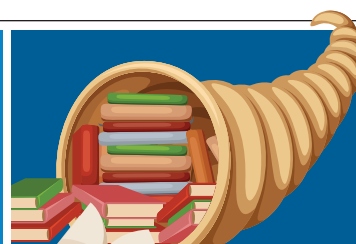


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THERE'S NO C IN SEPSIS

VITAMIN C ISN'T A
MAGICAL CURE FOR
SEVERE SEPSIS
AND SEPTIC SHOCK

by JEREMY SAMUEL FAUST,
MD, MS, MA, FACEP

IS a vitamin C–based cocktail the cure for severe sepsis and septic shock? If you read headlines and news items that appeared widely in the mainstream media in 2017, you might have concluded that it is. After all, a recent paper in *Chest* had found that when a single intensive care unit (ICU) rolled out a new protocol in which a “cocktail” of vitamin C, thiamine, and hydrocortisone was given to patients with severe sepsis

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THE EQUITY EQUATION

THINKING OUTSIDE OF THE HOSPITAL

How to support breast-feeding at conferences and testing centers

by EMILY CLEVELAND MANCHANDA, MD, MPH; LARA D. VOGEL, MD, MBA; AND SHADA A. ROUHANI, MD, MPH

Physicians have been taught to advocate for breastfeeding with our patients; however, our profession makes it challenging to practice what we preach.

Background

The World Health Organization and American College of Obstetricians and Gynecologists (among many others) support

breastfeeding exclusively for six months and continued breastfeeding for two years or more based on evidence showing benefits to mother and child.¹⁻³ Some parents

choose formula instead of breast milk for a variety of reasons, but in the United States, working mothers' right to express (pump) breast milk for their infants is protected through amendments to the Fair Labor Standards Act.⁴ Nevertheless, returning to work correlates strongly with a decision to stop breastfeeding, particularly for those working in environments that are unsupportive.^{5,6}

Our workplace, the hospital, is where many mothers learn to breastfeed. Supporting breastfeeding and pumping is a key strategy in recent efforts to make hospitals “baby-friendly.”³ For working physicians, resources and policies that encourage pumping on shift are critical. But that's not where it ends. Our careers, especially in academia, do not exclusively take place within the hospital walls.

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ANTIBIOTIC STEWARDSHIP BAD BUGS ARE HERE

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NEWS FROM THE COLLEGE

UPDATES AND ALERTS FROM ACEP

ACEP Working with TJC on Common Concerns

After conducting an all-member survey to collect feedback about concerning The Joint Commission (TJC) regulations, ACEP has summarized the member responses and is working with TJC to address relevant issues. The most common concern was the ability to eat and drink in the emergency department, a regulation that ACEP worked with TJC to clarify in Feb. 2019. It was confirmed that TJC and the Occupational Safety and Health Administration don't have policies forbidding eating and drinking in the ED, but some hospitals do have their own policies. We created resources to help you advocate for improvements at your place of employment. Visit www.acep.org/letseat for all of the details and resources related to eating and drinking in the emergency department.

The second-most common concern voiced by our members was the requirement for 1:1 sitters for patients who are suicidal, along with universal screening for suicidal patients. TJC recommends universal screening for suicidality but only requires it for patients who present with behavioral emergencies. TJC does, however, require 1:1 sitters for patients who are suicidal. ACEP is discussing appropriate alternatives with TJC.

Wondering what else came up in the survey? Cleaning the ultrasound machine, the need to laminate all posted notices, and the number of screens performed by triage nurses,

to name a few. ACEP and TJC are working through these concerns to determine how many are related to TJC regulations and how many are unique to specific hospital policies.

Thank you to everyone who filled out the survey. We will keep you posted on progress as ACEP's advocacy and clinical affairs teams continue discussions with TJC.

Nominate Your Peers for National Awards

ACEP is accepting nominations for the 2020 ACEP Leadership & Excellence Awards, which annually honor members distinguishing themselves for leadership and excellence in emergency medicine. All members are eligible to submit nominations by March 1, 2020. Learn more at www.acep.org/leadership-awards.

Know an outstanding educator? Nominations are open for National Emergency Medicine Faculty Teaching Award, Junior Faculty Teaching Award, and Excellence in Bedside Teaching Award. All educator award nominations are due April 15, 2020. Get more information at www.acep.org/teachingaward.

Board Nominations Due March 16

The ACEP Nominating Committee is accepting individual and component body recommendations for the ACEP Board of Directors. Submit applications to nominations@acep.org by March 16, 2020. To view the qualifications needed to apply, go to www.acep.org/board-nominations.

THE BREAK ROOM

We Shouldn't Compromise on Moral Convictions

I noticed in the "News from the College Section" of the December 2019 issue of *ACEP Now* that ACEP applauds the United States District Court for the Southern District of New York for rejecting the HHS rule that would shield health professionals who refuse to deliver care or medical services based on religious belief or moral conviction.

It astonishes how quickly we have forgotten the lessons of the recent past. A former governor of Colorado stated that for financial reasons, and the greater good, it was the "duty of the elderly to die."

It should be sadly remembered that the German 1930 sterilization law was largely modeled on a draft written by Harry Laughlin at the Eugenics Record Office in Cold Spring Harbor, New York. After Hitler's rise to chancellor in 1933, a radicalized eugenics program emerged in Germany, and its first victims were 70,000 Germans deemed "feeble-minded."

The euthanasia program was initially organized and carried out by German physicians. These physicians were encouraged to move from doctoring individuals to doctoring the nation. Dr. J. Barondess observed in the *Annals of Internal Medicine* "that physicians in Germany did not simply acquiesce; rather they accepted, supported, and were instrumental in the application of the policies."

Former U.S. Surgeon General Dr. C. Everett Koop stated, "At greatest risk are the poor,

elderly, disabled, disadvantaged, and others without access to good medical care for whom the 'choice to die' could become 'a duty to die.'" The frightening echoes of the concept of "lives not worth living" loudly resound.^{2,3}

I have witnessed authorized and approved hostile demonstrations against Jews and also Catholics by regimes in other countries. We cannot ignore that both Papa Doc Duvalier, Haiti, and Che Guevara, Cuba, were physicians, and they were known for their brutality. As physicians, we are not automatically immunized against inhumanity, and it appears that we can be changed by state dictates, personal agendas, career advancement, profit incentives, and personal biases.

Physicians, like any citizen, must have the right to refuse or provide treatments deemed not moral or unethical based on religious or moral conviction. As R. Orr, MD, director of clinical ethics at Loma Linda University, stated: "Become involved or the reprehensible will become the standard, and the standard of care will ultimately become your obligation."⁴

Joseph M. Soler, MD, FACEP
Bradenton, Florida

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ACEP4U: Value-Based Reimbursement

ACEP CAN HELP YOU NAVIGATE PAYMENT MODELS AND MAXIMIZE PAYMENTS



by JEFFREY DAVIS

Over the last several years, there has been a movement away from reimbursing health care practitioners based on the volume of services toward rewarding them for the quality or “value” of care provided.

The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 accelerated health care payment reform efforts by establishing the Quality Payment Program (QPP), the main quality reporting program in Medicare. There are two tracks in the QPP: the Merit-Based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs). MIPS includes four performance categories: quality, cost, improvement activities, and promoting interoperability (formerly electronic health record “meaningful use”). Performance in these four categories (which are weighted) rolls up

into an overall score that translates to a bonus that physicians receive on their Medicare payments two years after the performance period (for example, performance in 2020 impacts Medicare payments in 2022). Physicians and other health care practitioners who actively participate in certain Advanced APMs are exempt from MIPS and can receive a 5 percent payment bonus through 2024 and a higher payment fee schedule update starting in 2026.

Most emergency physicians participate in MIPS because there simply aren’t any opportunities to be in an Advanced APM. However, given the fundamental role emergency physicians play in our health care system, ACEP strongly believes that emergency physicians are well-positioned to be meaningful participants in APMs if given the opportunity.

What is an APM?

CMS defines an APM as a payment approach that gives physicians and other providers added incentive payments to provide high-quality and cost-efficient care. APMs can apply to a specific clinical condition, a care episode, or a population. Examples of APMs include accountable care organizations (ACOs), medical homes, and bundled payment models.

Advanced APMs are a subset of APMs with additional requirements, such as nominal financial risks. Financial risk means that a provider participant in the APM is held financially accountable if the services they provide wind up costing more than a predetermined target. In other words, participants must owe back some or all “losses” for which they are deemed responsible.

What is the AUCM?

ACEP created the Acute Unscheduled Care Model (AUCM, pronounced “awesome”), a Medicare Advanced APM proposal designed for emergency physicians.

The AUCM would provide a voluntary alternative to the traditional fee-for-service payments for Medicare patients who receive emergency care. It is structured as a bundled payment model, focusing

on specific “episodes” of unscheduled acute care. Under a bundled payment approach, if the cost of an episode of care is less than a predetermined price for that episode, then a participating provider or group can keep that difference. However, if the cost winds up being more than the predetermined price, participants would be responsible for those losses and owe Medicare the difference.

The AUCM is designed to last five years and be flexible enough to allow the full spectrum of emergency physicians to participate, should they choose, from those with dedicated infrastructure and experience accepting financial risk to smaller groups of physicians who do not have as much experience in this area. Emergency physicians and groups could participate regardless of employment model (independent group, regional group, national group, employed physicians).

The overall goal of the AUCM is to improve the ability of emergency physicians to reduce inpatient admissions and observation stays when appropriate through enhanced care coordination. Emergency physicians would become key members of the continuum of care as the model focuses on ensuring follow-up care for emergency patients, minimizing redundant post-ED services, and avoiding post-ED discharge safety events that lead to follow-up ED visits or inpatient admissions. ➔

Developing Solutions

Successful participation in MIPS has been a top priority for ACEP. In addition to working with the Centers for Medicare & Medicaid Services (CMS) to simplify MIPS requirements, ACEP provides members with resources to ease the reporting process. Thousands of emergency physicians are now using ACEP’s Clinical Emergency Data Registry (CEDR) and participating in the Emergency Quality Network (E-QUAL) to meet reporting and attestation requirements.

A brief word about CEDR. It was developed

as the first EM specialty-wide registry to measure acute care quality, outcomes, practice patterns, and trends in emergency care. The CEDR registry ensures that you, rather than other parties or payers, are identifying what works best for your clinical practice and patients. In 2018, 100 percent of CEDR customers were in a positive MIPS scoring bracket and 40 percent of customers’ quality scores were above 70, qualifying them for exceptional bonus. Learn more about CEDR at www.acep.org/cedr.

CONTINUED on page 4

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And what is E-QUAL? The E-QUAL Network is a virtual learning community designed to accelerate knowledge translation by disseminating evidence-based practices in a low-burden, high-impact manner. Emergency departments participate in an E-QUAL initiative by joining a learning collaborative offered annually focusing on a single clinical topic. Each learning collaborative has a six- to nine-month learning period during which the ED champion interacts with the virtual E-QUAL portal and reports on local quality improvement activities. Activities include engaging eligible providers in the local quality improvement project and providing access to educational toolkits, webinars, podcasts, benchmarking data, and self-assessment tools. Participation in E-QUAL can earn clinicians improvement activity credit. Learn more about E-QUAL at www.acep.org/equal.

When MACRA passed, ACEP immediately identified the gap in available emergency medicine-focused Advanced APMs. In 2015, ACEP formed the APM Task Force co-chaired by Jeff Bettinger, MD, FACEP, and Randy Pilgrim, MD, FACEP. The task force reviewed various APM proposals and eventually developed the Acute Unscheduled Care Model (AUCM, fondly known as “Awesome”). In 2017, ACEP submitted the AUCM proposal to a federal advisory committee called the Physician-Focused Payment Model Technical Advisory Committee (PTAC) for consideration.

The PTAC is tasked with recommending physician-focused APM proposals to the sec-



FURTHER READING

EFFECT OF ACOS ON EM PAYMENT AND CARE REDESIGN

A recent qualitative study in *Annals of Emergency Medicine* interviewed emergency department leaders and Accountable Care Organization (ACO) participants to assess how accountable care has affected emergency care redesign and payment. The study found a lack of evidence-based policy solutions to inform accountable and value-based care in the emergency department. The Acute Unscheduled Care Model is designed to address this critical gap. Read “Effect of Accountable Care Organizations on Emergency Medicine Payment and Care Redesign: A Qualitative Study” at www.annemergmed.com.

retary of the Department of Health and Human Services (HHS) for consideration based on criteria established by the HHS secretary. Dr. Bettinger, Dr. Pilgrim, and Susan Nedza, MD, MBA, FACEP, presented the AUCM proposal before the PTAC on Sept. 6, 2018, and the PTAC recommended the AUCM to the HHS secretary for full implementation. The AUCM met all 10 of the established criteria, and the PTAC gave one of the criteria (scope) a “deserves priority consideration” designation since the PTAC felt the model filled an enormous gap in terms of available APMs to emergency physicians and groups.

A year later, on Sept. 27, 2019, the HHS secretary responded to the PTAC’s recommendation by stating he believes that core concepts of the AUCM should be incorporated into APMs being developed by the Center for Medicare & Medicaid Innovation (CMMI). The response

paves the way for emergency physicians to finally be in a Medicare Advanced APM.

ACEP’s Next Steps

The HHS secretary’s supportive response is an important step in the process of getting an EM-focused APM like the AUCM implemented, but ACEP’s work is not finished. Now it is up to CMMI to carry out the HHS secretary’s request.

Since the CMMI timeframe for incorporating the AUCM into the Medicare APMs is unclear, ACEP has started our own initiative to promote participation in EM-focused APMs being offered by other payers like Medicaid and private insurers. As Medicaid and private payers move away from fee-for-service contracts toward value-based payment arrangements, an appropriately modified non-Medicare version of the AUCM would be an ideal APM construct for these payers to pursue. However, while ACEP

encourages Medicaid and private payers to incorporate core concepts of the AUCM into EM-focused APMs, we anticipate some features of the APM will be different from the AUCM, depending on the specific patient population.

Learn More

ACEP has developed resources to help emergency physicians and others understand more about the landscape of health care payment reform and how a model like the AUCM could help improve emergency care and lower costs; one such resource is a FAQ to help clarify any misperceptions about the AUCM, the QPP, or APMs in general. Dr. Bettinger, Dr. Pilgrim, and Dr. Nedza, along with Avi Baehr, MD, Heather Marshall Vaskas, MD, and Jennifer Wiler, MD, MBA, FACEP, co-authored an article in the *Annals of Emergency Medicine* called “Enhancing Appropriate Admissions: An Advanced Alternative Payment Model for Emergency Physicians,” which highlights the key features of the AUCM. All these materials and more are found on ACEP’s APM Strategic Initiative website at www.acep.org/apm.

Here to Help

As both public and private payers begin to explore developing EM-specific APMs, ACEP will help you make sense of it all. Email me your questions at jdavis@acep.org.

MR. DAVIS is ACEP director of regulatory affairs.

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EMERGENCY MEDICINE IN NORWAY

How a midlife crisis helped create a brand-new specialty

by GAYLE GALLETTA, MD, FACEP

In February 2013, I was contacted by a Norwegian anesthesiologist who had heard through the grapevine that there was an American emergency physician living on a potato farm in rural Norway, teaching swim lessons. That April, I was informed, they were to start a pilot project at Akershus University Hospital (AHUS), which has Norway's largest emergency room—not a department. This is the story of how my midlife crisis morphed into helping found the specialty of emergency medicine in a country that I was still just getting to know.

The year before, after being an attending emergency medicine physician at the University of Massachusetts for 12 years, I had taken a one-year leave of absence. I moved to Norway with my Norwegian husband and our three elementary school-aged children. I knew that I would not be able to work as a physician there, as there is no reciprocity between the United States and Europe. Nonetheless, I submitted my paperwork to start the process of obtaining a Norwegian medical license (which typically takes at least six years) just in case I decided to return there one day in retirement. We enrolled our children in the public school where my husband had matriculated, and I enrolled myself in a language class for immigrants. I worked hard to learn the language and tried to make as many connections with physicians as I could.

That unexpected message was the first indication that my efforts were paying off.

Emergency Care in Norway

Norway has a population of 5.4 million and a gross domestic product of approximately \$400 billion (or \$75,000 per capita), making it the fourth wealthiest country in the world today. It has one of the world's best health care systems, with universal health insurance and a well-organized primary care system that functions as a gatekeeper to specialty care. However, when I moved there, Norway did not have a specialty in emergency medicine nor a system that we would find familiar. Moreover, AHUS had faced many challenges. It had a poor reputation—patients had died in the waiting room, primarily due to the lack of resident supervision.

Here's how it "worked." Patients who required inpatient treatment were referred to the hospital's emergency room (actually "akuttmottak," which means "acute receiving area"). Patients would be processed for admission by an intern. If a patient was too sick to be treated as an outpatient, the primary care doctor (or "legevakt," which means "doctor on call") was required to refer them to a specialty service, such as medicine, surgery, orthopedics, neurology, gynecology, psychiatry, or pediatrics. However, approximately 30 percent of patients arrived by ambulance. Problems would arise when patients were referred to the wrong specialty (such as a patient with back pain being referred to orthopedics when the real diagnosis was an abdominal aortic aneurysm) or when patients had problems that spanned different



FROM LEFT: Kåre Løvstakken, MD, project leader at AHUS; Gayle Galletta, MD, FACEP; and Lars Petter Bjørnsen, MD, FACEP, founder of Norwegian Society of Emergency Medicine, at the Society's fourth national symposium on emergency medicine, November 2014, Trondheim, Norway.

specialties (such as a patient with chronic obstructive pulmonary disease and amyotrophic lateral sclerosis with respiratory distress referred to surgery for a bowel obstruction). Placing undifferentiated patients was a problem, as akuttmottaks were primarily staffed by nurses and resident physicians with an average of six months' experience. Something had to be done.

By the time I got involved in 2013, the CEO of the hospital happened to be from Iceland, a country that has recognized emergency medicine since 1992. In an attempt to improve the quality of care, she started a pilot project at AHUS modeled after the United States/United Kingdom/Australian model of staffing the medical receiving area 24 hours a day with supervising physicians. To help roll this out, I was fast-tracked to receive a Norwegian medical license. I was asked to lead a group of eight and a half full-time attending physicians from various specialties, including three American-trained emergency physicians, three Norwegian internists, a pediatrician, an anesthesiologist, and a surgeon. My one-year study abroad trip had morphed into a two-year adventure.

During the same time frame, several other hospitals also began developing permanent attending emergency medicine positions in their hospitals. Simultaneous with the development of these programs, there was increased focus on emergency care in the media, and pressure on the government was mounting. At AHUS, we invited politicians and the Minister of Health to see what we were doing. I was selected by AHUS to be featured on a television documentary series, "På Liv og Død" ("Of Life and Death"), that showcased a day in the life of the Norwegian health care system. Our pilot project on emergency medicine was now in the spotlight.

EM Gains Steam in Europe

Emergency medicine was in various phases of development throughout Europe at this time. While the United Kingdom had recognized the specialty for almost half a century,

most other European countries were in their infancy with regard to emergency medicine. In 2013, the European Society for Emergency Medicine administered its first written board exam in emergency medicine. I was among the first 100 physicians who sat for this exam. It was administered in five locations throughout Europe. I flew to London for my exam, knowing that I was helping to create history. The 36 of us who passed this exam were invited to take the oral exam in Italy the following May. It was similar to an objective structured clinical examination. While it was not in a hotel room with an examiner behind a binder, I felt like my residency training and American Board of Emergency Medicine certification and recertification had prepared me well for the European exam. At the 2014 European Society for Emergency Medicine (EUSEM) conference in Amsterdam, I was recognized as one of the first 12 physicians to have passed the first written and oral emergency medicine exam in Europe.

Back at AHUS, patient care was improving. Since starting our pilot project, there had been no unexpected deaths in the emergency room. I can think of several of my patients who certainly would have died without the attending-level emergency medicine supervision I was able to provide. I remember a type A dissection that I diagnosed with bedside ultrasound, an unrecognized acetaminophen overdose, a patient sent in for presumed urosepsis that I correctly identified as Fournier's gangrene, and a patient with pericardial tamponade (also diagnosed with bedside ultrasound), just to name a few.

At the same time, patient complaints to the ombudsman drastically decreased from 92 in the two-year, eight-month period before emergency medicine staffing to just two in the six-month period after staffing the emergency department with attending physicians around the clock. Lifesaving treatments such as cardioversion for unstable atrial fibrillation were now being performed immediately in the emergency room rather than after the

delays around admitting these patients to hallway beds on the cardiology floor for management. We also discharged patients faster from our observation unit. The nurses and EMS felt safer having a small, dedicated group of attending physicians in the emergency room rather than relying on inexperienced interns rotating from the various services.

Many Challenges, Many Successes

Despite the obvious improvement in patient care we provided, the specialists felt threatened, particularly the cardiologists. They did not understand our scope of practice. How could a physician who was not a cardiologist manage ventricular tachycardia or cardiovert atrial fibrillation patients? We were not even allowed to intubate, as that was the anesthesiologists' job. Despite having diagnosed tamponade, dissection, and several aortic aneurysms by bedside ultrasound, I was accused of not being trained as a radiologist. Our CEO stepped down after a staffing conflict with the nurses' union, so we lost our support at the top. After almost one year, all success aside, our pilot program was shut down.

But it was too late to stop the momentum that had started. In 2015, the Norwegian Society for Emergency Medicine (NORSEM), which had been formed in 2010 by a Norwegian emergency physician who had trained in the United States (and of which I am a board member), was asked by the Ministry of Health to help develop an education framework and curriculum for a primary specialty in emergency medicine that would comply with EUSEM's curriculum and international guidelines. In 2017, the Minister of Health approved emergency medicine as Norway's newest specialty. One year later, NORSEM joined the International Federation for Emergency Medicine as a full voting member. In March 2019, the Ministry of Health began accepting applications from those physicians wishing to be grandfathered in as Norway's first emergency medicine physicians. On Oct. 17, 2019, I received confirmation that I was to be one of them. The process of approving training facilities is currently under way.

More than two decades ago, during residency, I took my first trip to Norway and had a tour of an akuttmottak in Oslo. I knew at that time that someday I would like to work as an emergency physician in Norway. I knew I would first have to learn the language. I didn't know that I would have to help create the entire specialty. It was a pipe dream, but with hard work, good timing, and a little luck, that pipe dream came true.

I'm back in the States now with no immediate plans to move back to Norway. But if and when I do, I can proudly work as an emergency physician. 🍀



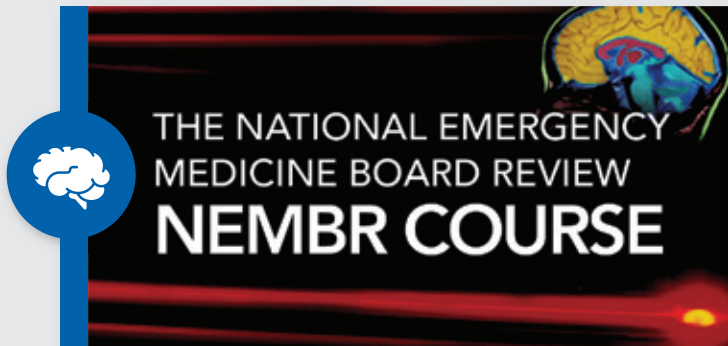
DR. GALLETTA is associate professor of emergency medicine at the University of Massachusetts in Worcester.

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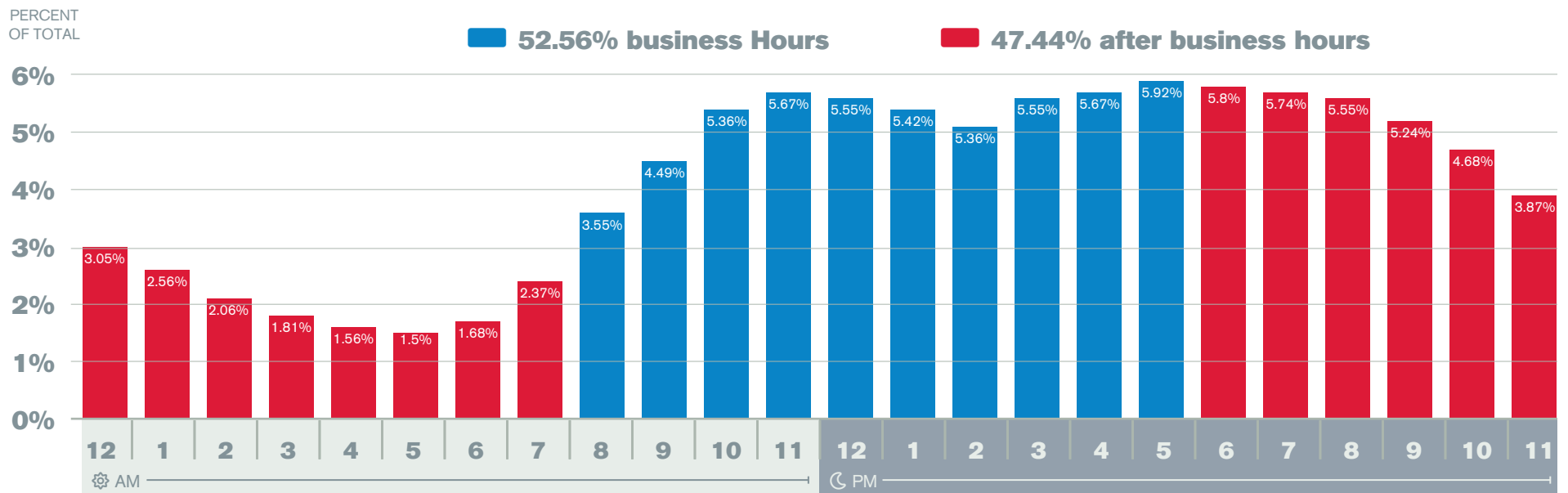
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by **SAM ASHOO, MD, FACEP**, founder and CEO of Admin EM. More at admin-em.com.

PHYSICIAN'S EVALUATION AND EDUCATIONAL REVIEW IN EMERGENCY MEDICINE

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FACEPs IN THE CROWD

In honor of Mardi Gras this month, we're spotlighting three emergency physicians who are Krewe members, working with their social organizations year-round to plan charitable activities and Carnival events.

MARY ANN EDENS, MD, FACEP



Mary Ann Edens, MD, FACEP, EM residency director at Louisiana Health Shreveport, had just moved to Shreveport when a nurse invited her to attend a Krewe meeting. She was instantly hooked, drawn to the Krewe's charitable work and how Mardi Gras "brings a sense of pride to the community." A member of the Krewe of Gemini since 2011, last year she served as captain, spending two years planning the year's programming, including overseeing fundraising, budgeting, picking the theme "Gemini's World Adventure," helping to design the costumes and floats, and planning the Grand Bal. Dr. Edens says the Krewe's time commitment is significant but worth it. "[Emergency physicians] deal with the struggles of life and death every day. ... But Mardi Gras gives everyone hope—hope for something better that is coming around the bend. Couldn't think of a better stress reliever than that!"

MICHAEL D. SMITH, MD, MBA, CPE, FACEP



Michael D. Smith, MD, MBA, CPE, FACEP, director of the Ochsner Clinical Simulation and Patient Safety Center in New Orleans, spends his time at work "taking care of the people who have had too much Mardi Gras," he jokes. But in his off time, he gets to be part of the fun. Dr. Smith and his wife joined the Krewe of King Arthur last year after she had previously been part of the all-female Mystic Krewe of Nyx. He says the Carnival season, which starts in early January, "envelops the whole area. Kids get off school for the last week of Carnival, and you plan your days and nights around the multiple parades per day." Now it's a family affair for the Smiths, whose 11-year-old twin daughters were on the Krewe of King Arthur Royal Court during its 2020 ball in January.

ANGELA CORNELIUS, MD, FACEP



Angela Cornelius, MD, FACEP, watched her fellow FACEP in the Crowd, Dr. Edens, participate in Krewe of Gemini for several years and knew she had to get involved after riding in her first Mardi Gras parade. "The people were so fun, and their love for Mardi Gras is absolutely contagious!" When she realized the Krewe was a community service organization, she loved the idea of making new friends while giving back to her community. "It's hard to meet those who are outside the hospital. This has given me the opportunity to get to know people from the community who I would have never had a chance to meet." She uses the organizational and multitasking skills she has developed in the emergency department to plan her Krewe's annual Grand Bal, attended by more than 1,000 revelers.

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Fine Tuning Emergency Medicine: Amplify Your Performance

Naloxone Just One Piece of the Opioid Puzzle

NALOXONE WITHOUT TREATMENT ENGAGEMENT DOESN'T PROLONG LIFE—IT SIMPLY DELAYS DEATH

by KEVIN LOZO AND LEWIS S. NELSON, MD

Drug overdose deaths nearly tripled in the United States between 1999 and 2014. The majority involved opioids.¹ The need to prevent overdose-related deaths is an absolute priority. Comprehensive strategies to address the opioid epidemic are moot if the patients are not alive. But are we leaning on naloxone too much? What does the evidence say?

Naloxone—a mu opioid receptor competitive antagonist—has the ability to reverse the clinical effects of an opioid overdose. Naloxone is easily administered and nonaddictive and poses no health risks to an opioid-naïve patient. Over the last decade, naloxone availability has widened nationwide in a variety of environments.

Two areas of substantial interest are expanding bystander access and extra-clinical access. Layperson (or off-duty provider) availability may be possible through institutional programs that dispense naloxone. Access outside of health care settings is possible via prescriptions for naloxone or, in some jurisdictions, via a centralized standing order. This means that anyone can obtain naloxone from a pharmacy and deliver it to a patient any time it is deemed necessary.

The necessity of this approach extends globally. In 2014, the World Health Organization conducted a systematic review that concluded “people likely to witness an opioid overdose should have access to naloxone and be instructed in its administration to enable them to use it for the emergency management of suspected opioid overdose.”² Since then, a broad range of literature has emerged evaluating naloxone distribution and education programs, supporting the general conclusion that, due to naloxone’s lifesaving potential and favorable safety profile, bystander access and use should be implemented while data from more rigorous and longer-term evaluations are gathered.

What the Data Say

Thus far, the data from available studies largely focus on outcomes that are merely surrogates for success. When scrutinized, they do not always correlate with the outcome of interest: saving a life without onloading undue risk (eg, favorable risk-benefit ratio). The lack of outcome data and number of simultaneous variables followed complicate the determination of naloxone’s impact on public health. Although some studies suggest naloxone availability is associated with lower deaths from opioid overdose, the data are limited to retrospective studies and highly confounded.³ Randomized, controlled trials would provide more information but would be very difficult, if not unethical, to do. Overall, the studies and recommendations have appropriately encouraged policymakers and funders to increase the availability of bystander naloxone. To be clear, naloxone dispensing and prescribing should

unquestionably be expanded until better data suggest otherwise.

Here’s where things get complicated. Yes, saving an individual from a fatal overdose is not only a worthwhile goal but an essential responsibility of our health care system. What muddies this pursuit is only four out of 100 opioid overdoses are fatal.⁴

This number may overestimate naloxone’s importance because of the tremendous difficulty determining whether an opioid overdose would have been fatal without it. Many patients demonstrating an opioid-like toxidrome appear moribund, but in reality, the vast majority will soon awaken. While a physician utilizes extensive training and physiological monitoring to determine the risk of impending death, laypersons with naloxone have to make the same decisions often without ample clinical experience to guide them. When naloxone is given to people who would not likely die (and therefore derive no benefit), well-meaning bystanders onload the risk of precipitated withdrawal. The risk of this is not inconsequential. Precipitated withdrawal increases catecholamine concentrations and can cause pulmonary edema, myocardial infarction, and intracranial hemorrhage. Furthermore, the associated vomiting may lead to aspiration if the patient does not awaken, often due to the presence of a cointoxicant. Additionally, the dangers around precipitated withdrawal may actually be increasing over time. How? Opioid withdrawal occurs proportionate to the degree of dependence and the dose and rate of naloxone administration. Modern opioid use disorder patients may be more physiologically at risk than patients in the past were. This may stem from changes in methadone use, higher purity of heroin, and the availability of potent fentanyl analogs.⁵

Naloxone Can’t Do It Alone

Naloxone is the just beginning of the solution, even if it reverses a fatal overdose as intended. One in 10 patients treated with naloxone dies within one year, with a standardized mortality ratio of 24.^{6,7} Regardless of the source of patients’ opioid use, engaging them in a medication-assisted treatment program is critical to preventing additional adverse events. Unfortunately, these interventions are often unavailable and underutilized.⁸

Meanwhile, naloxone is beginning to be viewed by outside observers as something more than it may be. For example, every naloxone administration is regularly reported as a “save” from an “overdose death.” There are complexities in both of these phrases. As detailed above, naloxone has a very small chance of actually “saving” any specific individual from death, and its use would be better phrased as “reversed an opioid overdose.” Even this is complicated since there is no correct amount of heroin or prescription

opioid when the cause of the use is abuse; by those standards, any amount is technically an “overdose.” Furthermore, naloxone is often stated to “reduce the risk of overdose.” However, there is no evidence that naloxone can or will decrease the risk of opioid overdose, only that it may reduce the risk of opioid overdose fatality following an overdose.³ As innocent and well-intended as public health messaging may be, misrepresenting the effect of naloxone in the media leads lawmakers and the general public to overestimate the true benefit and underestimate the true risk. The downside of this is that other equally important approaches to the opioid epidemic may be getting less attention and funding.

A discussion about naloxone would not be complete without mentioning risk compensation, where increased access to naloxone may actually encourage users to engage in higher-risk behavior. Two economists recently stirred controversy after publishing an article in which they concluded that naloxone may increase opioid abuse by “reducing the risk of death per use, thereby making riskier opioid use more appealing, and saving the lives of active drug users, who survive to continue abusing opioids.”⁹ Some critics correctly responded that naloxone has been inadequately studied in this context, and some evidence points to the contrary. However such effects are well-described in the public health literature in other contexts such as airbag use and public health warnings of potent batches of drugs.^{10,11}

Moreover, despite expanding training opportunities for naloxone administration, the opioid overdose fatality rate continues to rise. The apparent paradox is the number of naloxone distribution programs increases in parallel with the number of opioid overdose deaths.¹² Concerning as that may be, this observation cannot imply causality. Did naloxone distribution programs respond to an increasing demand, or did overdose deaths increase due to increased access to naloxone? However, this finding is itself confounded, and the increase in deaths may be due to the changes around decreased opioid prescriptions (shunting some of those patients to heroin) and from heroin to synthetic opioids such as fentanyl.

While naloxone’s role in overdose risk is still unclear, despite its increased availability, about half of those who die following naloxone treatment do so within a month of treatment.⁶ This clearly illustrates the need for further intervention, regardless of naloxone’s influence on future overdose.

What Else Is Needed

Any comprehensive solution to this nationwide crisis must be three-pronged: ending the



OPIOID USE DISORDER



CONTINUED on page 19

Finding Opioid Abuse Treatment That Fits

ONE APPROACH TO PRECIPITATED WITHDRAWAL AND PREHOSPITAL BUPRENORPHINE AFTER NALOXONE RESCUE

by RACHEL HAROZ, MD; GERARD G. CARROLL, MD; AND REUBEN J. STRAYER, MD



Abstinence-related, or spontaneous, withdrawal occurs gradually over hours to days, whereas precipitated withdrawal, caused by the administration of a receptor antagonist, occurs suddenly and with immediate peak intensity. Precipitated withdrawal is therefore often much more severe and distressing and more likely to be dangerous. In the case of opioid dependence, precipitated withdrawal is best known to occur after the administration of naloxone, a mu receptor antagonist. Though opioid withdrawal syndrome (OWS) is classically thought to

be unpleasant but benign, precipitated withdrawal causes an autonomic surge, which may be hazardous, especially in patients without generous cardiorespiratory reserve, in addition to physiological derangements that are often extremely unpleasant (total body pain, vomiting, diarrhea) and, perhaps most important, intense psychological dysphoria that may be unbearable and lead to desperate acts in search of relief. The prospect of OWS can lead opioid use disorder (OUD) patients to fear entering the health care system and is postulated to sometimes delay the summoning of emergency services to treat overdose.

Treatment Options

Naloxone is a lifesaving overdose rescue medication, but it can be overutilized and used at too high a dose. Health care professionals should differentiate between the patient who is dangerously opioid toxic, with physiologically consequential respiratory depression, and the patient who is somnolent, even poorly arousable, but ventilating adequately. The latter patient should usually not be treated with naloxone but rather allowed to recover through natural metabolism under close observation. Opioid-toxic patients who have dangerous respiratory depression but are not at imminent risk of decompensation should receive small doses of intravenous naloxone (eg, 0.04 mg) titrated every few minutes to adequate ventilation, not titrated to arousal.

Buprenorphine, a partial agonist with a mu receptor affinity higher than almost any other opioid, can similarly precipitate withdrawal in opioid-dependent patients by replacing the full agonist on the receptor, leading to a loss of agonism and subsequent buprenorphine-precipitated withdrawal (BPW).

Traditionally, buprenorphine treatment of OUD has been initiated using small doses (2–4 mg sublingually) only after a period of abstinence and the development of spontaneous withdrawal (often determined by satisfying a Clinical Opiate Withdrawal Scale score of greater than 8). These “test doses” are used to determine whether the patient is in sufficient withdrawal to avoid BPW. If the patient’s symptoms are improved (or at least do not worsen), increased doses are given. But if these smaller doses cause BPW, the process is halted, and symptoms are treated with non-agonist medications (eg, clonidine, ondansetron). Several hours later, if the patient is willing, buprenorphine initiation can be reattempted.

An Alternative Approach

A growing body of experience supports an alternative approach: the treatment of BPW with higher doses of buprenorphine. Early experience demonstrates this strategy to be significantly more effective in treating withdrawal symptoms than non-agonists. This pathway demonstrates buprenorphine’s ability to abol-

ish OWS and cravings while simultaneously transitioning the patient to medication-assisted therapy-based recovery. Future initiation pathways will likely skip the test doses and proceed to a single big dose (≥ 16 mg sublingually), which appears less likely to precipitate withdrawal and provides long-lasting protection from spontaneous withdrawal, cravings, and overdose. Protocols around high-dose initiation that account for appropriate patient selection and the possibility of provoking both protracted withdrawal and buprenorphine toxicity are being developed.

In Camden, New Jersey, our institution sits in an area with a high prevalence of opioid overdose and medical complications related to OUD. Our emergency department, recognizing its pivotal frontline role, waived all of our physicians to prescribe buprenorphine and opened a multidisciplinary bridge clinic where emergency patients could be immediately referred to facilitate ongoing buprenorphine therapy while outpatient comprehensive addiction care is arranged. We currently have the ability to bridge 22 patients weekly.

As our program developed, we found that traditional buprenorphine titration was poorly suited to the demands of our emergency department. As a result, many patients—even those in moderate withdrawal—were discharged with a buprenorphine prescription for home initiation. When we examined our resources in the prehospital arena, we were alarmed to discover that, in 2019, more than one-third of patients treated in the field for overdose refused transport to the emergency department. This resulted in a significant health care gap as well as provider frustration and compassion fatigue with patients who required rescue repeatedly, in some cases with multiple overdoses in a single day. Our only opportunity to engage this population was during the brief EMS encounter; we therefore started a program aimed at administering buprenorphine after naloxone reversal and directly linking these patients to care, all within the constraints of a busy EMS system.

Though published evidence is scant, through experience we have learned that high doses of buprenorphine are less likely to precipitate withdrawal and can rapidly and effectively treat naloxone-precipitated withdrawal (NPW). We created an EMS protocol where we treat NPW with 16–24 mg of sublingual buprenorphine.

In the first months of this program, results have been overwhelmingly positive: Patients have done well, NPW symptoms have been relieved, BPW has not occurred, and scene times and unit availability have not been affected. Remarkably, we have found no difference in bridge clinic follow-up rates between patients who refuse versus allow ED transport. To date, almost 70 percent of patients with OUD rescued in the field have attended their first clinic

appointment. This program also fundamentally changed the relationship of EMS providers to this underserved, vulnerable, and challenging population. “Just another overdose” is now an opportunity to make a difference.

Treatments That Work for Patients

OUD patients presenting to the emergency department and to EMS, whether after an overdose or due to medical complications related to opioid use, are at extraordinary risk for short-term mortality. Emergency providers can have a significant impact on outcomes by initiating buprenorphine treatment and referring patients for ongoing medication-based addiction care. However, traditional time-intensive initiation models are discordant with emergency care, where we often have only a brief window to engage these patients, especially patients in withdrawal, who are very likely to decline further care and leave.

Most patients find withdrawal symptoms intolerable, and despite being given a buprenorphine prescription at discharge, many are unable to bear the development of severe enough OWS to initiate buprenorphine at home using a conventional gradual dosing strategy. Treating precipitated withdrawal with high-dose buprenorphine has the potential to close this treatment gap by quickly relieving withdrawal symptoms without the fear of precipitated withdrawal. Administration of 16–24 mg of buprenorphine binds a high fraction of the patient’s opioid receptors, which decreases cravings, prevents withdrawal, and protects the patient from opioid overdose for 24 hours or longer. Initiating high-dose buprenorphine to ED and EMS patients with low Clinical Opiate Withdrawal Scale scores may therefore allow successful transition to buprenorphine recovery among a group of patients who would otherwise fail to establish therapy.

Though these strategies are in their infancy, they have thus far been demonstrated to be safe and effective. While more experience and outcome data are needed, treatment of precipitated withdrawal with high-dose buprenorphine has the potential to significantly expand the reach of emergency providers at the front lines of addiction care. +

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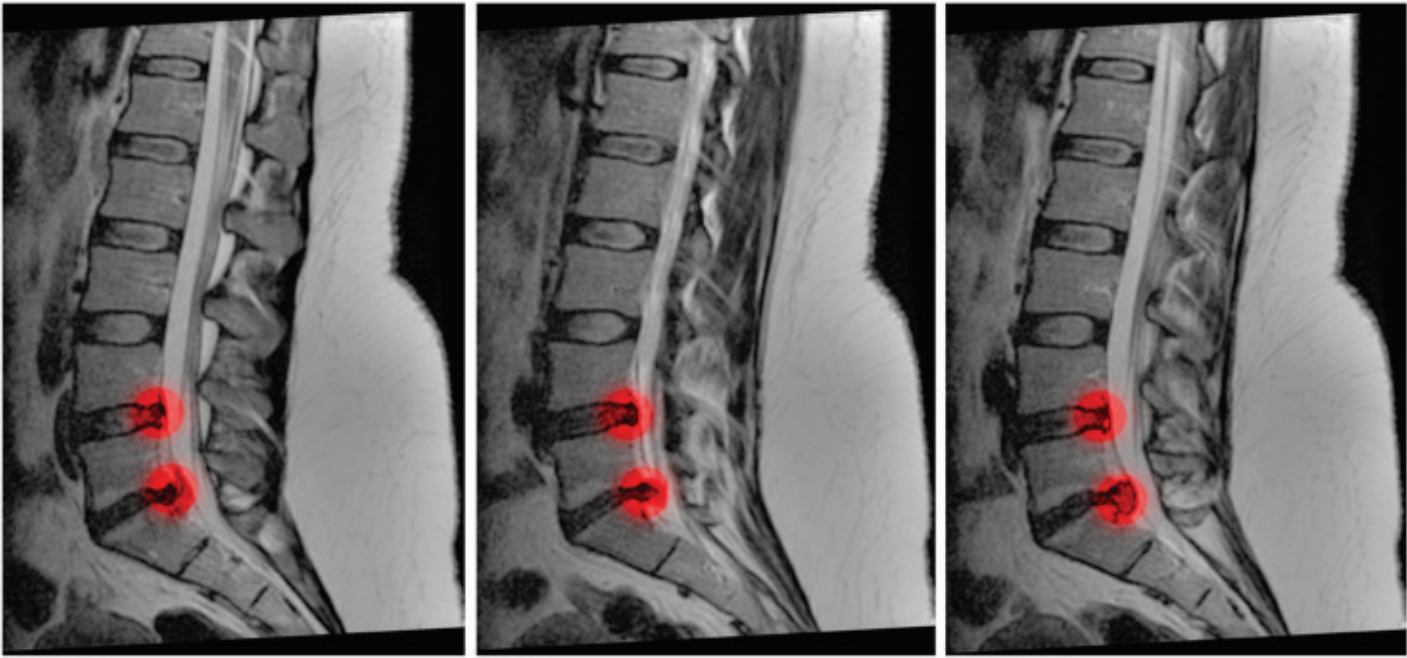
DER TREATMENTS



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A HUMBLING CONDITION

SPOT AND TREAT CAUDA EQUINA SYNDROME



MRI of the lumbar spine of a 29-year-old female diagnosed with cauda equina syndrome.

Table 1: Features Suggesting CES

EVALUATION	FINDINGS (DECREASING ORDER OF IMPACT ON PROGNOSIS)
History	Bladder dysfunction (urinary retention, incontinence) Defecatory dysfunction Sexual dysfunction Perineal anesthesia or hypoesthesia Severe back pain that suddenly worsened Lower extremity motor or sensory changes Bilateral sciatica Unilateral sciatica
Examination	Decreased perineal/urinary sensation Decreased anal tone Motor weakness in lower extremities Sensory deficit in lower extremities Depressed patellar and Achilles reflexes

Table 2: Reliability of History and Examination in CES¹⁷

FEATURE	SENSITIVITY (95% CI)	SPECIFICITY (95% CI)	LR- (95% CI)	LR+ (95% CI)
Back pain	34% (26–42%)	62% (51–72%)	0.64 (0.26–1.60)	1.98 (1.52–2.58)
Sciatica	43% (30–56%)	66% (59–73%)	0.90 (0.61–1.30)	1.50 (0.80–2.80)
Perineal anesthesia	38% (28–49%)	85% (81–89%)	0.80 (0.61–1.05)	2.00 (0.92–4.33)
Urinary retention	25% (17–35%)	72% (65–79%)	0.99 (0.82–1.20)	0.84 (0.53–1.32)
Urinary incontinence	24% (16–33%)	70% (61–77%)	1.05 (0.92–1.20)	0.76 (0.50–1.13)
Bowel incontinence	19% (9–33%)	86% (80–91%)	0.97 (0.78–1.20)	1.60 (0.66–3.89)
Reduced anal tone	30% (16–49%)	83% (76–88%)	0.90 (0.73–1.12)	1.83 (1.00–3.33)

Table 3

CES STAGES	
CES Suspected	Bilateral radicular pain
CES Incomplete	Urinary difficulties of neurogenic origin (altered urinary sensation, loss of desire to void, poor urinary stream, need to strain to micturate)
CES Retention	Neurogenic urine retention (painless urinary retention with overflow incontinence)
CES Complete	Objective loss of cauda equina function, absent perineal sensation, patulous anus, paralyzed and insensate bladder/bowel

by BRIT LONG, MD, FACEP, AND ALEX KOYFMAN, MD, FACEP, FAAEM

The Case

A 58-year-old male presents with worsening lower back pain. He has a history of L4/L5 disc disease and has been seen in this emergency department for this pain previously. Today, he says his back pain is different: It’s more severe and radiates down to both feet, and he notes some difficulty urinating. Could this be cauda equina syndrome (CES)? What should you look for on history and exam? Is there anything you can use to rule out the disease before heading to the MRI machine?

Characteristics of CES

We regularly see patients with severe back pain, and we are experts at screening for potentially dangerous conditions. When it comes to back pain, we are on the lookout for pyelonephritis, fracture, spinal epidural abscess/discitis, spinal epidural hematoma, mass, abdominal aortic aneurysm, retroperitoneal hematoma, and CES, as well as a variety of



potential abdominal conditions. If you think that asking back pain patients about urinary incontinence is enough, you’re

going to run into trouble eventually. The cauda equina (Latin for “horse’s tail”) is made up of the ascending and descending nerve roots from L2 to the coccygeal segments. It is responsible for lower limb movement and sensation, bladder control/urination, external anal sphincter control and defecation, sexual function, and sensation of the genitalia and perineal region.^{1–6} As you may have noticed, these play a huge role in our activities of daily living.

Any impingement or damage to these nerve roots may result in CES. While CES is most commonly due to central disc herniation or prolapse (usually in the setting of prior spinal disease), many conditions are associated with CES including chemotherapy, infection, radiation, vascular lesions, ischemia, trauma, epidural analgesia, and others.^{1–4,7,8} The list is long.

The challenge is that CES is more complex than that patient with worsening back pain and urinary changes. When we miss CES, it is often because we failed to consider the condition as a possibility. That cognitive error can lead to completing an inadequate history and exam and failing to perform the right diagnostic tests.^{2,9–12}

It takes, on average, 11 days from onset of symptoms until the correct diagnosis is made. Many cases are missed on the first ED evaluation.¹³ Back pain is the most common presenting symptom, followed by saddle sensory changes and bladder dysfunction.^{14–17} Back pain is chronic in almost 70 percent of patients with acute CES, though up to 89 percent of patients experience a sudden worsening of symptoms within 24 hours.^{1–4,9,18}

Table 1 lists red flag features for CES. Looking for urinary incontinence alone will miss

CES.^{9–12} Along with your standard questions concerning pain severity and location, urinary changes and retention, focal neurological deficits, and perineal sensory changes, you should also ask about sexual dysfunction (erectile dysfunction), changes in sensation during urination or passing urine, and bowel function.^{1–4,9,18–20} When inquiring about perineal sensory changes, ask about differences in sensation with sitting, when defecating, and during hygiene activities such as wiping with toilet paper. These symptoms are frequently not offered by the patient unless directly questioned.

When looking at the data behind history and exam, it’s humbling how poorly these findings perform in our evaluation of CES (though we teach them with confidence). While the findings from Table 1 can suggest CES, no single finding or combination of findings can reliably diagnose or exclude CES (see Table 2). None have sensitivities over 50 percent, but perineal anesthesia and bowel incontinence possess a specificity of 85 percent and 86 percent, respectively.^{14–17} Urinary retention and incontinence have a specificity of 72 percent and 70 percent, respectively. What about the rectal exam? Unfortunately, rectal tone does not correlate with the severity of CES (based on studies with confirmed CES on imaging), and its reliability varies significantly among providers.^{21–23} While a consulting surgeon may ask you about rectal tone, don’t rely on it to rule in or rule out CES. An absent anal wink reflex, assessed by gently stroking the skin around the anus with a cotton swab or applicator and looking for contraction of the external anal sphincter, suggests sacral nerve root dysfunction.^{3,4,8}

Another confusing aspect about CES is its classifications—more than 15 total!^{1,7,24} Rather than using all of these systems, we advocate for thinking about CES as occurring in stages (see Table 3).²¹ The prognosis worsens with more advanced stages (stage 4, or complete, is far worse than stage 1, or suspected).^{1–4,8,21,25,26} Complete CES, or stage 4, is usually associated with irreversible deficits.

Tests and Treatment

If you suspect the disease based on your history and exam, what next? Labs are not helpful. X-rays are unreliable.^{1,2,8,9} Bladder ultrasound for postvoid residual (PVR) can evaluate for urinary retention. In CES, urinary changes typically begin with decreased sensation of urinary flow, increased difficulty in passing urine, and sensation of incomplete emptying, followed by retention and finally overflow incontinence. There are a variety of cutoffs for PVR used to exclude CES evaluated in the literature. A PVR less than 50–100 mL strongly suggests against CES. However, values over this in combination with other signs or symptoms concerning for CES warrant further evaluation. One study suggests a PVR over 500 mL has an odds ratio of 4 for diagnosis of CES.¹⁶ The odds ratio reaches 48 for diagnosis when this is combined with two of the following: bilateral sciatica, patient subjectively experiencing urinary dysfunction, and rectal incontinence.¹⁶

The gold standard test for suspected CES is MRI.^{6,17,27} However, there are several caveats. Unfortunately, there are not great data directly evaluating the ability of MRI to rule in or out the disease. A recent systematic review found MRI had a sensitivity and specificity of 81 percent for diagnosing disc herniation,

though this likely underestimates the sensitivity and specificity for MRI when evaluating for CES.²⁷ Unfortunately, MRI may not be feasible in all centers. The next best option is a CT myelogram, but this is also difficult as it requires placement of a spinal needle into the spinal canal for injection of contrast dye.²⁸ What about lumbar and sacral CT with IV contrast? One study of 151 patients suggests that CT findings showing more than 50 percent thecal sac effacement has a specificity of 86 percent for diagnosis of CES, while less than 50 percent effacement is able to rule out CES with a sensitivity of 98 percent.²⁹ These data have not been validated (ie, they are not ready for prime time just yet), but keep a lookout for more literature evaluating CT with contrast in the future.

If you suspect the condition based on your history, exam, and PVR, you should discuss

the case with a spinal surgeon. They will assist in determining further workup and management. Treatment includes operative management in patients with CES.^{4,9,30–34} Data suggest patients with rapid onset of symptoms (typically defined as 24 hours) and worsening bladder function benefit the most from surgery, preferably within 24 hours of presentation.^{4,9,30–34} Operative delays beyond 48 hours can result in permanent dysfunction.

Case Resolution

Your exam demonstrates decreased perineal sensation and weakness in L5 bilaterally. When questioned, the patient also highlights changes in bowel function. The patient’s PVR is 400 mL, and you call the surgeon, who asks for an MRI. The MRI demonstrates central disc protrusion at L5/S1. The patient is admitted and taken to the operating room. ➔

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CONTINUED on page 21



FROM HOSPITAL TO HOME™

FOR YOUR ADULT PATIENTS WITH CABP AND ABSSSI



➔ VISIT [NUZYRA.COM/HCP](https://www.nuzyra.com/hcp) TO EXPLORE THE CLINICAL DATA AND SIGN UP FOR MORE INFORMATION

INDICATIONS AND USAGE

NUZYRA® is a tetracycline-class antibacterial indicated for the treatment of adult patients with the following infections caused by susceptible microorganisms:

Community-Acquired Bacterial Pneumonia (CABP) caused by the following: *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Klebsiella pneumoniae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, and *Chlamydia pneumoniae*.

Acute Bacterial Skin and Skin Structure Infections (ABSSSI) caused by the following: *Staphylococcus aureus* (methicillin-susceptible and -resistant isolates), *Staphylococcus lugdunensis*, *Streptococcus pyogenes*, *Streptococcus anginosus* grp. (includes *S. anginosus*, *S. intermedius*, and *S. constellatus*), *Enterococcus faecalis*, *Enterobacter cloacae*, and *Klebsiella pneumoniae*.

USAGE

To reduce the development of drug-resistant bacteria and maintain the effectiveness of NUZYRA and other antibacterial drugs, NUZYRA should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

NUZYRA is contraindicated in patients with known hypersensitivity to omadacycline or tetracycline class antibacterial drugs, or to any of the excipients.

WARNINGS AND PRECAUTIONS

Mortality imbalance was observed in the CABP clinical trial with eight deaths (2%) occurring in patients treated with NUZYRA compared to four deaths (1%) in patients treated with moxifloxacin. The cause of the mortality imbalance has not been established. All deaths, in both treatment arms, occurred in patients > 65 years of age; most patients had multiple comorbidities. The causes of death varied and included worsening and/or complications of infection and underlying conditions. Closely monitor clinical response to therapy in CABP patients, particularly in those at higher risk for mortality.

The use of NUZYRA during tooth development (last half of pregnancy, infancy and childhood to the age of 8 years) may cause permanent discoloration of the teeth (yellow-gray-brown) and enamel hypoplasia.

The use of NUZYRA during the second and third trimester of pregnancy, infancy and childhood up to the age of 8 years may cause reversible inhibition of bone growth.

Hypersensitivity reactions have been reported with NUZYRA. Life-threatening hypersensitivity (anaphylactic) reactions have been reported with other tetracycline-class antibacterial drugs. NUZYRA is structurally similar to other tetracycline-class antibacterial drugs and is contraindicated in patients with known hypersensitivity to tetracycline-class antibacterial drugs. Discontinue NUZYRA if an allergic reaction occurs.

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents and may range in severity from mild diarrhea to fatal colitis. Evaluate if diarrhea occurs.

NUZYRA is structurally similar to tetracycline-class of antibacterial drugs and may have similar adverse reactions. Adverse reactions including photosensitivity, pseudotumor cerebri, and anti-anabolic action (which has led to increased BUN, azotemia, acidosis, hyperphosphatemia, pancreatitis, and abnormal liver function tests), have been reported for other tetracycline-class antibacterial drugs, and may occur with NUZYRA. Discontinue NUZYRA if any of these adverse reactions are suspected.

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

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥2%) are nausea, vomiting, infusion site reactions, alanine aminotransferase increased, aspartate aminotransferase increased, gamma-glutamyl transferase increased, hypertension, headache, diarrhea, insomnia, and constipation.

DRUG INTERACTIONS

Patients who are on anticoagulant therapy may require downward adjustment of their anticoagulant dosage while taking NUZYRA.

Absorption of tetracyclines, including NUZYRA is impaired by antacids containing aluminum, calcium, or magnesium, bismuth subsalicylate and iron containing preparations.

USE IN SPECIFIC POPULATIONS

Lactation: Breastfeeding is not recommended during treatment with NUZYRA.

To report SUSPECTED ADVERSE REACTIONS, contact Paratek Pharmaceuticals, Inc. at 1-833-727-2835 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see Brief Summary of Full Prescribing Information on the following pages.



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or septic shock, mortality fell from 40.4 percent to 8.5 percent.¹ This result was both extraordinary and almost implausible, despite some compelling physiological justifications bolstering the theory.

The hype could barely be controlled. Some physicians began using the cocktail right away. A flurry of trials were designed and approved by hospital review boards around the globe. Trialists moved as quickly as they could to begin studying this seriously and employing a variety of rigorous methodologies, assessing various patient populations and a variety of outcome measures. We needed some answers, and we needed them

quickly.

Last month, the results from the Vitamin C, Hydrocortisone and Thiamine in Patients With Septic Shock (VITAMINS) trial, the first major international multicenter randomized, controlled effort to be completed, were unveiled in *JAMA*.²

The findings: negative. Across the board.

The Results

For virtually every outcome that the authors assessed for efficacy in septic shock, the patients who received the vitamin C–based cocktail (often referred to as the Marik protocol, metabolic resuscitation, or HAT for hy-

drocortisone, ascorbic acid, and thiamine) experienced no added benefit over patients in the control arm who received hydrocortisone only.

The study’s primary outcome was duration of time alive and free of vasopressor administration up to day 7 of treatment. The trial, which enrolled patients from 10 hospitals in Australia, New Zealand, and Brazil, also reported data on 10 prespecified secondary outcomes, including 28- and 90-day mortality, the need for dialysis, and mechanical ventilation, among others. For each of these, the Marik protocol failed to bestow any benefit. Out of 10 secondary outcomes, the only sig-

nal of benefit to emerge from the VITAMINS trial was a one-point improvement over controls in the sequential organ failure assessment score. However, as the other outcomes clearly demonstrate, patients who received the Marik protocol fared no better overall in any patient-centered outcome. Numerically, though not statistically, more deaths actually occurred in the vitamin C cocktail group. (In fairness, this was not even a trend; it is only worth mentioning because *so very few* patients died in the vitamin C group in the 2017 study.)

This will be seen as a major disappointment for observers desperately looking for

NUZYRA® (omadacycline) injection for intravenous use
NUZYRA® (omadacycline) tablets, for oral use

BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION
For complete details, please see Full Prescribing Information.

INDICATIONS AND USAGE

Community-Acquired Bacterial Pneumonia (CABP)
NUZYRA is indicated for the treatment of adult patients with community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Klebsiella pneumoniae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, and *Chlamydia pneumoniae*.

Acute Bacterial Skin and Skin Structure Infections (ABSSSI)
NUZYRA is indicated for the treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI) caused by the following susceptible microorganisms: *Staphylococcus aureus* (methicillin-susceptible and -resistant isolates), *Staphylococcus lugdunensis*, *Streptococcus pyogenes*, *Streptococcus anginosus* grp. (includes *S. anginosus*, *S. intermedius*, and *S. constellatus*), *Enterococcus faecalis*, *Enterobacter cloacae*, and *Klebsiella pneumoniae*.

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

CONTRAINDICATIONS: NUZYRA is contraindicated in patients with known hypersensitivity to omadacycline or tetracycline-class antibacterial drugs, or to any of the excipients.

WARNINGS AND PRECAUTIONS

Mortality Imbalance in Patients with Community-Acquired Bacterial Pneumonia -Mortality imbalance was observed in the CABP clinical trial with eight deaths (2%) occurring in patients treated with NUZYRA compared to four deaths (1%) in patients treated with moxifloxacin. The cause of the mortality imbalance has not been established.

All deaths, in both treatment arms, occurred in patients >65 years of age; most patients had multiple comorbidities. The causes of death varied and included worsening and/or complications of infection and underlying conditions. Closely monitor clinical response to therapy in CABP patients, particularly in those at higher risk for mortality.

Tooth Discoloration and Enamel Hypoplasia -The use of NUZYRA during tooth development (last half of pregnancy, infancy, and childhood up to the age of 8 years) may cause permanent discoloration of the teeth (yellow-gray-brown). This adverse reaction is more common during long-term use of the tetracycline-class drugs, but it has been observed following repeated short-term courses. Enamel hypoplasia has also been reported with tetracycline-class drugs. Advise the patient of the potential risk to the fetus if NUZYRA is used during the second or third trimester of pregnancy.

Inhibition of Bone Growth -The use of NUZYRA during the second and third trimester of pregnancy, infancy and childhood up to the age of 8 years may cause reversible inhibition of bone growth. All tetracyclines form a stable calcium complex in any bone-forming tissue. A decrease in fibula growth rate has been observed in premature infants given oral tetracycline in doses of 25 mg/kg every 6 hours. This reaction was shown to be reversible when the drug was discontinued. Advise the patient of the potential risk to the fetus if NUZYRA is used during the second or third trimester of pregnancy.

Hypersensitivity Reactions -Hypersensitivity reactions have been reported with NUZYRA.

Life-threatening hypersensitivity (anaphylactic) reactions have been reported with other tetracycline-class antibacterial drugs. NUZYRA is structurally similar to other tetracycline-class antibacterial drugs and is contraindicated in patients with known hypersensitivity to tetracycline-class antibacterial drugs. Discontinue NUZYRA if an allergic reaction occurs.

Clostridium difficile-Associated Diarrhea -*Clostridium difficile* associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile*. *C. difficile* produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibacterial drug use.

Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents. If CDAD is suspected or confirmed, ongoing antibacterial drug use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibacterial drug treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.

Tetracycline-Class Effects -NUZYRA is structurally similar to tetracycline-class of antibacterial drugs and may have similar adverse reactions. Adverse reactions including photosensitivity, pseudotumor cerebri, and anti-anabolic action (which has led to increased BUN, azotemia, acidosis, hyperphosphatemia, pancreatitis, and abnormal liver function tests), have been reported for other tetracycline-class antibacterial drugs, and may occur with NUZYRA. Discontinue NUZYRA if any of these adverse reactions are suspected.

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

ADVERSE REACTIONS: The following clinically significant adverse reactions are described in greater detail in the Warnings and Precautions section of the labeling:

- Mortality Imbalance in Patients with Community-Acquired Bacterial Pneumonia
- Tooth Development and Enamel Hypoplasia
- Inhibition of Bone Growth
- Hypersensitivity Reactions
- Tetracycline-Class Effects

Clinical Trials Experience -Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Overview of the Safety Evaluation of NUZYRA: NUZYRA was evaluated in three Phase 3 clinical trials (Trial 1, Trial 2 and Trial 3). These trials included a single Phase 3 trial in CABP patients (Trial 1) and two Phase 3 trials in ABSSSI patients (Trial 2 and Trial 3). Across all Phase 3 trials, a total of 1073 patients were treated with NUZYRA (382 patients in Trial 1 and 691 in Trials 2 and 3) of which 368 patients were treated with only oral NUZYRA.

Imbalance in Mortality: In Trial 1, eight deaths (2%) occurred in 382 patients treated with NUZYRA as compared to four deaths (1%) in 388 patients treated with moxifloxacin. All deaths, in both treatment arms, occurred in patients >65 years of age. The causes of death varied and included worsening and/or complications of infection and underlying conditions. The cause of the mortality imbalance has not been established [see Warnings and Precautions (5.1)].

Serious Adverse Reactions and Adverse Reactions Leading to Discontinuation: In Trial 1, a total of 23/382 (6.0%) patients treated with NUZYRA and 26/388 (6.7%) patients treated with moxifloxacin experienced serious adverse reactions. Discontinuation of treatment due to any adverse reactions occurred in 21/382 (5.5%) patients treated with NUZYRA and 27/388 (7.0%) patients treated with moxifloxacin.

Most Common Adverse Reactions: Table 4 lists the most common adverse reactions occurring in ≥2% of patients receiving NUZYRA in Trial 1.

Table 4: Adverse Reactions Occurring in ≥2% of Patients Receiving NUZYRA in Trial 1

Adverse Reaction	NUZYRA (N = 382)	Moxifloxacin (N = 388)
Alanine aminotransferase increased	3.7	4.6
Hypertension	3.4	2.8
Gamma-glutamyl transferase increased	2.6	2.1
Insomnia	2.6	2.1
Vomiting	2.6	1.5
Constipation	2.4	1.5
Nausea	2.4	5.4
Aspartate aminotransferase increased	2.1	3.6
Headache	2.1	1.3

therapies to offer patients with life-threatening sepsis syndromes. However, this was always the most likely outcome, given the improbable magnitude of reported benefit found in the original Marik study, upon which the entire vitamin C frenzy has been based. Alas, desperation, hope, and hype were never going to be enough. What we always needed was a well-executed trial to either confirm or refute Marik’s hypothesis and potentially game-changing findings. We now have the first credible report. From the looks of it, it’s back to the drawing board.

Breaking Down What Happened

How did we get here? When the vitamin C protocol first made news in 2017, there were two polar responses to this. The believers celebrated the treatment as a brilliant in-

novation, based on a genuine understanding of complex physiology, that could save hundreds of thousands of lives. The skeptics pointed out that the study upon which the excitement was based was a before-after retrospective chart study design performed in a single ICU. Many noted that the study, designed and led by the outspoken intensive care physician Paul Marik, MD, FCCP, was not a genuine trial. Rather, it amounted to a quality improvement project. In the Marik study, all patients with severe sepsis or septic shock received the vitamin C–based cocktail over a six-month period in early 2016. Those outcomes were then compared to those of a similar number of patients treated in that ICU before the protocol was rolled out in 2016 and who met similar inclusion criteria.

It bears mentioning that quality improve-

ment studies almost always yield favorable results for the problem being addressed. When resources—institutional, financial, and cognitive—are being applied to a challenging task, the short-term results are frequently good, yet difficult to maintain. The hidden costs of quality improvement efforts, however, are difficult to assess and not usually reported. For example, if a project to expedite CT for every patient with a neurological complaint is undertaken, a few patients may have their cerebrovascular accidents diagnosed sooner. But how many patients with acute aortic syndromes had diagnoses delayed because of that? Similarly, when we concentrate substantial human and financial resources onto one problem, do other problems suffer in silence?

This is why randomized, controlled tri-

als are required to make statements about the effectiveness of experimental therapies. Double-blinding is preferred as well because patients in the control arm are assured to receive as much attention as those in the intervention arm. The VITAMINS trial was unblinded (open label). This occurred because the study was initially an unfunded “passion” project by the team of investigators. Blinding is expensive and requires administrative muscle (which is not free). Treatments need to be concealed from both the providers and the subjects. While this study would be stronger if it had been blinded, you could argue that the lack of blinding favored the intervention. While we can’t know whether the authors were skeptical or optimistic about the cocktail’s chances, it is difficult to imagine that providers in 10 ICUs across three countries were all biased *against* an inexpensive therapy that had the potential to save lives.

As before, the mainstream media covered this story. National Public Radio, which widely publicized the protocol in 2017, again took notice. Dr. Marik told NPR that “in his experience, the treatment is only effective if given within six hours after someone has suspected sepsis.” (The typical time-to-treatment with the cocktail was around 12 hours in the VITAMINS trial.) But this is simply another way of saying that early detection and treatment of severe sepsis and shock are important. The patients for whom Dr. Marik declares the protocol is effective are precisely the ones receiving timely treatments we know to be crucial, including antibiotics and, in some patients, fluids and vasopressors. It is safe to propose that for patients who do not receive these proven therapies promptly, nothing will work later. However, in the VITAMINS trial, that is not what occurred. Instead, all patients received antibiotics prior to randomization. Nor do we know how quickly patients received either antibiotics or the vitamin C cocktail in the Marik study, as these data were not reported. However, the authors of the VITAMINS trial have already indicated that a subgroup analysis that takes time-to-treatment into account may be forthcoming.

Eighteen other studies assessing this cocktail are under way. With that many trials, each with its own patient inclusion criteria and unique outcome measurements, one of them is bound to find some signal of benefit by chance alone. But based on the VITAMINS study, I believe we can conclude that this miracle cure is not to be. If benefit is uncovered by any of these subsequent trials, it is likely to be small and incremental at best. Knowing that, we must again widen our perspective in our continued search for therapies that can truly turn the tide against sepsis. ➕

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NUZYRA® (omadacycline) injection for intravenous use
NUZYRA® (omadacycline) tablets, for oral use

Serious Adverse Reactions and Adverse Reactions Leading to Discontinuation: In the pooled ABSSSI trials, serious adverse reactions occurred in 16/691 (2.3%) of patients treated with NUZYRA and 13/689 (1.9%) of patients treated with comparator. Discontinuation of treatment due to adverse events occurred in 12 (1.7%) NUZYRA treated patients, and 10 (1.5%) comparator treated patients. There was 1 death (0.1%) reported in NUZYRA treated patients and 3 deaths (0.4%) reported in linezolid patients in ABSSSI trials.

Most Common Adverse Reactions: Table 5 includes the most common adverse reactions occurring in ≥2% of patients receiving NUZYRA in Trials 2 and 3.

Table 5: Adverse Reactions Occurring in ≥2% of Patients Receiving NUZYRA in Pooled Trials 2 and 3

Adverse Reaction	NUZYRA (N = 691)	Linezolid (N = 689)
Nausea*	21.9	8.7
Vomiting	11.4	3.9
Infusion site reactions**	5.2	3.6
Alanine aminotransferase increased	4.1	3.6
Aspartate aminotransferase increased	3.6	3.5
Headache	3.3	3.0
Diarrhea	3.2	2.9

*In Trial 2, which included IV to oral dosing of NUZYRA, 40 (12%) patients experienced nausea and 17 (5%) patients experienced vomiting in NUZYRA treatment group as compared to 32 (10%) patients experienced nausea and 16 (5%) patients experienced vomiting in the comparator group. One patient (0.3%) in the NUZYRA group discontinued treatment due to nausea and vomiting.

*In Trial 3, which included the oral loading dose of NUZYRA, 111 (30%) patients experienced nausea and 62 (17%) patients experienced vomiting in NUZYRA treatment group as compared to 28 (8%) patients experienced nausea and 11 (3%) patients experienced vomiting in the linezolid group. One patient (0.3%) in the NUZYRA group discontinued treatment due to nausea and vomiting.

**Infusion site extravasation, pain, erythema, swelling, inflammation, irritation, peripheral swelling and skin induration.

Selected Adverse Reactions Occurring in Less Than 2% of Patients Receiving NUZYRA in Trials 1, 2 and 3: The following selected adverse reactions were reported in NUZYRA-treated patients at a rate of less than 2% in Trials 1, 2 and 3. **Cardiovascular System Disorders:** tachycardia, atrial fibrillation; **Blood and Lymphatic System Disorders:** anemia, thrombocytosis; **Ear and Labyrinth Disorders:** vertigo; **Gastrointestinal Disorders:** abdominal pain, dyspepsia; **General Disorders and Administration Site Conditions:** fatigue; **Immune System Disorders:** hypersensitivity; **Infections and Infestations:** oral candidiasis, vulvovaginal mycotic infection; **Investigations:** creatinine phosphokinase increased, bilirubin increased, lipase increased, alkaline phosphatase increased; **Nervous System Disorders:** dysgeusia, lethargy; **Respiratory, Thoracic, and Mediastinal disorders:** oropharyngeal pain; **Skin and Subcutaneous Tissue Disorders:** pruritus, erythema, hyperhidrosis, urticaria.

DRUG INTERACTIONS

Anticoagulant Drugs- Because tetracyclines have been shown to depress plasma prothrombin activity, patients who are on anticoagulant therapy may require downward adjustment of their anticoagulant dosage while also taking NUZYRA.

Antacids and Iron Preparations- Absorption of oral tetracyclines, including NUZYRA, is impaired by antacids containing aluminum, calcium, or magnesium, bismuth subsalicylate, and iron containing preparations.

USE IN SPECIFIC POPULATIONS

Pregnancy: **Risk Summary**—NUZYRA, like other tetracycline-class antibacterial drugs, may cause discoloration of deciduous teeth and reversible inhibition of bone growth when administered during the second and third trimester of pregnancy.

The limited available data of NUZYRA use in pregnant women is insufficient to inform drug associated risk of major birth defects and miscarriages. Animal studies indicate that administration of omadacycline during the period of organogenesis resulted in fetal loss and/or congenital malformations in pregnant rats and rabbits at 7 times and 3 times the mean AUC exposure, respectively, of the clinical intravenous dose of 100 mg and the oral dose of 300 mg. Reductions in fetal weight occurred in rats at all administered doses (see *Data*). In a fertility study, administration to rats

during mating and early pregnancy resulted in embryo loss at 20 mg/kg/day; systemic exposure based on AUC was approximately equal to the clinical exposure level. Results of studies in rats with omadacycline have shown tooth discoloration.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15-20%.

Results of animal studies indicate that tetracyclines cross the placenta, are found in fetal tissues, and can have toxic effects on the developing fetus (often related to retardation of skeletal development). Evidence of embryotoxicity also has been noted in animals treated early in pregnancy.

Lactation: **Risk Summary**—There is no information on the presence of omadacycline in human milk, the effects on the breastfed infant or the effects on milk production. Tetracyclines are excreted in human milk; however, the extent of absorption of tetracyclines, including omadacycline, by the breastfed infant is not known.

Because there are other antibacterial drug options available to treat CABP and ABSSSI in lactating women and because of the potential for serious adverse reactions, including tooth discoloration and inhibition of bone growth, advise patients that breastfeeding is not recommended during treatment with NUZYRA and for 4 days (based on half-life) after the last dose.

Females and Males of Reproductive Potential

Contraception Females: NUZYRA may produce embryonic or fetal harm. Advise patients to use an acceptable form of contraception while taking NUZYRA.

Fertility Males: In rat studies, injury to the testis and reduced sperm counts and motility occurred in male rats after treatment with omadacycline.

Females: In rat studies, omadacycline affected fertility parameters in female rats, resulting in reduced ovulation and increased embryonic loss at intended human exposures.

Pediatric Use—Safety and effectiveness of NUZYRA in pediatric patients below the age of 18 years have not been established. Due to the adverse effects of the tetracycline-class of drugs, including NUZYRA on tooth development and bone growth, use of NUZYRA in pediatric patients less than 8 years of age is not recommended.

Geriatric Use—Of the total number of patients who received NUZYRA in the Phase 3 clinical trials (n=1073), 200 patients were ≥65 years of age, including 92 patients who were ≥75 years of age. In Trial 1, numerically lower clinical success rates at early clinical response (ECR) timepoint for NUZYRA-treated and moxifloxacin-treated patients (75.5% and 78.7%, respectively) were observed in CABP patients ≥65 years of age as compared to patients <65 years of age (85.2% and 86.3%, respectively). Additionally, all deaths in the CABP trial occurred in patients >65 years of age. No significant difference in NUZYRA exposure was observed between healthy elderly subjects and younger subjects following a single 100 mg IV dose of NUZYRA.

Hepatic Impairment—No dose adjustment of NUZYRA is warranted in patients with mild, moderate, or severe hepatic insufficiency (Child-Pugh classes A, B, or C).

Renal Impairment—No dose adjustment of NUZYRA is warranted in patients with mild, moderate, or severe renal impairment, including patients with end stage renal disease who are receiving hemodialysis.

OVERDOSAGE No specific information is available on the treatment of overdosage with NUZYRA. Following a 100 mg single dose intravenous administration of omadacycline, 8.9% of dose is recovered in the dialysate.

To report SUSPECTED ADVERSE REACTIONS, contact Paratek Pharmaceuticals, Inc. at 1-833-727-2835 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

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THE BAD BUGS ARE HERE

Is your ED ready?

by ROBERT REDWOOD, MD, MPH, FACEP; LARISSA MAY, MD, MSPH, MSHS; AND MICHAEL PULIA, MD, MS, FACEP

You may already know the names: vancomycin-resistant *Staphylococcus aureus* (VRSA), carbapenem-resistant *Pseudomonas aeruginosa* (CRPA), extended-spectrum beta-lactamase (ESBL) *Escherichia coli*. These are just some of the next-generation “superbugs” that are popping up in emergency departments across the United States. In 2018,



ANTIBIOTIC STEWARDSHIP

12 of the most concerning multi-drug-resistant organisms (MDROs) were ranked by lethality, earning the nickname “the dirty dozen.”¹ More concerning is that some of these bacteria, like the carbapenem-resistant *Klebsiella pneumoniae* that recently resulted in fatal sepsis for a woman in Reno, Nevada, are resistant to all available antibiotics. In other words, they are invincible.²

Or are they? The antibiotic pipeline has largely dried up in recent years, so what can emergency physicians do to combat MDROs?³ Antibiotic stewardship.⁴ As Benjamin Franklin said, “An ounce of prevention is worth a pound of cure.”

When we unnecessarily prescribe antibiotics for viruses, misdiagnose noninfectious conditions (eg, pseudocellulitis), or provide suboptimal antibiotic regimens, we exert selective pressure on our local community’s biome. Selective pressure encourages resistant bacteria to thrive by killing off weaker bacteria.

It is not too late. We are living in a crucial time. The prevalence of superbugs remains low in most communities. By practicing what we call the “5 D’s of antibiotic stewardship”—right diagnosis, right drug, right dose, right duration, right de-escalation—we can reduce the prevalence of MDROs in our hospitals and communities.⁵ Future generations will thank us—or better yet, they won’t even realize they have to.

Meet the 5 D’s

Here are the 5 D’s applied to emergency medicine practice.

- **Right Diagnosis:** Take a diagnostic stand and call a virus a virus. Acute otitis media, bronchitis, sinusitis—all of these entities are far more often viral than bacterial. When the patient is not seriously ill, is not immunocompromised, and clearly had a recent viral prodrome, you can usually avoid antibiotics.
- **Right Drug:** For patients with uncomplicated bacterial infections that require antibiotics, consult your institution’s ED antibiogram to identify the most common causative organism and narrowest spectrum agent that is typically effective (eg, nitrofurantoin for *Escherichia coli*).
- **Right Dose:** Practice weight-based dosing of antibiotics for pediatric patients, and for noncritically ill adults, err on the low side

Table 1: Top 5 Tips to Improve Antibiotic Stewardship in the Emergency Department

TIP	RATIONALE
Avoid “double coverage” for uncomplicated cellulitis.	The addition of methicillin-resistant <i>Staphylococcus aureus</i> coverage for uncomplicated, nonpurulent cellulitis does not reduce treatment failure rates. ^{9,10}
Do not use antibiotics for asymptomatic pyuria or bacteriuria in immunocompetent, nonpregnant patients.	The 2019 Infectious Diseases Society of America clinical practice guidelines indicate that routine prescribing should be avoided, even for older adults with cognitive impairment, in favor of close observation. ¹¹
Utilize severity of illness and evidence-based scoring systems to determine which patients with pneumonia require broad-spectrum antibiotics.	Health care–associated pneumonia is no longer considered a valid paradigm; instead use clinical severity and/or the Drug Resistance in Pneumonia (DRIP) score to determine which pneumonia patients require broad-spectrum antibiotics. ¹²
Consider watch-and-wait (delayed) prescribing for uncomplicated infections.	This strategy has demonstrated dramatic reductions in antibiotic use for respiratory conditions (eg, otitis media). ¹³
Engage pharmacists in your culture follow-up process.	Besides the benefit of reduced cognitive load for physicians in the emergency department, several studies indicate that pharmacist-driven culture follow-up results in significant improvements in antibiotic prescribing. ^{14,15}

of the suggested dose range.

- **Right Duration:** It is a poorly-kept secret in medicine that the recommended length of most antibiotic regimens was chosen arbitrarily in initial studies and has been subject to inertia ever since. When offered a range of duration of therapy, choose the shortest duration. If you are prescribing any antibiotic for more than seven days, favor a shorter course.^{6–9}
- **Right De-escalation:** Antibiotic de-escalation is a new trend in emergency medicine. Emergency physicians make decisions that generate therapeutic momentum for inpatient antibiotic prescribing. The act of simply writing in the chart, “These broad-spectrum agents should be narrowed to a single-effective agent once culture results have returned,” can save your patients days of unnecessary antibiotics.

For those looking for more specific ways to implement the 5 D’s, we have provided our five tips you can use on your next shift (see Table 1).

Become a Champion for Your ED

Ready for the next level? What about becoming an ED antibiotic stewardship champion or starting an ED-specific antibiotic stewardship program? Yes, this is in our wheelhouse!

Hospital antibiotic stewardship programs are now required by The Joint Commission and the Centers for Medicare & Medicaid Services (CMS), and emergency medicine needs to have a seat at the germ-infested table. Practicing at the intersection of the community and the hospital, we are the frontline providers for patients with MDROs. Our role is to try to select the correct initial antibiotic, despite diagnostic uncertainty. This unique and often challenging task requires an informed plan. We, as emergency physicians, should be the ones making the plan, not just following orders from others who don’t have experience doing what we actually do.

For an in-depth implementation guide to antibiotic stewardship in the emergency department, check out the MITIGATE toolkit, available at http://shea-online.org/images/priority-topics/MITIGATE_TOOLKIT_final.pdf. This tool takes the Centers for Disease Control and Prevention’s recommended core elements for outpatient antibiotic stewardship (which include a commitment to using antibiotics appropriately, implementing one policy or practice, tracking and reporting, education, and expertise) and adapts them to emergency de-

partment and urgent care settings. The toolkit leverages improvement science and behavioral economics to nudge clinicians to do the right thing in avoiding antibiotics for viral infections.

ED champions are critical to any program’s success. Interventions are more effective when they take the unique ED environment and workflow into account.

Still on the fence about leading the antibiotic stewardship charge? There are plenty of other ways you can start to engage beyond day-to-day patient care.

First, make sure someone from your emergency department sits on the antibiotic stewardship committee. Think about how local guidelines and clinical pathways can support better antibiotic use. For instance, do you really need a urine sample in the nurse-driven order set for chest pain? How about working with pharmacy and therapeutics to develop an empiric antibiotic prescribing guide based on antibiograms for your emergency department? The same goes for sepsis order sets, which should include evidence-based empiric antibiotic prescribing decision support. We can even facilitate de-escalation by making sure relevant cultures are ordered.

The goal of antibiotic stewardship programs is to improve patient outcomes, but they can also make your life easier. Find out the pain points to optimizing antibiotic use in your emergency department and then design a simple quality improvement project to fix them. There are a number of stewardship targets to explore, and some of these efforts can be made seamless through the use of behavioral nudging—for example, setting a default duration for antibiotics in your electronic health record by indication or making the first-line agents pop up for the default diagnosis. These fixes are better for patient care, they preserve physician autonomy, and they require fewer clicks. Win-win-win.

The fight against superbugs and MDROs is not coming to our emergency department’s doorstep; it is already here. As the frontline physicians for any epidemic, we will be the ones wearing the hazmat suits, placing the central line to hang the fourth antibiotic, and watching our patients suffer. ACEP has a team of emergency physicians working to prepare antibiotic stewardship resources for our workforce. In the meantime, we ask, Are you ready to step up and be an antibiotic steward? Is your emergency department ready for an antibiotic stewardship program? And before we just throw broad-spectrum agents into an IV, what

the heck is the source of that 102°F fever in the patient in bed four? ➔

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As part of career advancement and professional requirements, we attend professional conferences. We use testing centers to take standardized exams, including the United States Medical Licensing Examination (USMLE) and specialty board certification exams. Although “tips” exist for lactating women who want to pump at national conferences, systemic challenges remain.⁷ Similarly, social media backlash for the lack of lactation support at testing centers has made it clear that there is extensive room—and need—for improvement.⁸ When breastfeeding women are not supported to pump and/or breastfeed at conferences and testing centers, they are forced to choose between professional opportunities and their personal and family health. Like many women’s issues, this affects more people than is commonly appreciated: Women troubleshoot quietly or silently stay home, skipping conferences and thus losing out on networking and career development opportunities. Clearly, allowing for the physiological necessity of expressing breast milk in these overlooked venues is an issue of gender equity for our field.

Breastfeeding at Conferences: Mothers Without Infants On-Site

Basic requirements to allow women to pump at conferences are not extensive. Lactation spaces must:

- Provide spaces to sit with a power outlet within three to four feet.
- Be close to the conference hall and easy to get into with minimal (or no) help; requiring security to provide a key to a room is a burdensome step.
 - » Consider multiple pumping areas for large convention centers.
- Ensure privacy even with opening the door.
 - » Portable screens can create visual barriers as well as multiple private lactation stations within a larger room.
 - » Commercial options also exist for stand-alone stations (eg, Mamava).
- Offer nearby running hot water and soap for handwashing and cleaning pumping parts.
- Have cold storage space to store expressed milk during the conference day and either bagged ice or freezer space to protect ice packs for travel.

In addition to these basic accommodations, if feasible, it’s also helpful to provide:

- Storage space for individual breast pumps.
- Sanitizing wipes for surfaces in the pumping room and gloves to wear while cleaning up.
- Multi-user (hospital-grade) breast pump(s) that conference participants can use—these can be rented—with advertising about the type of pump in advance so participants can bring appropriate adapters.
- Information on conference hotels that can guarantee cold storage for guests.
- Breast milk donation. Facilitating expressed milk donation gives participants the option of skipping transport home. The American Academy of Pediatrics has a Donor Milk Drive toolkit available to those interested in organizing this.⁹

For estimating the amount of space required for lactation, organizers should ask registrants about their lactation needs. Esti-

ating that women will use these spaces for 20–30 minutes every three to four hours, with disproportionate use during break time, a reasonable starting point would be to offer one lactation station for every four women who will need to pump during the event.

Breastfeeding at Conferences: Mothers with Infants On-Site

The best lactation support includes providing accommodations for mothers who prefer to bring their infants with them and breastfeed at conferences and other events. Very young infants are rarely disruptive, and conferences should allow them in sessions.

- Signs such as “Mothers with Breastfeeding Infants Are Welcome” or “Breastfeeding and/or Pumping Are Welcome Here” signal all participants to accept the mild disruption of hearing noises from infants or from pumps being used by women who are comfortable pumping in public (with subtle wearable pumps or covered traditional pumps).
- Remote viewing options, such as a separate room where the conference content is live-streamed, allow parents to step out or share child-care responsibility among multiple care providers.
- Advertising inclusion of young children and breastfeeding in addition to pumping will support *all* early parents, not just lactating women, during a time of early career development that is often overlooked.

Special Considerations for Testing Centers

No matter the specialty, becoming a licensed physician requires sitting for multi-hour examinations. Given that lactating women have a physiological need to express breast milk at least once or twice during a full-day examination, testing centers must allow for pumping as a matter of gender equity for all participants. This can be accomplished with the same rigor as other test accommodations.

- **Timing:** Lactating women need additional break time to allow for pumping (approximately 30 minutes every three to four hours). Test administrators can increase total available break time for all participants to maintain parity among test takers, acknowledging this will likely be utilized only by those who need to pump or have another extenuating reason.
- **Administrative barriers:** Currently, there are significant hurdles to being allowed to pump during testing. These should be removed. One example: In addition to a three-page application for obtaining extra break time during USMLE examinations, mothers who want to pump during the exam must submit, weeks ahead of time, photos of their personal equipment and a letter from their personal physician stating the medical necessity of pumping.¹⁰ For any lactating woman, pumping is a medical necessity. These barriers must be reexamined and removed.
- **Storage:** Testing centers are unlikely to be able to provide durable lactation stations with multi-user devices, making it critical to allow for the safe storage of personal breast pumps within the testing center. Regulations regarding in-center storage and a test taker’s access to their personal equipment need to be altered for lac-

tating health professionals. In addition, testing centers should provide access to a refrigerator in which lactating women may store breast milk throughout their testing day(s).

Conclusion

Support for lactating women during clinical shifts has been a focus of gender equity in emergency medicine in recent years.¹¹ Though there is still much to accomplish, it is critical to recognize that support for lactating professionals in other settings, including episodic events like standardized testing and medical conferences, is part of supporting the professional development of women in our field. The accommodations described here supplement several ways emergency medicine is moving to support work-family balance, including child care at medical conferences and family-friendly networking events. Parents with young families make up a considerable segment of our early career professional group. By showing support for lactating women and those with young children, we can all benefit from the inclusion of some of the most active members in our field.

For a more extensive discussion, please see our related article “Best Practices for Lactation Support at Conferences and Standardized Testing Centers” in *Obstetrics & Gynecology*, doi: 10.1097/AOG.0000000000003661. ☛

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By the Numbers

TEEN DATING VIOLENCE

1.5 MILLION

high school students report experiencing physical violence perpetrated by a dating partner each year

OF HIGH SCHOOL STUDENTS

1 IN 9 FEMALE

1 IN 36 MALE

report being the victim of dating partner sexual violence during the past year



SEXUAL MINORITY GROUPS ARE DISPROPORTIONATELY AFFECTED

by all types of violence, including teen dating physical and sexual violence

73% OF GIRLS

66% OF BOYS

report experiencing at least one instance of emotional/verbal abuse by a dating partner while in high school

Compiled by Dina Burstein, MD, MPH, CPSTI, FAA, assistant professor of emergency medicine, and Michael J. Mello, MD, professor of emergency medicine, Warren Alpert Medical School of Brown University in Providence, Rhode Island.

Visit [ACEPNow.com](https://www.acepnow.com) for the sources of these statistics.



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2019 Year in Review

Updates on seizures, pulmonary embolism, cardiac arrest, and sepsis

by RYAN PATRICK RADECKI, MD, MS

Each year, the medical evidence piles inexorably higher. Even though it's literally impossible to keep up, we still try. Without further ado, a short list of new developments from 2019:

What to Do When Benzodiazepines Fail

This year saw the publication of several studies involving second-line treatment for status epilepticus when patients' seizures are refractory to benzodiazepines. There has been a general shift toward using levetiracetam (Keppra), likely due to ease of administration and perceived advantages implicit to its newness. Three pediatric studies tested levetiracetam against other second-line agents.¹⁻³ Two of



these studies were head-to-head comparisons against phenytoin, and one added a third arm featuring valproic acid. Across all three studies, despite minor variations in secondary outcomes, no clear "winner" was found. An individualized choice of any of these agents may be considered reasonable while we await further developments in antiepileptic therapy.

The State of Pulmonary Embolism (PE) Exclusion

Thankfully, we are continuing to make progress toward reducing the use of advanced imaging in the evaluation of PE. Two studies published in the past year illustrate potential strategies to address imaging overuse.^{4,5} The first looks at the use of the YEARS protocol for the evaluation of PE in pregnant women, using the combination of high-risk features and two different D-dimer thresholds to increase the number of women we can safely conclude do not require imaging. While this prudent application of YEARS was shown to improve imaging stewardship, it also illuminated the regrettable over-triage of pregnant women to evaluation for PE and an underlying baseline culture of pervasive advanced imaging. Further useful work in this field may incorporate trimester-adjusted D-dimer in addition to further decision support.

A second study parallels the YEARS concept except it uses the Wells Score as the foundation, dividing the cohort into low-, intermediate-, and high-pretest likelihood for PE. The D-dimer Testing Tailored to Clinical Pretest Probability in Suspected Pulmonary Embolism (PEGED) study doubled the D-dimer imaging threshold cutoff for patients with a low-pretest likelihood, and no cases of missed PE were observed. While this is a successful demonstration of their strategy, considering clinical equipoise for PE allows a miss rate of around 1 percent to balance harms

and benefits, even more aggressive strategies are likely reasonable. At the least, this study still represents another important step further establishing pretest-adjusted D-dimers as appropriate.

Finally, the most concise update is from the realm of syncope. Several years ago, a systematic evaluation of hospitalized patients with syncope found a prevalence of PE of 16 percent.⁶ Now, another prospective study finds the prevalence of PE *at presentation* (which is mainly what we care about when making decisions about who to work up) to the emergency department to be much lower: only 1.4 percent in these data.⁷ An evaluation for PE is necessary only as otherwise clinically indicated in the context of syncope.

Post-Arrest Care

When patients present following cardiac arrest, a continuing controversy has been the utility of emergency coronary angiography. In patients presenting with suspected ST-segment elevation myocardial infarction, the advantage seems clear. In those presenting with nondiagnostic electrocardiographic findings, the observational evidence likewise seems to support intervention. However, the first *randomized* trial evidence is trickling out now, and the Coronary Angiography after Cardiac Arrest (COACT) study found no clear benefit.⁸ This is the first of what are likely to be many forthcoming study reports, but it is the highest-quality evidence we have to date.

Another recent study reports on the expansion of therapeutic hypothermia to those presenting to the emergency department after cardiac arrest with a nonshockable rhythm.⁹ The overall survival of this population is dismal, comparatively, with 90-day mortality of greater than 80 percent. The use of targeted temperature management (TTM) in this population was observed to provide a small absolute advantage in neurologically intact survival, increasing the justification of using TTM in this population. However, deviations from TTM resulted in febrile episodes in the normothermia cohort only. Failure to prevent these episodes may have contributed to poorer outcomes and muddies the reliability of this trial's observations. It may still be that the most critical thing we can do is to prevent fevers in these patients.

Sepsis Steps Forward and Backward

Despite abundant face validity to the observation that all patients suffering overwhelming infection are not the same, our sepsis protocols offer little room for reasonable variation. Researchers at the University of Pittsburgh finally provided some hard data to back up better differentiation of those

presenting with sepsis, performing a complex analysis of cytokine and gene expression in response to infection.¹⁰ Their data show clear differing phenotypes among what we currently just call "sepsis," with a wide range of mortality for each phenotype, as well as variable enrichment of clinical trials with the differing phenotypes. While their analysis does not provide any specifically actionable utility, this demonstration should help future research better tailor interventions to specific subgroups of sepsis patients.

Meanwhile, the Early Goal Directed Therapy Using a Physiological Holistic View (ANDROMEDA-SHOCK) investigators put the classic lactic acid clearance target as a marker of sepsis treatment success to the test.¹¹ In one arm of this study, patients were resuscitated per protocol as guided by serial lactic acid measurements, or to clinical peripheral perfusion targets. In the other arm, investigators used glass slides and held manual pressure to the distal tips of patients' fingers, then observed the length of time necessary for capillary perfusion to occur. At 28-day follow-up, all-cause mortality was 43.4 percent in the lactic acid clearance arm compared to 34.9 percent in those resuscitated to peripheral perfusion targets. The study was small enough that this difference in mortality could have occurred by chance alone, but it certainly provides a note of concern regarding even the most well-known practices underpinning our current approach to sepsis.

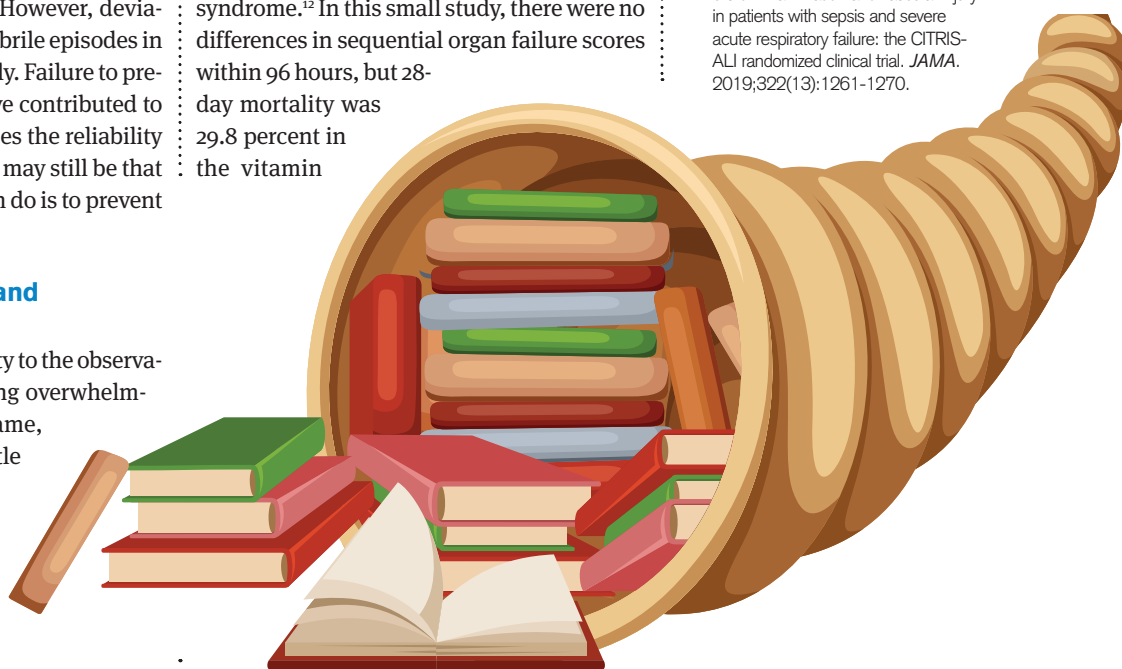
Lastly, we are beginning to receive the first trickle of results regarding the importance of high-dose vitamin repletion in sepsis. The Vitamin C Infusion for Treatment in Sepsis Induced Acute Lung Injury (CITRIS-ALI) trial started before much of the hullabaloo over combining steroids, thiamine, and vitamin C for patients with septic shock, and it looked solely at the use of vitamin C for reducing organ failure in a subgroup of patients with septic shock and acute respiratory distress syndrome.¹² In this small study, there were no differences in sequential organ failure scores within 96 hours, but 28-day mortality was 29.8 percent in the vitamin

C arm compared to 46.3 percent with placebo. These data must be considered exploratory, however, owing to the structure of the trial, and we will need to await more robust results to have reliable information regarding the utility of vitamins in sepsis. (Turn to page 1 for more on recent research on vitamin C and sepsis.)

The opinions expressed herein are solely those of Dr. Radecki and do not necessarily reflect those of his employer or academic affiliates. ☛

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VAPING-RELATED ILLNESS

by CARAL EDELBERG, CPC, CPMA, CAC, CCSP, CAC

A new ICD-10 diagnosis code for vaping-related illness (U07.0, vaping-related disorder) has been assigned due to the increase in vaping-related illness since 2017. The condition is termed "EVALI" for e-cigarette or vaping related lung illness, and the World Health Organization Family of International Classifications developed a temporary code for it effective for use starting Sept. 24, 2019. Additional code assignments are expected at the March 2020 ICD-10 Coordination and Maintenance Committee meeting.

Guidance suggests that all related signs, symptoms, and associated cannabis- and nicotine-related disorders should also be documented and coded. Toxic effects should be documented and identified with appropriate codes—for example, T40.7X1, poisoning by cannabis (derivatives), accidental (unintentional).

Documentation of any lung-related complications and substance use, abuse, and dependence requires a unique code to identify the condition accurately for payment purposes. Coding professionals should be advised to assign as many codes as appropriate to ensure recognition and payment for this problem (eg, cannabis-related disorders, nicotine-related disorders, and specifically for vaping of nicotine, F17.29-).

For patients who are diagnosed with EVALI, documentation should identify the specific condition such as bronchitis due to chemicals, pneumonitis due to inhalation of oils, acute respiratory distress syndrome, pulmonary eosinophilia, acute interstitial pneumonitis, or other specified interstitial pulmonary disease.

If no specific diagnosis can be made, any other relevant signs

and symptoms should be documented and coded, such as myalgia, dyspnea, shortness of breath, wheezing, tachypnea, chest pain, hypoxemia, generalized abdominal pain, unspecified abdominal pain, vomiting, diarrhea, fever, fatigue, hyperhidrosis, abnormal weight loss, chills, etc.

The CDC coding guidelines for vaping can be found at www.cdc.gov/nchs/data/icd/Vapingcodingguidance2019_10_17_2019.pdf.

Stay tuned for updates following the March ICD-10 Coordination and Maintenance Committee meeting. ➕

Brought to you by the ACEP Coding and Nomenclature Committee.

MS. EDELBERG is founder and chairman of Edelberg + Associates.

Resources

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initiation of patterns of hyperalgesia, abuse, and addiction; preventing harm to allow treatment access; and restoring normalcy to the lives left tattered through treatment initiatives. Recovery programs aim to provide long-term stability through social support systems or, more successfully, evidence-based medication-assisted treatment programs. However, the reality is that those with opioid use disorder are constantly at risk of overdose, whether due to a highly potent or adulterated illicit supply, loss of tolerance during abstinence or treatment, or an attempt to pursue the elusive "next best high."

Naloxone is a drug with the ability to save lives in the hands of bystanders. But it is just one piece of the puzzle, and the long-term consequences of this public health initiative are still unknown. Additionally, the adverse effects have been understated and the benefits overstated. If we are to address this epidemic realistically, we need to be honest about the tools we have at our disposal. Naloxone is just the beginning of the answer to the opioid epidemic. We can manage precipitated opioid withdrawal and cannot resuscitate someone who has died, but real solutions to prevent death in those with opioid use disorder include expanding harm reduction efforts; implementing medication-assisted treatment programs;

CONTINUED on page 21

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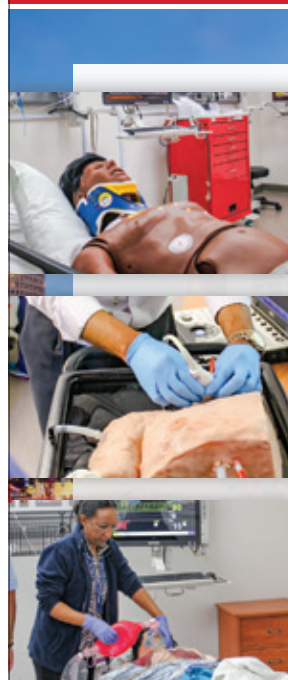
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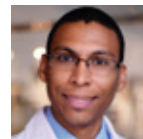
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DR. DARK is assistant professor of emergency medicine at Baylor College of Medicine in Houston and executive editor of PolicyRx.org.

Mind the Medicaid Gap

Medicaid expansion has helped patients and physicians in states that opted for it

by CEDRIC DARK, MD, MPH

The Patient Protection and Affordable Care Act (ACA) has brought about massive changes to the structure of the American health care financing system. As a consequence, an additional 20 million Americans have coverage, and for the first time ever, the uninsured rate dove below 10 percent.¹

For emergency physicians, the ACA has resulted in dramatic shifts in our payer mix, especially among the nonelderly adult population. While the ratios of emergency patients with Medicare have remained relatively stable over the past decade, there has been a slow but steady decline in private coverage. However, in 2013, when the ACA's Medicaid expansion went into full



effect, a dramatic shift in payer mix from uninsured to Medicaid became evident. This has been demonstrated in multiple studies of general emergency department patients, in states such as Illinois and Maryland, for young adults, and for trauma patients.²⁻⁹

What does this portend for our specialty? A few years ago, Jon Mark Hirshon, MD, PhD, MPH, FACEP, the current Chair of the ACEP Board, co-authored a paper suggesting that this shift in payer mix from uninsured to Medicaid represented \$3.97 additional revenue per RVU for the average emergency physician.¹⁰ The calculus for Medicaid expansion is crystal clear. The swath of preexisting data combined with a new paper, presented in this month's EMRA+PolicyRx Health Policy Journal Club, builds upon what we should agree is an unimpeachable fact.

The ACA positively shifts payer mix for emergency care and ultimately leads to improved financial viability for our specialty.

Emergency physicians in the 14 states that have yet to expand Medicaid should strongly consider advocating for the 2.5 million Americans who remain stuck in the Medicaid gap.^{11,12} ➔

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EMRA+POLICYRx HEALTH POLICY JOURNAL CLUB

ACA Expanded Coverage for Emergencies

by GREGORY JASANI, MD

The Patient Protection and Affordable Care Act (ACA) sought to reduce the number of uninsured Americans. Advocates hoped that this would increase access to outpatient resources and potentially decrease ED utilization and inpatient admissions.

Researchers sought to determine if the ACA changed the number of uninsured patients visiting emergency departments and whether rates of inpatient admission fluctuated.¹ They examined data from the National Hospital Ambulatory Care Survey and the Healthcare Cost and Utilization Project from the years 2006–2016. These dates allowed the authors to see trends both before and after the ACA was implemented.

The study found that while overall emergency department visits increased during the study period, the rates of uninsured patients visiting emergency departments decreased. During this time, the proportion of Medicaid patients visiting emergency departments increased. These trends were most pronounced after 2013, when many states expanded Medicaid. This effect was most pronounced among patients ages 18–64, who typically have the highest risk for being uninsured.

The data also showed that rates of admissions from the emergency department actually decreased after ACA implementation. Interestingly, this was not due to decreased emergency department utilization. In fact, the number of ED visits consistently increased during the

study period.

This study shows that more patients who visited the emergency department after ACA implementation were insured and that more of these patients were ultimately discharged home. The ACA has provided health coverage to more than 20 million Americans and has translated to higher rates of insured patients visiting emergency departments. This was also associated with lower inpatient admissions. Decreased admission rates could be due to expanded insurance leading to greater access to outpatient resources, obviating the need for inpatient admission. Yet the authors note that other factors, such as increasing use of observation services, may have also had an effect on this trend.

The ACA has greatly expanded health insurance coverage in the United States, changing the insurance status of our patients and possibly even increasing our willingness to discharge patients. As debates about the future of the ACA and other health policy issues continue, emergency physicians should remain engaged. This study shows that the outcome of these debates will influence the health and longevity of the patients we treat. ➔

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connecting patients to support programs; and being mindful of how powerful a compassionate, nonjudgmental, nonstigmatizing, and supportive system can be to the health of our patients. 🍎

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Penn State Health, Hershey PA, is expanding our health system. We offer multiple new positions for exceptional physicians eager to join our dynamic team of EM and PEM faculty treating patients at the only Level I Adult and Level I Pediatrics Trauma Center in Central Pennsylvania.

What We're Offering:

- Salaries commensurate with qualifications
- Sign-on Bonus
- Relocation Assistance
- Retirement options, Penn State University Tuition Discount, and so much more!

What We're Seeking:

- Emergency Medicine trained physicians with additional training in any of the following: Toxicology, Ultrasound, Geriatric Medicine, Pediatric Emergency Medicine, Research
- Completion of an accredited Emergency Medicine Residency Program and Fellowship for PEM positions
- BE/BC by ABEM or ABOEM
- Observation Medicine experience is a plus

What the Area Offers:

We welcome you to a community that emulates the values Milton Hershey instilled in a town that holds his name. Located in a safe family-friendly setting, Hershey, PA, our local neighborhoods boast a reasonable cost of living whether you prefer a more suburban setting or thriving city rich in theater, arts, and culture. Known as the home of the Hershey chocolate bar, Hershey's community is rich in history and offers an abundant range of outdoor activities, arts, and diverse experiences. We're conveniently located within a short distance to major cities such as Philadelphia, Pittsburgh, NYC, Baltimore, and Washington DC.



PennState Health

FOR MORE INFORMATION PLEASE CONTACT:

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Penn State Health is committed to affirmative action, equal opportunity and the diversity of its workforce. Equal Opportunity Employer – Minorities/Women/Protected Veterans/Disabled.



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