneumonia, malnutrition, poor mobility, trauma, burns, prolonged antibiotic use, and presence of invasive devices. Genetic defects also have been identified as potentially increasing susceptibility to specific classes of microorganisms.

Additionally, the guidelines delineate the following poor prognostic factors for patients with sepsis: hypothermia with the inability to spike a fever; leukopenia (low white cell count); persons older than 40 years of age; comorbidities such as AIDS; hepatic failure; cirrhosis; cancer; alcohol dependence and immunosuppression; a nonurinary source of infection; a nosocomial source of infection (acquired in a hospital or other healthcare facility); inappropriate antibiotic coverage; and failure to restore perfusion aggressively and early (failure to initiate early goal directed ther-apy). In the context of sepsis- related litigation, plaintiffs tend to focus their claims on the last three poor prognostic factors.

U.S. Government Mandates

On August 4, 2014, the Centers for Medicare and Medicaid Services (CMS) announced its intent to institute new federal reporting requirements and guidelines for how clinicians should treat patients with severe sepsis and septic shock, as well as new definitions for each of these conditions. *See* Ctrs. for Medicare and Medicaid Servs., *CMS to Improve Quality of Care During Hospital Inpatient Stays*, Fact Sheet (Aug. 4, 2014), https://www.cms.gov/newsroom/mediareleasedatabase/fact-sheets/2014-fact-sheets-items/2014-08-04-2.html (last visited Feb. 9, 2016). Various providers and health-care groups expressed concern over these anticipated mandates because of the broad definitions included in them and the potential that this measure overall may result in over treatment. *See, e.g.*, The Advisory Bd. Co., *CMS's New Sepsis Measure Makes Some Providers Worried. Here's Why* (Aug. 24, 2015), https://www.advisory.com/daily-briefing/ 2015/08/24/new-cms-sepsis-measures (last visited Feb. 9, 2016). The CMS mandate became effective on October 1, 2015. *See* Nat'l Quality Forum (NQF), NFQ #0500 Severe Sepsis and Septic Shock: Management Bundle, http://emcrit.org/wp-content/uploads/2015/06/0500.pdf (last updated Jan. 5, 2015).

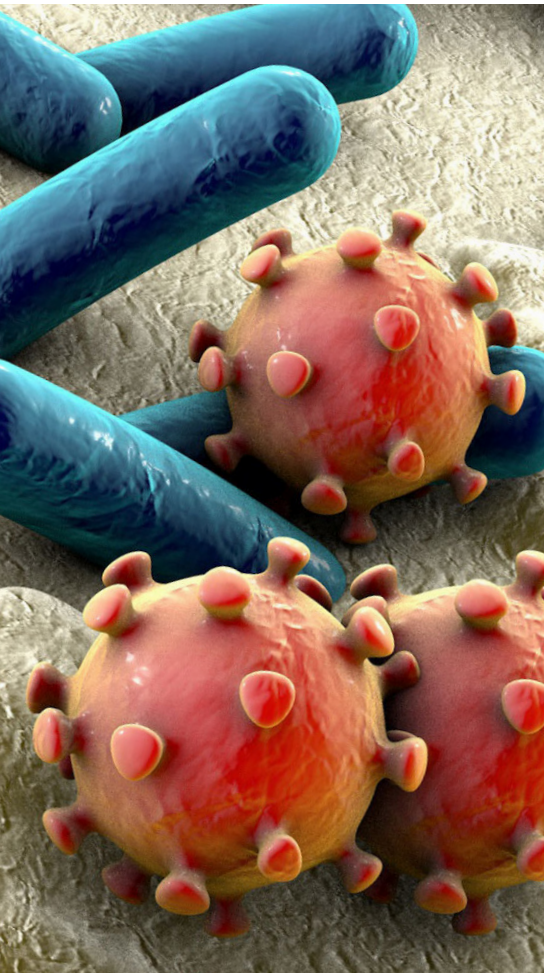
In 2011, the UnitedStates spent more than 20 billion dollars on the diagnosis and treatmentof sepsis, making it the most expensive condition treated in hospitals.

The concerns identified by various individuals and groups in response to the CMS mandates offer cross-examination material beneficial to defense litigators. For example, "Dr. Smith, isn't it true that the Infectious Diseases Society of America is concerned about over-treatment as a result of this mandate?" Additionally, attempts by plaintiffs to use the CMS mandates during litigation can be countered by the disclaimer at the end of the measure, expressly designed to preempt and negate any legal effect: "These performance measures are not clinical guidelines and do not establish a standard of medical care, and have not been tested for all potential applications." *See id.*

SEPSIS-RELATED CONDITIONS

Sepsis always begins with an infection from some source. There are four sepsis related conditions every litigator should be familiar with: SIRS, sepsis, severe sepsis, and septic shock. SIRS is often presented in litigation as the precursor to sepsis and is defined as a systemic response to an insult. While a bodily insult can be bacterial in origin, it also can be fungal, viral, or parasitic. It is a truism that SIRS and early sepsis often annot be easily distinguished, and a common refrain from plaintiffs is that a source of sepsis should be sought whenever SIRS is suspected, along the same lines as the reptilian "worst first" mantra. For a patient to be considered as meeting SIRS criteria, two of the following must be present: (1) a fever of greater than 38.3° C (101° F) (hyperthermia), or a temperature of less than 36° C (96.8° F) (hypothermia); (2) an elevated heart rate of greater than 90 beats per minute (tachycardia); (3) an elevated respiratory rate of greater than 20 breaths per minute (tachypnea); and (4) a white blood cell count high of greater than 12,000 (leukocytosis) or a white blood cell count low of less than 4,000 (leukopenia), or greater than 10 percent bands (bandemia). *Bone et al., supra.*

Sepsis is defined by the CDC as "the body's overwhelming and life-threatening response to infection, which can lead to tissue damage, organ failure and death." Ctrs. for Disease Control and Prevention, Sepsis, http://www.cdc.gov/sepsis/ (last visited Feb. 9, 2016). Sepsis is the presence—probable or documented—of infection together



with systemic manifestations of infection; in other words, it is a confirmed or sus-pected infection plus the existence of two or more of the SIRS criteria. Surviving Sepsis Campaign, *International Guide-lines 2012, supra*. Other potential manifestations of infection that plaintiffs may raise include the following: altered mental status (confusion, anxiety, agitation); significant edema (swelling); high blood glucose of greater than 140 mg/dL without diabetes; plasma C-reactive protein (CRP) of greater than 2 SD (standard deviation) above the normal value; plasma procalcitonin of greater than 2 SD above the normal value; systolic blood pressure (SBP) of less than 90 mmHg or SBP decrease of greater than 40 mmHg in adults below their baseline; arterial hypoxemia (PaO2/FiO2 <300); acute oliguria (urine output of less than 0.5 mg/kg per hour for at least 2 hours despite adequate fluid resuscitation); creatinine increase of greater than 0.5 mg/dL; coagulation abnormalities (INR >1.5 or aPTT >60 seconds); ileus (absent bowel sounds); thrombocytopenia (platelet count <100,000); hyperbilirubinemia (plasma total bilirubin >4 mg/dL); hyperlactemia (>1 mmol/L); decreased capillary refill (>3 seconds); and mottling. *Id.*

Severe sepsis is defined as sepsis plus sepsis-induced tissue hypoperfusion or organ dysfunction thought to be due to the infection. Id. (It is important to note that the recent CMS mandates removed the "thought to be due to infection" phrase from its definition of severe sepsis.) Sepsis-induced tissue hypoperfusion or organ dysfunction is defined as sepsis-induced hypotension, elevated lactate, or oliguria (low urine output <0.5 mL/kg/hr for more than two hours despite adequate fluid resuscitation). Sepsis-induced hypotension is defined as a systolic blood pressure (SBP) of less than 90-mmHg, or mean arterial pressure (MAP) of less than 70 mmHg, or a SBP decrease of greater than 40 mmHg below baseline without other causes of hypotension. Neviere *et al., Sepsis and the Systemic Inflammatory Response Syndrome: Definitions, Epidemiology and Prognosis*, http://www.uptodate.com/ (last searched Feb. 9, 2016) (search "sepsis").

Signs and symptoms of organ dysfunction in cases of severe sepsis include the potential manifestations of infection identified previously, as well as Glasgow coma scale abnormalities, acute lung injury with low oxygen saturations of less than 90 percent in the absence or presence of pneumonia as the infection source or acute respiratory distress syndrome (ARDS), elevated liver enzymes (AST, ALT, Alkaline Phosphatase), jaundice, decreased albumin, disseminated intravascular coagulation (DIC), abnormal EKG, left ventricular dysfunction, anuria, and blood in nasogastric aspirate. Al-Khafaji *et al., Multiple Organ Dysfunction Syndrome in Sepsis* (Mar. 20, 2015), http://www.medscape.com/ (last searched Feb. 9, 2016) (search title).

Septic shock is defined as severe sepsis plus sepsis- induced hypotension that does not respond to standard treatment (fluid resuscitation); lactate levels greater than or equal to 4 mmol/L; perfusion abnormalities resulting in cellular hypoxia; and imbalance between oxygen supply and demand. Surviving Sepsis Campaign, *International Guidelines 2012, supra*.

STATE-MANDATED SEPSIS PROTOCOLS AND SCREENING TOOLS

Concerns exist about state regulatory mandates for sepsis care due to the fact that there is still much to learn regarding the best way to organize sepsis care, and reliable tools do not exist to measure sepsis incidence. *See* Rhee *et al., Regulatory Mandates for Sepsis Care—Reasons for Caution*, New Engl. J. Med. 370:1673–76 (2014). However, that has not stopped states and individual facilities from implementing sepsis protocols and screening tools for evaluating patients for severe sepsis in emergency departments, on the medical and surgical floors, or in ICUs, and then instituting template treatments.

For example, effective May 1, 2013, New York became the first state to

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mandate that all hospitals in the state adopt a sepsis protocol because of the sad case of Rory Staunton. Rory was a 12-year-old from Queens, New York, who had cut his arm while diving for a basketball in the school gym. He vomited after midnight later that evening. He was taken to the family physician later the next day with a fever, severe leg pain, and delayed capillary refill. His family physician suspected a stomach bug and sent him to the emergency department for fluids. The emergency medicine physician thought that Rory had improved after Rory received IV fluids and the physician discharged him with some Zofran for nausea. Rory died three days later from septic shock; group A streptococci had entered his bloodstream through the cut on his arm.

Known as "Rory's Regulations," Sections 405.2 and 405.4 of Title 10 (Health) of the official New York Codes, Rules and Regu-lations were amended. Of particular note, the amendments included the addition of subparagraph (8) of Section 405.2, which states that "hospitals shall have in place evidence-based protocols for the early recognition and treatment of patients with severe sepsis/septic shock that are based on generally accepted standards of care as required by subdivision (s) of section 405.4 of this Part." Subparagraph 4 of Section 405.4 specifies processes for sepsis screening and treatment protocols, as well as guidelines for hemodynamic support and fluid resuscitation in children. The state required hospitals to submit protocols by July 1, 2013, for review, in accordance with subparagraph 6. Subparagraph 5 mandated sufficient training of medical staff with respect to the implementation of sepsis protocols. Subparagraph 7 addressed the collection, use, and reporting of quality measures related to the recognition and the treatment of sepsis, and subparagraph 8 provided definitions for sepsis, severe sepsis, and septic shock that mirrored those set forth in the Surviving Sepsis Campaign guidelines.

The New Jersey Hospital Association Institute for Quality & Patient Safety developed the New Jersey 2015 Sepsis Learning-Action Collaborative with one of the stated goals being for all hospitals in the state to implement early recognition sepsis-screening and treatment protocols by December 2015. See N.J. Hospital Ass'n Inst. for Quality & Patient Safety, Charter, 2015 Sepsis Learning-Action Collaborative, http://www.njha.com/media/315870/Charter-NJHA-Quality-Institute-New-Jersey-2015-Sepsis-Learning-Action-Collaborative.pdf (last visited Feb. 9, 2016). On June 29, 2015, various assemblymen and assemblywomen introduced a bill to supplement Chapter 2H of Title 26 of the New Jersey Revised Statutes to require hospitals to establish sepsis recognition and treatment protocols. See Assemb. B. 4678, 216th Leg. (N.J. June 29, 2015), *available at* http://www.njleg.state.nj.us/2014/Bills/A5000/4678_I1.HTM (last vis-ited Feb. 9, 2016).

On February 20, 2015, Illinois introduced Senate Bill 1862 for the purpose of amending 20 Ill. Comp. Stat. 2310/2310-314 and 210 Ill. Comp. Stat. 85/6.23a. This bill will require hospitals to adopt evidence-based protocols for the early recognition and treatment of patients with sepsis, severe sepsis, or septic shock based on generally accepted standards of care. Senate Bill 1862 is substantially similar to "Rory's Regulations." See S.B. 1862, 99th Leg. (Ill. Feb. 20, 2015), *available at* http://www.ilga.gov/legislation/fulltext.asp?DocName=&SessionId=88&GA=99&DocTypeId=SB&DocNum=1862&GAID=13&LegID=&SpecSess=&Session= (last visited Feb. 9, 2016).

To date, neither the New Jersey nor the Illinois legislation have been passed or signed into law, but it is expected that both will in the future in light of the push toward regulatory mandates for the management of sepsis patients. In addition, many individual hospitals, such as Charleston Area Medical Center in Charleston, West Virginia, Baylor University Medical Center in Dallas, Texas, and St. Joseph Mercy Ann Arbor in Ann Arbor, Michigan, have instituted sepsis-screening tools.

Each litigator should know whether or not his or her state or the applicable facility has developed such a sepsis-screening tool or protocol. In litigation, plaintiffs will advance these tools and protocols as mandating the guidelines for and the methodologies by which providers must investigate, diagnose, and treat sepsis-related conditions. Plaintiffs and their experts will argue that using a sepsis-screening tool to identify sepsis early is essential and that screening must be a multidisciplinary process that involves all providers, thus

inferring a duty of care across multiple providers. Plaintiffs and their experts also will argue that a sepsis protocol reflects the accepted standard of care with respect to treatment and that any deviation from a sepsis protocol constitutes a breach of the duty of care.

Generalizations About Mandated Protocols

As for these protocols generally, a bedside nurse, as the healthcare team member the most often with patients, is responsible for the initial screening. If a paper tool is used, a bedside nurse gathers the data required and documents it; if the screening tool is electronic, the nurse receives the alerts. In either case, the information is verified and it is expected that positive screening results be communicated to the medical team so they can make a decision about the appropriate intervention.

Most sepsis-screening tool checklists begin with making a determination whether infection is suspected. First, a screening provider must determine whether or not a patient's history suggests a new infection, such as meningitis, endocarditis (infection of a heart valve), or a wound infection, such as if the patient recently underwent a surgical procedure. Then a provider must evaluate the signs and the symptoms of the patient to determine if there are any indicators of infection, such as altered mental status, tachycardia, hyperthermia, tachypnea, or leukocytosis. If at least two of these items are present and are new to the patient and the history suggests a new infection then a suspicion of infection, then a suspicion of infection is present and the provider should obtain lactic acid, blood cultures, CBC with differential, basic chemistry labs, and bilirubin. At the physician's discretion, a urinalysis, chest X-ray, amylase, lipase, ABG, CRP, CT scan or combination of these may be obtained.

Next, a determination is made whether organ dysfunction criteria exist at a site remote from the site of infection. Signs of this include a systolic blood pressure of below 90 or a mean arterial pressure of lower than 65, creatinine of greater than 2.0 mg/dL or urine output of less than 0.5 mL/kg/hour for two hours (indicating renal insufficiency), or a platelet count of less than 100,000 µL or an acute lung injury with a PaO2/FiO2 of less than 250 (absent pneumonia as infection source) or of less than 200 (in the presence of pneumonia as infection source). If an infection is suspected, and organ dysfunction is present, then a patient meets the criteria for severe sepsis (as defined above, sepsis plus sepsis-induced tissue hypoperfusion, or organ dysfunction thought to be due to the infection), and the patient should begin receiv-ing the treatment specified by the severe sepsis protocol, as outlined in the treatment bundles described in the next section.

Each litigator should know whether or not his or her state or the applicable facility has developed such a sepsis-screening tool or protocol.

TREATMENT BUNDLES

Therapeutic priorities for patients with severe sepsis and septic shock include securing the airway, correcting hypoxemia (low oxygen), and administering IV fluids and antibiotics. Intubation and mechanical ventilation may be required in some patients. Treatment bundles have been developed to improve outcomes because early treatment is the most important factor in improving patient outcomes. Surviving Sepsis Campaign, *International Guidelines* 2012, *supra*. It has been reported that each hour of delay in antibiotic administration in patients with severe sepsis results in a corresponding 7.6 percent increase in mortality. Kumar *et al.*, *Duration of Hypotension Before Initiation of Effective Antimicrobial Therapy Is the Critical Determinant of Survival in Human Septic Shock*, Crit. Care Med. 34:1589–96 (2006).

The Surviving Sepsis Campaign guidelines continue to use triage time as "time zero" in patients presenting to an emergency department, but the guidelines recognize that a percentage of patients may not meet criteria for severe sepsis or septic shock during triage in an emergency department. Remember that while the Surviving Sepsis Campaign guidelines discuss SIRS, sepsis, severe sepsis, and septic shock, the treatment bundles provided are for severe sepsis and septic shock.

The three-hour bundle is to be completed within three hours of presentation, that is, the time of triage in an emergency department, or if presenting from another care venue, from the earliest chart annotation consistent with all elements of severe sepsis or septic shock as ascertained through chart review. This bundle includes the following: (1) measuring the lactate level; (2) obtaining two sets of blood cultures before administering antibiotics; (3) administering broad spectrum antibiotics; and (4) administering 30 mL/ kg crystal-

loids for hypotension or a lactate level of greater than or equal to 4 mmol/L. Cultures of other sites (e.g., urine, cerebrospinal fluid, wound, respiratory secretion, body fluid) that may be the source or pathway of infection should be obtained before antibiotic therapy, as long as doing so does not cause significant delay in antibiotic therapy. It is recommended that IV antimicrobials be administered within the first hour of recognition of septic shock and severe sepsis without septic shock.

The six-hour bundle is to be completed within six hours of presentation. Vasopressors are to be applied for hypotension that does not respond to the initial fluid resuscitation, to maintain a mean arterial pressure of greater than or equal to 65. If hypotension persists after the initial fluid administration, or if the initial lactate level was greater than or equal to 4 mmol/L, volume status and tissue perfusion should be reassessed. The lactate should be measured again if the initial lactate was elevated. To reassess volume status and tissue perfusion, a focused exam of vital signs, cardiopulmonary signs, capillary refill, pulse, and skin findings should be repeated. Alternatively two of the following should be done: a patient's central venous pressure should be measured, the patient's central venous oxygen saturation should be measured, a bedside cardiovascular ultrasound should be performed, or a dynamic assessment of fluid responsiveness through passive leg raise or fluid challenge should occur.

WHAT DOES THIS MEAN IN LITIGATION?—PLAINTIFF CLAIMS

Similar to most other medical malpractice cases, sepsis cases follow the traditional legal formula of duty, breach of the standard of care, proximate causation (or loss of a chance), and damages. Plaintiffs focus on alleged breach or breaches of the standard of care and proximate causation, since duty and damages usually are foregone conclusions. Most providers whose names are not somewhere on a chart are not named in the litigation, and most septic patients have had prolonged hospitalizations with significant attendant medical costs, and possibly long-term deficits. The common claim regarding sepsis is that (1) a provider or providers failed to diagnose sepsis or there was an improper delay in the diagnosis, and (2) as a consequence, necessary antibiotic, fluid resuscitation, and other treatments were delayed, leading to serious injury or death to a patient.

Many plaintiffs' firms advertise specifically for sepsis cases. See, e.g., http://www.beasleyfirm.com/medical-malpractice/sepsis-or-infection/; and http://www.indianamalpracticelawyer.com/Sepsis_and_Septic_Shock_Due_To_Malpractice.htm (all last visited Feb. 9, 2016). This is not necessarily surprising. Septic patients often have adverse outcomes and therefore significant damages. The mortality rate is up to 30 percent for sepsis, up to 50 percent for severe sepsis and up to 80 percent for septic shock. Jawad et al., *Assessing Information on the Burden of Sepsis: Global Estimates of Incidence, Prevalence and Mortality*, J. of Global Health, Vol. 2, No. 1 (June 2012). Additionally, plaintiffs' attorneys are cognizant of the lists of risk and poor prognostic factors, the nonspecific infection signs and symptoms, and the screening and treatment templates that can be used as informal standard of care checklists during depositions and during trials.

With that in mind, plaintiffs' attorneys in sepsis cases tend to review a medical record to identify the first instance that a patient met two or more of the SIRS criteria. They review all temperature readings and pull out those that demonstrate a fever greater than 101 or less than 96.8 Fahrenheit. They focus on each heart rate reading greater than 90 beats per minute, and each respiratory rate greater than 20 breaths per minute. They examine all complete blood count results, with particular focus on a patient's WBC count and percentage of bands. They pinpoint any other results or symptoms potentially indicative of infection, such as the following: confusion/altered mental status; low platelet level (potentially indicative of bacteremia); and urinalysis with a positive leukocyte esterase (an enzyme in WBCs). They also review a patient's medical and family history to identify all factors that may place the patient at increased susceptibility for infection. With this information in hand, and knowledge of the outcomes—unlike the providers involved in the litigation—plaintiffs' attorneys generally will argue that a provider ignored or otherwise failed to recognize the hallmark signs of SIRS, the "precursor to sepsis." Alternatively, if a probable infection source can be identified (*e.g.*, recent surgery), or suggested (*e.g.*, the patient visited his mother in a nursing home regularly or showered in gym locker rooms every day), plaintiffs' attorneys generally will argue that a provider ignored or failed to diagnose sepsis.

Plaintiffs claim that the point when two or more of the SIRS criteria are fulfilled is when the treatment modalities, described above, should be initiated. They claim blood cultures should be done, broad spectrum antibiotics initiated and fluid resuscitation administered immediately without waiting for the results of the cultures.

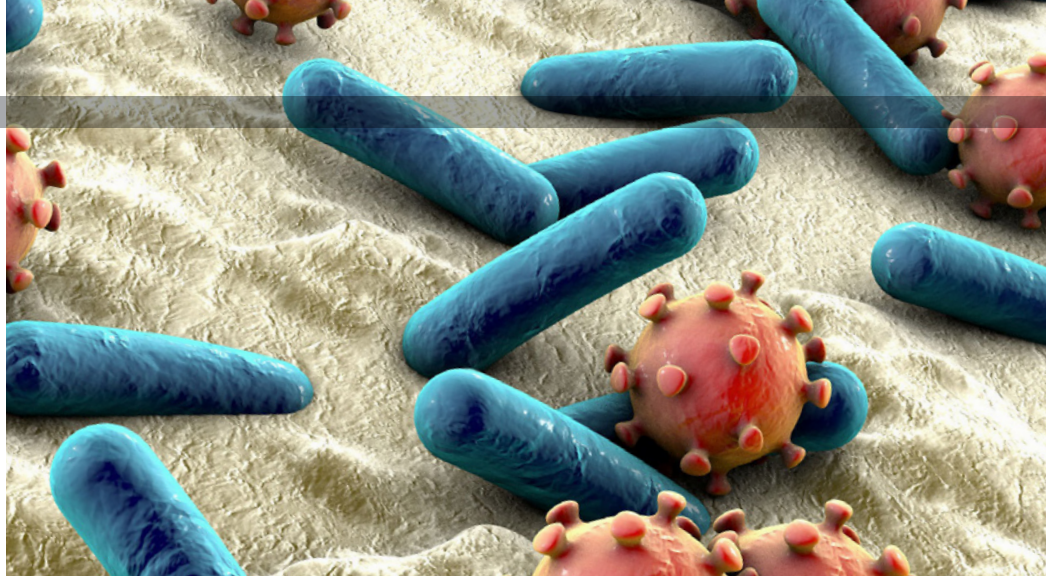
The reasoning underlying immediate ini-tiation of broad spectrum antibiotics is that depending on the facility or the lab, it can take a prolonged period of time for the results of blood cultures to become available. Given the concerns that accompany delaying treatment by as little as one hour, plaintiffs expect providers to "err on the side of caution" and begin treatment with medica-

tions that are considered "harmless" to a patient in comparison with the possible outcomes for a septic patient left untreated.

Other claims in sepsis cases can include the alleged failure to communicate and to coordinate with other healthcare providers regarding a patient's care; failure to evaluate and follow up on the results of diagnostic tests ordered to ensure timely and appropriate management of infection; failure to follow the sepsis protocol (if one exists at the particular facility); improper medication management, such as failure to order the appropriate type or dosage of antibiotic; failure to reevaluate and change the treatment plan if a patient's condition does not improve; failure to perform surgery in a timely manner; failure to develop a differential diagnosis; failure to determine sensitivity of the infecting organism to the antibiotics ordered (once the culture results became available); postoperative negligence such as failing to recognize and treat complications arising from surgery organ perforation, peritonitis, or respiratory failure; failure to order the necessary consults (e.g., infectious disease); and failure to send a patient to a specialist if the current physician's care is insufficient.

WHAT DOES THIS MEAN IN LITIGATION? DEFENSE THEMES AND PRACTICE POINTERS

One common defense theme in sepsis cases is that a patient unfortunately would have succumbed inevitably to the overwhelming systemic inflammatory response to the infection and no intervention, regardless of how timely, would have changed the outcome, *i.e.*, a classic "absence of proximate causation" theme. This theme often is appropriate in a sepsis case because patients may choose not to seek medical care for what they consider initially to be cold- or flu-like



It is important for a defense litigator to undertake a thorough analysis of each aspect of a patient's presentation to a provider and to establish through the plaintiff's and the defense experts each of the other medical conditions that can manifest with the same clinical picture.

symptoms. It may not be until a patient demonstrates more serious indications of an infection, such as a rash of the torso or altered mental status, that a patient will seek treatment by and present serious symptoms to a healthcare provider. By that time, a patient often will have fallen into a poor prognostic category and intervention may make no difference in the outcome. Key sources of information for such an analysis are any autopsy report, culture reports, and radiological reports that yield important information regarding the severity and the timing of the infection (*e.g.*, seeding of bacteria), and the overall progression of the systemic inflammatory response. Infectious disease and pathology expert witnesses are important for developing this causation theme.

A standard of care theme is that a patient's vital signs, physical exam, and laboratory findings all were consistent with a provider's alternative impression of the patient's condition. For example, hyperthermia can be caused by minor viral processes such as the common cold or the flu, medications, cancer, vaccines, and other conditions that cause inflammation. Tachycardia can be caused by exercise, sudden stress including fright, smoking, fever, drinking too much alcohol, caffeine, medications, hyperthyroidism, and cardiac issues. Tachypnea can be caused by exercise, asthma, chronic obstructive pulmonary disease (COPD) and other lung diseases, heart failure, anxiety, and pneumonia. Leukocytosis can be caused by stress, exercise, medications, cancer, and viral infections.

Also, specific to lab values, keep in mind that the "normal" ranges provided with each CBC, CMP, UA, or some other report vary from facility to

facility. Additionally, patients' baseline lab values also are not uniform. Thus, for example, a patient with a WBC value of 11,000 does not automatically indicate an abnormality or leukocytosis. It is important for a defense litigator to undertake a thorough analysis of each aspect of a patient's presentation to a provider and to establish through the plaintiff's and the defense experts each of the other medical conditions that can manifest with the same clinical picture. Another defense theme is to establish that a patient has no suspected source of infection because the definition of sepsis mandates the existence of a suspected source of infection. If a patient discloses no recent surgical procedure, respiratory infection, urinary or GI infection, skin or soft tissue infection, or has no open wound to serve as a pathway for bacteria into the bloodstream, the lack of a suspected source of infection should be a strong defense. The factual information related to this defense theme should exist in the history, review of systems, and physical exam portions of a provider's notes and warrants close scrutiny.

Yet one more defense theme involves attacking the SIRS criteria by demonstrating that they are not specific to sepsis alone. As the 2001 International Sepsis Definitions Conference proceedings noted, "The SIRS concept is valid to the extent that a systemic inflammatory response can be triggered by a variety of infectious and non-infectious conditions. Signs of systemic inflammation can and do occur in the absence of infection among patients with burns, pancreatitis, and other disease states." Levy *et al.*, *supra*. A 2015 article published in the *New England Journal of Medicine* addressed this issue, as well. The authors observed that not only do the SIRS criteria apply to patients without infection, but they also exclude patients who have infection and organ failure. Kaukonen et al., *Systemic Inflammatory Response Syndrome Criteria in Defining Severe Sepsis*, NEJM 372:1629–38 (Apr. 23, 2015). For example, a patient may be tachycardic and tachypneic if he or she just walked briskly into an emergency department after parking far away from the entrance. The body temperature also may be elevated. Even though such a patient has met the SIRS criteria, that would not be a sufficient predicate for initiating antibiotic and fluid resuscitation therapy, in particular if the patient's tachycardia, tachypnea, and hyperthermia resolve in the emergency department. However, if such a patient did die from septic shock four days later, a plaintiff's attorney certainly would key in on those vital sign measurements from that hospital visit.

Other items for investigation include the deficits that a patient was likely to not just secondary to sepsis, but also stemming from the underlying infection, for example, neurological issues caused by meningitis, encephalitis, or a brain abscess. Audit trails should be scrutinized to prepare for and to explain timing issues or discrepancies in the medical record.

Finally, contributory or comparative negligence defenses also may be warranted if a patient introduced the source of the bacteria to him- or herself, such as through IV-drug use, or if a patient did not comply with discharge instructions from a previous healthcare provider.

CONCLUSION

We hope that the information presented here provides you with some facts and develop, suggestions useful in the defense of your clients who may be faced with failure to diagnose, delay in diagnosis, misdiagnosis or mismanagement of sepsis claims. The definitions for the sepsis-related conditions, the lists of risk and poor prognostic factors, and the recommended treatment bundles provide a roadmap of the topics and the details upon which your client will be cross-examined by a well prepared plaintiff's attorney. These materials will assist you to evaluate a provider's care and potential exposure thoroughly, and they will arm you with the information that you need to develop appropriate themes to explain and to defend against the theories advanced by plaintiffs' attorneys. ❧

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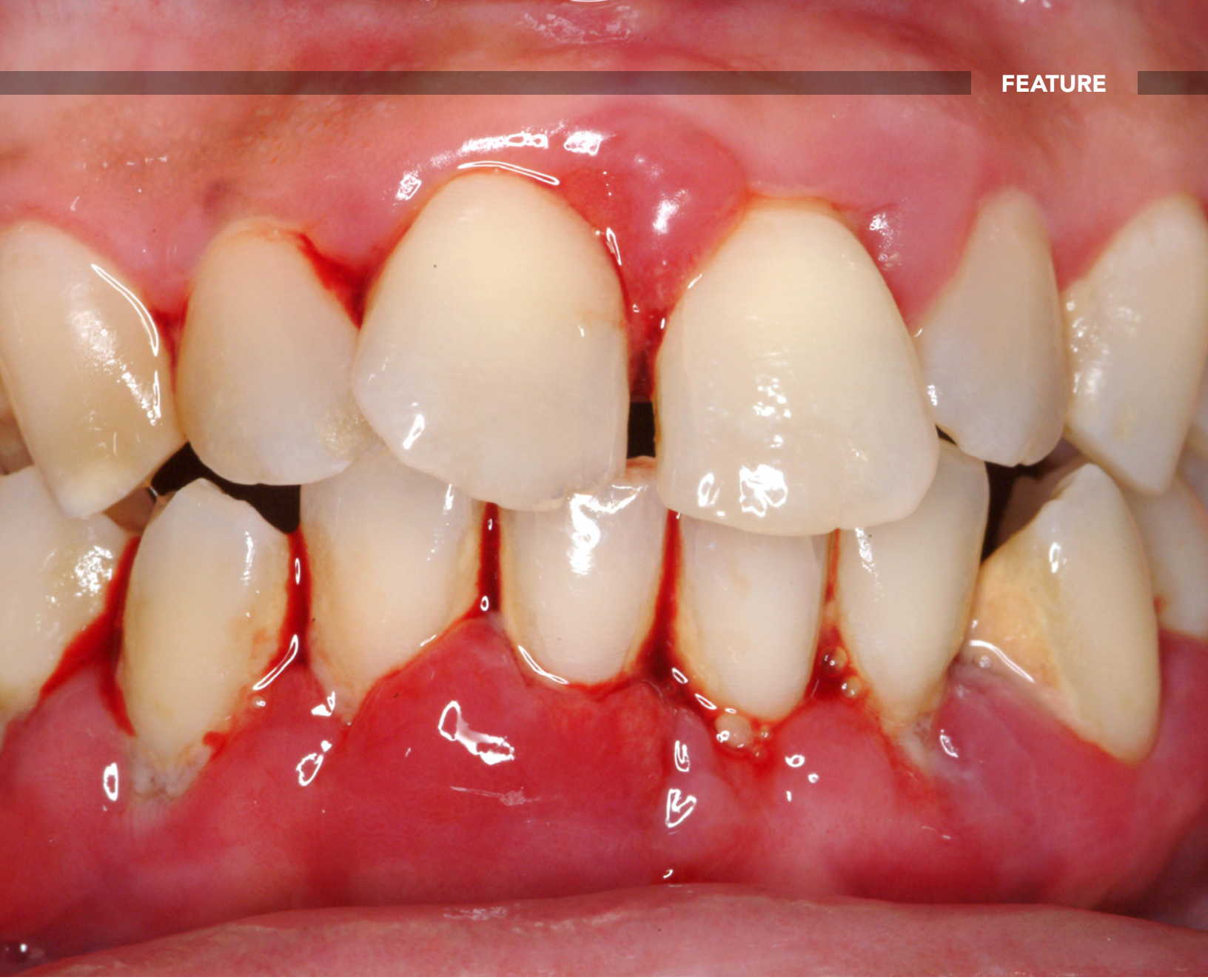

Dental Infection Issues that Contribute to Dental Malpractice

Sunie Keller RN, RDH, BS, CLNC

Keywords: dental infection, dental malpractice, dental unit waterlines, periodontal, implantitis, root canal, osteonecrosis

Dental malpractice affects thousands of people each year. According to the National Practitioner Data Bank (2004-2014), 15% of medical malpractice claims involve dentists. This article describes some dental infections and how a legal nurse consultant can use this information.

COMMON FORMS OF DENTAL MALPRACTICE

There are four common forms of dental malpractice:

1) Infections caused by improperly sterilized instruments and dental unit water lines
2) Failure to diagnose and treat periodontal and implant infections
3) Root canal infections
4) Infections from medication-related osteonecrosis of the jaw

Oral infections can cause significant morbidity. Studies indicate that some may have systemic effects on, among others, cardiac disease, pregnancy, kidney disease, and diabetes. Between 2008 and 2011, 101 people died in Emergency Departments due to preventable dental disease (*Journal American Dental Association, 2014*).

INFECTIONS CAUSED BY IMPROPERLY STERILIZED INSTRUMENTS AND DENTAL UNIT WATERLINES

Infection prevention in dentistry has gained more attention in recent years and guidelines for prevention are common practices in most countries. Agents such as hepatitis B and Legionella pneumophila are real threats for cross infection.

The oral cavity naturally harbors a large number of microorganism and can be a reservoir for pathogens that pose a risk for cross contamination and even cause systemic infections.

Pathways of contamination can be bidirectional; infectious microorganisms may be transferred from the patient to a member of the dental team and via the hands of the dental team to the patient. Inadequate sterilization of dental instruments can also cause infectious pathogens to move from patient to patient.

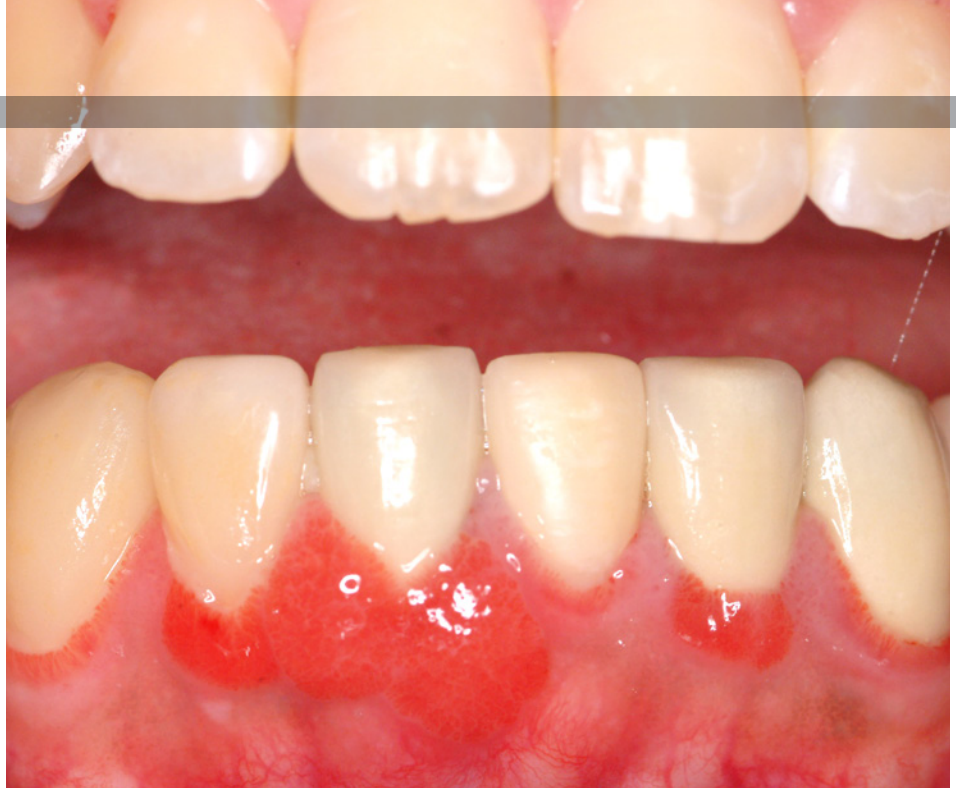

Image: Implant Infection

L.pneumophila causes legionellosis, a respiratory disease, and can cause a severe form of pneumonia called Legionnaires' disease. Outbreaks are often associated with contaminated aerosol-producing water systems, dental unit water lines (DUWL), commonly found in dental offices. This poses a risk to both dental staff and patients. L.pneumophila multiplies readily in water at temperatures between 25 and 45 degrees CelciusCelsius. In fact, according to the American Dental Association (2012), many studies have documented the presence of L.pneumophila contamination in DUWL.

An Italian woman was infected with L.pneumophilia (serogroup one)1 originating from a dental office. She died from pulmonary complications. By using molecular typing methods, the source of the legionella infection was shown to be a DUWL. This case was the first documented Legionnaires' disease transmission from a dental office. A report can be found at http://www.ncbi.nlm.nih.gov/pubmed/22340301. Read at http://www.ada.org/en/science-research/science-in-the-news/transmission-of-legionnaires-disease-traced-to-contaminated-dental-unit-waterline.

LNC Tips: The LNC working in a related case should:

- Obtain the sterilization records of the dental office. Compliant offices send a test indicator out each week to see if the sterilizer is functioning properly and log the results (Centers for Disease Control, 2015).
- Discover whether warm water is being used in a DUWL. While this is more comfortable than cold water for the patient, it can be a breeding ground for infection.
- Obtain logs as to whether the water lines are flushed every day.

FAILURE TO DETECT PERIODONTAL AND IMPLANT INFECTIONS

Periodontal diseases is are infections of the gums and bone around the tooth. Swollen and bleeding gums are early signs that the gums are infected. If a person's hands bled when washed, that would be concerning. Yet many people think it normal if their gums bleed when they brush or floss.

Fifty percent of American adults 30 years and older have periodontal disease. In adults 65 years and older, prevalence is 70% (American Academy

of Periodontology, 2012). If left untreated, periodontal disease can lead to tooth loss. Research has shown that periodontal infections are associated with other chronic inflammatory diseases such as diabetes, cardiovascular disease, and has been linked with to Alzheimer's disease. Periodontal pathogens, such as Fusibacterium nucleate, increase permeability and damage the arterial endothelium, increasing the risk of myocardial infarction and stroke (Fardini, Wang, & Temoin, 2011). Identifying specific periodontal pathogens and eliminating active periodontal infection is critical to maintain arterial wellness. The oral-systemic connection is strong.

Standard of care (SOC) for detection is a comprehensive annual periodontal evaluation, performed by a general dentist, periodontist, or hygienist. This consists of observing for presence or absence of inflammation (usually exhibited by bleeding on probing), probing depths, extent of loss of periodontal attachment and bone, medical and dental history, plaque distribution, calculus, pain, and mobility.

In May 2015, Dentists Advantage (2015) reported a net verdict of $295,378 for a case that demonstrated failure to recognize and treat periodontal disease. The plaintiff was a patient of the defendant's dentist starting in 1999. The plaintiff alleged she began having periodontal problems in 2005, which progressed over the next four years. Of the 14 office visits during those four years, 11 were with the defendant dentist.

When the plaintiff saw the defendant dentist in August 2009, the plaintiff reported "pimples" on her gums. The defendant referred her to a periodontist. She required extraction of 14 teeth, underwent implants, and needed more at the time of trial. The plaintiff alleged negligence in failure to diagnose her gum disease timely. A jury found negligence by the defendant dentist and hygienist in that group, assessing 65% fault to the dentist, 25% to the hygienist and 10% to plaintiff.

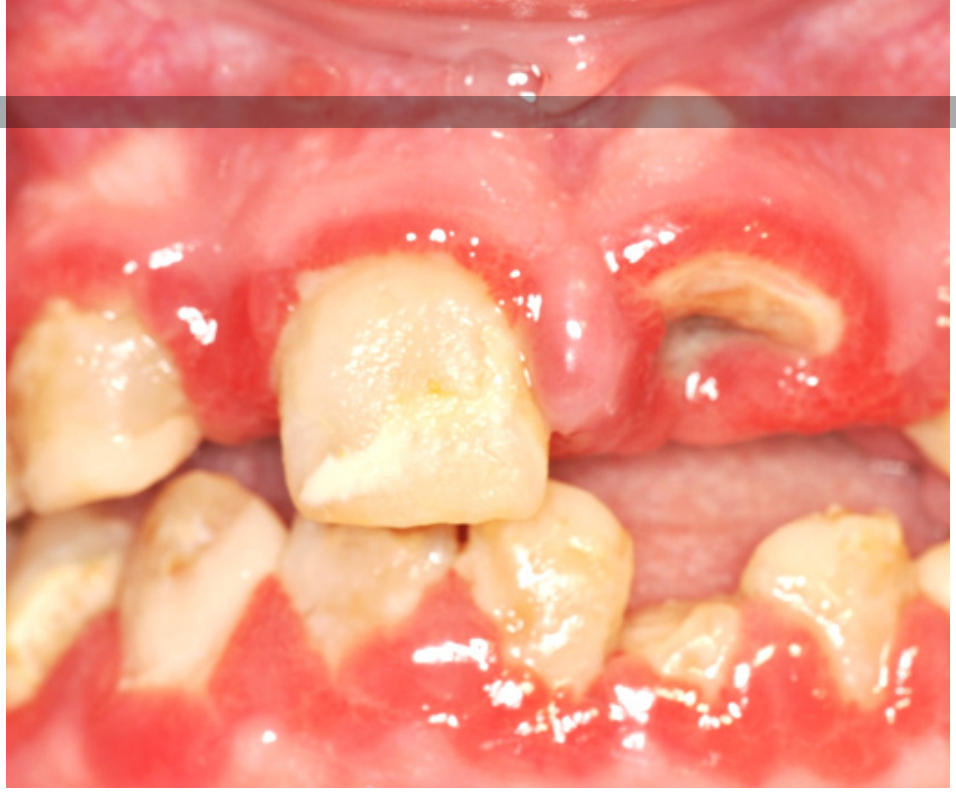

Image: Perio Disease

Professional liability claims pertaining to periodontal infections most commonly allege failure to diagnose, failure to inform, failure to refer, or failure to treat. Often the diagnosis of periodontal infection is made by another general dentist; that leads the patient to conclude that the diagnosis should have been made by the former dentist.

LNC Tips: The LNC working in a related case should:

- Determine whether the dental staff completed an annual full mouth periodontal probee was. Any pockets over 55mm should be noted in the chart.
- Discover whether staff noted in the chart that they explained periodontal disease and suggested treatment, and that the patient acted on the suggested treatment. The comprehensiveness and accuracy of clinical records will have important details.

IMPLANTITIS

Peri-implantitis and peri-implant disease are nonspecific terms for infection or inflammation around a dental implant, which can affect surrounding soft and hard tissue. Clinical signs are similar to periodontitis. A baseline radiograph and periodontal probe are used for identifying bone loss. True peri-implantitis occurs when inflammation spreads to underlying bone, causing bone loss; because the periodontal ligament is missing after implant, so inflammation can progress there directly.

Conditions that contribute to systemic inflammation can exacerbate local inflammation around implants. In diabetes, poor glycemic control appears to aggravate peri-implant disease because elevated blood glucose levels impairs host defenses and neutrophilic functions. Rheumatoid arthritis, which exacerbates the local inflammation triggered by biofilm insult, is also a risk factor.

More than three million implants are placed by general dentists in the United States annually. Failure of implants is largely due to insertion. The bone can be too thin to support the implant or it can be inserted into the sinus or a nerve if not done properly. See also Osteonecrosis, below.

LNC Tips: The LNC working in a related case should:

- Determine whether the implants were placed by a general dentist who took a weekend course at a destination resort conference to learn how, or a board-certified surgeon with two2 years of post-doctoral training.
- Discover whether the dentist used cone-beam computed tomography, also known as CBCT, to assess for adequate bone near the nerves and the sinus cavity.

ROOT CANAL INFECTIONS

A root abscess involves pus in bone tissue at the tip of the infected tooth, usually caused by bacterial infection in the tooth's pulp. In some cases, it may perforate bone and drain into surrounding tissue, creating local swelling. Sometimes cervical lymph glands will be tender. Treatment is root canal therapy and antibiotics, if swelling is significant.

If not treated properly, a tooth abscess can result in swelling, fever, intense pain, tooth loss, sinus infection, endocarditis, brain abscess, osteomyelitis, cellulitis, or Ludwig's angina (cellulitis in the floor of the mouth).

Endodontists specialize in treatment of the pulp or nerve. They have two or moregreater years of specialized training beyond dental school. The average endodontist does 25 root canals per week; general dentists average two per week. Most endodontists use electron microscopes for their detailed work, which most general dental offices do not have available.

Baxter (2007) reviewed 41 malpractice cases, all by general dentist, involving complications due to endodontic procedures. These include instruments left in canals, nerve and sinus perforations, air embolism, and life-threatening infections. There were eight life-threatening infection, seven due to brain abscesses and one to osteomyelitis. Of these eight, four were fatal and four resulted in irreversible brain damage.

LNC Tips: The LNC working in a related case should:

- Discover who performed the root canal, a general dentist or an endodontist. Remember, the general dentist will be held to the same SOC as the specialist.
- See if the records show that the dentist used a rubber dam. A rubber dam prevents instruments, solutions, tooth parts, and debris from going down the patient's throat. The SOC requires the use of a rubber dam during endodontic therapy.
- Determine qualifications of the dentist. Dentists often get into trouble when they attempt work that they should have referred to specialist.

INFECTIONS FROM MEDICATION RELATED OSTEONECROSIS OF THE JAW

In the mid-1990s, reports began to appear in the professional literature of dental implant failures and osseous destruction, osteonecrosis of the jaw (ONJ), affecting both the mandible and maxilla in individuals who took an oral form of bisphosphonate. At first, all case reports involved Fosamax (alendronate), a drug used to ameliorate the effects of osteoporosis. Later, reports revealed that intravenous bisphosphonate drugs, principally with chemotherapy, were associated with similar destruction.

New medications unrelated to bisphosphonates came on the market in the 2000s, among them Prolia (denosumab). Osteonecrosis of the jaw (ONJ) began to be reported in individuals who took denosumab. Recently, the FDA has issued advisory warnings regarding potential ONJ development for antiangiogenic chemotherapy agents, Sutent (sunitinib) and Avastin (bevacizumab). (Berenson and Stopeck, 2016)

Infection can be a contributing factor, since periodontal or apical disease in the presence of antiresorptive drugs appears to increase risk for ONJ. A 2014 study identified an Actinomyces species, an uncommon microorganism associated with oral infection, in specimens of necrotic bone. Fungi and viruses require "sophisticated therapies to combat the multiorganisms associated biofilms." (Atherton Pickett, 2015)

The risk for ONJ in cancer patients prescribed antiresorptive or antiangiogenic medications range from zero to 1.9 cases per 10,000 patients. With bisphosphonates, the risk is higher (100 cases per 10,000), 1% of all cases. More than 400 lawsuits have been filed against the manufacturer of Fosamax. Among cancer patients with ONJ who had pre-existing infection, oral disease increased the risk for medication related ONJ (Ruggiero, 2014).

Cancer patients cannot stop their medications. The goal for patients receiving IV antiresorptive or antiangiogenic treatment is to reduce the potential for oral surgery by eliminating oral infection early in the chemotherapy regimen. One study's conclusion recommended drug cessation for more than four months before oral surgical procedures. (Kim, Lee, & Song, 2014).

LNC Tips: The LNC working in a related case should:

- Determine whether a MD expecting to prescribe any medication associated with ONJ consulted the patient's dentist. Oral procedures to bring the mouth to optimum health can be recommended before chemotherapy begins. Dentists should do a thorough clinical exam and eliminate any infection or potential infection.
- Determine whether there was a drug holiday for procedures that involved osseous surgery.
- Look for documentation on patient teaching about risk of ONJ, which

increases the longer the drugs are taken. Patients should be educated not to take bisphosphonates for longer than four years.

SUMMARY

Most dental infection cases are filed against general dentists. If these dentists had referred the patients to specialists sooner, many dental malpractice cases could have been avoided. Anaerobic infections from endodontic procedures can be deadly. Because implants are another potential source of infection, patient evaluation should include the history of smoking and systemic disease or medications that can affect healing, bone density, and decrease resistance to infection.

REFERENCES

Atherton Pickett, F (2015) Update on medication related osteonecrosis of the jaw. RDHmag. Oct 2015. pg 69-73.

Baxter, C. (2007) Malpractice Survey: A Survey Of 242 Dental Negligence Cases With Breakdown As To The Sex Of The Defendant Dentist. http://www.experts.com/Articles/Malpractice-Survey-A-Survey-Of-242-Dental-Negligence-Cases-With-Breakdown-As-To-The-Sex-Of-The-Defendant-Dentist-By-Dr-J-Crystal-Baxter Retrieved 2/15/2016

Berenson JR and Stopeck AT (2016) Medication-related osteonecrosis of the jaw in patients with cancer. http://www.uptodate.com/contents/medication-related-osteonecrosis-of-the-jaw-in-patients-with-cancer Retrieved 8/18/2016

Clementini, M., Rossetti, P.H., Penarrocha, D. (2014, March). Systemic Risk Factors for Peri-implant Bone Loss: A systematic review and meta-analysis. Int J Oral Maxillofac Surg., 43(3): 323-34. Epub 2013 http://www.ncbi.nlm.nih.gov/pubmed/24373525 Accessed 2/15/2016

Dentistry IQ (n.d.) A review of dental negligence. http://www.dentistryiq.com/articles/wdj/print/volume-2/issue-8/you-and-your-practice/a-review-of-dental-negligence.html

Dentists Advantage Case Study (2015, May). Retrieved from http://www.dentists-advantage.com/sites/DA/rskmgt/casestudy/Pages/FailuretoRecognizeandProperlyTreat.aspx Retrieved 2/15/2016 16

Fardini, Y., Wang, X., & Temoin, S. (2011, December). Fusobacterium Nucleatum Adhesion FadA Binds Vascular Endothelial Cadherin and Alters Endothelial Integrity. Molecular Microbiology, 82(6):1468-80. http://www.ncbi.nlm.nih.gov/pubmed/22040113 Retrieved 2/15/2016

Kim, Y.H., Lee, H.K., Song, S.I. (2014, Oct.). Drug Holiday as a Prognostic Factor of Medication-related Osteonecrosis of the Jaw. J Korean Assoc Oral Maxillofac Surg., 40(5): 206-10. Epub 2014 Oct 24. http://www.ncbi.nlm.nih.gov/pubmed/?term=Drug+holiday+as+a+prognostic+factor+of+medication Retrieved 2/15/2016

Laheij, A.M., Kistler, J.O., Belibasakis, G.N. (2012). Healthcare-associated Viral and Bacterial Infections in Dentistry. J Oral Microbiol. 4.10:3402/jom.v4io.Epub 2012 June 12. http://www.ncbi.nlm.nih.gov/pubmed/22701774 http://www.ncbi.nlm.nih.gov/pubmed/22701774/?term=Healthcar Retrieved 2/15/2016

Lee, M.K., Allareddy, V., Nalliah, R.P. (2015, Dec.). Hospital-based Emergency Department Visits Involving Dental Conditions: Profile and Predictor of Poor Outcomes and Resource Utilization. Journal Amer Dent Ass. http://www.ncbi.nlm.nih.gov/pubmed/24686965 Accessed 2/15/2016

National Practitioner Data Bank (2004-2014). Malpractice Reports for all Practitioners. Retrieved from http://www.npdb.hrsa.gov/resources/npdbstats/npdbStatistics.jspNational Practitioner Data Bank (2004-2014). Malpractice reports for all practitioners. http://www.npdb.hrsa.gov/resources/npdbstats/npdbStatistics.jsp#contentTop Retrieved 2/15/2016

Papapoulos, S., Chapurlat, R., Libanati, C. (2012, March). Five years of Denosumab Exposure in Women with Post-menopausal Osteoporosis. Results from the First Two Years of the FREEDOM Extension. J Bone Miner Res, 27(3): 694-701. http://www.ncbi.nlm.nih.gov/pubmed/22113951 Retrieved 2/15/2016

Fardini Y., Wang, X., & Temoin, S. (2011, December). Fusobacterium nucleatum adhesion FadA binds vascular endothelial cadherin and alters endothelial integrity. Molecular Microbiology, 82(6):1468-80. http://www.ndbi.nlm.nih.gov/pubmed/22040113 Retrieved 2/15/2016

Ricci, M.L., Fontana, S., & Pinci, F. (2012, February). Pneumonia Associated with a Dental Unit Water Line. The Lancet.,Lancet. 376 (9816) 684. http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(12)60074-9/abstract Retrieved 2/15/2016

Papapoulos S, Chapurlat R, Libanati C. @012, March). Five years of denosumab exposure in women with post-menopausal osteoporosis. Results from the first two years of the FREEDOM extension. J Bone Miner Res, 27(3): 694-701. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/22113951

Ruggiero, S.L. (2015, November). Medication-related oosteonecrosis of the jjaw. (MRONJ) that is linked to the treatment of malignant. Introduction. Oral Maxillofac Surg Clin North Am., 27(4). http://www.ncbi.nlm.nih.gov/pubmed/26608159 Accessed 2/15/2016362366

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Aspiration Pneumonia in the Elderly Tube Fed Patient -- Avoidable or Unavoidable: Considerations for the LNC

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Keywords: aspiration, avoidable, micro-aspiration, pneumonia, unavoidable

Impaired cough reflex sensitivity plays a crucial role in pneumonia in the elderly. Cough reflex sensitivity is markedly depressed in elderly patients with aspiration pneumonia. Silent aspiration is not always avoidable despite adherence to best evidence-based practice. In August 2007 the Centers for Medicare & Medicaid Services (CMS), recognizing that not all accidents are avoidable, issued an interpretive guideline which differentiates between "avoidable" and "unavoidable" accidents. The legal nurse consultant (LNC) may need to identify documentation in the medical record that either supports or refutes an argument for avoidable aspiration pneumonia.

Aspiration, a major contributor to death among the frail elderly, is defined as the inhalation of oropharyngeal secretions or gastric contents into the airways beyond the vocal cords. The elderly, especially those with swallowing difficulties, cardiovascular disorders, poor functional capacity, and dementia, are at risk of aspiration. The incidence of swallowing problems or dysphagia among nursing home residents has been estimated to be as high as 50% to 75% (Marik & Kaplan, 2003).

Aspiration, overt or silent (without choking or coughing), can exacerbate chronic lung disease, pneumonitis, pneumonia, and lead to death (Robbins, n.d.; Mollot, 2015). Although there are few studies examining dysphagia as a major contributing factor, (Cabre, 2010; Singh & Hamdy. 2006) suggest the risk of aspiration pneumonia is increased seven times in the presence of dysphagia (Singh & Hamdy, 2006). Incidence increases with advanced age; approximately half of dysphagia-related aspiration is "silent" and goes unrecognized (Summers, et al., 2009).

Unfortunately not all EBP is based on reliable research, so clinicians must turn to clinical judgment and expertise, considering, for example, age, neurological condition, gastroesophageal reflux, medication side effects, poor oral hygiene, and patient values to develop treatment plans. However, there is no way to predict aspiration with certainty, and no evidence indicating feeding tubes prevent it (Sura, Madhaven, Carnaby, & Crary, 2012). While tube feedings may be necessary for nutrition in dysphagic residents, tube feeding is associated with increased gastric reflux which can lead to pneumonia (Levenson & Crecelius, 2003).

The Omnibus Budget Reconciliation Act (OBRA) established nursing home resident rights and set the expectation that a resident can "attain and maintain her highest practicable physical, mental, and psychosocial well-being (Mollot, R. (2015)." Enteral feedings, addressed by 42 CFR §483.25(g) and interpretive guideline F tag 322, require that residents receive appropriate treatment and services to prevent aspiration. Best practices in nursing care suggest aspiration prevention include oral care and elevation of the head of the bed to at least 30 degrees during and 30 minutes after tube feedings. (Metheny, 2012; American Association of Critical Care Nurses, 2016). *(N.B. Oral care EBP guidelines are not available.)*

According to the Centers for Medicare and Medicaid Services (CMS) §483.25(g) F tag 322:

There may be situations where other co-existing factors influence decisions about elevating the head of the bed; for example, repositioning a resident being fed by a tube who may be at risk for shearing by sliding down the sheets when the head of the bed is elevated to a recommended angle (CMS, 2012).

Personal care (e.g., bath with full linen change, cleaning after incontinence, straight catheterization) may require lowering the head of a bed (CMS, 2012; Schallom, Dykeman, Metheny, Kirby, & Pierce, 2015). It is important to determine whether any aspiration was avoidable or unavoidable despite the staff's adherence to safe practices.

In August 2007 the Centers for Medicare & Medicaid Services (CMS) recognized that not all accidents (defined as any unexpected or unintentional incident, which may result in injury or illness to a resident) are avoidable. CMS issued an interpretive guideline for 42 CFR 483.25(h)(1) and (2) requiring facilities to provide an environment that is "free from accident hazards over which the facility has control and provides supervision and assistive services to each resident to prevent avoidable accidents." The guideline differentiates between avoidable and unavoidable accidents. An avoidable accident occurred because a facility failed to identify and evaluate the risk of an accident, implement interventions including adequate supervision, and monitor intervention effectiveness. An unavoidable accident occurs despite an effort to identify and evaluate the risk of an accident and implement interventions (CMS Manual System, Transmittal 27, August 17, 2007).

SIGNS AND SYMPTOMS

Aspiration can cause cough, shortness of breath, wheezing, low oxygen saturation, fatigue, malaise, and excessive sweating. Age-related decreased ciliary and macrophage activity, respiratory muscle strength and cough reflex, and diminished drier mucus, and decreased response to hypoxia and hypercapnia will mask signs and symptoms and change the clinical presentation (McAdams-Jones & Sundar, 2012).

DIAGNOSIS OF ASPIRATION PNEUMONIA

Currently, there are no bedside tests available to detect microaspiration (American Association of Critical Care Nurses, 2016). Diagnosis is based on clinical signs and symptoms when risk factors and history are consistent with likelihood of aspiration.

Oxygen saturation rate will be decreased, mental alertness diminished, blood pressure low, pulse rapid, and respirations labored with decreased breath sounds and crackling. The complete blood count may show leukocytosis. Although sputum culture, if obtained, may identify pathogens, the diagnosis is usually made before the results are available. X-rays, CT scans and MRIs are inconclusive.

CASE STUDY

Mrs. C, 87, had multiple admissions to the hospital for urinary tract infections (UTI), diabetic ketoacidosis, hypoglycemia, gastritis, and altered mental status with progressive memory loss. In May 2010 she was admitted with pneumonia and acute renal failure. Due to her poor appetite and refusal to eat, her physician placed a percutaneous gastrostomy tube (PEG). After discharge she was admitted to the nursing home with a guarded prognosis. Over the next five months she returned to the hospital ten times for evaluation and treatment of mental status changes, congestive heart failure exacerbation, chronic obstructive pulmonary disease (COPD) exacerbation, hypoxemia, intracranial hemorrhage, UTI, hyperglycemia, hypoglycemia, and persistent bilateral bronchiectasis.

In October 2010 she was admitted to the hospital with the diagnosis of altered mental status, acute renal failure, and aspiration pneumonia. Chest x-rays showed patchy airspace opacities in both lung bases and mild pulmonary edema. Over the next week, her health declined and the physicians questioned aspiration pneumonia due to tube feeding. Tube feedings were stopped and she died five days later. The death certificate listed the cause of death as aspiration pneumonia. The family sued the nursing home for negligence.

Medical History:

- Congestive heart failure, coronary artery disease, chronic obstructive lung disease, pneumonia, diabetes with fluctuating sugar levels, hypoglycemia, hypertension, osteoarthritis, cervical spondylitis, lumbar disc disease, chronic urinary tract infections, irritable bowel syndrome, incontinence, cerebral vascular accident, severe dementia and dysphagia; history of methicillin-resistant Staphylococcus aureus (MRSA) and Clostridium difficile
- Dependent upon tube feedings for nourishment
- Frequent hospitalizations to evaluate and treat multiple labile conditions (e.g., difficult to control blood sugar, congestive heart failure, widely varying blood pressure, urinary retention, bladder infections, nutrition/tube feedings.)
- Serum albumin 2.8

Plan

- Close supervision
- Enteral Feeding Protocol activated
- Monitor intake and output
- Monitor nutritional needs and adjust feedings as warranted
- Aspiration precautions in place
- NPO but son with durable power of attorney (DPOA) admitted to occasionally giving the resident food and liquids orally and is willing to take the risk of the resident aspirating

Outcome

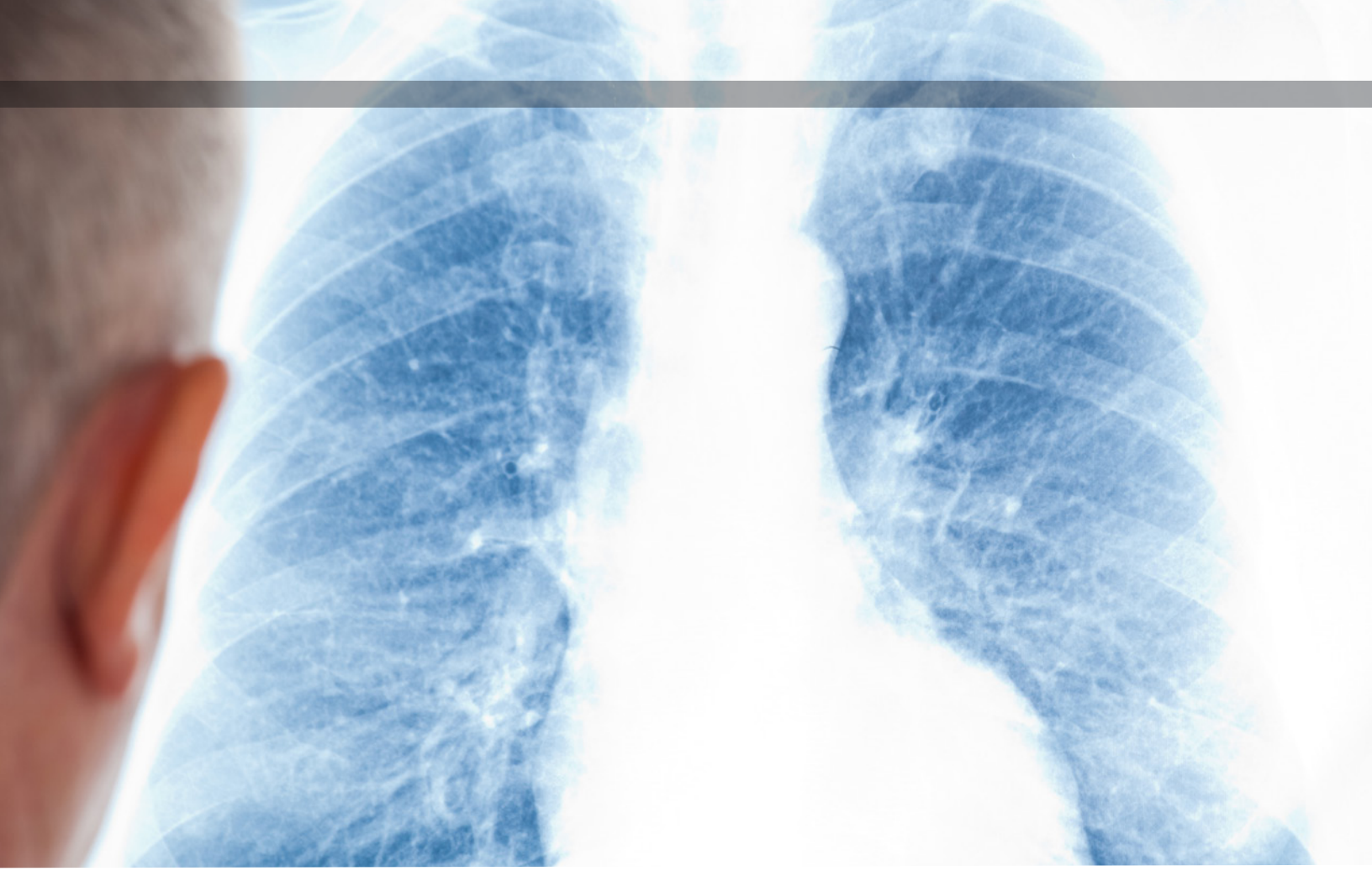
- On October 10, 2010, Mrs. C experienced mental status changes and diaphoresis. The physician sent her to the emergency room for further evaluation. She was admitted.
- Chest x-ray indicated mild pulmonary edema but no apparent consolidation.
- Tube feedings provided nutritional needs.
- During the course of her admission she was diagnosed with aspiration pneumonia secondary to tube feeds and/or increased secretions.
- Scopolamine patch given to decrease salivation.
- Pronounced two weeks later.
- Immediate cause of death given as aspiration pneumonia; underlying causes of death, respiratory failure and heart failure.

CONSIDER THESE FACTS

The LNC reviewing this case must determine whether nursing home staff:

- Implemented interventions to maintain Mrs. C's functional and baseline capabilities
- Monitored and implemented actions to address her aspiration risk
- Adhered to enteral protocol; monitored and implemented actions to decrease potential tube feeding complication risk
- Assessed for and notified the attending physician of Mrs. C's condition changes
- Monitored and implemented action to address her variable blood sugars and blood pressure
- Adhered to EBP for catheter care; monitored and implemented actions to decrease risk for UTI; treated UTI if present
- Assessed, analyzed, and documented pertinent changes in health status
- Documented assessments and interventions in keeping with the standard nursing home practice of "charting by exception"

The LNC should also review the autopsy report, if available, and consider the findings listed on the death certificate. Keep in mind that a study by Kliff (2013) found that 30% of certifications were incorrect.



DEATH CERTIFICATE

According to Sterns, Swaminathan, Varkey, and Varkey, (n.d.) "the prognosis of aspiration pneumonia is dependent on underlying diseases, complications, and the patient's health status" with the 30-day mortality rate up to 29.7% in hospital-associated aspiration pneumonia. In 2003 the Center for Disease Control and Prevention (CDC) published a revised edition of Medical Examiners' and Coroners' Handbook on Death Registration and Fetal Death Reporting which instructs that the cause of death represent the coroner's best opinion (p.14). "Regarding certification of death due to aspiration pneumonia, death certificate guidelines indicate that aspiration pneumonia is almost always due to some debilitated state." (Santa Clara County, 2005). A 2013 study by Komiya et al. found that 52% of respondents considered aspiration pneumonia to be age-related, i.e., due to advanced age, bedridden status, difficulty swallowing, and dementia.

"Cause of death is the most important statistical research item on the death certificate" serving as a basis for mortality statistics (CDC, 2003, p. 62). The immediate cause of death refers to the complication directly causing the death, not the mechanism of death (CDC, 2003, p. 15). Since it common among the elderly to have multiple conditions and sequencing of conditions resulting in death, the coroner should select the sequence that most accurately describes the condition causing death; if it is not possible determine precisely, to make a judgment (CDC, 2003, p. 17 & 40) and state it in as few words as possible (CDC, 2003, p. 20). When processes like aspiration are reported, they should be qualified as "presumed." (CDC, 2003, p. 42).

CONCLUSION

In reviewing a case alleging negligence resulting in aspiration pneumonia, determine whether the medical record confirms that the nurses conducted ongoing assessments and instituted appropriate measures to ensure a resident was able to attain and maintain her highest practical physical, mental, and psychosocial wellbeing. Further, weigh the role of comorbidities and continuing decline in silent aspiration. ❧

REFERENCES

American Association of Critical Care Nurses. (2016). ACCN Practice Alert: Prevention of aspiration pneumonia. Critical Care Nurse, 36(1): e20-e24. Retrieved June 22, 2016 http://www.aacn.org/wd/practice/docs/practice-alerts/aspiration-pa-feb2016ccn-pages.pdf

Cabre, M., Mateu Serra-Prat, M., Palomera, E., Almirall, J., Pallares, P. & Clave, P. (2010). Prevalence and prognostic implications of dysphagia in elderly patients with pneumonia. Age, 39 (1): 39-45. Retrieved June 22, 2016

Aspiration, a major contributor to death among the frail elderly, is defined as the inhalation of oropharyngeal secretions or gastric contents into the airways beyond the vocal cords.

from http://ageing.oxfordjournals.org/content/39/1/39.long

Centers for Disease Control and Prevention. (2003). Medical examiners' and coroners' handbook on death registration and fetal death reporting. Retrieved June 22, 2016 from http://www.cdc.gov/nchs/data/misc/hb_me.pdf

Centers for Medicare & Medicaid. (2012). Interpretive Guidelines for Long-Term Care Facilities F tag 322 (Feeding Tube). P. 112. Retrieved June 22, 2016 from https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-12-46.pdf

Department of Health & Human Services Centers for Medicare & Medicaid Services. (August 17, 2007). CMS Manual System, Transmittal 27. Retrieved June 22, 2016 from https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R27SOMA.pdf

Kliff. S. (May 12, 2013). Study: Nearly one-third of all certificates are wrong. Washington Post. Retrieved June 22, 2016 from http://www.washingtonpost.com/news/wonkblog/wp/2013/05/12/study-nearly-half-of-all-death-certificates-are-wrong/

Komiya, K., Ishii, H., Kushima, H., Sato, S., Kimura, H., Yasuda, T., Kadota J.Physicians' attitudes toward the definition of "death from age-related physical debility" in deceased elderly with aspiration pneumonia.13(3):586-90

Levenson, S. & Crecelius, C. (2003). Evidence-Based Practice in LTC. The Facts about Dysphagia & Swallowing Studies. Caring for the Ages; 4(2):17-18.

Marik, P.E & Kaplan, D. (2003). Aspiration pneumonia and dysphagia in the elderly. Chest; 124:328–336.

McAdams-Jones, D. & Sundar, K. M. (2012). Jump into action against aspiration pneumonia. American Nurse Today, 7(6). Retrieved June 22, 2016 from http://www.americannursetoday.com/jump-into-action-against-aspiration-pneumonia/

Metheny, N.A. (2012). Preventing aspiration in older adults with dysphagia. Try this. The Hartford Institute for Geriatric Nursing. Retrieved June 22, 2012 from. http://consultgerirn.org/uploads/File/trythis/try_this_20.pdf

Mollot, P. (2015). Nursing home quality standards. A primer for managed Care Organizations. The Long Term Care Community Coalition, NY, NY. Retrieved June 22, 2016 from http://www.ltccc.org/publications/documents/LTCCC-Primer-Nursing-Home-Quality-for-MCO-FINAL_000.pdf Quality of Care, 42 CFR §483.25(g) (2011) Quality of Care, 42 CFR 483.25(h) (1) and (2) (2011)

Robbins, J. (n.d.). The current state of clinical geriatric dysphagia research. Retrieved June 22, 2016 from http://www.rehab.research.va.gov/jour/02/39/4/guested.htm

Santa Clara County Medical Examiner-Coroner's Office Santa Clara County Vital Records and Registration. (2005). Death certificate guidelines. Retrieved June 22, 2016 from https://www.sccgov.org/sites/sccphd/en-us/FindForms/Documents/Birth%20and%20Death%20Certificate%20Forms/PHDCGuidelinesSep05.pdf

Schallom, M., Dykeman, B., Metheny, N., Kirby, J., and Pierce, J. (2015). Head of the bed elevation and early outcomes of gastric reflux, aspiration, and pressure ulcers: A feasibility study. American Journal of Critical Care, 24(1), 57-65. Retrieved June 22, 2016, from http://www.aacn.org/wd/Cetests/media/A152401.pdf

Singh, S., & Hamdy, S. (2006). Dysphagia in stroke patients. Postgraduate Medical Journal, 82 (968), 383-391.

Sterns, D. A., Swaminathan, A. Varkey, A. & Varkey B. (n.d.). Aspiration pneumonitis and pneumonia. Retrieved June 22, 2016 from http://misc.medscape.com/pi/android/medscapeapp/html/A296198-business.html

Summers, D., Leonard, A., Wentworth, D., Saver, J. L., Simpson, J., Spilker, J.A., Hock, N.; Miller, E. & Mitchell, P.H. (2009). Comprehensive Overview of Nursing and Interdisciplinary Care of the Acute Ischemic Stroke Patient. American Heart Association Scientific Statement. Retrieved June 22, 2016 from http://stroke.ahajournals.org/content/40/8/2911.full.pdf

Sura, A., Madhaven, A., Carnaby, G. & Crary, M.A. (2012). Dysphagia in the elderly: management and nutritional considerations. Clin Interv Aging.; 7: 287–298. Retrieved June 22, 2016 from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3426263/

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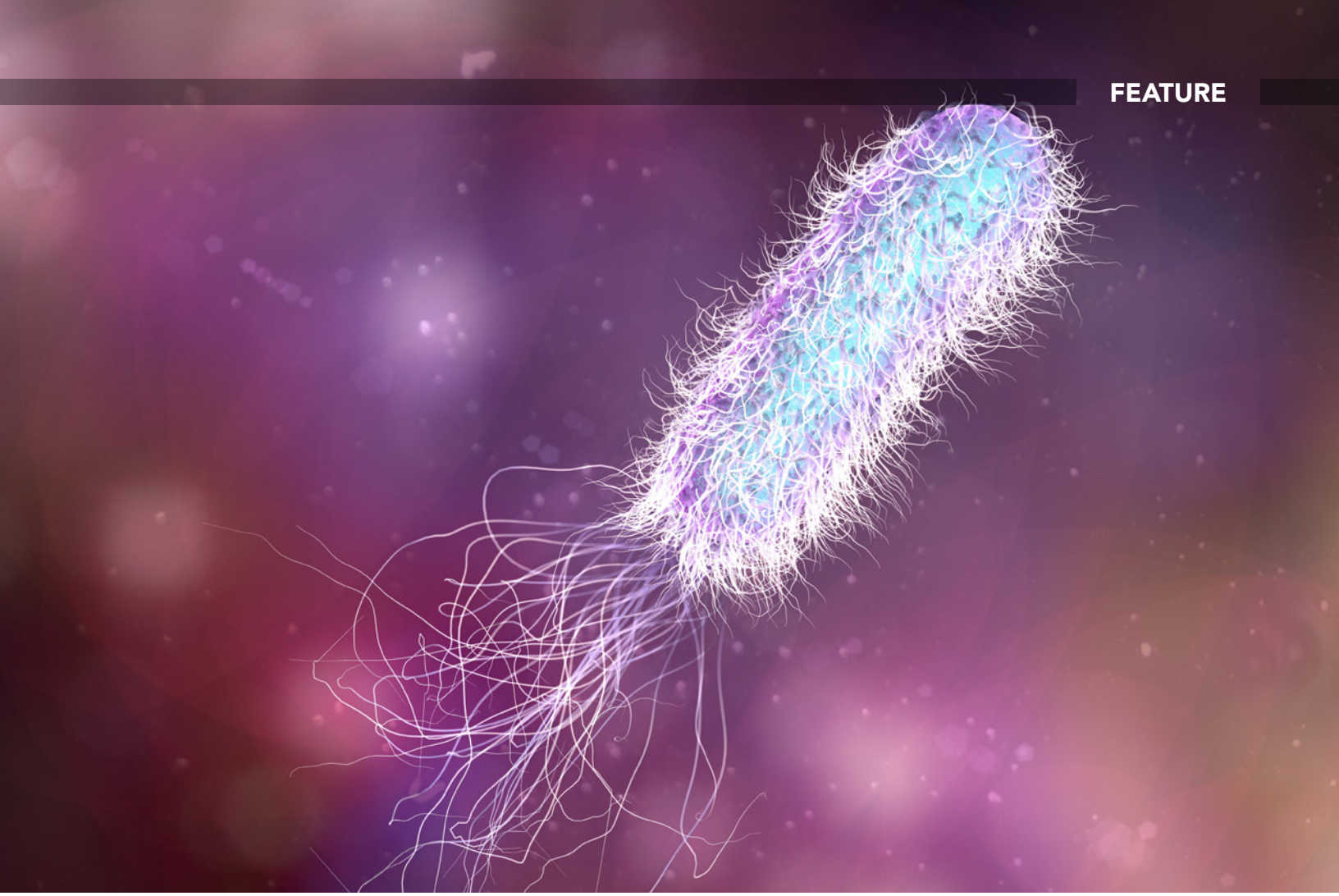


Carbapenem-Resistant Enterobacteriaceae (CRE): The Latest in Antibiotic Resistance

Kelly W. Tanner, RN, BSN, CCRN, CCTC

Keywords: antibiotic resistance, superbug, CRE, carbapenem-resistant Enterobacteriaceae, endoscopes, multi-drug resistance, antibiotic stewardship, deadly bacteria, duodenoscope litigation

Antibiotic-resistant infection is increasing rapidly, contributing to increased mortality and costs. In 2013, the CDC (Centers for Disease Control and Prevention) issued a classification system to define the most severe infections and preventative care strategies. CRE (carbapenem-resistant enterobacteriaceae) is an emerging threat classified by the CDC as urgent. CRE has the potential to become resistant to all available antibiotics and to confer resistance to other organisms. Transmission occurs mostly via nosocomial fomites. Among the many risk factors is the use of flexible endoscopes for gastrointestinal procedures; currently, at least one endoscope maker is facing related litigation. Treatment is complicated and carries potentially fatal side effects. Prevention is critical.

When we think of a superhero, we often envision superhuman strength, extraordinary talents, and overwhelming dedication to protecting the public from harm. However, now think about the emergence of a superbug. While these new microorganisms possess some superhero qualities, they are in fact archnemeses.

Alexander Fleming discovered penicillin in 1928. Through the years, newer and more potent antibiotics have come into being (American Chemical Society, 1999). Although they have saved countless lives, we are now seeing alarming levels of antibiotic resistance developing.

THE AGE OF RESISTANCE

According to Lautenbach and Perencevich (2014), "Approximately 10% of hospitalizations are complicated by a healthcare-associated infection, and up to 75% of these are due to organisms resistant to first-line antimicrobial therapy" (p.333). Morbidity and mortality have notably increased, and with them, annual healthcare costs by $20 billion. Lost productivity can cost society another $35 billion a year (CDC, 2013; Lautenbach & Perencevich, 2014; Orsini et al., 2012). In September 2014, President Obama signed an Executive Order to launch Federal efforts to combat antibiotic-resistant bacteria; the details can be found here https://www.whitehouse.gov/sites/default/files/docs/carb_national_strategy.pdf.

In 2013, the CDC (Centers for Disease Control and Prevention) published a report outlining the threat of antibiotic resistance and how the medical community can fight back. They prioritized bacteria into three categories according to their level of risk: urgent, serious, and concerning.

In the 2013 report, the CDC characterizes *urgent* as, "… high-consequence antibiotic-resistant threats because of significant risks identified across several criteria. These threats may not be currently widespread but have the potential to become so and require urgent public health attention to identify infections and to limit transmission" (pg. 21). These include Clostridium difficile (C. difficile), carbapenem-resistant enterobacteriaceae (CRE), and drug-resistant Neisseria gonorrhoeae.

They describe *serious* this way: "These are significant antibiotic-resistant threats. For varying reasons (e.g., low or declining domestic incidence or reasonable availability of therapeutic agents), they are not considered urgent, but these threats will worsen and may become urgent without ongoing public health monitoring and prevention activities (pg 21)." These risks include the following drug-resistant organisms:

- Acinetobacter
- drug-resistant Campylobacter
- fluconazole-resistant Candida (a fungus)
- extended spectrum B-lactamase-producing Enterobacteriaceae (ESBLs)
- vancomycin-resistant Enterococcus (VRE)
- multidrug-resistant Pseudomonas aeruginosa
- drug-resistant non-typhoidal Salmonella
- drug-resistant Salmonella typhi
- drug-resistant Shigella
- methicillin-resistant Staphylococcus aureus (MRSA)
- drug-resistant Streptococcus pneumoniae
- drug-resistant tuberculosis

The final category, *concerning*, is: "These are bacteria for which the threat of antibiotic resistance is low, and/or there are multiple therapeutic options for resistant infections. These bacterial pathogens cause severe illness. Threats in this category require monitoring and in some cases rapid incident or outbreak response" (pg. 21). Examples of this category include vancomycin-resistant Staphylococcus aureus (VRSA), erythromycin-resistant group A Streptococcus, and clindamycin-resistant group B Streptococcus.

FIGHT RESISTANCE

The CDC identifies four core actions to prevent antibiotic resistance (CDC, 2013):

Preventing infections & preventing the spread of resistance Avoiding infection altogether would eliminate the need for antibiotics and therefore, the chance of developing resistance. Prevent drug-resistant infections by proper hand hygiene, judicious use of antibiotics, safe food preparation, and immunizations.

Tracking patterns of resistance The CDC gathers data to help experts understand patterns and develop strategies to prevent the spread of resistant bacteria.

Antibiotic stewardship About half of all antibiotics prescribed unnecessarily or are used incorrectly. Creating protocols and adhering to them is paramount.

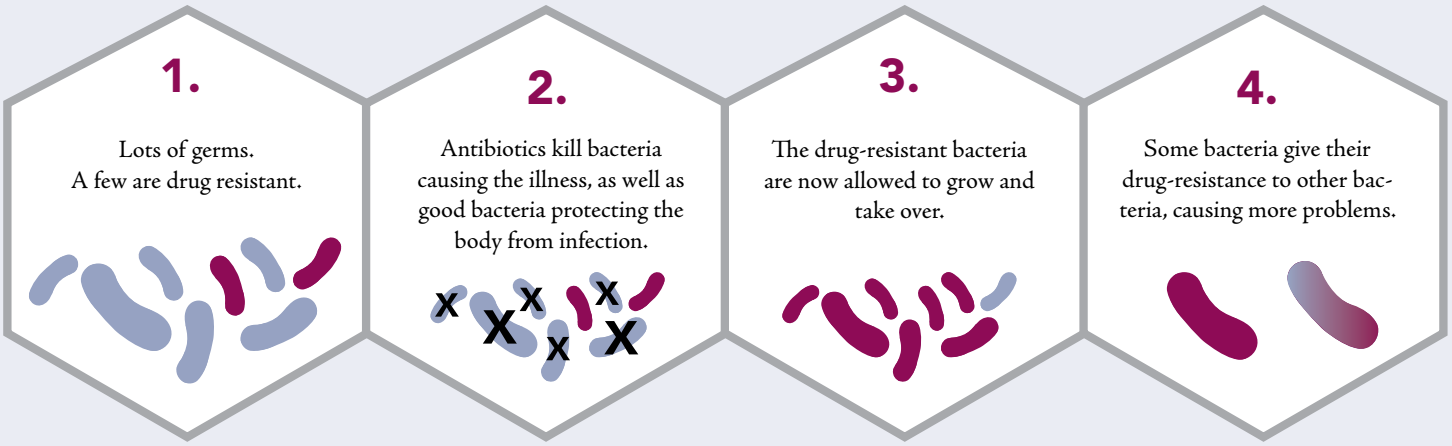
Developing new antibiotics and diagnostic tests As bacteria will continue to evolve, clinicians will need new antibiotics and new methods to track resistance.

CARBAPENEM-RESISTANT ENTEROBACTERIACEAE (CRE)

The first reported US CRE case occurred in 2001. By 2012, it had spread to over 200 hospitals in 42 states (Deen & Debbie, 2014). In 2013, the CDC reported approximately 9,300 health-care associated Enterobacteriaceae infections annually, with nearly 600 deaths. The literature characterizes CRE as a "deadly superbug," "nightmare bacteria," and "dangerous" (Davis & Cunha 2014; Deen & Debbie, 2014).

HOW ANTIBIOTIC RESISTANCE HAPPENS

Figure 1: How antibiotic resistance occurs. Centers for Disease Control and Prevention, 2015.
http://www.cdc.gov/drugresistance/pdf/2-2013-508.pdf



WHY IS CRE SO DANGEROUS?

Klebsiella and Escherichia coli are two common Enterobacteriaceae, both found in the intestines and not usually pathogenic there. However, they can move from the digestive system to cause infections in the urinary tract, bloodstream, wounds, and lungs (Deen & Debbie, 2014).

Muscarella (2014) described what sets CRE apart. "First, these bacteria are resistant to multiple classes of antimicrobial drugs. In fact, some strains of CRE are pan-resistant (i.e., resistant to all antibiotics). Second, these resistant bacteria can share mobile pieces of genetic material, conferring their antibiotic resistance to other once-susceptible bacteria that are physically nearby and of either the same or a different species or family of bacteria" (pg. 461). (Figure 1.) Patients with these infections have significantly worse clinical outcomes; once CRE reaches the bloodstream, mortality can be as high as 50% (Muscarella, 2014).

TRANSMISSION

CRE is transmitted by direct contact, either person-to-person or with contaminated surfaces. Studies have found CRE on intensive care unit sinks, staff stethoscopes, and name badges. Deen and Debbie (2014) found a significant number of colonized patients and contaminated surfaces in post-acute care and long-term care facilities.

Medical instruments such as the duodenoscope pose an especially high risk of transmission due to their intricate design. Duodenoscopes are most commonly used for a procedure called endoscopic retrograde cholangiopancreatography (ERCP), used to evaluate the bile ducts, pancreatic duct, and the gallbladder (Understanding ERCP). These scopes are different from endoscopes due to a moveable "elevator" mechanism at the tip. While this allows the operator more flexibility with the angle of the scope, this causes a challenge for cleaning and high-level disinfection (U.S. Food and Drug Administration, 2015).

In 2010, Olympus made a major change to the design of their scope which made it even more difficult to clean. This change was not reported to the FDA, so the new model (Q180V) was not evaluated for safety until years later (Kaiser Health News, 2016). In 2013 the CDC found a potential link between multidrug-resistant bacteria and duodenoscopes; the FDA continues to monitor this association ans recommend following the reprocessing guidelines and practices established by infection control and endoscopy experts (U.S. Food and Drug Administration, 2015).

RISK FACTORS

Factors that increase a patient's risk of becoming infected include (Deen & Debbie, 2014; Muscarella, 2014):

- advanced age
- previous exposure to broad-spectrum antibiotics
- being in acute and long-term care settings
- invasive devices such as a urinary catheter or central venous line
- mechanical ventilation
- immunosuppression (e.g., transplant recipients)
- endoscopic procedures such as ERCP

TREATMENT

Treating CRE is challenging due to the limited number of effective antibiotics available. It typically includes a combination of drugs, e.g., aminoglycosides,

polymyxins (such as colistin), tigecycline, fosfomycin, and temocillin. This does not come without risk. Many have toxic side effects leading to further complications (Davis & Cunha 2014; Deen & Debbie, 2014; Muscarella, 2014).

Colistin can cause neurotoxicity and nephrotoxicity. Clinicians have questioned tigecycline's efficacy, and clinical trials have shown higher mortality rates with this drug as compared with others. Most experts discourage using it as monotherapy. Nausea is the most common side effect with tigecycline but other issues (pancreatitis, extreme alkaline phosphatase elevation) have been reported. Aminoglycosides carry risks for ototoxicity and nephrotoxicity (Perez & Duin, 2013).

SUPERBUG LITIGATION

In February 2015, the U.S. Food and Drug Administration issued a safety warning on the intricate duodenoscope design and resulting cleaning and disinfection challenges, possibly related to design flaws (U.S. Food and Drug Administration, 2015). One year later, January 15, 2016, the FDA cleared the Olympus Q180V duodenoscope after further modifications; Olympus voluntarily recalled the original model (U.S. Food and Drug Administration, 2016).

A Los Angeles Times article quoted these FDA statistics: "As many as 350 patients at 41 different medical facilities in the U.S. and worldwide were infected or exposed to tainted gastrointestinal scopes from Jan. 1, 2010 to Oct. 31, 2015" (Terhune, 2016).

Olympus America is already facing litigation, with the likelihood of more suits to come. A legal nurse consultant working with these cases should determine:

- Did the patient have a procedure with a scope (especially ERCP) after 2010?
- Was the device made by Olympus?
- Did the patient have a severe infection possibly caused by the procedure?

CONCLUSION

With the growing antibiotic resistance and fewer antibiotics to treat these "superbug" infections, healthcare practitioners must be more vigilant in preventing the spread of resistant organisms. The current CDC recommendations for good hand hygiene, implementing contact precautions, providing education, antibiotic stewardship, staff and patient cohorting, and CRE screening only work if clinicians consistently implement and monitor them.

REFERENCES

American Chemical Society International Historic Chemical Landmarks. Discovery and Development of Penicillin. (1999). From American Chemical Society. Retrieved June 28, 2016: https://www.acs.org/content/acs/en/education/whatischemistry/landmarks/flemingpenicillin.html

Centers for Disease Control and Prevention. (2013, April 23). Antibiotic Resistance Threats in the United States, 2013. Retrieved September 8, 2015 from Centers for Disease Control and Prevention: http://www.cdc.gov/features/antibioticresistancethreats

Davis, C. P. (2015, February 24). CRE Bacteria Infection: MedicineNet.com. (J. P. Cunha, Editor) Retrieved September 7, 2015 from MedicineNet.com: http://www.medicinenet.com/cre_infection/article.htm

Deen, R., & Debbie, D. (2014). Carbapenem-resistant Enterobacteriaceae: Deadly superbugs on the rise. Prevention Strategist , 44-46.

Kaiser Health News. (2016). From Summary of Proposed Legislative Provisions. Retrieved June 29, 2015: https://kaiserhealthnews.files.wordpress.com/2016/04/scope-legislation.pdf

Muscarella, L. (2014). Risk of transmission of carbapenem-resistant Enterobacteriaceae and related "superbugs" during gastrointestinal endoscopy. World Journal of Gastrointestinal Endoscopy , 6 (10), 457-474.

Orsini, J., Mainardi, C., Muzylo, E., Karki, N., Cohen, N., & Sakoulas, G. (2012). Microbiological Profile of Organisms Causing Bloodstream Infection in Critically Ill Patients. J Clin Med Res , 4 (6), 371-377.

Perez, F., & Duin, D. V. (2013). Carbapenem-resistant Enterobacteriaceae: A menace to our most vulnerable patients. Cleveland Clinic Journal of Medicine , 80 (4), 225-233.

Terhune, C. (2016, 15 April). Los Angeles Times. From Los Angeles Times. Retrieved on June 29, 2016: http://www.latimes.com/business/la-fi-0415-olympus-scopes-20160414-story.html

U.S. Food and Drug Administration. (2015, 19 February). From Safety Communications; U.S. Department of Health and Human Services. Retrieved September 8, 2015: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm434871.htm

U.S. Food and Drug Administration. (2016, 15 January). From FDA News Release. Retrieved June 29, 2016: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm481956.htm

Understanding ERCP. (n.d.). From American Society for Gastrointestinal Endoscopy Retrieved June 2016: http://www.asge.org/patients/patients.aspx?id=386

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Surgical Infection Claims: A Fool's Errand or an Astute Pursuit?

Peter I. Bergé, JD, MPA, PA

Until very recently, medical malpractice attorneys would reject cases involving post-surgical infections (absent delay in diagnosis or mismanagement), under the theory that such infections were inevitable and that negligence leading to the infection could not be proven. Then, in October 2008, a dramatic change in policy by the Centers for Medicare and Medicaid Services (CMS) brought about a new perspective on healthcare-acquired infections. Medicare stopped paying for care related to some hospital-acquired infections (HAIs) under the theory that they generally should be preventable (Centers for Medicare and Medicaid Services (CMS), 2013).

It's not clear if the CMS changes in policy reflected or drove the surge of interest in preventing HAIs (money is often the prime motivator for change), but in the last few years a number of studies have demonstrated that there are ways of improving the stunningly low rates of compliance with hand hygiene, which is one of the simplest and most effective infection prevention methods. (Dunn, 2014; Roehr, 2007) Given evidence that there is so much more that can be done to prevent HAIs, they are no longer seen as inevitable, and providers have a clearer duty to make all practical efforts to reduce their incidence.

In the context of the marked changes in perspective on the preventability of HAIs, I took an interest in evaluating such claims as potential causes of action. My criteria were to evaluate the timing and nature of manifestation of the infection and type(s) of bacteria (including resistance patterns), and that all had to point strongly toward a preventable nosocomial infection. This article is a discussion of what was, in many ways, the ideal example of such a case.

In 2010, John Lancaster (pseudonym) was a healthy, muscular man in his late 30s who had a physically demanding occupation. He had survived a rollover automobile collision some years earlier,

after which he was paralyzed for several months due to a C-spine injury, and had been rehabilitated to the point that he was left with minimal left upper arm atrophy. He maintained a rigorous physical fitness regimen, and was bench-pressing about 225 pounds one day when he felt a pop in his left shoulder.

In October 2008, a dramatic change in policy by the Centers for Medicare and Medicaid Services (CMS) brought about a new perspective on healthcare-acquired infections.

Several consultations and two MRIs determined that he had suffered a left pectoralis tendon rupture. This was notable for the fact that it was a closed injury, so that there was no break in the skin to allow for the entry of bacteria into his system. A posterior labral tear was incidentally identified, and he was scheduled for repair of both the labrum lesion and the pectoralis tendon rupture in a privately-owned, free-standing surgical center (Superb Surgical, pseudonym) by Dr. Rex Huesos (pseudonym). Pre-surgical blood work revealed no disease process.

The repairs were performed in two stages, first the labral repair endoscopically, and then the biceps tendon repair through an open incision. The tendon repair took longer than expected due to pronounced retraction of the tendon, and the procedures were otherwise uneventful. However, Mr. Lancaster began to experience fevers and shaking chills within 24 hours of the surgery (postoperative day 1, or POD 1), accompanied by increasing pain. He was instructed by telephone to take Tylenol for the fever, which he was told was probably of pulmonary origin.

He was seen by Dr. Huesos on POD 3. Vital signs were not recorded in the chart. The physical examination note stated that there was no erythema at the wound site, and that there were no signs of infection. Nonetheless, Dr. Huesos ordered a complete blood count (CBC) with differential, erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP), he and prescribed Augmentin (amoxicillin-clavulanate). The laboratory was closed by the time Mr. Lancaster left the appointment, so he went to have the blood drawn the next day. Dr. Huesos received the results on POD 5, but did not contact Mr. Lancaster prior to his scheduled follow-up visit on POD 7. The results were notable for an ESR of 36 mm/hr (upper limits normal 15 mm/hr) and CRP of 234.8 mg/L (upper limits normal 4.9 mg/L). The WBC and differential were normal.

On examining Mr. Lancaster, Dr. Huesos found that erythema had developed at the incision site since the prior visit. Taking into account the appearance of the wound, the laboratory results and the continued report of fever and chills, Dr. Huesos determined that there was likely infection "just outside the joint," and arranged urgent hospitalization for "immediate irrigation and debridement of the left shoulder pectoralis major repair." Once again, no vital signs were documented in the chart.

The hospital course was complicated. Mr. Lancaster required three surgeries for debridement, including removal of the implants and sutures used in the pectoralis repair, resulting in complete reversal of the repair. Cultures from the operating room grew both Enterococcus faecalis and Serratia marcescens, organisms associated with healthcare acquisition.

Despite being administered prophylactic anticoagulants he developed a deep vein thrombosis, requiring placement of an inferior vena cava filter to attempt to prevent pulmonary thromboemboli. Although he was treated with intravenous antibiotics he developed sepsis, but was ultimately discharged after 12 days, subsequently requiring weeks of intravenous antibiotics via a peripherally inserted central catheter (PICC).

In addition to the permanent loss of the pectoralis major repair resulting in decreased function related to loss of the accessory action of the pectoralis major, and his life-threatening illnesses experienced in the hospital, Mr. Lancaster was left with severe scarring in the left infraclavicular area and left upper arm.

A suit captioned Lancaster v. Superb Surgical et al was brought in superior court against Superb Surgical, Dr. Huesos, and various John Does (fictitious pleadings). Discovery revealed a number of deficits in the infection control program at Superb Surgical, although none could be conclusively linked to this infection. Plaintiffs' experts, an orthopedist and a specialist in infectious diseases, asserted that the characteristics of the infection strongly supported the contention that it was the result of contamination deep in the surgical wound of the biceps tendon repair in the operating suite, and that the nature of this particular infection was evidence of negligence. Neither expert could identify the particular negligence that resulted in the infection, nor did they expect to, but the circumstances surrounding Mr. Lancaster's complications indicated that, to a reasonable degree of probability, the deep contamination of his sterile surgical wound was due to a

breakdown in infection control measures at Superb Surgical.

Multiple defense experts (infectious diseases and orthopedics) agreed on two points: the contamination of the surgical wound probably did occur in the operating suite at Superb Surgical, and that the infection did not support the conclusion that negligence had occurred. The most common theme was that "infections are a risk of surgery" and there will always be post-surgical infections, so there was no evidence of negligence. Some experts also pointed out that no specific break in aseptic technique, or in the instrument processing or infection control procedures of Superb Surgical was identified, and so the plaintiffs could not meet their burden of proving negligence by any party.

Plaintiffs' position was that the characteristics of this infection strongly supported the contention that it was the result of negligence. First, the onset of signs and symptoms (increasing pain, fever, rigors) occurred within 24 hours of the surgery (File, 2007). This was consistent with a large inoculum of bacteria at the time of surgery. A few stray bacteria floating in the air or being introduced by happenstance in the wound, if they caused an infection at all, would have resulted in signs and symptoms days or weeks later, and would likely not have caused such severe local and systemic illness so quickly. Second, in Mr. Lancaster's example, deep pain and systemic symptoms occurred several days before erythema manifested at the incision site, demonstrating an "inside out" development (making an external source unlikely). In addition, finding those two types of bacteria deep inside the wound, both of which are infamous for healthcare acquisition, was a particularly unusual occurrence, particularly in an outpatient setting involving a clean surgery on a healthy patient. During opening arguments, I planned to point out to the jury that bacteria that are normally found in feces and in soil (Enterococcus and Serratia, respectively) should not be deposited deep in a sterile wound in any operating room.

Defense counsel for Suberb Surgical and Dr. Huesos intended to defend the case, and it was assigned to a judge for trial in superior court. During jury selection and pretrial motion practice the judge reviewed the expert reports and strongly encouraged the parties to settle the case. Ultimately, Dr. Huesos was dismissed, as the weight of the evidence was against Superb Surgical, and the case settled on the third day of jury selection. The amount of the settlement was relatively modest only because the damages were limited by plaintiff's prior neck injury affecting the shoulder and upper arm function, and the subsequent accident affecting the elbow and distal arm.

RES IPSA LOQUITUR

Well-known but often poorly understood, the legal theory of res ipsa loquitur comes from a phrase that means "the thing speaks for itself." The example most commonly given is that of a clamp left inside a patient after surgery. Just looking at the x-ray, it is said, proves that there was negligence. The doctrine, however, is not so simple.

The prototypical res ipsa case is Byrne v. Boadle. 2 H. & C. 722, 159 Eng. Rep. 299 (Exch. 1863), an old British common law case (Lawnix, n.d.). In Byrne, plaintiff was walking by a shop on the street and was knocked unconscious by a barrel that fell from a window of a shop. It was unknown how the barrel came to fall out of the window. Most simply put, it was found that the shop owner had a duty to keep barrels from falling out of the window and injuring someone, and the fact that the barrel fell out of the window created a rebuttable presumption of a breach of that duty. No negligence could be attributed to plaintiff Byrne, who was innocently walking by. The barrel was, until shortly before it hit Mr. Byrne, in control of defendant Boadle. Under those circumstances, the plaintiff was not required to demonstrate defendant's negligence, but instead, the negligence on the part of defendant was presumed, and the burden shifted to Boadle to prove that he was not negligent. He could not, and judgment was found for the plaintiff.

The summary of the general criteria for res ipsa are

(1) the event does not ordinarily occur in the absence of negligence,

(2) the injured party has no fault, and

(3) the instrumentalities of the injury were under control of the defendant(s).

A case that contains additional elements that correspond to Lancaster is Summers v. Tice, 33 Cal. 2d 80, 199 P.2d 1 (Cal. 1948) (Lawnix, n.d.). In Summers, the parties were hunting birds. Both defendants shot at a quail and plaintiff was struck in the face. It was impossible for plaintiff to prove which of the defendants had caused the injury, or if it was both. The court held that as a matter of public policy, since both defendants were negligent, each was to be held entirely responsible for the harm to the injured party, since it would be unfair to

deprive the plaintiff of redress because the nature of the negligence of defendants did not allow for apportionment of liability.

In Lancaster we were faced with two defendants, either of whom might have been liable. In general, when there are multiple parties who might have liability, and it will be difficult to prove who was responsible, one must have all potentially responsible parties before the court, meaning that all must be named in the lawsuit. That is a common scenario in OR cases, such as those involving nerve or blood vessel injuries due to positioning. It was for this reason that Dr. Huesos was named in the suit. Plaintiffs' counsel also considered naming the manufacturers of the sutures and anchors that had been placed at the site of the infection. However, investigation revealed that there were no recalls or reported outbreaks related to the products used, so it was extremely unlikely that contaminated sutures or anchors were responsible. Those facts were brought in during depositions of personnel from Superb Surgical and through testimony of plaintiffs' infectious disease expert. This strategy neutralized attempts by the defense to use the manufacturers as "empty chair" tortfeasors, which is to say, to point the finger at parties who were not named in the suit.

While analyzing this case some time after the settlement, we came to the conclusion that in the absence of a fact pattern that argued otherwise, we would not as a matter of routine name the surgeon in future suits of this kind. The experts in Lancaster agreed that it was highly likely that the surgical center was the source of the wound contamination, and barring specific evidence to the contrary it would be appropriate to name only the facility and its employees (and potentially any contractors) as defendants.

WAVE OF THE FUTURE?

Now that many healthcare acquired infections are considered to be preventable, will there be a surge of litigation involving surgical infections? Probably not. Post surgical infections are common, and their characteristics usually suggest contamination some time after surgery, and often well after discharge from the facility. The bacteria involved are usually ones commonly found on human skin (and/or the human mouth or throat) and generally are prevalent in the community. Often, there is a foreign body reaction involved, particularly one caused by a retained stitch. In those examples, the likelihood that the infection was caused by medical negligence is quite low. Even when a post surgical infection is caused by bacteria such as methicillin resistant Staphylococcus aureus (MRSA) that shows a susceptibility pattern suggestive of healthcare acquisition, the timing of manifestation of the infection usually presents great challenges to proving negligence under a res ipsa theory.

The successful litigation of the claim in Lancaster followed evaluation of numerous potential HAI claims. Essential to that success was meticulous analysis of the facts of the claim to be certain that there was solid evidence that the most probable cause of the infection was negligence. In order to evaluate similar HAI claims, attorneys must have a solid understanding of the medical issues, with an emphasis of infectious diseases and infection control, and would benefit from the assistance of medicolegal consultants with expertise in those areas, as well as in the medical or surgical specialties that are involved in the case. Highly well-qualified experts in infectious diseases and in infection prevention are also critical to such cases.

I believe that HAI claims, and particularly surgical infection cases, will never become commonplace, and they should be handled by attorneys and firms who have the expertise and resources both to select the rare claim that is viable and to successfully handle these complex and challenging matters. ❧

REFERENCES

Centers for Medicare and Medicaid Services (CMS) (2013) Medicare Non-Payment of Hospital-Acquired Infections: Infection Rates Three Years Post Implementation. Medicare & Medicaid Research Review: 2013, Vol. 3, No. 3.

https://www.cms.gov/mmrr/Downloads/MMRR2013_003_03_a08.pdf Retrieved 7/29/16

Dunn, L (2014) http://www.beckershospitalreview.com/quality/the-road-to-eliminating-hais-hand-hygiene-improvement-at-cedars-sinai.html Retrieved 7/29/16

File TM. (2007) Impact of community-acquired methicillin-resistant Staphylococcus aureus in the hospital setting. Clev Clin J Med 74: 4, S6-S11 2007.

Lawnix (n.d.) http://www.lawnix.com/cases/byrne-boadle.html Retrieved 7/29/16

Lawnix (n.d.) http://www.lawnix.com/cases/summers-tice.html Retrieved 7/29/16

Roehr, R (2007) Suspension of privileges improves physician adherence to hand hygiene. http://www.medscape.com/viewarticle/564005 Retrieved 7/29/16

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Legal Considerations For Antimicrobial Prescription

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Keywords: antibiotic resistance, urinary tract infection, pathogens, prescribing, litigation

Antibiotic resistance is a global health threat affecting the treatment of simple urinary tract infections. Initial treatment with antibiotics can fail due to resistant pathogens. Treatment failure from inappropriate prescribing is preventable; judicious prescribing is possible with knowledge of guidelines and local patterns of resistance. Antibiotic resistance limits choices for treatment, placing patients at risk for adverse effects. Since adverse drug reactions are a common source of malpractice claims, knowledge of antibiotic resistance and safe prescribing practice may prevent litigation.

Antibiotics are one of the most commonly prescribed classes of drugs in the United States (U.S.) and are unique in their ability to save lives. Prescribing is most common in the outpatient setting. Inappropriate prescribing is a major driver for antibiotic resistance (AR); up to 50% of all such prescriptions deemed unnecessary (Holmes et al., 2016).

Resistance and treatment failure related to inappropriate prescribing places patients at risk for adverse events and healthcare providers at risk for litigation.

Resistance and treatment failure related to inappropriate prescribing places patients at risk for adverse events and healthcare providers at risk for litigation. Healthcare fraud, a serious federal crime, includes prescribing unnecessary treatment, supplies, or services (Dolan & Farmer, 2016). Healthcare providers should be aware of potential medicolegal implications and how to protect themselves in the event of litigation.

Inappropriate use increases adverse effects, treatment failure, and cost. Organ system complications range from mild to profound; a single dose can cause death. Costs range from minimal to extraordinary.

Microorganisms produce many antimicrobial drugs naturally. Only two classes of drugs commonly used to treat UTIs, the sulfonamides and fluoroquinolones, are wholly synthetic (Holmes et al., 2016). Penicillins and cephalosporins, other drug classes of antibiotics used to treat UTIs, accounted for almost 60% of antibiotics sold in the U.S.in 2011(Poetker & Smith, 2015). *Escherichia coli (E coli), Klebsiella pneumoniae, and Staphylococcus aureus*, are common urinary pathogens now resistant to penicillins and cephalosorins. A drug shortage occurs when there is an inadequate supply of clinically interchangeable versions of any FDA-regulated drug product that would be expected at the user level, and anti-infective drugs account for 15% of all drug shortages (Quadri et al., 2015). For almost two decades, no new class of antibiotic has been manufactured or is available to treat systemic infections (Theuretzbacher, 2015).

URINARY TRACT INFECTIONS (UTIS)

UTIs are one of the most common problems treated in the outpatient setting and one of the most common reasons for antibiotic use (Lin et al., 20152). Up to 50-70% of women may have a UTI during their lifetime (Lin et al., 20152; MishraMishra, Srivastava, Singh, Pandey & Agarwal, 2012) Resistant strains of E coli, causing 70-90% of all UTIs, have spread from inpatient to outpatient settings globally (Holmes et al., 2016; , Nozvarko, 2013). E.coli is now resistant to beta-lactam antimicrobial drugs, such as penicillin and cephalosporins, and ciprofloxacin, a synthetic fluoroquinolone. Treating UTIs in the US costs an estimated at $2.4 billion annually, with $218 million in outpatient prescriptions (Romina Lo-Montano, John, & Weiss, 2015).

The International Clinical Practice Guidelines for the Treatment of Acute Uncomplicated Cystitis and Pyelonephritis in Women: A 2010 Update by the Infectious Diseases Society of America and the European Society for Microbiology and Infectious Diseases (Gupta et al., 2010) is an educational tool that promotes a standard of care for the treatment of UTIs. Gupta et al. recommend avoiding prescribing antibiotics for UTIs when local resistance exceeds 20% and screening for asymptomatic bacteriuria (ABU) to avoid unnecessary prescribing. ABU is often improperly diagnosed as UTI based on clinical signs, symptoms, and urinary microscopy (George, 2015). Up to 20-80% of ABU is inappropriately treated (Lee et. al., 2015.), and 1/3 of antibiotic prescriptions are written for ABU (Nelson & Good, 2015). Gupta et al. recommend reserving treatment with antibiotics for ABU in patients who are pregnant or for those patients undergoing invasive urologic procedures.

The standard of care for antibiotics for UTIs should be based on symptoms and interpreting urinalysis (U/A) and culture and sensitivity (C&S) correctly. Knowing when to order and how to interpret a U/A is essential to avoid inappropriate tests yielding false positive results. Prescribing based on U/A alone contributes to AR and is not standard of care; C&S is definitive test for UTI diagnosis.

Knowing local patterns of resistance can significantly reduce initial antibiotic treatment failure. Watchful waiting, when appropriate, is acceptable. Choosing narrow-spectrum antibiotics that are safe for patients and based on resistance rates minimizes the chance for adverse patient reactions and the spread of resistant pathogens. Shared decision-making strategies for treatment maximize efficacy and decrease resistance. Minimizing uncertainty in decision-making strategies for treatment promotes a reasonable standard of care that would be expected of professional peers (Goldenberg, 2012).

CHECKLIST FOR LITIGATION ABOUT ANTIBIOTIC PRESCRIBING

The prescriber should…

1. Read and review the chart for past allergies and reaction to allergies
2. Obtain a complete history and appropriate physical exam
3. Update the list of current medications
4. Assess for potential drug-drug interactions or intolerances
5. Counsel patients on antibiotic therapy, complications, adverse effects, and resistance
6. Consider watchful waiting
7. Order culture and sensitivity as indicated
8. Prescribe based on evidence and resistance patterns
9. Consult with pharmacist if necessary
10. Prescribed correct, dose, duration, and antibiotic
11. Check culture results, and inform patient if a medication change is necessary
12. Recommend one to two day follow up for patients with infections that have potential for failure with outpatient treatment

IMPLICATIONS FOR THE LNC

Maintaining a standard of care promotes best practice and helps prevent legal issues. Medical malpractice claims are based on state law (Lang, 2015). Common plaintiff allegations related to antibiotic therapy are summarized in Table 1 on page 52.

Clinical negligence includes diagnosis delay or failure. The Physician Insurers Association of America reviewed 1993 lawsuit data from their member companies and found medication errors to be the second most common claim against physicians, (Poetker & Smith), with antibiotics as the most common drug (Poetker & Smith, 2015).

Documenting simple infections should include practice-based evidence to support the diagnosis and treatment plan, including prescribing appropriate antimicrobials based on local resistance rates. Optimal antimicrobial therapy requires keen diagnostic skills; watchful waiting for culture results, when indicated, can avoid unnecessary prescribing without compromising standard of care. Dosage and duration of treatment should be individualized. Patient education regarding AMR should include instruction on possible treatment failure and potential for adverse events from the prescribed drug. The LNC should look for patient teaching, appropriate referrals, collaboration with pharmacists or infectious disease specialists, and billing codes for clues.

CONCLUSION

Considering empirical therapy, counseling patients on delayed antibiotic therapy, and using resistance patterns and guidelines to assist in antimicrobial choice, dosage, and duration of treatment are vital in decreasing litigation.

As multiple national and international stakeholders become more aware of AMR, they can use medical records to guide future policy and regulatory standards of care to promote best prescribing practice (Dolan & Farmer, 2016). The influence of harmful drug and host interactions, clone emergence, and cross-resistance are of intense interest. Global tourism and vaccination rates contribute to AMR, and environmental concerns, especially the use of antimicrobials in the agricultural industry, significantly affect the spread of resistant pathogens. Funding for pharmaceutical advances is limited, and antibiotic prescribing habits are scrutinized for standard of care.

Providers should consider cost, patients' allergies, history, and patterns of AR in the community in which they practice. Medical errors may be preventable when documentation includes rationales for prescribed drugs and an adequate medical history to include past tolerance of antimicrobials.

Documentation should include rationales for prescribed antibiotics and an adequate medical history to include past tolerance of prescribed antibiotics. Treatment choices should be based on what is reasonably prudent, acceptable care, and actions should be scientifically defensible (Lang, 2015). Consultation and patient teaching aid in treatment decision-making, improving chances for success. If treatment is uncertain, consultation and referrals should be sought and documented in the medical record.

Health care providers have an ethical and cultural responsibility to reduce inappropriate prescribing. Prescribing optimal therapy requires keen diagnostic skills. Watchful waiting for culture results, when indicated, can avoid unnecessary prescribing without compromising standard of care. Provider mindfulness of potential unintended consequences from treatment for simple infections can help prevent legal issues and improve patient outcomes. ❧

Table 1.

COMMON PLAINTIFF ALLEGATIONS RELATED TO ANTIBIOTIC THERAPY
(Poetker and Smith, 2015)

- Allergy
- Provider failed to note a documented allerwgy; failure to read medical record
- Inadequate medical history
- Communication failure between provider and patient
- Failure to order a culture and sensitivity
- Failure to follow up on a culture
- Failure to prescribe an antibiotic
- Prescribed a lower dose than required
- Most appropriate drug not used (based on culture)
- Errors in writing the prescription
- Providers did not review potential complications with patient

REFERENCES

Dolan, C. M., & Farmer, L. J. (2016). "Let the record speak…": The power of the medical record. The Journal for Nurse Pract 12 2 88-94. http://dx.doi.org/10.1016/j.nurpra.2015.09.018

George, C.E., Norman, G., Ramana, G.V., Mukherjee, D., & Rao, T. (2015). J Family Med Prim Care 4(3) 416-421. doi.10.4103/2249-4863.161342

Goldenberg, S.D., Vope, H., & French, G.L. (2012). Clinical negligence, litigation and healthcare-associated infections. Journal of Hospital Infection. 81 156-162. doi.10.1016/j.jhin.2012.04.020

Gupta, K., Hooton, T.M., Naber K.G., Wullt, B., Colgan, R., Miller, L.G. … Soper, D.E. (2010).

International clinical practice guidelines for the treatment of acute uncomplicated cystitis and pyelonephritis in women: A 2010 update by the Infectious Diseases Society of America and the European Society for Microbiology and Infectious Diseases. Clinical Infectious Diseases, 52(5). e103-e120.

Holmes, A. H., Moore, L. P., Sundsfjord, A., Steinbakk, M., Regmi, S., Karkey, A., & ...

Piddock, L. V. (2016). Understanding the mechanisms and drivers of antimicrobial resistance. Lancet, 387 North American Edition (10014), 176-187, 12p. doi:10.1016/S0140-6736(15)00473-0

Lang, D. M. (2015). The failure to deliver as promised. Clinician Reviews, 25(8). 32-33.

Lee, M. J., Kim, M., Kim, N., Kim, C., Song, K., Choe, P. G., & ... Kim, H. B. (2015). Why is asymptomatic bacteriuria overtreated?: A tertiary care institutional survey of resident physicians. BMC Infectious Diseases, 15(1), 289-289 1p. doi:10.1186/s12879-015-1044-3

Lin, E., Bhusal, Y., Horwitz, D., Shelburne, S. A., & Trautner, B. W. (2012). Overtreatment of enterococcal bacteriuria. Arch Intern Med 172 (1), 33-33-38.

Lo-Montano, R., John, D., & Weiss, S. (2015). Uncomplicated UTIs in women. Nurse Practitioner Perspective, 41-44. http://nurse-practitioners-and-physician-assistants.advanceweb.com/Continuing-Education/CE-Articles/Uncomplicated-UTIs-in-Women.aspx

Mishra, B., Srivastava, S., Singh, K., Pandey, A., & Agarwal, J. (2012). Symptom-based diagnosis of urinary tract infection in women: are we over-prescribing antibiotics? International Journal of Clinical Practice, 66(5), 493-498 6p. doi:10.1111/j.1742-1241.2012.02906.x

Nelson, J. M., & Good, E. (2015). Urinary tract infections and asymptomatic bacteriuria in older adults. The Nurse Practitioner, 40, (8). 43-48. doi.10.1097/01.NPR.0000460855.44987.c1

Nazarko, L. (2013). Recurrent urinary tract infection in older women: An evidence-based approach. British Journal of Community Nursing 18(8), 407-412.

Poetker, D. M., & Smith, T. L. (2015). What rhinologists and allergists should know about the medico-legal implications of antibiotic use: A review of the literature. International Forum of Allergy & Rhinology (5) 2, 104-110. doi. 10.1002/alr.21433

Quadri, F., Maxer-Amirshahi, M., Fox, E. R., Hawley, K. L., Pines, J. M., Zocchi, M. S., & May,

L. (2015). Antibacterial drug shortages from 2001 to 2013: Implications for clinical

practice. Clinical Infectious Disease,60 (12). 1737-1742. doi: 10.1093/cid/civ201

Shepard, A. K., & Pottinger, P. S. (2013). Management of urinary tract infections in the era of increasing antimicrobial resistance. Med Clin N Am 97 737-757 http://dx.doi.org/10.1016/j.mcna.2013.03.006

Theuretzbacher, U. (2015). Recent FDA antibiotic approvals: Good news and bad news. The Center for Disease Dynamics, Economics & Policy. Retrieved from: http://cddep.org/blog/posts/recnet.fda.antibiotic.approvals.good.news.and.bad.news#sthash.yOxBN452.dpuf

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