

# RHODE MEDICALJOURNAL



SPECIAL SECTION

#### INFECTION CONTROL

GUEST EDITOR: JOHN R. LONKS, MD

**MARCH 2020** 

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# PATIENT CARE QUALITY OUTCOMES CYBER SECURITY REIMBURSEMENTS

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John R. Lonks, MD

17 Examining the Components of Effective Infection Control and Prevention
JOHN R. LONKS, MD
GUEST EDITOR



Methicillin-Resistant *Staphylococcus Aureus* (MRSA)

This and the cover image of *Clostridioides difficile* appear in the CDC's Antibiotic Resistance Threats in the United States 2019 Report, which includes the latest national death and infection estimates that underscore the continued threat of antibiotic resistance in the U.S.

According to the report, more than 2.8 million antibiotic-resistant infections occur in the U.S. each year, and more than 35,000 people die as a result. In addition, 223,900 cases of *Clostridioides difficile* occurred in 2017 and at least 12,800 people died.

The full report is available online at www.cdc.gov/DrugResistance/Biggest-Threats.html

[CDC IMAGES: ANTIBIOTIC RESISTANCE THREATS IN THE UNITED STATES, 2019. ATLANTA, GA: US DEPARTMENT OF HEALTH AND HUMAN SERVICES, CDC; 2019.]

- 18 MRSA Prevalence in Preoperative S. aureus
  Nasal Culture Isolates is Significantly Different
  From a Traditional Hospital-wide Antibiogram
  ANDREW R. CRAWFORD, MD
  NANCY VALLANDE, MS
  JOHN R. LONKS, MD
- **21** Safety and Nosocomial *Clostridioides difficile* Infections

SUSAN STEEVES, MSN, RN NANCY VALLANDE, MS JOHN R. LONKS, MD

**24** Antibiotics and Nosocomial *Clostridioides difficile*, a Retrospective Chart Review

KELLY A. SKRABLE, MD, MPH JOHN R. LONKS, MD

**28** Rate of *Clostridioides difficile* Culture Positivity Among Hospitalized Patients

JOHN R. LONKS, MD ERIC NOLETTE, BS JENNIFER L. CADNUM, BS CURTIS J. DONSKEY, MD

**31** To Treat or Not to Treat: UTI or Bacteriuria?

RAUL MACIAS-GIL, MD EMILY O'NEILL, PharmD MELISSA M. GAITANIS, MD

# RHODE ISLAND MEDICAL JOURNAL



#### **8 COMMENTARY**

Prognostic Implications of Myocardial Infarction and Coronary Stenting Among Politicians KENNETH S. KORR, MD, FACC

Are We Right When We're Certain? Overconfidence in Medicine

JEFFREY A. LAM, BA, MD'21 EDWARD FELLER, MD, FACP, FACG

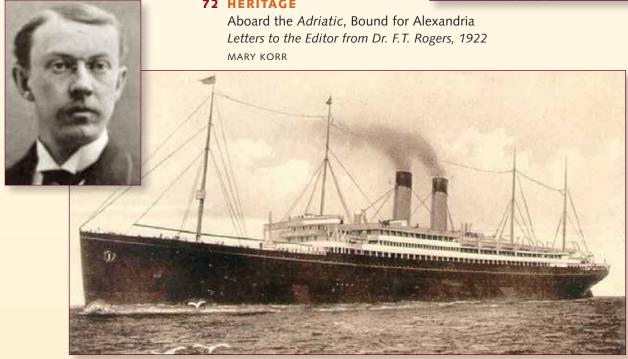
The Perspective of a **Human Computer** KATHLEEN GARVEY, PC '20

#### 14 RIMJ AROUND THE WORLD Rancho Mirage, California

#### **56 RIMS NEWS**

Are you reading RIMS Notes? Working for You

#### **72 HERITAGE**





#### IN THE NEWS

- CORONAVIRUS IN RHODE ISLAND 60
- RIDOH announces second presumptive positive COVID-19 case; testing a third individual
  - send message of support to
    - academic medical center partner
      Wuhan Union Hospital
    - CARE NEW ENGLAND 63
  - releases fiscal year 2020 First Quarter results
    - CARE NEW ENGLAND 63
- purchases new beds for Women & Infants, Kent
  - STROKE RESEARCH 64
  - new drug helps to preserve brain cells

- **65** COASTAL MEDICAL, LIFESPAN sign LOI to pursue affiliation
- of University Orthopedics performs breakthrough surgery for treatment of cervical disc degeneration
- 66 LIFESPAN acquires da Vinci Xi's for Miriam, RIH to expand robotic-assisted, minimally invasive procedures
- **67 PROVIDENCE VA MEDICAL CENTER**holds ribbon cuttings for new ICU, garage



#### PEOPLE/PLACES

- joins University
  Gastroenterology
  as COO
- REBECCA BOSS 68 joins CODAC as COO
- awarded AHA Gold for workplace health
- **69 INTEGRA COMMUNITY CARE NETWORK**#2 in overall quality score in national ranking of 'Next Generation ACOs'
- 70 LINDSAY ORCHOWSKI, PhD earns Selya Award for Excellence in Research
- 71 OBITUARIES
  Vincent A. DeConti, MD
  Alceu L. Pedreira, MD
  Jacob Y. Schinazi, MD





#### MARCH 2020 VOLUME 103 • NUMBER 2

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#### CONTRIBUTION

- 36 Disseminating Education and Treatment for Children and Adolescents with Eating Disorders Across Levels of Care EVA-MOLLY PETITTO DUNBAR, MA CHRISTINA TORTOLANI, PhD ABIGAIL DONALDSON, MD; DIANE DERMARDEROSIAN, MD MICHELLE RICKERBY, MD ANDREA B. GOLDSCHMIDT, PhD
- 40 Proposed Healthcare Initiatives to Mitigate Opioid Risk and Advance Safety of Pain Management

DANIELLE FAMULARO ANGELA KUZMANOSKI JAYNE PAWASAUSKAS, PharmD, BCPS

**45** Prescription Opioid Prescribing in Western Europe and the United States

AIDEN MEYER CHERYL LECLAIR, MSW JAMES V. MCDONALD, MD, MPH

#### **PUBLIC HEALTH**

- **49** HEALTH BY NUMBERS

  Sleep Deprivation among Rhode Island High School Students

  TRACY L. JACKSON, PhD, MPH

  TARA COOPER, MPH
- 53 Vital Statistics
  ROSEANN GIORGIANNI, DEPUTY STATE REGISTRAR
- 54 RIMJ Guide for Authors

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#### Prognostic Implications of Myocardial Infarction and Coronary Stenting Among Politicians

KENNETH S. KORR, MD, FACC

Recent news reports and debate commentary have focused, among other important issues, on the cardiovascular health of several current presidential contenders. Bernie Sanders had a recent myocardial infarction (MI), underwent urgent coronary stenting and returned to a vigorous campaign schedule within a few weeks. Mike Bloomberg had a stent procedure in 2000 and has apparently done well since then. Both candidates, now in their late 70s, have cardiac histories which raise concerns regarding their overall health risk, their fitness for high office and their likelihood of surviving a grueling four-year term.

Coronary artery disease and acute MI are not new among our political leaders. President Dwight Eisenhower had what was described as a "massive anterolateral wall MI" while playing golf in Denver during his first term as president in 1955. He was 64 years old and had been a four-pack per day smoker for more than 30 years. He was treated by the pre-eminent Boston cardiologist Paul Dudley White and made a seemingly uneventful recovery, returning to golf within five months. Treatment at that time was conservative by present standards and included four weeks of bedrest with IV heparin and oxygen followed by another three weeks of home convalescence before returning to work. At a subsequent American Heart Association national meeting, Dr. White described the important risk factors for myocardial infarction: older age, male gender, robust stocky build, active, ambitious personality, heredity and cigarette smoking. He added that, in his opinion, golf was not a risk factor and likely forestalled the risk of a cardiac event by 5-10 years. Eisenhower went on to complete a second presidential term without additional cardiac problems. He was not free from further cardiac events, however, and had a total of seven MIs and multiple cardiac arrests before dying from congestive heart failure at age 78, 10 years after his presidency.1

Lyndon Johnson, a three-pack per day smoker, also had a heart attack in 1955, at age 47, while serving in the Senate. He went on to serve as both President and Vice President without further cardiac events, but then had four more heart attacks after leaving office in 1969. He died shortly thereafter in 1973 at the age of 65.

Former Vice President Dick Cheney, another heavy smoker (2–3 ppd) with a strong family history of premature coronary artery disease, had his first heart attack at age 37 while campaigning for Congress. He went on to have a total of five heart attacks and benefited from just about every cardiac procedure, device and technology, including bypass surgery, coronary stents, a cardiac defibrillator, a left ventricular assist device (LVAD) and ultimately a cardiac transplant in 2012 at age 71. He is alive today, 11 years after leaving office.2

Bill Clinton also had a strong family history of heart disease and even with the best care he ignored many of the warning signs during his presidency, according to interviews in the general press. After leaving office in 2001, he developed severe angina and underwent quadruple vessel bypass surgery in 2004. He subsequently adopted a vegetarian lifestyle and lost considerable weight but, in spite of that, he required additional stent placement in 2010. George W. Bush also had a stent procedure shortly after leaving office in 2009. In fact, only one president, Warren G. Harding suffered a fatal heart attack while in office. He was 58 years old.

So what can we expect for our present political leaders in the current era where coronary stent placement is the standard of care for acute MI and unstable angina? Clearly there are immediate benefits from coronary stenting both in terms of survival and reduction in infarct size and many patients return to a full and active lifestyle within a few weeks, as did Bernie Sanders. But stent placement does not confer freedom from future events. In fact, one in five stented patients will experience a major adverse cardiac event (MACE) within five years, including cardiac death (5.7%), recurrent MI (6.9%) and need for a repeat revascularization procedure (13.1%). Between years 1 and 5, the annual rate of target vessel revascularization is about 2% per year.3

Thus, our current group of candidates is not out of the proverbial woods



yet. Age alone is a significant cardiovascular risk factor and affects a majority of the current candidates, including the President. Added to that is the significant stress involved in a contentious political campaign and an order of magnitude more as president. On the plus side, however, are the advantages of close medical follow-up and ongoing advances in cardiac surveillance and treatment, which will likely have a favorable impact on survival, although not necessarily event-free survival. In the final analysis, none of us can predict the future health of any of our political candidates, but voters should not lose heart, for if recent history is any example, these politicians are survivors. \*

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#### Are We Right When We're Certain? Overconfidence in Medicine

JEFFREY A. LAM, BA, MD'21; EDWARD FELLER, MD, FACP, FACG

Why do the overwhelming majority of college professors, medical students, and clinicians rate their skill as "above average?" (Table 1)

Humans can be inappropriately overconfident in our skill, reasoning, and decisions. Overconfidence describes the misalignment between actual competence or accuracy compared to subjective, self-rated expertise.<sup>1,2</sup> In medicine, overconfidence contributes to poor decision-making, medical error, sub-standard patient care, and increased risk of bad clinical, organizational, and research outcomes. Our objective in this commentary is to explore the cognitive and cultural aspects of overconfidence and its effect on clinical decision-making.

#### What are the cognitive underpinnings of overconfidence?

The human brain has a limited capacity to perceive and integrate the innumerable stimuli continually presented for analysis. Consequently, we may erroneously fit incomplete, unclear or contradictory data to fit the oversimplified ways we want to see the world.<sup>3</sup> For example, we may jump to a too quick conclusion about a positive laboratory result, without looking up its accuracy and examining any disconfirming data. Moreover, these beliefs are often resistant to change, despite contradictory evidence. Overconfidence encompasses a failure of metacognition, or the capacity for self-reflection in recognizing our own deficiencies, assumptions, and biases.<sup>4</sup>

#### Does Dr. Google facilitate overconfidence?

Today, it is all too simple to "Google" the capital of Alabama or a differential diagnosis of dyspnea with a few taps on the keyboard. This frictionless access to unlimited material may make learners less motivated to gain a deep understanding of the content. Instead of knowing evidence-based antibiotic prescribing guidelines, we tend to remember that online guidelines exist and where to access them.<sup>5</sup> Self-questioning morphs from "What do I know?" to "Where can I find it?"

While the availability of resources such as UpToDate and Epocrates has greatly enhanced clinical practice, impaired cognition and an "illusion of knowledge" occur when people conflate access to information with understanding information. Studies demonstrate searching the Internet for information can result in exaggeration in self-assessed knowledge for even unrelated domains. Furthermore, experimental evidence suggests that after Googling answers to questions, many people are convinced they knew these answers independently of

Table 1. Overconfidence in Medicine Examples

Construct	Description
Clinical Procedures	When performing clinical procedures, resident physicians had no correlation between self-rated confidence and supervisor-assessed competence. <sup>11</sup>
Diagnostic Ability	Diagnosing vignette cases, physicians made correct diagnoses in 55% of easy cases and 6% of difficult cases even though self-rated confidence was similar for both easy and difficult cases. <sup>2</sup>
Ultrasound Imaging	For difficult ultrasound cases, the least experienced and most inaccurate clinicians were most overconfident. <sup>12</sup>
Diagnostic Certainty	Among physicians self-rating their diagnostic certainty as "definite" antemortem, 46% of cases were misdiagnosed at autopsy. 13
Cancer Diagnoses	When asked to diagnose melanoma, dermatologists were "confident" in 55% of cases, but were incorrect in 30% of these diagnoses. <sup>14</sup>
Teaching Ability	Ninety-four percent of professors rated their teaching ability as above average. <sup>15</sup>
Medical Student Exam	Medical students' self-assessment of anatomy knowledge correlated weakly to actual performance. 16

the resource, termed an exaggerated "cognitive self-esteem," a marker of overconfidence.<sup>6</sup> Clinicians must remember the existence of unlimited online data is not equivalent to a personal understanding of it.

#### Who is most at risk for overconfidence?

Individual overconfidence can be situational or a fixed personal trait. Inbred inaccurate self-assessment of ability seems to be more common in those with specific personal characteristics such as level of risk-taking behavior, tolerance of uncertainty, impulsivity, narcissism, arrogance, or complacency. Overconfident physicians seem to be more susceptible than their peers to a "therapeutic illusion" of deciding that a positive outcome is due to their expert decision-making.<sup>7</sup>

Perhaps surprisingly, those with the least ability or knowledge tend to be the most overconfident, termed the Dunning-Kruger effect. <sup>8,9</sup> In their landmark study, Kruger and Dunning demonstrated that students scoring in the lowest quartile had the largest discordance between actual and self-rated competence. <sup>9</sup> Thus, the less expert one is at a task, the more likely there will be a mismatch between an inflated



self-perception and actual expertise. This miscalibration renders these lowest performing individuals both error-prone and unaware of their lack of ability.

The prevalence of overconfidence in diverse settings is impossible to determine. The vast literature includes both clinical and experimental studies, widely variable definitions, study populations, diagnoses, contexts, process measures, and outcomes. Yet, most investigators rate overconfidence bias as one of the most common, consequential cognitive vulnerabilities encountered in medicine. 1,3,4,8

#### What are the clinical consequences of overconfidence?

Cognitive biases in thinking, such as overconfidence, rather than a lack of knowledge or experience, may be the most frequent cause of medical error. Overconfident clinicians may oversimplify the complexity of clinical reasoning. Physicians' personal level of confidence influences how often they request additional resources and support from others. When overconfident, physicians may curtail questions about symptoms, abandon or fail to search for relevant medical literature, and order fewer diagnostic tests or consultations independent of whether this high confidence is justified.<sup>2</sup>

Overconfident clinicians are more likely to discontinue active cognitive reasoning and stop investigating, termed "premature diagnostic closure." Overconfident clinicians tend to downplay or ignore new data which questions their current clinical impression. Furthermore, confirmation bias propels overconfident individuals to search for evidence confirming their existing hypothesis. This error-engendering flaw reflects a failure to ask vital questions, "What else could this be?" or "Do I know enough?" Uncertainty can be protective, as it may guard against overconfidence and encourages clinicians to continue to keep an open mind.

Underconfidence, or having lower confidence than accuracy, also impairs decision-making and can be equally dangerous. For example, underconfident clinicians tend to mistrust their physical examination skills which can result in overuse of technology, such as CT scans. 10 Indecisiveness leads to unnecessary over-testing or consultations, which may delay appropriate patient care and increase medical interventions and resource utilization.

Knowing what we don't know is critical for doctors. Yet, at times, confidence in our knowledge and insights misaligns with actual knowledge and performance. This miscalibration reflects impaired self-awareness and unwarranted overconfidence. Determining the origin and identifying individuals at a higher risk for overconfidence is difficult. Too commonly, the least experienced or skilled physicians exhibit the most striking overestimation of their own ability. Failure of self-reflection can lead to poor decisions, inappropriate use of resources, diagnostic error and adverse healthcare outcomes for patients and institutions.

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#### The Perspective of a Human Computer

KATHLEEN GARVEY, PROVIDENCE COLLEGE '20

My Job as a medical scribe can seemingly be defined in a single sentence: I analyze, interpret, and record the medical charts for patients who walk through the doors of the Emergency Department. Paired with an ED physician, scribes are the flies on the wall, documenting the interaction with the patient. Essentially, acting as walking computers. With a job description which is purely mechanical, I was trained in the same automated manner. After weeks of didactic training, one-on-one shadowing sessions, personal study time, homework, progress quizzes and a final exam, I was finally a trained medical scribe. I learned to listen, consolidate, and type. I was advised on when to pay attention to the patient and when to "tune out." I learned to filter the patient's narrative to consist of only what is necessary for the provider to get a concise snapshot of the patient's story. Despite the automated aspect of my job, the role of a medical scribe requires empathy and sensitivity to recognize human suffering. Successful medical scribes, along with anyone working in the health care industry, understand that health encompasses more than one's physical condition.

The patients that arrive at the Emergency Department come with a wide range of complaints, from sprained ankles to car crashes to heart attacks. Before meeting the patient, I register both the physician and myself as a part

of their treatment team. The accuracy of my medical chart helps facilitate that a patient receives care pertinent to their condition. The medical chart is my responsibility; therefore the patient is my responsibility as well. In every shift, there is at least one person who

Despite the automated aspect of my job, the role of a medical scribe requires empathy and sensitivity to recognize human suffering. Successful medical scribes, along with anyone working in the health care industry, understand that health encompasses more than one's physical condition.

sticks with you. There was a man with heartburn, who only visited urgent care to please his wife. He collapsed at his car in the parking lot before he reached the entrance of the clinic and was unable to be resuscitated in the ED. Another man was rushed in on a stretcher who had not had a pulse since EMS arrived at the scene. His hand dangling off the stretcher brushed against my stomach as his body was wheeled into critical care. By no means are these cases forgettable.

I was trained to write a medical chart, but not for the potential dark experiences and patients I face in the room. The first time a patient died before my eyes was within the first month of my training. I was not prepared for the sound of a flat line on the electrocardiogram, or how quickly a patient without blood flow can turn grey. In this moment, shock, empathy and sensitivity fused, striking me so hard it almost knocked me over. In the ED, I am a witness to human suffering in varying degrees of severity. This was an aspect of the job which is excluded from the formal definition. One patient, let's call him John, is playing in a soccer game when he tripped and rolled his ankle. Another patient, Elizabeth, is sitting at home when her abusive spouse becomes upset and grabs her, breaking her wrist. Two wildly different histories for similar injuries, and both are charted in the same manner. I limit the patient into a component of their parts, allowing providers to better understand how to give them proper care and piece the patient's broken parts back together. I witness the whole person, dismantling their condition in a sequential manner, from personal to family to social history. Within the medical field this process is efficient, yet still we can also label this method as slightly dehumanizing. It's a clash which exists across all areas of health care: are we treating a patient or their parts?

The ethical battle between the excitement and organized chaos of the critical care room duels against the looming



recognition that sometimes the human on the table may die in front of you. As a scribe, I input the facts: how many doses of epinephrine were administered, how long has the patient been unresponsive, any and every pertinent detail. As a human, I watch another human being suffer in front of my eyes as I type notes. I hand the distraught spouse a box of tissues and offer a seat. I leave the room, submit my chart, and move onto the next one which is 10 minutes out.

My return home from one of these shifts, especially back to a relatively predictable and stable college environment, can be a shock to the system. Friends ask how the shift went and I must filter my answer. Are they being polite, or do they really want to know that a dead man's hand brushed up against me and I had three patients confess their

suicidal thoughts to me? What do I do when friends are dazed by my monotone voice? In these moments I am caught in this emotional battle of health care. If you feel too much, you become overwhelmed by the uncertainty of mortality and cannot effectively move forward to treat new patients. If you don't feel enough, you are a robot. Physicians are trained over the years to function within that sweet spot; as a scribe I had to quickly train myself to find that similar balance.

Finding the strength to witness, understand, and move forward from the heavy experiences seen in the ED is an essential part of my role as a scribe. Although scribes are not treating patients ourselves, we are part of their care team, responsible for the care patients receive. Despite the deceivingly

computational job description, I exist as an essential part of the health care system. I see a wide range of patients, some major and some minor cases, but ultimately, with every patient I am a witness to their pain. My role requires much more of me than the job description; I must find my place in the health care industry, to serve as a member of the care team while maintaining empathy for those being treated. I am expected to be a computer with ears, but I should strive to be more. ❖

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#### **Examining the Components of Effective Infection Control and Prevention**

JOHN R. LONKS, MD GUEST EDITOR

The depth and breadth of Infection Control includes many different microorganisms as well as sites of infection. The number one microorganism causing hospital infections is Clostridioides difficile (formerly Clostridium difficile). C. difficile poses many challenges for its reduction both here in the United States and abroad.2 In this issue, Steeves et al showed that it took multiple interventions to reduce the rate of hospital acquired C. difficile. Kelly et al performed a retrospective chart review of antibiotics received by patients with nosocomial C. difficile and showed that there was no overuse of high-risk antibiotics or unnecessary use of antibiotics. Lonks et al showed that at least 5.5% of hospitalized patients were colonized with C. difficile. These colonized patients if inappropriately tested for C. difficile would be misclassified as infected. Patients with unrecognized C. difficile colonization may act as a reservoir in the hospital. Additionally, one patient was misclassified as having nosocomial C. difficile since the stool specimen was sent to the clinical laboratory on hospital day 4; however, culture data showed that they were colonized at the time of admission.

The empiric choice of antibiotics for surgical prophylaxis is challenging. One strategy is to base antibiotic surgical prophylaxis on the hospital's antibiogram. Crawford et al compared the rate of methicillin resistance among *Staphylococcus aureus* isolated from nares cultures of patients undergoing elective lower extremity joint replacement to the hospital's antibiogram. The antibiogram markedly overestimated the proportion of *Staphylococcus aureus* that is methicillin resistant.

Urinary tract infections are common. Asymptomatic bacteriuria and colonization of urinary catheters lead to positive laboratory culture result. However, these conditions do not require treatment with antibiotics. Positive culture results may lead to a patient being falsely classified as having a catheter associated urinary tract infection. Moreover, unnecessary antibiotic therapy can lead to adverse side effects, drug-drug interactions, *C. difficile* infection and antibiotic resistance. Macias-Gil et al provide a clinically oriented, in-depth review of this topic.

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# MRSA Prevalence in Preoperative *S. aureus* Nasal Culture Isolates is Significantly Different From a Traditional Hospital-wide Antibiogram

ANDREW R. CRAWFORD, MD; NANCY VALLANDE, MS; JOHN R. LONKS, MD

#### **ABSTRACT**

Hospital antibiograms, because they are typically derived from samples obtained from hospitalized patients, may overestimate the prevalence of methicillin resistance in S. aureus in individuals presenting to the hospital for surgery. Because hospital antibiograms are commonly used to justify empiric perioperative prophylactic antibiotic selection prior to surgery, this may lead to unnecessary treatment with broad-spectrum antibiotics such as vancomycin. In a single-institution study, we observed that in our hospital antibiogram the proportion of S. aureus that are methicillin-resistant (MRSA) was significantly higher (45%) than isolates in preoperative nasal cultures obtained at the same hospital in outpatients prior to their lower extremity joint replacement surgery (13%): mean difference 0.32, [95% CI 0.25, 0.39], p < 0.0001. These data suggest that hospital antibiograms may overstate the true prevalence of MRSA in those at risk for MRSA surgical site infections who present from the outpatient setting.

**KEYWORDS:** antibiogram, antibiotic prophylaxis, arthroplasty, surgery, microbial colonization

#### INTRODUCTION

Surgical site infections (SSI) are potentially catastrophic complications of lower extremity joint replacements. They contribute to increased postoperative morbidity and mortality, and produce a substantial financial burden on the healthcare system. According to National Healthcare Safety Network data, *Staphylococcus aureus* (*S. aureus*) was responsible for 30% of SSIs, and 47% of SSIs following orthopedic procedures. Methicillin-resistant *S. aureus* (MRSA) were found in 44% of SSIs in which *S. aureus* was the causative bacteria. 1

Providers select an agent active against *S. aureus* when prescribing an antibiotic perioperatively and must strongly consider the risk of MRSA SSI. To assist with this decision, they often rely on institution-specific data regarding the incidence of SSI involving methicillin-resistant gram-positive bacteria. Alternatively, they may rely on a hospital-wide antibiogram, which provides data on institution-specific bacterial resistance patterns. Antibiograms include the antibiotic susceptibilities of bacteria cultured from samples

collected by that institution's laboratories each year.<sup>2</sup> Samples which make up these antibiograms are often collected primarily from inpatients, which could over-represent the prevalence of local antibacterial resistance. We hypothesized that the hospital-wide antibiogram at The Miriam Hospital, a 247-bed teaching hospital, may overstate the true proportion of *S. aureus* which is methicillin-resistant in a population at risk for MRSA SSI. We propose that an antibiogram composed specifically from *S. aureus* nasal cultures from patients undergoing lower extremity joint replacement would more accurately reflect the prevalence of the burden of colonization with methicillin-resistant *S. aureus* in this population.

#### **METHODS**

All hip or knee replacements at The Miriam Hospital in 2012 were identified using the TheraDoc™ clinical surveillance software. The following demographic data was then obtained from the hospital EMR for each corresponding patient: age, gender. Preoperative S. aureus testing date was collecting along with testing method and result. Only results from culture-based nasal S. aureus (methicillin-susceptible and methicillin-resistant) testing were included in the study. Some patients underwent more than one joint replacement during the year. For these patients, intervals between subsequent surgeries were considered re-colonization opportunities. The hospital-wide antibiogram, accessed from the Microbiology Laboratory, was developed using a patient-based algorithm; it includes the first isolate per patient during 2012. The hospital-wide antibiogram does not include results from MRSA screening. Stata/SETM version 12 software was used for statistical analysis.

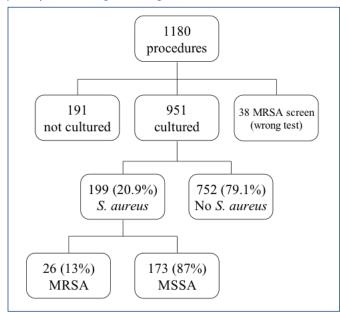
This study was part of a quality improvement project and did not meet the definition of research. Hence, it was exempt from the need of approval of an institutional review board.

#### **RESULTS**

There were 1180 procedures among 1129 patients: 749 knee replacements and 431 hip replacements. 64% of patients in these procedures were women, 36% men. Mean and median ages were 67 and 66, respectively. For 81% (951) of these procedures, patients underwent nasal *S. aureus* culturing

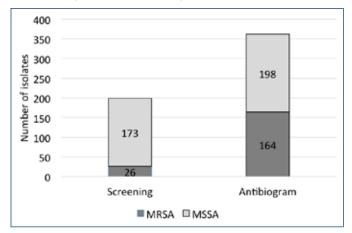


**Figure 1.** Preoperative *S. aureus* nasal culture results among 1180 total joint replacement surgeries during 2012.



prior to surgery. Results from 38 tests using MRSA screens (of which 2 were positive), which did not detect MSSA, were not included in the data analysis. For 191 procedures, there was no preoperative *S. aureus* testing performed. The mean interval between culturing and surgery was 24.7 days, with a median of 26 days. 199 (21%) of nasal cultures were positive for *S. aureus*. Of those, 26 (13%) were MRSA, the remainder being MSSA. The results of the cultures are summarized in **Figure 1**. The hospital-wide antibiogram contained 362 *S. aureus* isolates; 164 (45%) of these were MRSA, the remainder being MSSA. The proportion of *S. aureus* isolates

**Figure 2:** Proportion of methicillin-resistance in *S. aureus* isolated in lower extremity joint replacement preoperative screening nasal culture (n=199), compared to isolates in hospital-wide antibiogram (n=362).



MSSA = methicillin-sensitive *S. aureus*. MRSA = Methicillin-resistant *S. aureus*. Proportions were compared using two-sample test of proportions, difference was 0.32, [95% CI 0.25, 0.39], p <0.0001.

that were found to be MRSA during preoperative culturing was compared to the same proportion in the 2012 Miriam Hospital antibiogram using the two-sample test of proportions (**Figure 2**). The difference was 0.32, [95% CI 0.25, 0.39], p <0.0001.

#### **DISCUSSION**

Several different organizations recommend a first-generation cephalosporin such as cefazolin or vancomycin as first-line for perioperative prophylaxis during orthopedic surgery.<sup>3</sup> In these guidelines, vancomycin is not recommended for routine use, but rather for individuals with beta-lactam allergies or risk factors for MRSA. Vancomycin use is also justified in instances of high institutional prevalence of colonization or infection with methicillin-resistant gram-positive bacteria, although no threshold for this has been defined.

Antibiograms are important tools for the empiric treatment of suspected bacterial infections in the hospital setting before specific culture and sensitivity results are available, and for prophylaxis perioperatively to reduce the risk of postoperative SSI. However, these are typically composed of samples isolated mainly from inpatients. The hospital provides a niche for bacteria to become exposed to multiple antibiotics as they travel between patients and the hospital environment; this selective pressure drives resistance. Thus, samples from the inpatient population are not an accurate representation of the bacterial skin flora that put patients at risk of SSIs when they present for surgery from the community. Furthermore, it is more common for bacteria colonies from the patient's own skin, rather than exogenous spread from the hospital environment or providers, to be the inciting organisms for a SSI.4 Hospital-wide antibiograms may therefore lead to the overuse or misuse of perioperative antibiotics.

Several novel approaches have been proposed to enhance the utility of hospital-wide antibiograms. These include a "weighted-incidence" antibiogram, which integrates the relative frequency of organisms causing a particular infection with their resistance patterns.<sup>5</sup> Studies creating hospital unit-specific antibiograms have demonstrated that the percentage of *S. aureus* isolates susceptible to methicillin may be significantly higher in the medical ICU when compared to a hospital-wide antibiogram.<sup>6,7</sup> One study demonstrated that antibiotic sensitivities can differ significantly when comparing antibiograms developed from bacteria isolated >48 hours after admission (hospital-acquired) and those isolated <48 hours before admission (community acquired).<sup>8</sup>

Our study demonstrates that using susceptibility results of preoperative nasal cultures for *S. aureus* will allow for the more rational selection of empiric antibiotic prophylaxis during lower extremity joint replacement, as compared to using a hospital-wide antibiogram which displays a significantly higher proportion of *S. aureus* which are resistant



to methicillin. Among the 951 patients who underwent nasal culturing for *S. aureus*, only 2.7% had MRSA. This strongly suggests that reliance on a hospital-wide antibiogram, which typically display a significantly higher prevalence of methicillin-resistance in *S. aureus* isolates, will lead to unnecessary use of vancomycin.

Our study has limitations. Our data was obtained from preoperative cultures at one institution, so these may not be generalizable to other institutions or to populations with greater risk factors for MRSA colonization. Swabbing in other locations known to contain S. aureus such as the perineum or axillae could potentially improve the sensitivity of the preoperative culturing and provide a larger sample of S. aureus isolates, although it is unlikely that this would affect the comparison. Further work to obtain preoperative nasal culturing for S. aureus from patients preparing for a wider variety of surgeries would give us a more robust sample size and more demographically diverse patient makeup, thus increasing the utility of our preoperative nasal culture antibiogram. Future studies could also be employed to determine the clinical effectiveness of a preoperative culture antibiogram in preventing S. aureus SSI as compared to the traditional hospital-wide antibiogram.

#### **Acknowledgments**

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#### Safety and Nosocomial Clostridioides difficile Infections

SUSAN STEEVES, MSN, RN; NANCY VALLANDE, MS; JOHN R. LONKS, MD

#### **ABSTRACT**

The rate of nosocomial *C. difficile* in the state of Rhode Island is among the highest in the country. Multiple factors impact the occurrence of nosocomial *C. difficile*. Improvement in a single factor may not lead to a decrease in the rate. We report the results of a multidisciplinary team that implemented multiple interventions, which led to a 42% reduction of nosocomial *C. difficile* at The Miriam Hospital.

**KEYWORDS:** Clostridioides difficile, multidisciplinary, safety, nosocomial

#### INTRODUCTION

Clostridioides (formerly Clostridium) difficile is the most common organism causing nosocomial infections.¹ In the United States, C. difficile is estimated to cause about 450,000 infections and approximately 29,000 deaths.² Previous studies have demonstrated that up to 15% of adults are colonized with toxigenic C. difficile, and almost 50% of elderly adults in long-term care facilities or nursing homes may be colonized with the bacteria .³,⁴ Infections due to C. difficile can cause devastating complications such as acute renal failure, colectomy and death as well as leading to increased length of stay, excess morbidity and rising healthcare costs. The rate of nosocomial C. difficile in Rhode Island (RI) is among the highest in the country. In the period April 1, 2018 to March 31, 2019, Rhode Island ranked 49 out of 50.⁵

#### **BACKGROUND**

The Miriam Hospital is a 247-bed teaching hospital in Providence, RI. Despite reduction efforts during 2014–2015, the rate of nosocomial *C. difficile* remained above the national benchmark. During the second quarter of 2016, a multidisciplinary team was created that included Infection Control, Housekeeping, Nursing, Administration, Quality, Safety and Patient Care Equipment staff. Implementation of the recommendations of this group, based on literature review of best practices started during the third quarter of 2016. Consensus best practices include antimicrobial stewardship, surveillance, case isolation, use of personal protective equipment,

effective cleaning within the hospital environment, and education.<sup>2,6</sup> The team took a multi-pronged approach to implementing in-hospital interventions.

#### **METHODS/INTERVENTIONS**

#### Ordering (correct ordering)

Appropriate and inappropriate stool testing was addressed. Education was provided to nurses and providers to send only loose stool specimens for *C. difficile* testing. An electronic order panel was created for ordering C. difficile testing and consisted of two questions, 1) has the patient had 3 or more loose stools (appropriate testing) within 24 hours and 2) has the patient had recent laxative use (inappropriate testing). It was discovered upon review of documentation in the electronic medical record that not all stools were recorded. Nurses documented whether a patient had a bowel movement, but nursing assistants did not. The electronic medical record was modified so that nursing assistants could document frequency and consistency of bowel movements. As part of the C. difficile electronic order panel, the number of bowel movements was displayed to the provider as an aid for appropriate testing. Hence, inappropriate testing could occur if a stool was collected from a patient who was given a laxative, developed loose stools and was colonized with C. difficile thus producing a false positive lab result.

#### **Initiation of precautions**

In order to initiate early precautions and reduce inappropriate testing, nurses were educated and feedback provided on a nurse driven protocol so that a stool for *C. difficile* could be obtained by a nurse and sent to the lab, provided the patients had 3 or more loose bowel movements in 24 hours and had not recently received a laxative. This would lead to earlier detection of *C. difficile* infection. Patients were placed on contact precautions while the *C. difficile* test was pending, leading to a potential reduction in transmission prior to a lab test to confirm the diagnosis.

#### **Duration of contact precautions**

Patients with *C. difficile* infection are maintained on Contact Precautions for the duration of their hospitalization. If the diarrhea resolves, the patient's room and the equipment in the room can still be contaminated with *C. difficile*.



Because the spores can persist in the environment for extended periods – months or years on inanimate surfaces – patients are not taken off contact precautions.<sup>7</sup>

#### Hand hygiene and Personal Protective Equipment (PPE)

Transmission via healthcare workers can be decreased using personal protective equipment (PPE), e.g. gowns and gloves, when taking care of patients who have *C. difficile* infection. Therefore, poor compliance with using gowns and gloves is one latent factor in the development of nosocomial *C. difficile*. Despite compliance, during the process of removing gowns and gloves, there may be inadvertent contamination of a healthcare worker's hands or clothing. All nurses received competency training on hand hygiene and use of PPE during 2017. The training included hands-on demonstration of competency.

#### **Environment (room)**

Reducing environmental contamination includes cleaning of patients' rooms daily and upon discharge from the hospital. Patient rooms should be thoroughly cleaned prior to receiving the next patient. Optimum cleaning of the room includes sufficient dedicated time, equipment and appropriate cleaning agents. Environmental cleaning practices including the use of cleaning agents (hydrogen peroxide and sodium troclosene) and disposable mop heads and cloths were implemented. A stainless-steel cleaning cart was purchased to hold the cleaning agents and supplies used for rooms that housed patients with *C. difficile* and other micro-organisms that required special cleaning. Discharge cleaning was per-

formed with two housekeeping staff. Ultraviolet light surface decontamination has been successfully used in infection control and was used in rooms after a patient is discharged and the room cleaned.<sup>8</sup> As part of the *C. difficile* improvement process, the use of ultraviolet light surface decontamination was prioritized to those rooms that had housed a patient with *C. difficile*.

#### **Environment (equipment)**

*C. difficile* can contaminate shared equipment that is used in patients' rooms. Thorough cleaning of the equipment is needed to prevent transmission to other patients. Patient-care equipment was cleaned with bleach wipes after each use.

#### Cleaning: "Scrub Club"

Contaminated equipment and surfaces are potential environmental reservoirs. When a patient with nosocomial *C. difficile* was identified on a ward, high touch areas in all patient rooms, nurse's station and shared equipment that was on the ward was cleaned with a bleach-based product. The cleaning program was named "Scrub

Club," (comprehensive cleaning using a sporicidal agent). Departments involved in "Scrub Club" included House-keeping, Nursing and Patient Care Equipment staff. The purpose was to enhance cleaning on the ward in case there was inadvertent environmental contamination.

#### Bedpans and commode liners/blood pressure cuffs

Bedpans and commodes, particularly those used by patients with diarrhea, can lead to splashing and contamination of the environment. Bedpan/commode liners were purchased, and their use was encouraged for all patients with loose stools. These liners absorbed the liquid to eliminate splashing. Additionally, disposable blood pressure cuffs were purchased and used in all in-patient rooms, replacing the need to clean the blood pressure cuff when a patient was discharged.

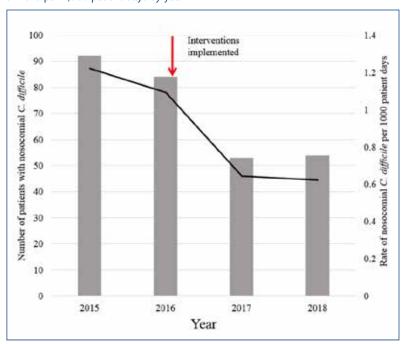
#### **Antibiotics**

Another factor associated with *C. difficile* infection is exposure to antibiotics. Unnecessary exposure to antibiotics could be decreased or eliminated to decrease the rate of *C. difficile* infections. During 2014 a formal Antimicrobial Stewardship program was started; its activities and interventions increased over time.

#### **RESULTS**

The number of patients with nosocomial *C. difficile* decreased from 92 in 2015 to 84 in 2016 to 53 in 2017 and 54 in 2018. There was a 42% reduction in the number of cases when comparing 2017 to 2015. (**Figure 1**)

**Figure 1.** Number of patients with nosocomial *C. difficile* and rate of nosocomial *C. difficile* per 1,000 patient days by year.





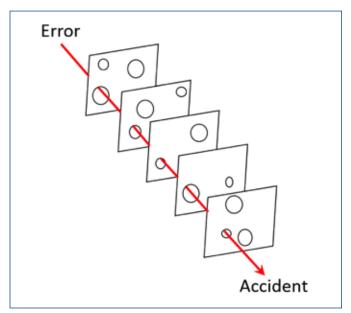
#### **DISCUSSION**

Transmission of *C. difficile* may occur in a healthcare setting when the organism is transferred from patient-to-patient via the hands of healthcare workers or from a contaminated environment. The development of nosocomial *C. difficile* in various patient populations on different wards throughout the hospital was not necessarily due to an individual safety error, but suggested potential systemic, hospital-wide deficiencies in infection control. Previous efforts to eliminate specific sources of infection were unsuccessful in reducing nosocomial *C. difficile* infections. Instead, a collaborative, interdisciplinary approach involving multiple intervention points and several departments resulted in a reduction in nosocomial *C. difficile* infections.

There may have been unrecognized improvements in other processes due to the Hawthorne effect. Other unmeasured processes may have also contributed to the reduction such as increased thoroughness of cleaning by Housekeeping.

Cases of nosocomial *C. difficile* can be explained by the Swiss cheese model of accident causation (**Figure 2**). For an accident to take place, alignment of the holes in the Swiss cheese must occur such that an error will flow through all the holes emerging from the other end producing an accident. This model shows the defenses as pieces of Swiss cheese which have holes or flaws (latent defects) in them. Some examples of latent factors include equipment design, equipment choice, equipment maintenance, procedures, policies, training, communication, resources, staffing, workload, physical environment, noise, interruptions, roles, responsibilities and supervision. In order to reduce

**Figure 2.** The Swiss cheese model of accident causation illustrates that there are many layers between an error and an accident. Holes, in each slice, represent flaws (latent failures) that if aligned can allow the accident to occur.



*C. difficile* on the wards, some of these factors were addressed. Appropriate testing, early identification of infected patients, initiation of contact precautions, bleach cleaning of patient rooms, shared equipment and the nursing ward, use of bedpan liners, as well as other improved compliance may have protected against the development of nosocomial *C. difficile*. The numerous interventions involving multiple hospital departments resulted in the reduction in the rate of nosocomial *C. difficile*. The goal will be to not only sustain these improvements but to further reduce the rate of nosocomial *C. difficile*.

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# Antibiotics and Nosocomial *Clostridioides difficile*, a Retrospective Chart Review

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#### **ABSTRACT**

*C. difficile* is a complication of antibiotic therapy. Certain antibiotics are associated with a higher rate of developing *C. difficile*. The charts of 54 patients with nosocomial *C. difficile* were reviewed and very few had received a high-risk antibiotic. Seven (13%) of 54 patients had not received any antibiotics in the hospital prior to the positive stool test for *C. difficile*. Moreover, 6 of the 7 had no documentation of receiving an antibiotic in the 56 days prior to admission suggesting that they might be colonized with *C. difficile*.

**KEYWORDS:** Clostridioides difficile, antibiotics, healthcare-associated infections

#### **INTRODUCTION**

Clostridioides difficile (formerly Clostridium difficile) infection is a rare, but potentially devasting, complication of antibiotic therapy. Since about one-half of all hospitalized patients receive an antibiotic, a rare complication can affect many patients. In 2017 there were 223,900 people hospitalized with *C. difficile* in the United States with 12,800 deaths.

Certain antibiotics such as clindamycin and cefotaxime, a third-generation cephalosporin, are associated with a higher risk of developing *C. difficile* infection.<sup>3</sup> Doxycycline, penicillin, macrolides, trimethoprim/sulfamethoxazole and cefazolin, a first-generation cephalosporin, are low-risk antibiotics. Ciprofloxacin, levofloxacin, meropenem (a carbapenem) and certain cephalosporins are medium risk. In addition to antibiotics, proton pump inhibitors may increase the risk of developing *C. difficile* infection.

The rate of nosocomial *C. difficile* in the state of Rhode Island is among the highest in the country. At The Miriam Hospital, a 247-bed teaching hospital in Providence, RI, numerous interventions were used to decrease the rate of nosocomial *C. difficile* (See accompanying article, "Safety and Nosocomial *Clostridioides difficile* Infections", Steeves S, et al). As part of a quality improvement project to further reduce the rate of nosocomial *C. difficile*, a retrospective chart review was performed to determine which antibiotics were received by patients with nosocomial *C. difficile*. This data may help to determine if antibiotic use could be optimized to reduce the rate of nosocomial *C. difficile* infection.

#### **METHODS**

This descriptive study includes data from persons admitted to The Miriam Hospital (TMH) in Providence, RI who developed hospital onset *C. difficile* infection using National Healthcare Safety Network (NHSN) Laboratory-identified data from January 1, 2018 through December 31, 2018. Electronic medical records were reviewed. This study was a retrospective chart review conducted for internal quality improvement at TMH and thus was exempted from needing Institutional Review Board approval.

#### **Case Definition**

A case of hospital onset *C. difficile* was defined as per the NHSN criteria of a positive laboratory diagnostic test >3 days after admission. The date of admission to an inpatient unit was coded as hospital day 1. The Microbiology laboratory uses a PCR-based diagnostic test. As per NHSN, an incident case was defined as a patient without symptom onset or a positive laboratory test in the previous eight weeks (56 days). A recurrent case was defined as a patient with a positive *C. difficile* test within the previous 56 days. Patients diagnosed with a second hospital-onset *C. difficile* infection >56 days after their first infection during the period of study were counted as separate incident cases.

#### Variables of Interest

Patient data were de-identified and patients were assigned a code for analysis. All data were extracted from patients' electronic medical record unless otherwise noted. Age was recorded in years as the age of the patient at the time of C. difficile diagnosis. Sex was defined as male or female per patient chart. The admission date was defined as the admission date of the hospitalization to an inpatient unit during which the patient was diagnosed with C. difficile. The location from which the patient was admitted was defined as the location in which the patient had spent the previous 24 hours and was coded as home, nursing home or transfer from another hospital. Home included any private residence. Nursing home included patients who were admitted from rehabilitation facilities and skilled nursing facilities. Patient charts were also reviewed to identify if patients had undergone a surgical procedure or been hospitalized during the eight weeks prior to the index admission. Hospitalization was defined as an overnight admission of a minimum of



one day; emergency department visits that did not result in admission were excluded. Surgical procedures were defined as invasive surgical procedures done in the operating room and excluded procedures such as bedside central line/PICC line placement, suturing of wounds, etc. Hospitalizations and surgical procedures that were performed outside of The Miriam Hospital but documented in patients' electronic medical record were included.

Previous antibiotic use was defined as any antibiotic for which the patient was prescribed at least one dose in the previous 56 days. Antimicrobial agents during hospitalization were defined as any antibiotic of which patient received at least one dose prior to the patient's *C. difficile* diagnosis during the hospitalization of interest. Number of days received was defined as the number of days patient received each antibiotic prior to diagnosis with *C. difficile*. The day the *C. difficile* specimen was collected was not counted as a "day received" for antimicrobial agents. One dose of antibiotic was counted as one day independent if patient received the full therapeutic amount of antibiotic for that day.

Proton pump inhibitor (PPI) use was coded as "yes" if patients had one or greater doses of PPI documented in the chart at any time in the six months prior to *C. difficile* infection. Site of infection was defined as the documented infection site for which antimicrobials were prescribed. The culture site was the site from which positive cultures were obtained. Negative cultures were not recorded. Culture organism was the organism(s) that grew from the positive culture sites; some sites grew more than one organism and all organisms were recorded. Sepsis was defined as "yes" when patients had a diagnosis of sepsis recorded during the hospitalization in which they were diagnosed with *C. difficile*. Other positive tests were defined as other positive microbial tests, including, MRSA/VRE screen positive patients and positive respiratory pathogen panels.

#### **Data Quality**

Charts were reviewed in a standardized manner and data were extracted from the same location in the chart when possible. In addition, outpatient records were reviewed for all patients with such data included in their electronic medical record to ensure that all possible information on prior hospitalizations, surgical procedures, antibiotic and PPI use, etc. was recorded. A list of operational definitions for each variable was created to ensure standardization in the interpretation and documentation of all variables. Any discrepancies or ambiguities were reviewed with the senior author, who made a final decision.

#### **Data Analysis**

Data were entered into a spreadsheet and descriptive statistics were run. The mean, minimum and maximum values were calculated for patient age and days between admission and *C. difficile* diagnosis. Percent distributions were calculated for all other variables.

#### **RESULTS**

#### **Demographics**

There were a total of 54 hospitalizations with hospital onset incident *C. difficile* cases from January 1, 2018–December 31, 2018 representing 52 unduplicated patients. Two patients were diagnosed with *C. difficile* twice in separate hospitalizations >56 days apart during the study period. Thus, each *C. difficile* diagnosis was counted as a separate incident case for the purposes of this analysis. Of the 54 incident cases, 26 (48%) were male and 28 (52%) were female. The average age of patients was 72.6 years (range 42 –94 years) at the time of *C. difficile* diagnosis. The majority (n=43, 80%) of patients were admitted from home with ten (19%) admitted from a nursing home and one patient (2%) transferred from another hospital.

Forty-three percent (n=23) of patients were neither hospitalized nor had a surgical procedure in the eight weeks prior to their C. difficile diagnosis. A total of 41 percent were hospitalized and almost a quarter (n=12; 22%) had a surgical procedure in the previous eight weeks. Eight patients (15%) had a previous C. difficile infection >56 days prior to the incident case; the remaining 46 (85%) had no previous C. difficile infection documented in their electronic medical records. One half (n=27) had taken a proton pump inhibitor in the six months prior to diagnosis.

Almost sixty percent (n=33; 61%) of patients did not have documented antibiotic use in the eight weeks (56 days) prior to admission. Of those who did receive antibiotics, the most commonly used were intravenous vancomycin (15%), followed by ceftriaxone (13%) and piperacillin/tazobactam (11%). The remaining antibiotics used were taken by less than ten percent of patients (**Table 1**).

#### **Admission Clinical Data**

The average number of days between admission and *C. difficile* diagnosis was seven (range 3 – 25; median 5 days). The vast majority (n=47; 87%) of patients took at least one antibiotic during admission prior to being diagnosed with *C. difficile*. Of those who used antibiotics, the most common site of infection for which the antibiotics were prescribed was the lower respiratory tract (22%) followed by the urinary tract (19%) and the bloodstream (15%). Approximately ten percent of infections were in the skin and soft tissue (9%), gastrointestinal tract (11%) or undetermined/empirical (11%) respectively. Of note, the undetermined/empirical category included peri-operative antibiotic administration. Seven (13%) patients had a documented diagnosis of sepsis during the admission. Five patients had more than one site of infection (**Table 2**).

A total of twenty-six patients had a positive infection site culture. Eleven patients (20%) had positive urine cultures, seven (13%) had positive blood cultures, four (7%) had positive abscess site cultures and four (7%) had positive sputum cultures.

The most commonly used antibiotics during admission



**Table 1.** Antibiotics used in the 56 days prior to admission of patients diagnosed with *C. difficile*, January 1–December 31, 2018.

Antibiotic	Number (percent)
Vancomycin (intravenous)	8 (15)
Ceftriaxone	7 (13)
Piperacillin/tazobactam	6 (11)
Cefazolin	4 (7)
Levofloxacin	4 (7)
Amoxicillin/clavulanate	3 (6)
Ampicillin/sulbactam	2 (4)
Cefepime	2 (4)
Ciprofloxacin	2 (4)
Metronidazole (intravenous)	2 (4)
TMP/SMX	2 (4)
Metronidazole (oral)	1 (2)
Cefuroxime axetil	1 (2)
Azithromycin	1 (2)
Meropenem	1 (2)
Penicillin	1 (2)

**Table 2.** Admission clinical data of patients diagnosed with *C. difficile*, January 1–December 31, 2018

Site of infection*	Number (percent)
Lower respiratory tract	12 (22)
Urinary tract	10 (19)
Bloodstream	8 (15)
Sepsis	7 (13)
None	7 (13)
Gastrointestinal tract	6 (11)
Undetermined/empirical**	6 (11)
Skin and soft tissue	5 (9)
Bone and joint	1 (2)
Hepatobiliary system	1 (2)
Asymptomatic bacteriuria	1 (2)
Fever and neutropenia	1 (2)
Other***	1 (2)

Five patients had more than one site of infection

**Table 3.** Antibiotics used during hospitalization of patients diagnosed with *C. difficile*, January 1–December 31, 2018.

Antibiotic	Number (percent)	Average Number of Days Used			
Piperacillin/tazobactam	27 (50)	4.1			
Vancomycin (IV)	25 (46)	3.4			
Ceftriaxone	11 (20)	2.8			
Cefazolin	8 (15)	3.0			
Cefepime	8 (15)	3.5			
Azithromycin	6 (11)	3.5			
Metronidazole I.V.	4 (7)	1.3			
Aztreonam	3 (6)	2.3			
TMP/SMX	2 (4)	2.0			
Doxycycline	2 (4)	2.0			
Ciprofloxacin	2 (4)	1.5			
Levofloxacin	2 (4)	3.0			
Ertapenem	2 (4)	7.0			
Meropenem	2 (4)	3.0			
Ampicillin/sulbactam	1 (2)	4.0			
Amoxicillin/clavulanate	1 (2)	2.0			
Clindamycin	1 (2)	1.0			

were piperacillin/tazobactam (50%), followed by vancomycin IV (46%), ceftriaxone (20%), cefazolin (15%), cefepime (15%) and azithromycin (11%). All other antibiotics administered were used in less than ten percent of the patients *C. difficile* (**Table 3**).

Seven (13%) patients did not receive any antibiotics during their hospital stay prior to the positive test for *C. difficile*. One patient recently completed an outpatient course of amoxicillin/clavulanate prior to admission. Three of the seven had a prior positive test 22, 297 and 682 days prior to admission. The patient with the positive test 22 days earlier was an inpatient at an outside hospital. One patient received oral magnesium oxide which can cause diarrhea.

#### **DISCUSSION**

*C. difficile* infection is a complication of antibiotic therapy. Certain antibiotics, such as clindamycin, are associated with a higher risk for developing *C. difficile* infection. One strategy to reduce the rate of nosocomial *C. difficile* is to reduce the use of high-risk antibiotics. At The Miriam Hospital during 2018 very few patients with nosocomial *C. difficile* received a high-risk antibiotic.

Approximately 30-50% of prescribed antibiotics may be inappropriate or unnecessary.<sup>4</sup> In this study of patients with nosocomial *C. difficile*, very few received unnecessary antibiotics.

If *C. difficile* is solely a complication of antibiotic therapy,

then it is remarkable that seven patients (13%) classified by NHSN as having hospital-acquired *C. difficile* did not receive any antibiotics while in the hospital. Moreover, six of the seven did not receive any antibiotics in the 56 days prior to their admission. Three of the seven had a prior positive stool test for *C. difficile*. Hence, they may be chronically colonized and did not acquire *C. difficile* while in the hospital. Four-percent to 15% of healthy adults are colonized with *C. difficile*. Hence, if a colonized patient is admitted to the hospital and develops diarrhea for some other reason, when a stool sample is tested it will be positive for *C. difficile* even though the diarrhea is not due to *C. difficile*.

This study has several limitations. The data were collected via retrospective chart review. While every effort was made to extract data for each variable in a systematic manner, the data completeness and quality for each patient was limited by what was documented. Additionally, some variables, such as antibiotic use and surgery/hospitalization in the prior 56 days depended on access to and completeness of outpatient records. For the sake of consistency in operational definitions and analytical purposes, "PPI use" was coded as a dichotomous variable with one recorded use of any PPI coded as "yes". This is not, however, representative of how these medications are used in clinical practice, with the vast majority of conditions requiring multi-day/week courses.



<sup>\*\*</sup> Includes empiric peri-operative antibiotics

<sup>\*\*\*</sup>Respiratory pathogen panel positive for

*C. difficile* infection is a complication of antibiotic therapy. At The Miriam Hospital during 2018 use of high-risk antibiotics or unnecessary use of antibiotics was found in very few of the cases of nosocomial *C. difficile*. Moreover, 13 percent of patients did not receive an antibiotic in the hospital. Hence, some of the patients classified as having nosocomial *C. difficile* may be colonized but not infected.

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# Rate of *Clostridioides difficile* Culture Positivity Among Hospitalized Patients

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#### **ABSTRACT**

The rate of nosocomial C. difficile in Rhode Island is among the highest in the country. Colonization with *C*. difficile is uncommon but can lead to falsely identifying a patient as having C. difficile infection. Additionally, unrecognized C. difficile colonization may act as a reservoir in the hospital. During a 19-day period, rectal swabs obtained for routine VRE surveillance were cultured for C. difficile. Overall, 51 (7.9%) of 649 patients had C. difficile by culture. The majority (n=36, 71%) of patients from whom a rectal swab grew C. difficile did not have a sample sent to the clinical laboratory. Hence, at least 5.5% of the 649 patients were colonized. One patient was classified as having hospital-acquired C. difficile since the clinical specimen was sent to the clinical laboratory on hospital day 4. This patient was culture positive on admission and hence misclassified as having hospitalacquired C. difficile.

**KEYWORDS:** Clostridioides difficile, health careassociated infections, microbial colonization

#### INTRODUCTION

In January 2013, the Centers for Medicare and Medicaid Services (CMS) began requiring acute-care hospitals to submit any laboratory-identified (LabID) Clostridioides difficile cases to the Centers for Disease Control and Prevention's surveillance system, the National Healthcare Safety Network.1 Data from the first quarter of 2013 demonstrated Rhode Island ranked 51st among the 50 states and the District of Columbia for C. difficile LabID standardized infection ratios (SIRs).<sup>2</sup> It has been proposed that the high rate of C. difficile in Rhode Island might be explained in part by the relatively high proportion of the population that is elderly and by the fact that hospitals in the state may have switched more rapidly and uniformly to nucleic acid amplification testing methods for C. difficile than other states.<sup>2</sup> However, the high rate of C. difficile in Rhode Island also suggested a need to re-assess infection control strategies in hospitals and nursing homes and to consider other contributing factors.

Several recent studies suggest that a substantial proportion of *C. difficile* cases classified as healthcare-associated

C. difficile infection (CDI) were colonized on admission.<sup>3-12</sup> For example, Gonzalez-Orta et al.<sup>3</sup> reported that 14% of patients admitted to an acute care hospital were asymptomatic carriers of toxigenic C. difficile on admission and 9% of the carriers subsequently were diagnosed with health-care-associated C. difficile versus only 1% of those with negative admission cultures. Such studies raise concern that patients with asymptomatic carriage on admission are often falsely diagnosed with C. difficile when they develop diarrhea for other reasons.<sup>13</sup> However, most prior studies evaluating carriage on admission have been small studies often involving single wards. Therefore, we conducted an Infection Control quality improvement project to determine the frequency of C. difficile carriage at an acute care teaching hospital in Rhode Island.

#### **METHODS**

The study was conducted at The Miriam Hospital, a 247-bed teaching hospital in Providence, RI. Rectal swabs are obtained as part of the routine Infection Control surveillance for vancomycin-resistant enterococci (VRE) on hospital admission or admission/discharge from ICUs. For 19 consecutive days during 2014, the rectal swabs obtained for VRE culture were also cultured for *C. difficile*. The swabs were kept frozen at -80 until shipped on dry ice for *C. difficile* culture.

The rectal swabs were plated directly onto selective media for culture of toxigenic *C. difficile* as previously described. <sup>14</sup> After plating, the swabs were submersed in *C. difficile* brucella broth with thioglycolic acid and l-cystine (CDBB-TC) and incubated for up to 72 hours to identify low-level colonization. <sup>15</sup> All *C. difficile* isolates were tested for *in vitro* cytotoxin production using *C. difficile* Tox A/B II (Wampole Laboratories) and isolates that did not produce toxin were excluded from the analysis. For a subset of isolates, polymerase chain reaction (PCR) analysis for the binary toxin gene *cdtB* and fluorescent PCR ribotyping was performed as previously described. <sup>16</sup> For the directly plated swabs, the number of colonies recovered per swab was counted.

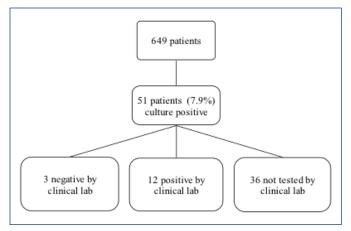
The percentage of directly plated swabs with greater than 25 colony-forming units (CFUs) per swab was calculated as this level of contamination has previously been associated with increased frequency of skin and/or environmental contamination in asymptomatic carriers.<sup>14</sup>



#### **RESULTS**

A total of 754 swabs were cultured from 649 patients. 86 patients were cultured twice, 8 cultured 3 times and one patient was cultured 4 times during the 19 days. Patients were considered positive if they had one or more positive cultures. Overall, 51 (7.9%) patients had cultures positive for toxigenic *C. difficile*, including 28 (4.3%) on directly plated agar culture and 23 (3.5%) in broth culture only. (**Figure 1**)

Figure 1. C. difficile cultures and clinical laboratory testing.



A chart review of the 51 culture positive patients demonstrated that 15 had a clinical laboratory test for *C. difficile*; 12 were positive and 3 were negative. The three negative test results from the clinical laboratory test were 2 days prior to the positive culture, 10 days after the culture and 11 days after the culture. Twenty-eight patients (54.9%) had positive cultures on agar culture plates and 23 (45.1%) patients had low-level carriage only detected by broth enrichment cultures. Culture positivity by the broth method only occurred more frequently (53%) among patients who did not have a specimen sent to the clinical lab compared to those who were *C. difficile* positive by the clinical lab (25%). (**Table 1**)

**Table 1.** Recovery of toxigenic Clostridioides difficile on agar culture plates versus only in broth enrichment cultures, stratified by clinical laboratory testing results.

Clinical Lab	<b>Agar</b> Number (%)	Broth Only Number (%)
Not tested	17 (47)	19 (53)
Positive test	9 (75)	3 (25)
Negative test	2 (66)	1 (33)

There was one patient among the 51 culture positive patients who was classified as having hospital-acquired *C. difficile* since the clinical specimen was sent to the clinical laboratory on hospital day 4. This patient was culture positive by directly plated agar on admission and hence misclassified as having hospital-acquired *C. difficile*.

#### **DISCUSSION**

We found that 51 (7.9%) of 649 patients admitted to The Miriam Hospital were culture-positive for toxigenic C. difficile. Most of these culture-positive patients (71%) did not have a specimen sent to the clinical laboratory for C. difficile testing suggesting that they were colonized rather than infected. Fifteen of 51 (29%) patients with a positive culture had a specimen sent to the clinical laboratory and 12 (80%) had positive PCR tests for toxigenic C. difficile. Of these 12 patients, 11 (91.7%) had positive tests during the first 3 days of admission and were classified as community-acquired cases. The three negative clinical laboratory results were 2 days prior and 10–11 days after the positive culture. As the cultures and clinical laboratory C. difficile tests were several days apart, it is possible that these patients cleared colonization during their hospital stay. Factors such as receipt of antibiotics with inhibitory activity against C. difficile may contribute to clearance of colonization.<sup>13</sup>

One patient was colonized with *C. difficile* on admission and subsequently was diagnosed with hospital-acquired *C. difficile*, using National Healthcare Safety Network (LabID) criteria, based on a stool specimen submitted to the clinical laboratory on hospital day 4. As noted previously, positive tests in patients colonized on admission could result in a false-positive diagnosis of *C. difficile* if factors such as laxatives are the cause of diarrhea.

In summary, this quality improvement project was undertaken to determine the rate of colonization with *C. difficile* in an acute care hospital in Rhode Island. At least 5.5% and possibly 6.0% of patients are colonized with *C. difficile*, a rate consistent with previous studies.<sup>13</sup> Although a minority of new admissions were colonized, these patients could potentially be a source of transmission as they are not isolated and inappropriate testing could result in false-positive diagnosis of *C. difficile*.

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#### To Treat or Not to Treat: UTI or Bacteriuria?

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#### INTRODUCTION

An 85-year-old male nursing home resident with dementia is admitted with altered mental status and decreased oral intake in the last 3 days. There has been a recent medication change and his dose of quetiapine had to be decreased due to a prolonged QT interval. He was afebrile and hemodynamically stable. On exam, he was found disoriented to time and place. He had no costovertebral or suprapubic tenderness on palpation. His complete blood count showed a WBC of 7000 per microliter. The staff noted some cloudiness in the urine the day prior to admission. Urine was sent for urinalysis (UA) showing +Leukocyte esterase (LE), pyuria [40–60 white blood cells (WBCs)], and few bacteria. Reflex urine culture grew >100,000 colony-forming units (CFU)/mL of *E. coli*.

- a. Start ciprofloxacin for E. coli UTI
- b. Start broad-spectrum antibiotics pending infectious work-up
- c. Restart the higher dose of quetiapine and give Haldol to calm the patient down
- d. Hold antibiotics, hydrate and continue a careful workup for metabolic issues and medication side effects.

This case may seem familiar to many of us in medicine. When we see a patient with a positive urine test, there is an automatic need to react to it. As a result, many patients like the one described above end up receiving unnecessary antibiotics. Inappropriate use of antibiotics is associated with an increased risk for complications affecting not only our patients but also healthcare systems.

This article provides a summary of UTIs, catheter-associated UTIs, and asymptomatic bacteriuria. Understanding the difference between these etiologies is crucial for appropriate diagnosis and management.

#### **URINARY TRACT INFECTIONS (UTIS)**

To accurately diagnose a UTI, patients must have symptoms with or without a positive urine culture. Symptoms of UTI include dysuria, urgency, hesitance, frequency, new incontinence. Other constitutional symptoms such as fever, chills, can also be present in the acute setting. An infection of the lower urinary tract can progress in an ascending fashion until reaching the kidneys, causing pyelonephritis. Patients with significant constitutional symptoms and

hemodynamic instability may present with changes in mental status. However, altered mental status, change in urine color, cloudy urine or foul-smelling urine alone should NOT be used to diagnose a UTI.<sup>1</sup>

Urine is often easy to collect and is often "positive." The bladder is not as sterile as we are taught, particularly in the elderly. We have relied on using pyuria for the definition of UTI and although its absence is associated with a 96% negative predictive value (NPV) for bacteriuria, its presence has a low (39%) positive predictive value (PPV) for bacteriuria. About 75–90% of patients with asymptomatic bacteriuria (ASB) do not develop a systemic inflammatory response or other signs or symptoms to suggest infection. Treatment of ASB does not effectively prevent symptomatic UTI.

The clinical significance of asymptomatic bacteriuria in catheterized patients is undefined. A significant proportion, 15-25% of hospitalized patients, may receive indwelling catheters. In many cases, catheters are placed for inappropriate indications and healthcare providers are often unaware that their patients have catheters, leading to prolonged unnecessary use. National data from NHSN acute care hospitals in 2006 showed a range of a pooled mean CAUTI rates of 3.1–7.5 infections per 1000 catheter days. The highest rates of CAUTIs were in burn ICUs followed by inpatient medical wards and neurosurgical wards. The lowest rates are in med-surg ICUs. An estimated 17–69% of CAUTI may be preventable with recommended infection control measures, up to 380,000 infections and 9000 deaths related to CAUTI per year could be prevented.

In addition, catheters may be used disproportionately in long-term care (LTC) facilities. The rate of catheter use for managing chronic voiding dysfunction in LTC residents ranges from 7–10%.<sup>2</sup> In non-catheterized residents, asymptomatic bacteriuria has been estimated at 18% to 57% for women and 19% to 38% for men.

#### **ASYMPTOMATIC BACTERIURIA (ASB)**

Asymptomatic bacteriuria (ASB) is defined as the absence of clinical symptoms suggesting a UTI in the setting of presence of at least one type of bacteria in the urine at a concentration of  $>10^5$  cfu/mL or  $>10^8$  cfu/mL, independent of the presence of white blood cells.

The estimated prevalence of ASB varies based on the age



cohort and patient population. ASB is more prevalent in men and women living in a long-term care facility (up to 50%) followed by elderly persons (>70 years old) living in the community (10.8 to 16% in women and 3.6 to 19% in men).<sup>3</sup> Persons with spinal cord injury requiring intermittent catheterization and sphincterotomy/condom catheter was as high as 69% and 57%, respectively.<sup>4,5</sup> One study has even reported a 100% prevalence of asymptomatic bacteriuria in persons with indwelling catheters.<sup>6</sup>

The risk of developing bacterial colonization in patients with indwelling catheters is directly proportional to the length of time the catheter will remain in place. Bacteriuria due to catheterization is acquired at a rate of 3–10% per day, the majority of whom are asymptomatic. By 30 days, 100% of patients with a catheter will show bacteria in a urine specimen. The duration of catheterization and antibiotic use also influences the incidence of bacteriuria and candiduria.

As we describe in the recommendations below, the vast majority of people with asymptomatic bacteriuria do not need screening or treatment, except for two groups: pregnant women (rates of asymptomatic bacteriuria can be as high as 9.5%)<sup>8</sup> and patients undergoing invasive urological procedures. Urological procedures can be classified as low, intermediate and high risk, depending on mucosal irritation, length of procedure, or potential invasion of colorectal space (class III/contaminated procedures as transrectal prostate bx).

#### IDSA RECOMMENDATIONS FOR MANAGEMENT OF ASB

The Infectious Diseases Society of America (IDSA) guidelines for asymptomatic bacteriuria were released in March 2019. These guidelines highlight the importance of identifying patients in whom screening for ASB is needed in order to prevent UTIs. Most importantly, they provide recommendations regarding which groups should or should not be screened for the presence of bacteria in the urine.

**Table 1** summarizes these recommendations, which include different groups of adults with asymptomatic bacteriuria. In regard to the management of asymptomatic candiduria, which are not included in these guidelines, IDSA guidelines for the management of candidiasis, 9 recommends removal of predisposing factors (ie indwelling catheter), when feasible. No antifungal treatment is recommended unless patient is at risk for disseminated infection (neutropenic patients or patients undergoing urologic invasive procedure).

Compared to 2005 guidelines, current guidelines highlight the importance of recognizing non-focal symptoms that historically have been attributed to a UTI. Many patients, especially the elderly, are at higher risk for delirium, changes in mental status, and falls. Similarly, these people are at higher risk for having bacteriuria. This association has led to many overdiagnosis of UTIs, thus overutilization of antibiotics and higher likelihood for patients to develop complications.

Table 1.

Group	Recommendation		
	Screening	Treatment	
Healthy, premenopausal, non-pregnant women	NO screen	NO	
Pregnant women	YES, screen with urine culture (UCX)	YES	
Older person (men or women) functionally impared or living in long-term care facilities	NO screen	NO	
Older person (men or women) functionally or cognitively impaired and non- localizing symptoms for UTI	NO screen >Look for other causes of delirium	NO	
Diabetic patients	NO screen	NO	
Patients who have received a kidney transplant (>1 month prior)	NO screen	NO	
Patients s/p non-renal solid organ transplant	NO screen	NO	
Patients with high-risk neutropenia [absolute neutrophil count (ANC) <100 cells/mm3, ≥7 days' duration following chemotherapy]	Recommendation deferred	Recommendation deferred	
Patients with spinal cord injury (SCI) leading to impaired voiding	NO screen	NO	
Patients with a short-term (<30 days) indwelling urethral catheter	NO screen	NO	
Patients undergoing elective non-urologic surgeries	NO screen	NO	
Patients undergoing endoscopic urinary tract procedures/manipulation (Prior to transurethral resection of the prostate (TURP) or any other urologic procedure with a risk of mucosal bleeding)	YES, screen with UCX	YES Short course (1-2 doses) of targeted antimicrobial therapy 30-60 min prior to procedure	
Patients planning to undergo surgery for an artificial urinary sphincter or penile prosthesis implantation	NO screen	NO	



Outcomes or concerns include but are not limited to adverse drug reactions (ADRs), drug-to-drug interactions, polypharmacy, increased risk for antimicrobial resistance, and other (sometimes lethal) complications such as *Clostridioides difficile* infection.

With increasingly complex patients having multiple comorbidities and polypharmacy, it may be difficult to tell whether patients are symptomatic for UTI. Previous studies have tried to tease out antibiotic appropriateness. One study showed that 54% (224/414) of patients treated on an acute medical ward with antimicrobials showed that UTI was the most common diagnosis (N=49). Of those who were treated for a UTI, 32.6% had no symptoms suggestive of a UTI.10 Catheterized patients were looked at in another study at a VA hospital. More than 50% of these patients were considered to have bacteriuria but 32% of these received inappropriate treatment.11 Another observational study found that the average length of inappropriate treatment for ASB was around 6.6 days, resulting in two cases of C. difficile infection and one case of QT prolongation.12 Treating patients who do not need to be treated could result in colonization with increasingly resistant urinary bacteria, untoward patient adverse events or hospital-acquired infections.

#### PHARMACOLOGICAL MANAGEMENT OF UTIS

When a patient does have urinary symptoms or a medical presentation consistent with a UTI, goal-directed therapy is aimed at evaluating and relieving urinary stasis or obstruction, removing unnecessary devices (i.e. indwelling catheters) and choosing antibiotic therapy to treat typical urinary pathogens. Urinary bacteria are most often coliform gram-negative organisms in the community at large. E coli causes 70–95% of both upper and lower UTIs. Other organisms to consider are S saprophyticus (younger women), Proteus species (spp), Klebsiella spp, Enterococcus faecalis (older men), and other enterobacteriaceae. For purposes of a concise overview, we will focus on treatment of community-acquired bacterial pathogens.

Current first-line recommendations for the treatment of acute uncomplicated cystitis includes nitrofurantoin monohydrate/macrocrystals 100 mg BID for 5 days or trimethoprim-sulfamethoxazole (TMP/SMX) 160/800 mg BID for 3 days. TMP/SMX use is restricted to facilities with local uropathogen resistance rates less than 20%. <sup>13</sup> Fosfomycin, typically dosed as a one-time 3 g sachet, is a novel antibiotic that can be considered for treatment of uncomplicated cystitis. It boasts limited collateral damage and low reported resistance due to its unique mechanism of action. Use of fosfomycin should be restricted to patients with allergies to first-line antimicrobial agents or infections with multi-drug resistant organisms. <sup>14</sup> Complicated cystitis that extends beyond the bladder should raise concerns for pyelonephritis. In these patients, duration of therapy can be extended to 10 or 14

days. The preferred antibiotic should have high bioavailability and great penetration. In these scenarios, fluoroquinolones are frequently preferred by many providers due to their extensive spectrum of activity, its excellent bioavailability (near 100%), and high penetration into the prostate.

Commonly used agents have risks for adverse drug reactions (ADRs) and/or drug interactions. Elderly patients who are most likely to receive treatment, are particularly at higher risk to develop antibiotic associated ADRs. <sup>15</sup> This risk is most likely due to decreased clearance of the drug (reduced renal or hepatic metabolism), drug interactions from polypharmacy, and increased pharmacodynamic sensitivity. <sup>16</sup>

Fluoroquinolones can prolong the QT interval, especially in patients receiving other QT-prolonging medications such as antipsychotics or antifungals. More concerning is the extensive list of black box warnings associated with this drug class. These warnings include hypoglycemia, tendonitis and tendon rupture, peripheral neuropathy, CNS effects, and potential myasthenia gravis exacerbations. In late 2018 the FDA warned for increased risk of life-threatening aortic aneurysms or dissections, especially in the elderly and patients with hypertension or vessel abnormalities. Prescribers should be aware of the association between fluoroquinolone use and risks for adverse outcomes. Thus, careful evaluation of patients, their comorbidities, and review of active medications is highly recommended prior to initiating treatment with fluoroquinolones.

Alternative agents to fluoroquinolones are not without associated ADRs and drug interactions. TMP/SMX can cause dermatological reactions (including life-threatening Stevens Johnson Syndrome), acute kidney injury, and hyper-kalemia; the latter two being most common in the elderly or when compounded with potassium sparing diuretics, ACE inhibitors, and other nephrotoxic agents. TMP/SMX also influences INR levels in patients on warfarin therapy by increasing the levels of warfarin, thus, increasing the risk of bleeding. Frequent INR monitoring along with a reduction of warfarin dosing is recommended in these patients.

Nitrofurantoin is contraindicated in patients with impaired renal functions. Previously, the creatinine clearance cut-off for use of nitrofurantoin was below 60 mL/min. In 2015, the American Geriatric Society decreased the threshold of creatinine clearance cut-off to less than 30 mL/min. <sup>18</sup> Risks associated with nitrofurantoin use include pulmonary and hepatic toxicity, hemolytic uremia, and peripheral neuropathy.

Beyond ADRs and potential side effects associated with antimicrobial use, inappropriate prescribing of these agents potentiates antibiotic resistance. Common uropathogens such as *E. coli* and *K. pneumonia* have been associated with the development of extended spectrum beta lactamase (ESBL) and even Carbapenemase-producing conferring resistance to the most commonly used "broad-spectrum



antibiotics." Increased exposure to these antibiotics is also associated with secondary opportunistic infections such as Clostridioides difficile (C. difficile) and yeast infections. The potential of ADRs, antibiotic resistance, and secondary infections associated with antibiotic use should reinforce judicious prescribing practices when considering antibiotics for a patient presenting with a low suspicion for UTI.

#### **OTHER INTERVENTIONS** TO IMPROVE OUTCOMES

#### Two-Step Urine Culture Ordering<sup>19</sup>

Alongside careful clinical judgement, one large academic medical center implemented a "two-step process" to justify treatment of UTI. Researchers utilized a specialized container to hold urine samples at room temperature for up to 48 hours at the time of presentation to the ED. Urine was not sent for culture until a validated diagnostic screen was completed by the ED physician with a subsequent order for culture.

Following implementation of this protocol, there was a decrease in the percentage of weekly ED visits associated with a processed urine cultures (UC) (5.97% vs 4.68%, p<0.001), a decrease in the percentage of monthly ED visits requiring callback for positive UC (1.84% to 1.12%, p<0.001), and a decrease in antimicrobial prescriptions for urinary indication among admitted patients (20.6% to 10.9%, p<0.01). The researchers reported a false omission rate of 1.35% (95% CI 0.7% to 2.2%), yet no identified cases of untreated urinary tract infection (UTI), or significant change in repeat ED visits or ED length of stay. Placing urinary specimens on hold (up to 48 hours) for further testing with urinary cultures may be a potential intervention to consider in medical centers to reduce the overuse of antimicrobials in the setting of ASB. The applicability of this intervention should be individualized as operational processes may differ at each medical center.

#### ANTIBIOTIC STEWARDSHIP AND EDUCATION

Data supporting the effectiveness of hospital antibiotic stewardship programs have been long-standing and voluminous. In 2017, the Joint Commission established inpatient AMS programs to be an accreditation standard for hospitals and expanded this standard to the outpatient arena in 2019.

Most of the studies on limiting treatment of asymptomatic bacteriuria have included participants from the community and healthy women. The excluded populations from many of these early studies are hospitalized or institutionalized patients, patients with chronic urinary tract conditions or stents, transplant patients, and spinal cord patients. Ironically these are the patients who need our attention and expertise. Education, combined with audit and feedback, can change clinician behavior. It is possible to incorporate interventions to guide providers toward thoughtful process and corrective action rather than reflex prescribing.<sup>20</sup> AMS programs led by physicians, pharmacists and nurses are able to offer educational guidelines, alternatives for prescribing (low likelihood cases), case-based learning for small group feedback, and evidenced-based lectures which can modify clinician practice.

#### **HOSPITAL REIMBURSEMENT** AND QUALITY STANDARDS

Antimicrobial stewardship goes hand in hand with infection control. Hospitals have an incentive to approach bacteriuria cautiously, testing only when needed, using antibiotics only when warranted, and removing unnecessary genitourinary catheters. In 2008 there was a significant policy change by which Medicare ceased reimbursement for hospital-acquired infections (HAIs), such as catheter-associated urinary tract infections (CAUTI). In 2015, C. difficile colitis was included in this HAI group. Treating HAIs proves to be more expensive than preventing them. As a result of monetary penalization, hospitals have implemented quality improvement initiations aimed at improving outcomes and reducing infection rates.

#### **GOING BACK TO OUR CASE**

In this 85-year-old gentleman, we may want to closely monitor clinical status, hydrate, assess for any metabolic abnormalities, and carefully evaluate what antipsychotics should be used (if any at all) in this elderly man with dementia. If he has urinary retention, this could be relieved and worked up, but if he has no systemic or localized signs of infection, his urine should not be tested or treated (unless he was going for cystoscopy with biopsy in the near future). Alternatively, you could consider a 2-step urine testing while continuing to monitor clinical status off antibiotics.

#### **DISCUSSION AND CONCLUSION**

Asymptomatic bacteriuria is defined as bacteria in the urine without symptoms referable to the urinary tract. Prevalence ranges from 1-5% of normal healthy women to 40-50% of those in long-term care facility. Diagnostic uncertainty in the institutionalized elderly leads to inappropriate antimicrobial use. The majority of patients with ASB require no treatment except pre-operative state for invasive urological procedure and in pregnancy.

Delirium or falls, especially in the elderly, should have a wide net cast for etiology of "mental status change." Mental status changes alone without symptoms referable to the urinary tract or systemic symptoms of infection does not accurately translate into UTI. In these instances, NO urine cultures or empiric antimicrobials for UTI are encouraged.

Antibiotics should be used judiciously for the treatment of UTIs. Targeted therapy is recommended when a causative organism has been identified.



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# Disseminating Education and Treatment for Children and Adolescents with Eating Disorders Across Levels of Care

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#### **ABSTRACT**

**BACKGROUND:** Eating disorders (EDs) are psychiatric illnesses with high rates of morbidity and mortality. Healthcare providers often receive inadequate training in evidence-based ED assessment and treatment.

**DESIGN:** Project CORE (Creating Opportunities for Rhode Island Eating Disorders Professionals) was developed to disseminate ED training/education and treatment approaches to the healthcare workforce. An interdisciplinary research team partners with pediatric healthcare professionals/trainees and supports them to better understand how to diagnose, manage, and collaborate across disciplines in the care of patients with EDs.

**METHODS:** Phase I involves a needs assessment of pediatric healthcare professionals' knowledge, attitudes and needs in treating EDs. Phase II involves the development of training/education approaches, and therapeutic interventions for patients with EDs. In Phase III approaches/interventions are further developed and disseminated across RI.

**PRINCIPAL CONCLUSIONS:** Project CORE's goals will address barriers to effective ED treatment in RI and broaden the workforce of interdisciplinary providers trained to recognize and treat patients with EDs across multiple healthcare settings.

**KEYWORDS:** eating disorders, pediatric healthcare providers, needs assessment, training and education, treatment

#### **INTRODUCTION**

Eating disorders (EDs) are serious psychiatric illnesses with deleterious effects on physical and emotional health and correspondingly high rates of morbidity and mortality. EDs often present during adolescence, <sup>1-3</sup> and early detection and intervention are associated with improved rates of remission and long-term maintenance of treatment gains. <sup>4,5</sup> Although community-based primary care medical providers are often the first point of contact for adolescents with EDs, many report knowledge gaps in ED assessment and treatment. <sup>6</sup> Project CORE (Creating Opportunities for Rhode Island

Eating Disorder Professionals), a novel multi-phase research project funded by a partnership between Rhode Island Medicaid and the Executive Office of Health and Human Services, seeks to improve the knowledge and competence of RI pediatric and mental health providers in recognizing, assessing, and treating patients with EDs. Project CORE is based on foundational research indicating that while early identification and management of EDs are critical for a favorable prognosis, these illnesses are often under-recognized in healthcare settings.7 In RI, there is a shortage of healthcare professionals trained in evidence-based treatment for patients with EDs, compelling many patients and families to seek medical and/or psychiatric care out of state or to utilize in-state treatment from providers with minimal ED experience. Project CORE aims to develop training and education opportunities for RI pediatric healthcare providers using a multidisciplinary, team-based approach, improving the scope of intervention services available to RI adolescents with EDs and advancing provider comfort with ED management in primary care and mental health settings.

#### **METHODS**

Project CORE is composed of an interdisciplinary research team representing Rhode Island College, The Miriam Hospital, Rhode Island Hospital, and the University of Rhode Island. The team collaborates with community-based primary care medical and mental health providers to address the shortage of ED services available in RI, inclusive of the Medicaid population, while encouraging healthcare professionals to practice integrated, team-based care. Families of lower socioeconomic status (SES) and/or racial/ethnic minority backgrounds may be disproportionately impacted by issues related to accessibility of evidence-based treatment, 8,9 thus highlighting the importance of expanding services to the Medicaid population. In 2018, the Rhode Island Executive Office of Health and Human Services/Medicaid Partnership awarded co-Principal Investigators Dr. Christina Tortolani and Dr. Andrea Goldschmidt grant support to advance three fundamental goals in the state of Rhode Island: (1) to provide the healthcare workforce, including licensed health professionals such as primary care medical providers and behavioral health interventionists, with knowledge and competence to recognize early ED symptoms; (2) to



learn evidence-based intervention strategies for EDs; and (3) to develop training opportunities for master's-level and pre-doctoral psychology students in evidence-based assessment and treatment of adolescents with EDs.

To achieve the above goals, we first created and designed Project CORE with three interlocking "phases" that will be carried out across multiple healthcare settings. Having completed Phase I, we are currently in Phase II of Project CORE and will describe plans for Phase III.

### Phase I: Needs Assessment, Identification of Community Partners, Program Development (completed) Phase Ia. Community Based Primary Care Setting

Phase 1 (**Table 1**) was designed to gather information from existing licensed health professionals in the community about their knowledge needs and priorities related to screening and intervening with patients with EDs. We developed an Internet-based survey assessing competence and current practices for addressing eating concerns in their patients, with the goal of identifying gaps in the provision of services for patients with EDs. The survey included published surveys on health professionals' knowledge of and attitudes toward EDs,<sup>10</sup> in addition to open- and closed-ended questions specific to providers' practices/organizations. Participants were

**Table 1.** Project CORE, Phase 1: Needs Assessment, identification of community partners, program development

Goals	Activity			
Phase I				
Develop training and education activities	Develop needs assessment, collect and analyze data (medical providers)			
for clinicians, and therapeutic interventions for Rhode Island eating	Identify community partners (medical providers, community mental health)			
disorder patients to be implemented in Phase II	Coordinate eating disorders training workshops (community mental health)			
	Develop protocol for parent-focused group Family-Based Treatment series (medical providers)			
	Conduct focus groups, and pre- and post- training clinician assessment (community mental health)			
	Develop materials for eating disorder courses (curriculum development)			
	Develop Eating Disorders Collaborative (curriculum development)			
Develop a training pipeline for advanced	Identify eating disorders rotations for advanced graduate students (hospital)			
graduate students	Develop practicum goals, expectations, and supervision requirements (medical providers, community mental health, hospital)			
	Identify supervisors (community mental health, hospital)			

solicited from five community-based pediatric settings in RI that commonly serve Medicaid populations. We achieved approximately 50% response rates from our needs assessment, which was designed to inform the content of subsequent in-services and program development (e.g., monthly consultation services, ongoing multi-family support groups) during Phase II.

### Phase Ib. Community Based Mental Health Setting

We partnered with a community-based mental health agency to implement family-based treatment (FBT) and enhanced cognitive behavioral therapy (CBT-E) within established enhanced outpatient service/home-based and outpatient teams. Both FBT and CBT-E are manualized treatments for EDs that have a strong evidence base. 11-14 FBT is a highly structured behavioral intervention in which caregivers are charged with the primary task of re-feeding their child and normalizing their eating behaviors and weight status;11 enhanced CBT-E is a short-term, individual treatment focused on normalizing eating behaviors and modifying underlying cognitions that contribute to the maintenance of eating disorder behaviors (e.g., over-importance of shape and weight in one's self-evaluation). 12 We conducted focus groups designed to assess providers' current practices and barriers to implementation of effective ED treatment. We further provided two workshops conducted by experts in EDs that focused on FBT and CBT-E for adolescents. Additionally, we collaborated with training site personnel to expand training opportunities in RI.

### Phase Ic. Hospital Setting

Several clinical rotations within Hasbro Children's Hospital were identified for master's-level and pre-doctoral practicum students to provide direct exposure to evidence-based treatment models for EDs. The rotations will provide current and future mental health professionals with invaluable training in ED management models of care across multiple levels (ED Outpatient Medical Clinic, Medical Inpatient Unit, and Partial Hospital Program) within an integrated, teambased system.

### Phase Id. Curriculum development

We have developed syllabi for two courses, "Foundations of Eating Disorder Assessment and Treatment," and "Advanced Treatment of Eating Disorders," which will have interdisciplinary content to expose mental healthcare providers to a broad spectrum of training backgrounds (counseling, social work, medical, nursing, psychiatry, and nutrition).

# Phase II: Education and Implementation (ongoing) Phase IIa. Primary Medical Care Setting

(**Table 2**) Monthly in-services are being established to provide healthcare professionals (e.g., medical doctors, nurses, nurse practitioners, physician's assistants, primary



**Table 2.** Project CORE, Phase II: Education and implementation (ongoing)

Phase II		
Pilot training and education activities for clinicians	Provide monthly in-services involving didactics and case consultation (medical providers)	
	Collect program outcome data from clinicians (medical providers, mental health)	
	Offer first two eating disorder courses (curriculum development)	
Pilot training and education activities for advanced graduate studies	Advanced graduate students complete rotations with weekly supervision (medical providers, hospital)	
Implement therapeutic interventions for Rhode Island eating disorder	Implement parent-focused group family- based treatment (FBT) series (medical providers)	
patients	Begin accepting treatment referrals and providing weekly supervision (community mental health)	
	Collect treatment outcome data from families (mental health)	
	Recruit "champions" (medical providers, community mental health)	

care-based social workers, etc.) with increased knowledge in the recognition, assessment, and team-based management of adolescent EDs. Based on data collected during the needs-assessment in Phase I, these in-services will include didactics and case discussions through a combination of in-person meetings, live-streamed webinars, and videotaping to accommodate clinicians in busy primary care clinics. We have identified expert consultants from a range of disciplines who will provide training in ED diagnosis and management (e.g., clinical assessment tools, treating medical comorbidities, streamlining state-wide referral processes) to support primary medical providers in engaging patients in care for EDs. Behavioral health practicum students will rotate through participating primary care locations as "behavioral health specialists" who will offer group-based FBT to families and patients with EDs, and collaborate with primary care providers to model FBT-based interventions in vivo during office visits.

### Phase IIb. Community Mental Health Setting

Therapists at the partner community-based mental health agency will begin accepting referrals for adolescents with EDs. Referred patients will be offered either home-based or outpatient FBT or CBT-E, depending on symptom profile, severity level, and appropriateness for treatment. Therapists will receive weekly group supervision from Drs. Tortolani and Goldschmidt. Building upon positive feedback and high rates of attendance to our FBT and CBT-E workshops, we will conduct additional training workshops focused on other

evidence-based ED treatment models for community-based mental health clinicians (e.g., interpersonal psychotherapy).

Focus groups will be conducted with providers at three-month intervals during this phase to assess their experiences of delivering evidence-based ED treatments to complex patients in the home-based settings. We will collect quantitative data from mental health providers on knowledge, efficacy, and adherence around diagnosis and delivery of evidence-based treatments for EDs, and from participating families, on eating-related outcomes and satisfaction with treatment. Qualitative interviews with select families before, during, and after completion of treatment will be conducted. Qualitative data gathered will be used to tailor the treatments for families presenting with unique demographic characteristics, life stressors, and other factors that could impact the course and outcome of treatment.

### Phase IIc. Hospital Setting

Practicum students' internship hours include hospital rotations shadowing senior interdisciplinary clinicians in their management of ED patients, attending rounds, and receiving individual and group supervision.

### Phase IId. Curriculum Development

Clinicians at the University of Rhode Island, the Rhode Island chapter of the International Association for Eating Disorder Professionals, Brown Medical School, and other local stakeholders, will form the state's first Eating Disorders Collaborative, which has developed a 15-credit ED certification program for health providers and graduate students. By bringing together local experts from diverse academic and professional environments, we hope that this collaborative will attract professionals and trainees from multiple healthcare disciplines (e.g., mental health, nutrition, nursing) and settings. Once we have established the collaborative and its multidisciplinary faculty, ED courses will be taught at Rhode Island College's campus.

# Phase III: Further Refinement and Dissemination (anticipated)

Phase III (Table 3) consists of further development and refinement of training, education, and therapeutic interventions for patients with EDs in the RI healthcare workforce. This includes a follow-up needs assessment with partner primary medical clinics and resulting modifications to the training approach; identification of providers ("champions") in the primary care, community mental health, and hospital-based settings who will commit to training and educating future generations of ED clinicians to achieve long-term sustainability; finalization of the curriculum development for ED certification; evaluation of ED outcomes among patients and families receiving evidence-based treatment through Project CORE; and state-wide dissemination of training and education activities.



Table 3. Project CORE, Phase III: Further refinement and dissemination

Phase III			
Refine training, education, and therapeutic interventions	Conduct follow-up needs assessment and analyze data (medical providers)		
	Revise format/content of monthly in-services based on clinician feedback (medical providers)		
	Evaluate therapist knowledge, competence, and practices (community mental health)		
	Refine therapeutic interventions based on family feedback (community mental health)		
	Disseminate program to larger Rhode Island community (medical providers, community mental health)		
Improve long-term sustainability of training and education opportunities	Recruit, observe, and supervise "champions" (medical providers, community mental health, hospital)		
	Offer third eating disorders course (curriculum development)		
	Finalize curriculum for eating disorders certification (curriculum development)		

### CONCLUSION

Project CORE addresses the shortage of ED medical and mental healthcare services available to adolescents and their families in RI. The implementation of Project CORE and its outcomes have the potential to broadly impact the scope and quality of care for patients with EDs and their families in RI. The network of ED providers formed by Project CORE will not only help train and retain interdisciplinary healthcare workers in RI who treat patients with EDs, but will also facilitate the early detection of EDs and expand the availability of services. This may reduce the need for costly and intensive hospital-based treatments which may be disruptive to daily life at school and home. Although the current reach of this project is local, this protocol and its findings could potentially impact dissemination and implementation of evidence-based practices for EDs in other geographic locations.

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# Proposed Healthcare Initiatives to Mitigate Opioid Risk and Advance Safety of Pain Management

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**KEYWORDS:** Opioid, abuse-deterrent, overutilization, naloxone, pharmacist, prescriber

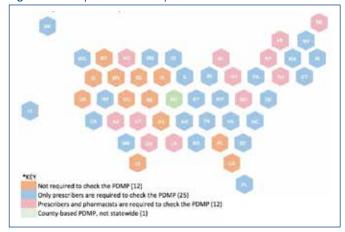
### INTRODUCTION

Between 1999 and 2017 more than 400,000 people died due to an opioid-related death from both prescription and illicit use. Opioid overdose can occur as a result of accidental misuse of a legitimate prescription or as a result of intentional drug abuse, and it is among the most preventable public health threats facing the United States. Numerous initiatives and strategies have been proposed and implemented to help with the growing opioid issue. This report aims to provide insight into programs and products available in the United States which address mitigation strategies to promote safe and appropriate opioid prescribing.

# PRESCRIPTION DRUG MONITORING PROGRAM (PDMP)

The prescription drug monitoring program (PDMP) is an electronic database used to track controlled substance prescriptions in each state. This database logs controlled drug prescription information including location, prescriber, and payment source. PDMP content, access, and utilization varies from state to state; however, they share the common goal of tracking the use of potentially abused medications and utilizing the data to implement positive change. Prescribers and pharmacists access the PDMP to obtain information about a patient's past medication history for controlled substances. The information included in a PDMP report allows for assessment of risks when issuing a new prescription, and also alerts the healthcare professional to recent prescription opioid use. This information may potentially serve as a deciding factor regarding opioid issuance, dosage, and duration of therapy. In Rhode Island, prescribers must check the PDMP prior to prescribing a controlled substance to a patient for the first time and if the patient remains on therapy it is recommended to check the PDMP every 3 months. For pharmacists in Rhode Island, it is recommended that they check the PDMP before dispensing a controlled prescription to a patient for the first time and every 3 months thereafter, if the patient remains on long-term therapy. For both prescribers and pharmacists in Rhode Island it is also suggested to check the PDMP before prescribing or dispensing a benzodiazepine or central nervous system-sedating medication.<sup>2</sup> All 50 states currently utilize a PDMP system. (**Figure 1**).

Figure 1. State Specific PDMP Requirements<sup>3</sup>

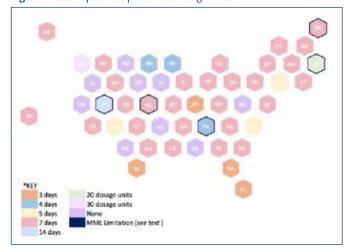


### INITIAL OPIOID PRESCRIBING LIMITS BY STATE

States have begun restricting the total daily amount (mg) of opioid prescribed and quantities dispensed by pharmacies. Furthermore, more stringent restrictions have been placed when the opioid is prescribed for the first time, defined as the initial fill. The designation of 'initial fill' is determined by review of the PDMP records, and is typically defined by absence of a prescription for an opioid medication within a specified amount of time (i.e. preceding 30 or 60 days). Limits range from a specific day supply to certain dosage units based on morphine milligram equivalents (MMEs), with the most common being a 7-day limit on initial fill of an opioid (Figure 2). Currently there are four states with a 3-day supply limit, three states with a 4-day supply limit, three states with a 5-day supply limit, 29 states with a 7-day supply limit, one state with a 14-day supply limit and nine states with no limit. Washington state law limits initial opioid prescriptions to no more than 30 dosage units and Oregon does not have a law that limits initial opioid prescriptions; however, the health authority recommends no more than a 7-day trial. Maine has implemented a 100 MME/day limit,



Figure 2. State Specific Opioid Prescribing Limits<sup>4</sup>



Tennessee has implemented a 60 MME/day limit, Nevada has implemented a 90 MME/day limit, and Nebraska has implemented a 50 MME/day limit. Rhode Island defines their initial opioid prescribing limit as 30 MME per day for a maximum of 20 dosage units.<sup>5</sup>

Although the states themselves are implementing limits on initial opioid fills, third-party payers may also limit initial fills to a pre-determined day supply. For example, Anthem, Inc. was among the first to limit patient's first fill of opioids to a 7-day supply. Similarly, in 2018 CVS Caremark also placed a 7-day supply limit on opioid prescriptions for an acute condition in which patients had not received opioids in the past 90 days.

### **NALOXONE ACCESSIBILITY**

Pharmacologically, naloxone is a mu-opioid antagonist that displaces opioids that are bound at mu-opioid receptor sites. The physiological response to using this drug is immediate reversal of respiratory suppression and it is available in injectable and intranasal formulations. Almost all states have enacted Good Samaritan laws which protect citizens from legal implications when administering naloxone to a person in need. Good Samaritan laws are vital to protect both parties to ensure that patients receive access to care without concern for prosecution. The majority of states allow pharmacists to dispense naloxone to patients without a prescription if deemed fit, with the exception of Connecticut, Idaho, Nebraska, and Oregon.<sup>8</sup>

Eight states require co-prescribing of naloxone when a patient is prescribed an opioid, and under specific conditions. For example, Arizona requires co-prescribing if the prescription issued exceeds 90 MME per day. In California, prescribers must offer a prescription for naloxone if the prescription dosage for the patient is 90 or more MMEs per day,

if the patient is concurrently using an opioid and benzodiazepine, or if the patient is deemed as having an increased risk for overdose, which could include history of substance use disorder or returning to a high dose of medication when the patient is no longer as tolerant to that dose. 10 New Mexico requires a naloxone prescription with any opioid prescription exceeding a 5 day supply.11 In Rhode Island, co-prescribing is mandatory under 3 different scenarios: the patient is taking 50 or more MME per day, the patient is taking opioid and benzodiazepine concurrently, or when prescribing an opioid to a patient who has a history of opioid use disorder.<sup>5</sup> Vermont requires co-prescribing for patients on 90 or more MME per day, or if the patient is using an opioid and benzodiazepine concurrently.12 Virginia requires co-prescribing if the patient's daily MME exceeds 120, or if the patient is using an opioid and benzodiazepine concurrently. 13 In Washington, prescribers must provide naloxone prescription when patient exceeds 50 MME per day. 14 Florida requires naloxone to be co-prescribed when a patient is being treated with a Schedule II controlled substance for a traumatic injury with an Injury Severity Score of 9 or greater. 15

### **ABUSE-DETERRENT FORMULATIONS**

In 2017, more than 190 million opioid prescriptions were dispensed from outpatient retail pharmacies; however of those, only about 3.8 million were written for an abuse-deterrent formulation (ADF).16 There are various mechanisms utilized to develop abuse-deterrent formulations: physical/chemical barriers, agonist/antagonist combinations, aversion, delivery systems and new molecular entities or prodrugs.<sup>1,17</sup> Through the addition of agents such as gel or microspheres, physical/chemical barriers make it significantly more difficult to abuse a drug through injecting, chewing, crushing, or snorting. There are currently seven abuse-deterrent opioids commercially available that utilize a physical/ chemical barrier formulation: Oxycontin®, Xtampza® ER, Morphabond™ ER, Hysingla™ ER, Arymo™ ER, ZoHydro® ER and RoxyBond<sup>TM</sup> IR (**Table 1**). In a review of 15 pre-market studies, several ADFs showed improvement in endpoint scores when compared to their non-ADF counterparts. For example, Hysingla™ ER was shown to have a noticeable effect on the primary endpoints, drug-liking and likelihood of taking the drug again, when compared to hydrocodone, and the same can be said for Embeda® when compared to morphine sulfate.18

The mechanism of action for drugs that use an agonist/ antagonist formulation is such that the antagonist component of the drug is released only when the drug is tampered with, or taken via a non-oral route. The antagonist portion would displace the opioid agonist from the receptor, precipitating a withdrawal syndrome.



Table 1.

DRUG	FORMULATION	MECHANISM OF ACTION
Oxycontin®	Physical/chemical barrier	Oxycodone formulated using high- molecular- weight polyethylene oxide as the tablets outer coating to resist crushing. Also becomes a viscous gel to resist use via needles/IV.
Xtampza® ER	Physical/chemical barrier	Oxycodone formulated with DETERx® technology, which incorporates oxycodone into fatty acid and wax microspheres resulting in slow diffusion- controlled drug release.
Morphabond™ ER	Physical/chemical barrier	Morphine sulfate formulated with SentryBond™ technology, which retains extended- release properties if manipulated and becomes viscous to resist use via needles/IV.
Hysingla™ ER	Physical/chemical barrier	Hydrocodone bitartrate formulated with Resistec <sup>TM</sup> , which hardens the tablet to increase difficulty of manipulation and becomes viscous when dissolved.
Arymo™ ER	Physical/chemical barrier	Morphine sulfate formulated using a polymer matrix to make it more difficult to cut, crush, grind or break.
Embeda®	Agonist/antagonist combo	Morphine sulfate + naltrexone HCl. The naltrexone is stored at core of the pill in a sequestering membrane and is only released when capsule is manipulated.
ZoHydro® ER	Physical/chemical barrier	A combination of 20% IR and 80% ER hydrocodone bitartrate formulated with BeadTek®, which forms a viscous gel if capsule is crushed or dissolved.
Roxybond™ IR*	Physical/chemical barrier	Oxycodone formulated with SentryBond™ technology to make release lower and slower when manipulated. Also becomes viscous to resist use via needles/IV.

<sup>\*</sup>First and only immediate release abuse-deterrent formulation

## MEDICARE PART D OPIOID OVERUTILIZATION POLICY

In 2019, Medicare implemented the Part D Opioid Overutilization Policy. This policy is primarily focused on encouraging interdisciplinary collaboration and coordination in order to improve universal patient care across providers. <sup>19</sup> The primary areas of the policy include pharmacy alliance data, drug management programs, day supply limits, and opioid care coordination alerts.

Pharmacy alliance data has three focal points: prevention of new cases of opioid overutilization, treatment of existing patients, and proper utilization of data. To prevent new cases, inappropriate prescribing must be identified, non-opioid treatments must be promoted, and opioid use disorder diagnoses must be enhanced. When treating existing pain patients, it has been recommended to offer a broad range of treatment options and to continuously implement updated practices. This data enables healthcare professionals to recognize opioid prescribing patterns and to monitor the effectiveness and safety of treatment.<sup>20</sup>

Drug management programs (DMP) proactively aid the healthcare professional in identifying patients who may be at risk for misuse, abuse or potential overdose when prescribed an opioid or benzodiazepine. Once identified, the Part D plan will contact the prescriber to determine medical necessity or potential risk for abuse. Medicare also determines if the patient may benefit from the implementation of a DMP to manage their prescriptions. Three major DMPs are patient-specific, point-of-sale claim edit (POS), pharmacy limitation, and prescriber limitation. Once a patient's insurance performs a case review and gives approval, POS can be used to limit the amount of frequently abused drugs that can be dispensed to a patient. Pharmacy limitation requires

a patient to fill all prescriptions for frequently abused drugs at a specific pharmacy of their choosing. Prescriber limitation requires a patient to obtain all medications of potential misuse from a sole provider, and contractual agreements between prescriber and patient may be utilized.

The most recent Medicare policy also enacted an initial 7-day supply limit for opioid- naïve patients and an opioid care coordination alert. The goal of a limiting day supply limit is to reduce long-term opioid use in patients who initially receive a prescription for treatment of acute pain. The opioid care coordination alert is intended to advise the pharmacist to consult the prescriber when a patient's overall daily oral morphine equivalence exceeds 90 mg, to confirm appropriate use.

### FDA OPIOID ACTION PLAN

The FDA has recognized opioid abuse, dependence, and overdose as a public health crisis in the United States. In response, the Administration unveiled their Opioid Action Plan in 2016, which sought to establish advisory committees, propose appropriate regulatory activities and policy development, with goals of improving the science of pain management and fostering communication and collaboration across fields.

The FDA aimed to establish an expert advisory committee that would review new opioid drug applications that are not manufactured as abuse-deterrent formulations. In addition, a pediatric advisory committee is intended to review and generate recommendations on labeling of opioids in regards to the pediatric population.<sup>21</sup>

Extended-release and long-acting opioid formulations are currently subject to a Risk Evaluation and Mitigation



Strategy (REMS) program. The FDA expanded REMS programs to include not only product-specific materials, but also educational programs in pain management. Training and education has been expanded to include more members of the health care team, rather than solely prescribers. Immediate release opioid labeling will expand to include any additional warning and safety information that is available, with the overall goal of this initiative being to promote safer prescribing practices of immediate release opioid formulations.

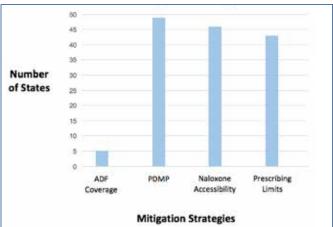
The development of ADFs has become a major area of interest in the pharmaceutical industry. The issue still persists, however, that the currently available ADFs are brand name products. This may pose a significant financial burden which limits their access for use. In response to the need to increase accessibility of opioid ADFs, the FDA has issued a high priority draft guidance to encourage the approval of generics.

The availability of naloxone varies from state to state. As outlined in the FDA's 2018 Strategic Policy roadmap, overthe-counter (OTC) naloxone is being reviewed to allow for expanded access.<sup>22</sup> States such as Rhode Island have approved the purchase of OTC naloxone and data from 2016-2018 correlated the reduction in opioid-overdose related deaths to the increased availability of naloxone during this time.<sup>23</sup>

### **CURRENT USE OF STRATEGIES**

The use of the PDMP remains the most common mitigation strategy in the US. Naloxone accessibility has also improved; however, further efforts are needed to increase access across all 50 states. Most states are implementing prescribing limits on initial opioid prescription fill quantities. Lastly, affordability and further access to ADF products is needed to aid in combating the opioid crisis. (Figure 3) While no single approach will be sufficient to mitigate opioid risks while balancing appropriate use, a strategy that considers multiple possible approaches is needed to improve the health care landscape regarding opioid safety.





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### Disclosure

The authors report no conflicts of interest in this work. Jayne Pawasauskas is a consultant for Heron Therapeutics and Mallinckrodt Pharmaceuticals.

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## Prescription Opioid Prescribing in Western Europe and the United States

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### **ABSTRACT**

Pain is universal, yet the prevalence of overdose and treatment of pain varies significantly between the United States (US) and Western Europe. Overdose deaths are seven times more common in the US compared to Western Europe. Cultural perceptions of pain, perception and treatment of opioid use disorder, pharmaceutical advertising, and rates and regulation of prescribing of opioids represent examples of factors that may be related to such differences between the US and Western Europe. As Rhode Island continues to battle the devastating and well-documented national opioid overdose epidemic, we should consider how cultural, regulatory differences, and economic factors may influence pain and its treatment.

**KEYWORDS:** opioids, pain, Western Europe

### INTRODUCTION

In 2016, drug overdoses killed 63,632 Americans, and nearly two thirds (41,998) were due to a prescription or illicit opioid. Locally, Rhode Island has an opioid death rate of 26.7 per 100,000, and it affects every city and town in the state. In the same year, approximately 9,000 lives were lost to drug overdoses in Turkey, Norway, and the 28 European Union (EU) member states combined, despite having a considerably larger population than the US. In other words, for every overdose death in the 30 aforementioned nations, there are seven in the US. Opioid use impacts all ages, sexes, ethnic and socioeconomic backgrounds, and especially those in rural settings. A variety of factors contribute to this disparity, including the over prescription of legal painkillers.

Chronic pain occurs at a similar rate in the US as in Western Europe. The current US opioid epidemic has a multifactorial etiology, including the desire to treat, resulting in increased advertising by pharmaceutical companies encouraging treatment of chronic pain with opioids. In addition, there was a widespread belief that opioids were safe for chronic pain. A culmination of less stringent regulation and management practices contributed to increased primary opioid exposure, lack of treatment resources, stigmatization of addiction, aggressive drug advertising, and an inherent cultural ethos which tended to overtreat pain with opioids.

### **ADVERTISING**

The US experienced aggressive marketing of prescription opioids, claiming these medications had little risk for addiction.<sup>5</sup> In addition, perceptions of pain treatment with opioids were facilitated, in part, through the conceptualization of pain as the fifth vital sign by organizations such as the American Pain Society, the Veteran's Health Administration, and the Joint Commission.8 Additionally, the emphasis on using patient satisfaction surveys, which often used pain relief as a proxy to indicate high quality care by the Institute of Medicine, further perpetuated a cultural shift.6 Concurrent with these events, sales of extended release oxycodone grew to exceed \$2 billion annually between 1996 and 2014,9 and the number of prescriptions for opioids in some states increased by 500% or more within the first five years of oxycodone being on the market. 10 Such a phenomenon is further instigated by a cultural perception, in the US, that pain must be completely eliminated despite some pain experts emphasizing that the goal of pain relief in perioperative conditions should be a 30% to 55% improvement of perceived pain.<sup>11</sup>

The US and Western Europe have very different approaches to pharmaceutical advertising. A British research group found that doctors who have frequent contact with drug representatives are more likely to prescribe new medications that are clinically unnecessary and avoid advice-only consultations.<sup>12</sup> These doctor-drug representative interactions are frequent in the US, although this has declined significantly in the past decade and is no longer allowed in many healthcare organizations. Alternatively, in Western Europe, it is generally prohibited to grant, offer, or promise benefits to physicians or to the organizations that employ them, and violators are actively reprimanded. For example, the medical associations in Germany penalized 163 physicians who accepted benefits from the pharmaceutical company Ratiopharm, in 2013. Such models of regulation result in lower rates of heavy marketing of prescription drugs.9

A 1978 agreement between the Swedish Medical Association and drug representatives requires representatives to both notify the appropriate level of government and have the meeting approved in order to talk to physicians. As a result of these requirements, many practices also adopt their own policies, such as requiring representatives to speak with all the physicians at once and getting prior approval from the department head. Furthermore, departments limit the



number of representative visits in a year, mandate representatives to inform the department head what they are going to say in the allotted time, restrict meetings to 15 minutes, and bar free gifts.<sup>13</sup>

Pharmaceutical companies in the US capitalize from a culture of consumerism, which typically promotes quick solutions for complex conditions, including pain. Companies increase patient demand for opioids using direct-to-consumer advertising, which is only legal in the US and New Zealand. Additionally, US patients may sue their practitioner for negligence if they feel their pain was inadequately controlled, which may further encourage appeasement of pain through use of opioids. Advertisement and doctor-drug representative interactions partially contributed to discrepancies between opioid prescribing practices in the US compared to Western Europe. While the medical community has made significant efforts to diverge from these influences in the US, it is important to note the long-term impacts such influences have had on the treatment of pain in the US.

### **REGULATORY OVERSIGHT**

Healthcare systems and healthcare regulatory oversight differ significantly between the US and Western Europe. The vertically integrated healthcare systems in much of Europe provide centralization to more efficiently limit overprescribing while advocating safe and effective prescribing practices<sup>16</sup> through guidelines and regulations that are effective on a national and cultural level.

The US lacks sufficient regulatory authority as is evident by The Ensuring Patient Access and Effective Drug Enforce-

ment Act. The Act, which was unanimously passed in both the House and the Senate in April 2016, restricts the Drug Enforcement Agency's (DEA) ability to investigate and discipline opioid distributors suspected of illegal behavior and prevents the DEA from being able to restrict large, suspicious narcotics shipments. After the law was passed, it was found to be partially responsible for fueling the black market and worsening the epidemic in West Virginia,5 where two pharmacies that served a population of only 3,000 ordered 20.8 million opioid pills.17

The US uses prescription opioids at a rate of 2.5 to 4 times higher than Western Europe<sup>9</sup> while also using more potent

opioids. As of 2014, the most frequently prescribed schedule II and schedule III drugs in the US were oxycodone with acetaminophen and hydrocodone with acetaminophen, and in the United Kingdom, it was morphine and codeine with acetaminophen. These differences also apply to the rest of Western Europe, emphasizing that the use of oxycodone is one of the main differences between the US and Western Europe. Between 2010 and 2012 the US prescribed 7,991 defined daily doses (DDD) per million, per day of oxycodone, accounting for 15.4% of opioid prescriptions. During the same time period in Western Europe, 654 DDD per million, per day, on average, were prescribed and accounted for roughly 5.3% of opioid prescriptions. The schedule of the schedule of the schedule of the use of th

These prescribing differences are part of what allowed the proportion of insured persons on oxycodone in Germany to only increase from 0.04% to 0.44% from 2000 to 2010.15 A more illustrative comparison shows an alarming increase, in the US, of prescribed oxycodone from about 60 mg/capita to 175 mg/capita during versus a minor increase in Western Europe from around 0 mg/capita to 10mg/capita [Figure 1]. In the US, dentists prescribed opioids at a rate of 37 times greater than dentists in the UK in 2016. In the US, 22.3% of all prescriptions written by dentists were for opioids compared to 0.6% of prescriptions written by UK dentists. Such differences are attributable to national guidelines and formularies and different perceptions of pain management in the US. In post-operative situations, US dentists prescribed a large array of strong opioids that have a high potential risk for abuse. In the UK, national guidelines recommend nonsteroidal anti-inflammatory drugs (NSAIDs) over opioids, and a national formulary restricts dentists' prescribing option to

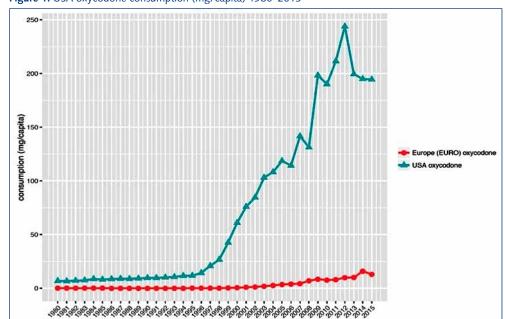


Figure 1. USA oxycodone consumption (mg/capita) 1980–2015

Sources: International Narcotics Control Board; World Health Organization population data



dihydrocodeine, a less potent opioid. <sup>18</sup> National guidelines are only one contributor to the differences in opioid use between the two nations, but their efficacy in reducing the number of strong opioid prescriptions is worth further investigation.

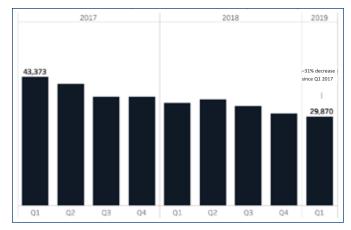
National formularies are often used in Western Europe to regulate what types of opioids may be prescribed under any set of circumstances. For example, in France, morphine is the only opioid authorized for non-cancer pain use. <sup>19</sup> Additionally, evidence shows that low-prescribing general practitioners in the UK were more likely to come from practices that had practice formularies. <sup>20</sup> Therefore, it is no surprise that the US, which approves 15% to 18% more drugs than many European countries, has higher prescribing rates, has the most flexibility for individuals' choice of drug benefits, and has no centralized formulary. This is concerning because in many countries, the national formulary list is the most important tool to regulating the prescription process besides implementation of fixed budgets and mandatory adherence to clinical practice guidelines.

One strategy in Western Europe to limit the prescribing of opioids is the use of special prescription forms which are a different color than normal prescriptions.<sup>19</sup> Within Italy, Portugal, and Spain doctors must travel to specific regional offices to access these prescription forms. Additionally, private Portuguese and Danish physicians are required to pay for these forms themselves.<sup>19,22</sup> These policies are intended to prevent inappropriate use of opioid prescriptions. Additionally, some countries have restrictions on the length of validity for these forms. In Germany, forms are only valid for one week, and in most Western European nations, forms are valid for about three weeks.<sup>19</sup> In contrast, prescriptions for schedule III and schedule III drugs in the US are valid for 90 days.

### CONCLUSIONS

Prescribing of opioids is different between the US and Western Europe for a variety of reasons, including cultural differences, economic drivers, and regulatory levers. In recent years, changes that have occurred in Rhode Island reflect more of this European influence. The state has seen a reduction in the number of new opioid prescriptions [Figure 2] for a variety of reasons, including more judicious prescribing, regulations regarding prescribing, and decreased patient demand. Our previous study has shown that State regulations can have significant impacts on, and change, prescribing behavior toward safer standards.2 Therefore, evidence-based regulations preventing the over-prescription of opioids may be an effective primary prevention strategy regarding the opioid epidemic in Rhode Island, specifically decreasing the number of new patients exposed to prescription opioids. Furthermore, our review of Western European practices indicates that the US has insufficient national regulatory oversight of opioid prescribing and drug marketing. In addition to the efforts to increase access to medication

**Figure 2.** Number of people receiving new opioid prescriptions (2017–2019)



Source: Rhode Island Department of Health; Department of Behavioral Healthcare, Developmental Disabilities, and Hospitals; and Brown University. Opioid Prescribing Data. Prevent Overdose Rhode Island. Accessed August 20, 2019. https://preventoverdoseri.org/prescribing-data/.

assisted treatment, insurance reform, and increasing the numbers of qualified prescribers, Rhode Island may want to consider establishing pharmaceutical marketing restrictions, potentially using laws and regulations that have effectively addressed tobacco advertising as replicable models.

Rhode Island Department of Health; Department of Behavioral Healthcare, Developmental Disabilities, and Hospitals; and Brown University. *Opioid Prescribing Data*. Prevent Overdose Rhode Island. Accessed August 20, 2019. https://preventoverdoseri.org/prescribing-data/.

On the provider level, we expect physicians to continue to build upon their practices to mitigate opioid exposure through increased pain management education and increased utilization of non-opioid medications and treatments. Abrupt cessation of opioids for existing chronic pain patients should be avoided, and instead, the goal should be to optimize the patient's function with the lowest possible doses.

As a nation, we may need to reconsider advertising pharmaceuticals of all types and the effect this has on patients driving demand. Substantial reforms have already occurred regarding the interactions between pharmaceutical representatives and prescribers, yet one wonders if there is a need for more oversight.

Healthcare entities may want to consider the implementation of practice formulary lists for acute and chronic pain medicine and of pharmacist oversight. Both of these strategies have been shown to help reduce prescribing rates.

Although there is not one solution to the opioid epidemic in Rhode Island, or the US, there are concepts we can borrow from Western European medicinal culture that may allow us to mitigate addiction and tragedy while optimizing health and wellness. Our cultural perceptions of pain, painkillers, drug marketing, and treatment for opioid use disorder are examples of these differences that could be explored.



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## Sleep Deprivation among Rhode Island High School Students

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Sleep is an essential component in adolescent health, well-being and development.<sup>1</sup> As children develop and mature into teenage years, biological changes alter circadian rhythms and the urge to fall asleep decreases, resulting in later sleep onsets.<sup>2</sup> Practical factors of teenage sleep deprivation include school responsibilities, family commitments, after-school jobs, extracurricular activities, and social media. Lack of sleep has been associated with an increased risk for injuries, hypertension, obesity and depression.<sup>3,4</sup> Guidelines from the American Academy of Sleep Medicine (AASM) recommend teens ages 13–18 years receive 8–10 hours of sleep per night.<sup>5</sup> The purpose of this study was to measure the burden of inadequate sleep among RI high school students and to assess demographic, environmental and health factors associated with lack of sleep.

### **METHODS**

Data are from the 2019 Rhode Island High School Youth Risk Behavior Survey (YRBS). The YRBS is a biennial national survey of public high school students conducted by the Rhode Island Department of Health (RIDOH) and the Centers for Disease Control and Prevention (CDC) and is designed to monitor health risk behaviors related to major causes of morbidity and mortality among youth. YRBS employs a two-stage, cluster sample design to produce a representative sample of students.6 Schools within the state are selected with probability proportional to school enrollment size and then classes from a required subject or period within each school are randomly selected. A weight is applied to each record to adjust for student non-response and to obtain population estimates and a distribution of students by grade, sex, and race/ethnicity that approximates that of the state public high school population. Based on standards set by the CDC, a school and student response rate of 60% is considered sufficient to obtain a valid weighted sample. In 2019 the combined response rate of schools and students in Rhode Island was 66%. In total there were 1,613 high school students from 21 public high schools who completed the YRBS. This sample is representative of 44,052 students statewide. More information on the RI YRBS is available on the RIDOH website.7

Sleep was assessed with the question, "On an average school night, how many hours of sleep do you get?" Based on guidelines from the AASM, 8 or more hours of sleep per

night was defined as recommended sleep. We measured the prevalence of inadequate sleep and then conducted chi square analyses to examine differences in sleep based on demographic characteristics. Demographic characteristics of interest were sex, grade in school, race/ethnicity, sexual identity, socioeconomic status (SES), and disability. Hunger was used as proxy for SES and was assessed with the question, "During the past 30 days, how often did you go hungry because there was not enough food in your home: Never, Rarely, Sometimes, Most of the time, Always". Those answering sometimes/most of the time/always were defined as going hungry. Disability was defined as any physical or learning disability, emotional problem, or long-term health problem.

Next, we conducted chi square analyses to examine the association between health and environmental factors and sleep. For purposes of these analyses we further classified amount of sleep into three categories: 5 hours or less, 6-7 hours, or 8 or more hours. Social environmental measures of interest included hunger and feeling safe in one's neighborhood ("How often do you feel safe and secure in your neighborhood? - Never, Rarely, Sometimes, Most of the time, or Always" - where those who answered sometimes/ rarely/never were defined as feeling unsafe). We also examined obesity, feelings of sadness/hopelessness ("During the past 12 months, did you ever feel so sad or hopeless almost every day for two weeks or more in a row that you stopped doing some usual activities?"), daily exercise, use of electronics, and current use of alcohol, e-vapor products, and marijuana. Body Mass Index (BMI) was calculated based on self-reported height and weight and obesity was defined as a BMI≥ 95th percentile for age and sex. Current substance use was defined as use within the last 30 days.

To further assess the association between modifiable or treatable risk factors and inadequate sleep we conducted two multivariable logistic regression analyses. The first model was a multivariable binary logistic regression model estimating the odds of receiving less than recommended (<8 hours) sleep. The second model was a multivariable multinomial logistic regression using the three-level variable for sleep to separately estimate the odds of receiving 5 hours of sleep or less, and 6–7 hours of sleep compared to the recommended 8 hours of sleep. Both models included modifiable and/or potentially treatable risk factors of e-cigarette use,



alcohol use, marijuana use, use of electronics, lack of exercise, obesity, and sadness/hopelessness and adjusted for the demographic characteristics sex, grade, race/ethnicity, sexual identity, disability, hunger, and neighborhood safety.

### **RESULTS**

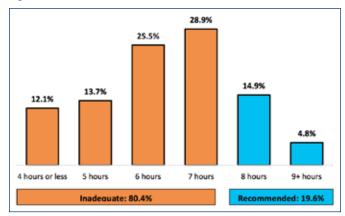
Overall, about 4 in 5 Rhode Island high school students (80.4%) receive less than the recommended amount of sleep on the average school night (**Figure 1**). Specifically, more than 1 in 4 students (26%) get 5 hours or less of sleep (**Figure 1**). Analysis of demographic factors found that prevalence of inadequate sleep increased each academic year, ranging from 73% among 9th graders to 86% among 12th graders (**Table 1**). Additionally, students who reported they at least sometimes went hungry in the past month; identified as lesbian, gay, or bisexual; and reported having a disability, were more likely

than comparison groups to receive less than the recommended amount of sleep.

Analysis of health and environmental measures found many measures were significantly associated with sleep (Table 2). These differences were particularly apparent when examining prevalence of getting 5 hours of sleep or less. More than 40% of students who felt unsafe in their neighborhood reported getting 5 or less hours of sleep, compared to 22% of those who felt safe. Those who exercise daily were more likely than those who did not exercise to report 8 or more hours of sleep (29.1% vs. 17.1%) and less likely to report receiving 5 hours of sleep or less (18.7% vs 27.9%). Hunger, obesity, sadness/hopelessness, electronics use, and use of alcohol, marijuana and e-cigarettes were also significantly associated with sleep.

Multivariable analysis estimating odds of receiving less than 8 hours of sleep found that those who did not exercise (Adjusted Odds Ratio [AOR] = 2.20; 95% Confidence Interval [CI] = 1.38-3.51] were more likely to receive inadequate sleep while those who were obese were less likely to receive inadequate sleep (Table 3). None of the other modifiable factors assessed were significant. Results of the multinomial model indicated feeling sad/hopeless, e-cigarette use, use of electronics 5+hr/day and lack of daily exercise, were significantly associated with odds of receiving 5 or fewer hours of sleep (compared to 8 hours of sleep). Only lack of daily exercise was significantly associated with odds of receiving 6-7 hours of sleep (compared to 8 hours of sleep).

**Figure 1.** Average number of hours of sleep on a school night, among RI high school students



Source: 2019 RI YRBS

**Table 1.** Hours of sleep per school night among Rhode Island high school students, by selected demographics, 2019

	Inadequate Sleep (<8 hours)			Recommended Sleep (8+ hours)		
	Unweighted n	Weighted n	Weighted %	Unweighted n	Weighted n	Weighted %
Sex						
Female	610	17,038	81.3%	161	3,907	18.7%
Male	594	16,962	79.1%	177	4,482	20.9%
Grade*						
9th	395	8,132	72.6%	150	3,072	27.4%
10th	311	8,532	80.4%	81	2,074	19.6%
11th	272	8,552	83.2%	66	1,721	16.8%
12th	221	8,670	85.9%	36	1,419	14.1%
Race/Ethnicit	у					
White, Non-Hispanic	603	19,745	80.5%	160	4,782	19.5%
Black, Non-Hispanic	85	2,744	80.2%	24	680^	19.8%
Other, Non-Hispanic	118	2,599	85.5%	28	440	14.4%
Hispanic	382	8,389	80.2%	113	2,075	19.8%
Sexual Identity	*					
Straight	996	28,352	80.0%	281	7,098	20.0%
Gay/Lesbian/ Bisexual	150	4,219	87.9%	22	580^	12.1%
Went hungry*						
Yes	235	6,026	84.0%	47	1,146	16.0%
No	955	27,574	80.0%	285	7,085	20.4%
Disability*						
Yes	274	7,917	84.6%	50	1,438	15.4%
No	925	26,012	79.1%	284	6,888	20.9%
Source: 2019 RI YI	RRS					

Source: 2019 RI YRBS

^Relative standard error>20%, estimate may be unstable, interpret with caution

\*p<.05



**Table 2.** Health factors and the average hours of sleep per school night among RI high school students

	5 hours or less	6-7 hours	8+ hours	
	N =11,506 25.9%	N = 23,362 54.5%	N = 8,389 19.6%	
Body Mass Index*				
Obese	28.1%	47.6%	24.3%	
Not obese	24.7%	56.5%	18.8%	
Went Hungry*				
Yes	38.8%	45.2%	16.0%	
No	23.0%	56.6%	20.4%	
Feel Safe in Neighborhood	*			
Always/Most of the time	22.4%	57.9%	19.8%	
Never/Rarely/Sometimes	41.6%	40.0%	18.4%	
Felt Sad/Hopeless*				
Yes	38.4%	47.2%	14.3%	
No	19.8%	58.0%	22.2%	
Exercise 1 Hr Everyday*				
Yes	18.7%	52.2%	29.1%	
No	27.9%	55.0%	17.1%	
Use Electronics 5+ Hr/Day	*			
Yes	32.9%	48.3%	18.7%	
No	24.1%	55.9%	20.0%	
Alcohol Use*				
Yes	33.6%	52.7%	13.7%	
No	22.6%	55.4%	21.9%	
E-Vapor Product Use*				
Yes	30.4%	56.5%	13.1%	
No	23.3%	54.4%	22.4%	
Marijuana Use*				
Yes	33.2%	54.2%	12.6%	
No	23.1%	55.0%	21.9%	

Source: 2019 RI YRBS

\*p<.05

### **DISCUSSION**

Results of the 2019 YRBS indicate that insufficient sleep is common among RI public high school students. The distribution of sleep duration on an average school night resembled a bell-shaped curve, with four out of five high school students reporting less than 8 hours of sleep, and 1 in 4 students (25.9%) with sleep duration of 5 hours or less. High school seniors, and students who identify as lesbian, gay, or bisexual were more likely to report inadequate sleep.

Several health-risk behaviors were associated with inadequate sleep. Students who felt unsafe in their neighborhood, and experienced food insecurity, two measures of social environment, had higher rates of inadequate sleep. The finding

**Table 3.** Adjusted odds of inadequate sleep by modifiable/treatable risk factors among RI high school students

	Model 1 Model 2		del 2
	<8 hours of sleep Adjusted odds ratio (AOR)	5 hours of sleep or less AOR	6–7 hours of sleep AOR
Sadness/	1.32	1.94	1.12
hopelessness	[0.77–2.27]	[1.07–3.53]	[0.63–1.97]
E-cigarette use	1.47	1.59	1.44
	[0.96–2.26]	[1.10–2.30]	[0.87–2.38]
Alcohol use	1.16	1.23	1.12 [
	[0.66–2.03]	[0.60–2.53]	0.64–1.96]
Marijuana use	1.11	1.17	1.09
	[0.68–1.82]	[0.75–1.84]	[0.62–1.92]
Electronics use	1.19	1.67	1.02
(5+ hr/day)	[0.80–1.78]	[1.23–2.26]	[0.63–1.64]
Do not exercise	2.20	2.06	2.25
1hr/day	[1.38–3.51]	[1.16–3.67]	[1.43–3.52]
Obesity	0.66	0.70	0.65
	[0.45–0.98]	[0.45–1.08]	[0.41–1.03]

Source: 2019 RI YRBS

Note: Statistically significant results are bolded Model 1: multivariable logistic regression model

Model 2: multivariable multinomial logistic regression model

Both models adjusted for demographic characteristics of sex, race/ethnicity, grade, disability, sexual orientation, hunger, and neighborhood safety.

that obese students were less likely to have inadequate sleep conflicts with findings from some other studies. Reasons for this discrepancy are unclear, but the relationship between sleep and obesity is complex and influenced by a variety of factors. Rhode Island students who engaged in daily exercise had the highest prevalence of sufficient sleep compared to the other health factors examined. These findings on daily physical activity are consistent with a prior analysis. 9

Sleep is an important determinant of health and well-being. Studies have found inadequate sleep is associated with problems with weight, decision-making, academic and job performance and numerous other health issues.  $^{10-12}$  In 2017, nationwide approximately 25% of high school students got at least eight hours of sleep per night. Healthy People 2020 identified sleep as a focus area with a specific objective to increase the proportion of students in grades 9–12 who get sufficient sleep to  $\geq$ 33.2%.

Solutions to addressing insufficient sleep among teens can be complex. At the systematic level, the American Academy of Pediatrics recommends local advocacy for delayed school start times. <sup>13</sup> On the clinician level, pediatricians can play an important role by discussing the consequences of inadequate sleep with parents. Pediatricians can also counsel families on healthy sleep practices and provide recommendations, such as establishing a consistent sleep schedule, setting a media curfew to limit use of electronic devices,



and encouraging physical activity.<sup>14</sup> Furthermore, medical facilities can help make sleep hygiene information more readily available in their office and/or website.

There were several limitations to this study. First, data are self-reported and prone to recall bias. Secondly, data are cross-sectional and therefore we cannot ascertain causality or the temporality of the relationship between sleep and other variables. Furthermore, we only measured the self-reported average hours of sleep per school night; a more comprehensive study of sleep would involve measures of sleep quality. Despite these limitations, this study provides important information on the burden of inadequate sleep among Rhode Island high school students.

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# Rhode Island Monthly Vital Statistics Report Provisional Occurrence Data from the Division of Vital Records

	REPORTING PERIOD		
VITAL EVENTS	SEPTEMBER 2019 12 MONTHS ENDING WITH SEPTEME		IG WITH SEPTEMBER 2019
VITAL EVENTS	Number	Number	Rates
Live Births	1010	11,160	10.5*
Deaths	840	10,562	10.0*
Infant Deaths	2	63	5.6#
Neonatal Deaths	1	47	4.2#
Marriages	960	6,558	6.2*
Divorces	257	2,930	2.8*

<sup>\*</sup> Rates per 1,000 estimated population

<sup>#</sup> Rates per 1,000 live births

	REPORTING PERIOD			
Underlying Course of Dooth Cotogon	MARCH 2020	12 MC	NTHS ENDING WI	TH MARCH 2020
Underlying Cause of Death Category	Number (a)	Number (a)	Rates (b)	YPLL (c)
Diseases of the Heart	242	2,545	240.2	3,129.5
Malignant Neoplasms	187	2,259	213.2	4,667.5
Cerebrovascular Disease	52	468	44.2	424.5
Injuries (Accident/Suicide/Homicide)	79	940	88.7	12,914.0
COPD	44	487	46.0	395.0

<sup>(</sup>a) Cause of death statistics were derived from the underlying cause of death reported by physicians on death certificates.

NOTE: Totals represent vital events, which occurred in Rhode Island for the reporting periods listed above.

Monthly provisional totals should be analyzed with caution because the numbers may be small and subject to seasonal variation.



<sup>(</sup>b) Rates per 100,000 estimated population of 1,056,298 (www.census.gov)

<sup>(</sup>c) Years of Potential Life Lost (YPLL).

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A complete print journal reference includes the following:

- Last name of author, first initial followed by comma and then additional authors
- Title of article (or book and chapter title)
- Abbreviated name of journal (Abbreviate and italicize names of journals according to the listing in the PubMed Journals database.)
- Year of publication; followed by Volume number and Issue number:
- Page numbers

**Example:** Gould P, Krahn A. Complications associated with implantable cardioverter defibrillator replacement in response to device advisories. *JAMA*. 2006; 295(16):1907–1911.

### Accompanying material

**Tables** should be provided as Microsoft Word documents; jpegs, pdfs, or image files should not be submitted for Tables.

### **Figures**

**A. Photos and images:** High-resolution photos or images should be provided separately in their original file format, and not embedded within the manuscript. High-resolution images (300 ppi) are required.

**B. Graphs or charts:** Provide as separate Microsoft Word files. Consider that figures may be published at 3 or 4 inches in width. Fonts and details must be legible when reduced to that size. Recommended for clarity are sans serif fonts, such as Calibri or Arial.

**C. Legends:** Figure legends should be provided individually as Microsoft Word documents.

### **Biographical** information

Biographical information for each contributing author must accompany the manuscript submission. This information must include name, title, and institutional/academic affiliation for each author.

### Correspondence

Include the name, title, and current position of the principal author with mailing address, telephone, fax, and e-mail address.

### Acknowledgment

Include research or project support/funding by individuals, organizations or institutions in an acknowledgment.

### Disclaimer

A disclaimer is used to separate the views of the authors from those of employers, funding agencies, organizations, or others.

**Example:** The views expressed herein are those of the authors and do not necessarily reflect the views of the US Army or the Department of Defense.

### Financial disclosure

All authors will need to complete a RIMJ financial disclosure form, available here. It can be filled out electronically or copied and scanned.

### **Electronic submission**

All submissions are to be by electronic copy. Microsoft Word documents are preferred.

Corresponding authors should e-mail copies of the complete article and accompanying material to the Co-Editors-in-Chief and Managing Editor.

### Letters to the Editor

Letters to the Editor are considered for publication (subject to editing and peer review) provided they do not contain material that has been submitted or published elsewhere.

The Rhode Island Medical Journal prefers to publish letters that objectively comment on or critically assess previously published articles, offer scholarly opinion or commentary on journal content, or include important announcements or other information relevant to the Journal's readers. Letters in reference to a Journal article should be approximately 500 words or less (excluding references), and must be received within four weeks after publication of the article.

A letter can have no more than five references and one figure or table. A letter can be signed by no more than six authors. The corresponding author should include address, phone number, email. Financial associations or other possible conflicts of interest must be disclosed.

### Images in Clinical Medicine

Original, high-resolution images which have not been published elsewhere will be considered for publication. Submit 2–4 images.

Submissions should include:

- Brief title: 8 words or less
- Content: Relevant clinical information, findings, clinical course, and response to treatment if initiated. Limit: 400 to 600 words
- **Legends**: All labeled structures in the image should be described and explained in the legend. Any identifying information should be removed from the image.
- Author information: Names, professional degree, academic/hospital affiliations, address, email and telephone number.



# It's a new day. The Rhode Island Medical Society now endorses Coverys. Coverys, the leading medical liability insurer in Rhode Island, has joined forces with RIMS to target new levels of patient safety and physician security while maintaining competitive rates. Call to learn how our alliance means a bright new day for your practice. 401-331-3207



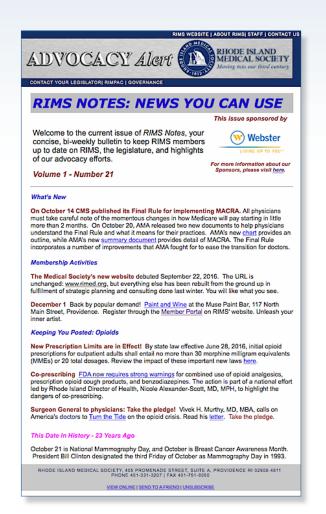
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# Are you e-reading

# RIMS NOTES: News You Can Use



The biweekly e-newsletter exclusively for RIMS members.

Clear.

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Respectful of your time.

## **RIMS NOTES**

is published electronically on alternate Fridays.

Contact Sarah if you've missed an issue, sstevens@rimed.org.



## Working for You: RIMS advocacy activities



US Senator Jack Reed and **Catherine Cummings, MD**, RIMS President-elect, who attended the AMA National Advocacy Conference on February 11 in Washington, DC. Dr. Cummings and RIMS staff met with Rhode Island's Congressional Delegation.

### February 3, Monday

RIMS Council: Christine Brousseau, MD, MPH, President. Guest: Marie Ganim, PhD, Health Insurance Commissioner

### February 4, Tuesday

RIMS Physician Health Committee: Herbert Rakatansky, MD, Chair Legislative Hearings

### February 5, Wednesday

Special House Commission on Step Therapy Protocols

Legislative hearings

Meeting with American College of Physicians regarding legislation

### February 6, Thursday

Legislative hearings

Senate President Ruggerio fundraiser

### February 10, Monday

RI Foundation *Health in Rhode Island:* A Long Term Vision roll-out

Meeting with RI Physical Therapists' Association on legislation

House Majority Leader Shekarchi fundraiser: Michael Migliori, MD, RIMS Public Laws Chair

Meeting with Department of Health Chief Operating Officer and RI American College of Emergency Physicians (RI ACEP), Otis Warren, MD, President, regarding Emergency Medical Services (EMS) regulations

### February 11, Tuesday

AMA National Advocacy Conference, Washington, DC: Catherine Cummings, MD, President-Elect and staff; meetings with Congressional delegation

### February 12, Wednesday

Board of Medical Licensure and Discipline

RI Long Term Care Coordination Council regarding Alzheimer's CME requirement

Governor's Overdose Intervention and Prevention Task Force: Sarah Fessler, MD, Past President

Special House Commission on Step Therapy Protocols: Alyn Adrain, MD, Past President and Nichole St. George, Rhode Island/Massachusetts Medical Group Managers Association presenting

Legislative hearings

### February 13, Thursday

Annual health care lobbyists meeting, RI Medical Society

Senate Majority Leader McCaffrey fundraiser

### February 14, Friday

RIMS Notes production

Meeting with CTC-RI and Blue Cross Blue Shield of RI regarding RIMS' Prior Authorization project

### February 18, Tuesday

OHIC Health Insurance Advisory Committee

### February 19, Wednesday

Primary Care Physicians Advisory Committee

### February 20, Thursday

Conference call with RI Psychological Association, RI Physical Therapists' Association, and American Nurses Association-RI regarding Governor's Budget Article 20, Interstate Licensing Compacts



**Alyn Adrain, MD**, a RIMS Past President, provided testimony to the RI House of Representatives Special Commission on Step Therapy Protocols on February 12.

### February 25, Tuesday

Senate Commission to Study Insurer Payment Impact on Health Care Legislative hearings

### February 26, Wednesday

Department of Health Diabetes Prevention Program Support Network

Special House Commission on Step Therapy Protocols

Legislative hearings

Senator Melissa Murray fundraiser Representative Grace Diaz fundraiser

### February 27, Thursday

Legislative hearings

### February 28, Friday

RIMS Notes production





## RIMS CORPORATE AFFILIATES

The Rhode Island Medical Society continues to drive forward into the future with the implementation of various new programs.

As such, RIMS is expanded its Affinity Program to allow for more of our colleagues in healthcare and related business to work with our membership. RIMS thanks these participants for their support of our membership.

Contact Marc Bialek for more information: 401-331-3207 or mbialek@rimed.org



www.nhpri.org

Neighborhood Health Plan of Rhode Island is a non-profit HMO founded in 1993 in partnership with Rhode Island's Community Health Centers. Serving over 185,000 members, Neighborhood has doubled in membership, revenue and staff since November 2013. In January 2014, Neighborhood extended its service, benefits and value through the HealthSource RI health insurance exchange, serving 49% the RI exchange market. Neighborhood has been rated by National Committee for Quality Assurance (NCQA) as one of the Top 10 Medicaid health plans in America, every year since ratings began twelve years ago.



www.ripcpc.com

RIPCPC is an independent practice association (IPA) of primary care physicians located throughout the state of Rhode Island. The IPA, originally formed in 1994, represent 150 physicians from Family Practice, Internal Medicine and Pediatrics. RIPCPC also has an affiliation with over 200 specialty-care member physicians. Our PCP's act as primary care providers for over 340,000 patients throughout the state of Rhode Island. The IPA was formed to provide a venue for the smaller independent practices to work together with the ultimate goal of improving quality of care for our patients.



# RIMS gratefully acknowledges the practices who participate in our discounted Group Membership Program































### Women's Medicine Collaborative

A program of The Miriam Hospital Lifespan. Delivering health with care.

### RIDOH Announces Second Presumptive Positive COVID-19 Case; Testing a Third Individual

All three individuals from the same European trip; Two Schools in Rhode Island Temporarily Closed

The Rhode Island Department of Health (RIDOH)'s State Health Laboratories have identified a second presumptive positive case of coronavirus disease 2019 (COVID-19), and a separate person has been tested for COVID-19 on Sunday, March 1. The presumptive positive case is a teenager. She is at home with mild symptoms. The adult being tested is in her 30s and is also at home with mild symptoms.

These two individuals went on the same trip to Europe in mid-February as the male in his 40s who RIDOH announced March 1 as Rhode Island's first presumptive positive case of COVID-19. Saint Raphael Academy, which organized the trip to Europe in mid-February, will be closed for the remainder of this week. The adult whose test results are still pending is a staff member at Achievement First Academy in Providence. Achievement First Academy will be closed for two days, pending the results of the staff member's tests. (The result is expected today, and the school is closing for an additional day to do environmental cleaning.)

All 38 of the people who went on this trip will be self-monitoring for symptoms at home for 14 days with public health supervision. They have been instructed to not go to school or work and to remain at home for these 14 days. "All three people went on the same trip to Italy," said Dr. Nicole Alexander-Scott. "This is precisely why we are being so aggressive in identifying contacts, ensuring monitoring, and testing people who are symptomatic."

Outreach to the people who were in direct contact with any of these three individuals is on going. These direct contacts will be self-monitoring for symptoms at home for 14 days with public health supervision. The Centers for Disease Control and Prevention (CDC) is managing contact tracing for people on the return flight that these three individuals took back to the United States.

There have been more than 60 US cases of COVID-19 confirmed. Globally, more than 80,000 cases have been confirmed. CDC reported the first US fatality on February 29th.

RIDOH is coordinating with other State agencies and community organizations to support anyone doing self-quarantining to ensure that people who are remaining at home have the support services they need. This includes support with everyday needs, such as prescriptions and groceries. The organizations that have offered support include agencies throughout the Executive Office of Health and Human Services (EOHHS), the Rhode Island Food Bank, the American Red Cross, and other members of Rhode Island's Voluntary Organizations Active in Disasters (VOAD).

### Testing in RI

In the past few weeks, RIDOH's State Health Laboratories worked to develop the capacity to perform testing for COVID-19 virus. In response to an urgent need, the State Health Laboratories expedited the final steps of implementation to run the test that identified this first case of COVID-19 in Rhode Island this weekend. Previously, all testing for COVID-19 was done at CDC. At this time, each presumptive positive test result must still be confirmed by the CDC Laboratories This might change in the coming days.

RIDOH continues to be notified by the federal government of asymptomatic travelers who are coming to Rhode Island after having been in China in the previous 14 days. These people are doing self-monitoring for symptoms for 14 days and are limiting their movement locally.

### RIDOH Provider Conference Call Scheduled for Tuesday, March 3

RIDOH is scheduling a conference call for interested healthcare providers on Tuesday, March 3, 2020 at 7:30am to discuss the rapidly evolving situation involving COVID-19. RIDOH infectious disease experts will offer an overview of the latest developments at the international, national, and state levels and answer questions from providers.

Call-in information:

Phone: 1-646-876-9923 Meeting ID: 536-369-6581

Due to the expected high level of interest in this call, RIDOH requests that participants in the same building/organization share a phone line to call in, if possible.

### The additional preparedness steps that RIDOH has taken include:

- Establishing an Incident Command System response, which is how RIDOH and other State agencies organize to prepare for (or respond to) an urgent situation that requires extensive coordination. It includes staff from the Rhode Island Emergency Management Agency (RIEMA), the Rhode Island Department of Behavioral Healthcare, Developmental Disabilities, and Hospitals (BHDDH), the Rhode Island Department of Education (RIDE), the Rhode Island Department of Human Services (DHS), the Rhode Island Department of Environmental Management (DEM), the Rhode Island Department of Education (RIDE), and Rhode Island
- Commerce. It also includes staff from RIDOH's State Health Laboratories, Center for Acute Infectious Disease Epidemiology, Center for Emergency Preparedness and Response, and Center for Public Health Communication, among other areas of RIDOH.
- Regularly communicating with RIDOH's Infectious Disease Epidemiology Advisory Committee (IDEAC) to track any clinical and epidemiological developments related to COVID-19. (IDEAC is a group of infectious disease physicians throughout Rhode Island that provides guidance to RIDOH leadership on emerging infectious disease matters.)



- Maintaining a robust system to receive and follow up on illness reports from Rhode Island healthcare providers.
- Regularly sending to local healthcare providers summaries of the national situation, criteria to guide evaluation of patients, and guidance on specimen collection, testing, and reporting.
- Coordinating closely with healthcare facilities and emergency medical services (EMS) providers to ensure their preparedness.
- Communicating regularly to community partners, such as schools, faith leaders, and municipal officials. •

### Provider evaluation chart

The Rhode Island Department of Health's Center for Acute Infectious Disease Epidemiology (CAIDE) is advising healthcare providers to evaluate patients according to the chart below and maintain a high level of suspicion for those with the following clinical features and epidemiologic risk.

CLINICAL FEATURES	AND	EPIDEMIOLOGIC RISK
Fever¹ <b>or</b> signs/symptoms of lower respiratory illness (e.g., cough or shortness of breath)	AND	Any person, including healthcare workers <sup>2</sup> , who has had close contact <sup>3</sup> with a laboratory-confirmed <sup>4</sup> COVID-19 patient within 14 days of symptom onset
Fever¹ <b>and</b> signs/symptoms of lower respiratory illness (e.g., cough or shortness of breath) requiring hospitalization	AND	A history of travel affected geographic areas <sup>5</sup> (see below*) within 14 days of symptom onset
Fever¹ with severe acute lower respiratory illness (e.g., pneumonia, ARDS) requiring hospitalization and without alternative explanatory diagnosis (e.g., influenza) <sup>6</sup>	AND	No source of exposure has been identified

- \* Areas are China, Iran, Italy, Japan, South Korea
- 1. Fever may be subjective or confirmed.
- 2. For healthcare personnel, testing may be considered if there has been exposure to a person with suspected COVID-19 without laboratory confirmation. Because of their often extensive and close contact with vulnerable patients in healthcare settings, even mild signs and symptoms (e.g., sore throat) of COVID-19 should be evaluated among potentially exposed healthcare personnel. Additional information is available in CDC's Interim U.S. Guidance for Risk Assessment and Public Health Management of Healthcare Personnel with Potential Exposure in a Healthcare Setting to Patients with Coronavirus Disease 2019 (COVID-19)
  - $https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html\ [cdc.gov].$
- 3. Close contact is defined as:
  - a) being within approximately 6 feet (2 meters) of a COVID-19 case for a prolonged period; close contact can occur while caring for, living with, visiting, or sharing a healthcare waiting area or room with a COVID-19 case
    - or –
  - b) having direct contact with infectious secretions of a COVID-19 case (e.g., being coughed on)
  - If such contact occurs while not wearing recommended personal protective equipment (PPE) (e.g., gowns, gloves, NIOSH-certified disposable N95 respirator, eye protection), criteria for PUI consideration are met.
  - Additional information is available in CDC's updated Interim Healthcare Infection Prevention and Control Recommendations for Patients with Confirmed COVID-19 or Persons Under Investigation for COVID-19 in Healthcare Settings
  - $https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations. html\ [cdc.gov].$
  - Data to inform the definition of close contact are limited. Considerations when assessing close contact include the duration of exposure (e.g., longer exposure time likely increases exposure risk) and the clinical symptoms of the person with COVID-19 (e.g., coughing likely increases exposure risk, as does exposure to a severely ill patient). Special consideration should be given to healthcare personnel exposed in healthcare settings, as described in CDC's Interim U.S. Guidance for Risk Assessment and Public Health Management of Healthcare Personnel with Potential Exposure in a Healthcare Setting to Patients with COVID-19
  - https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html [cdc.gov])
- 4. Documentation of laboratory-confirmation of COVID-19 may not be possible for travelers or persons caring for COVID-19 patients in other countries.
- 5. Affected areas are defined as geographic regions where sustained community transmission has been identified. Relevant affected areas will be defined as a country with at least a CDC Level 2 Travel Health Notice. Current information is available in CDC's COVID-19 Travel Health Notices https://www.cdc.gov/coronavirus/2019-ncov/travelers [cdc.gov].
- 6. Category includes single or clusters of patients with severe acute lower respiratory illness (e.g., pneumonia, ARDS (acute respiratory distress syndrome) of unknown etiology in which COVID-19 is being considered.



# Lifespan, Brown Medical School send message of support to academic medical center partner Wuhan Union Hospital

PROVIDENCE – Lifespan and the Warren Alpert Medical School of Brown University have actively collaborated with Wuhan Union Hospital on research projects since 2016, with the goal of fostering research and cultural awareness. Leaders of Lifespan and the Warren Alpert Medical School have reached out to pledge support to senior medical faculty colleagues at Union Hospital in Wuhan, Hubei Province, People's Republic of China, who have been working night and day with very limited medical resources to combat Novel Coronavirus (2019-nCoV) since the outbreak began.

"We know we cannot comprehend or even appreciate the challenges and hardship you all must be going through at this time. We want you to know that we treasure our relationship and academic collaboration with you and your great institutions and hospital," reads the letter to Wuhan Union Hospital President Yu Hu, MD, and senior team members and Huazhong University of Science and Technology (HUST). The joint letter is signed by members of the Wuhan – Brown program and Lifespan and Brown senior faculty.

The academic program of Wuhan Union Hospital, HUST's Tongji Medical College, Lifespan, and the Warren Alpert Medical School started in 2016. Over the years faculty visits from Providence to Wuhan and Wuhan to Providence have included lectures, workshops, and presentations at grand

rounds and international conferences, and joint work on research projects, manuscripts, and book chapters. Lifespan came together with HUST and Wuhan Union Hospital in 2018, establishing an exchange program centered around cardiovascular research and medical knowledge in cardiology, echocardiography and cardiovascular surgery. The Warren Alpert Medical School joined the program in 2019, and last June, Brown and Lifespan began hosting the first Wuhan echocardiology research fellow with plans to host another.

"This continues to be a truly inspirational collaboration. Our Wuhan partners are exceptional, and our thoughts and prayers go out to them, their families and community," said PHILIP HAINES, MD, associate director of echocardiography at Rhode Island Hospital, who together with FRANK SELLKE, MD, chief of cardiothoracic surgery at Rhode Island and the Miriam hospitals, founded and directs the program.

The joint initiative evolved from a conversation Dr. Haines had with mentor Tao Wang, MD, PhD, of the University of Pennsylvania, who studied at Tongji Medical College. After arriving in Rhode Island following his fellowship at the University of Pennsylvania, Dr. Haines said he had a vision of expanding the cardiovascular research collaborations of the Warren Alpert Medical School and the Lifespan hospitals and its major teaching affiliates. ❖



# CNE releases fiscal year 2020 First Quarter results

Care New England Health System (CNE) recently announced that in Fiscal Year 2020, first quarter (October-December) the System realized a loss of \$4.5 million from operations versus a budgeted loss of \$3.0 million.

Including non-operating activity (primarily investment gains), the System ended the first quarter with excess of revenue over expenses of \$5.5 million.

The greatest financial challenges facing the System this year are patient volumes at Women & Infants Hospital and Kent Hospital. However, Butler Hospital and the entire behavioral health service line are experiencing substantial increases in demand for services.

"We know we have work to do," said **JAMES E. FANALE, MD**, President and CEO. "We are diligently working with leadership across the System on various process and operations improvement initiatives, implementing action plans, and targeting areas for growth opportunities to help build a healthy financial future. Additionally, we are working hard to provide better, timely access to our programs and services." •

# Care New England purchases new beds for Women & Infants, Kent

PROVIDENCE – Care New England is replacing 421 patient beds with state-of-the-art Hillrom™ beds and surfaces at Kent Hospital and Women & Infants Hospital of Rhode Island. The new bed systems are connected medical devices designed to help deliver therapy and enhance patient safety, supporting Care New England's commitment to transforming the future of healthcare and ensuring the health of the people and communities it serves.

"There is so much more that goes into a hospital bed, than most people realize. A good hospital bed, with state-of-the-art technology, can have a positive effect on the healing and recovery process, and that's what we want for our patients, at our CNE hospitals. Our organization decided to use Hillrom beds, because of the company's reputation of offering a product which provides the highest quality of care and comfort for health care and home settings," said JAMES FANALE, MD, president and CEO, Care New England.

In late February, Women & Infants Hospital received 171 beds. Of those, 148 will be Centrella® Smart+ Beds, which will help advance patient safety and comfort with fall prevention and pressure injury reduction. The Affinity® 4 Birthing Bed will replace 21 birthing beds to deliver safety, comfort and convenience for the mother, baby and caregivers throughout the labor and delivery experience. Two Compella™ Bariatric Beds will enable safe, efficient and dignified transport of patients.

Kent Hospital will be installing 250 new patient beds. Of those, the hospital will receive 225 Centrella Smart+ Beds, 15 Progressa® Bed Systems for the Intensive Care Unit, 6 Compella™ Bariatric Beds and 4 Affinity® 4 Birthing Beds. At both hospitals, the Centrella beds will be connected to the nurse call system for quick response to patient needs, and include the Centrella pro Surface to provide pressure redistribution for optimal patient support and comfort.

All new bed deliveries are expected to be made to each hospital by mid-March. •

### **IMAGES IN CLINICAL MEDICINE**

Original, high-resolution images which have not been published elsewhere will be considered for publication. Submit 2–4 images.

Submissions should include:

Brief title: 8 words or less

**Content:** Relevant clinical information, findings, clinical course, and response to treatment if initiated. Limit: 400 to 600 words

**Legends:** All labeled structures in the image should be described and explained in the legend. Any identifying information should be removed from the image.

**Author information:** Names, professional degree, academic/hospital affiliations, address, email and telephone number.



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### Research shows new drug helps to preserve brain cells for a time after stroke

Rhode Island Hospital major participant in international study

Rhode Island Hospital was a major participant in a just-published international study that found new hope for preserving brain cells after stroke.

After 50 years of research and the testing of over 1,000 drugs, the study found that treating acute ischemic stroke patients with an experimental neuroprotective drug, combined with a surgical procedure to remove the clot, improves outcomes.

The research, published February 20 in *The Lancet*, was based on a clinical trial at 48 leading stroke centers around the world. Rhode Island Hospital enrolled the third highest number of patients in the trial. The trial was spearheaded at Rhode Island Hospital by RYAN A. MCTAGGART, MD, director of neurointerventional radiology at Rhode Island Hospital, and colleagues MAHESH V. JAYARAMAN, MD, and RICHARD HAAS, MD. All three are on the faculty The Warren Alpert Medical School of Brown University.

"Rhode Island Hospital's stroke center has again been a top enrolling site in a landmark clinical trial for large vessel occlusion (LVO) stroke," said McTaggart. "Our stroke center is dedicated to making sure all stroke patients in Rhode Island have early access to the best stroke care available; in many ways our team is defining it."

The double-blinded, randomized trial of the neuroprotective drug nerinetide, developed by NoNO Inc, was led by a team at the Cumming School of Medicine's (CSM) Hotchkiss Brain Institute at the University of Calgary and by Alberta Health Services. In one scenario, nerinetide was given to patients in addition to the clot-busting drug alteplase. In the second scenario, patients who were not suitable for alteplase received only nerinetide. Both groups of patients had concurrent endovascular treatment (EVT) to remove the clot.

"A significant clinical benefit was seen in the group that did not get the clot-busting medication alteplase (tPA). The treatment effect modification by alteplase was confirmed by blood tests. In the patients who received both drugs, the

alteplase negated the benefits of the nerinetide." This is the first study to show neuroprotection in humans is possible," McTaggart said.

He noted that a future trial is now being planned for LVO stroke patients ineligible for alteplase.

Images of patients' brains from the study show the expected size of the damage from the stroke is sizably reduced when nerinetide is administered and EVT is performed among patients not concurrently receiving alteplase.

"Compared to placebo, almost 20 per cent more patients who received nerinetide along with endovascular treatment, but did not receive alteplase, recovered from a devastating stroke – a difference between paralysis and walking out of the hospital," said MICHAEL HILL, MD, a neurologist at Foothills Medical Centre (FMC) and professor in the departments of Clinical Neurosciences and Radiology at the CSM.

Hill says the study provides evidence of a biological pathway that protects brain cells from dying when they are deprived of blood flow. Nerinetide targets the final stage of the brain cell's life by stopping the production of nitric oxide within the cell.

"We really believe this is a new scientific observation," said Hill. "There is evidence nerinetide promotes brain cell survival, offering neuroprotection until we can extract the clot. It opens the door to a new way of treating stroke."

The results in the current study, called the ESCAPE-NA1 Trial, build on the success of the ESCAPE trial, in which the Calgary Stroke Program proved that a clot retrieval procedure known as EVT can dramatically improve patient outcomes after an acute ischemic stroke. During the procedure, a catheter is inserted in the groin and guided through blood vessels into the brain. A tiny metal mesh device is used to grab the clot and pull it out. The current study investigates whether administering nerinetide in addition to clot retrieval improves the patient's ability to recover. ❖



# Coastal Medical, Lifespan sign LOI to pursue affiliation

Coastal Medical and Lifespan have signed a Letter of Intent to pursue an affiliation in which Coastal, a large Rhode Island independent primary care provider, would join Lifespan's comprehensive academic health care system.

Signing the Letter of Intent is the first step in a due diligence process as both parties evaluate and design a new relationship to better integrate primary and specialty care and expand services to patients in communities across Rhode Island. A definitive agreement is expected before the end of the year.

"We are proud that our value-based, coordinated care model is at the forefront of primary care medicine and we seek to bring that value to more Rhode Islanders," said ALAN KUROSE, MD, Coastal President and CEO.

Current conversations about joining together focus on furthering their shared vision of integrated, coordinated patient care that provides patients a holistic care experience across a lifetime.

"Lifespan believes there is great benefit in better unifying health care services in Rhode Island," said TIMOTHY J. BABINEAU, MD, Lifespan President and CEO. "Coastal Medical has set the standard for excellence in primary care nationally and we look forward to bringing that expertise to all of the patients Lifespan serves. There are already relationships and natural synergies between our two organizations, and we share strong values in doing what is best for our patients and communities."

With over 125 primary care physicians and advanced practitioners and more than 500 employees at 20 offices around the state, Coastal has consistently earned high marks for delivering the patient-centered, high quality, high value health care to which Rhode Island and the country aspire.

Coastal Medical is particularly known for its team-based approach to patient care and its focus on improving wellness. With this quality and value focused approach, Coastal has received the National Committee for Quality Assurance's highest rating possible, while simultaneously lowering the overall cost of care delivery. ❖

# University Orthopedics' Dr. Kleinhenz performs breakthrough surgery for treatment of cervical disc degeneration

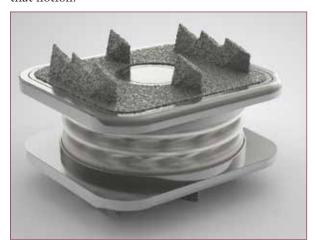
EAST PROVIDENCE — Continuing the tradition of using the latest and best technology to provide the highest quality care possible for its patients, University Orthopedics announced one of its surgeons recently became the first in Rhode Island to perform a cutting-edge surgery to treat patients with cervical disc degeneration.

**DOMINIC THOMAS KLEINHENZ, MD,** recently began implanting the M6-CTM artificial cervical disc into patients suffering from cervical disc degeneration. Recently approved by the U.S. Food and Drug Administration, the M6-C disc was designed as an innovative



option for patients needing artificial disc replacement as an alternative to spinal fusion. Featuring a shock-absorbing nucleus and fiber annulus that work together to mimic the anatomic structure of a natural disc, the M6-C device is the only artificial cervical disc available in the U.S. that enables compression or "shock absorption" at the implanted level. The disc also provides a controlled range of motion when the spine transitions in its combined complex movements.

"There's nothing better than treating a patient who's been suffering from back or neck pain for days, months, years and seeing them, very quickly after surgery, get better and get back to the life that they want to live," Dr. Kleinhenz said. "Patients often come in with the myth that all back and neck surgery is bad. However, using cutting-edge technology like the M6-C – combined with our expertise – helps us dispel that notion."



The M6-CTM artificial cervical disc is manufactured and distributed by Orthofix, a global medical device company focused on musculoskeletal products and therapies.

Dr. Kleinhenz treats patients with neck and back problems. His practice focuses on patients who suffer from disc herniation, degenerative cervical, thoracic, and lumbar disease, spine trauma, and spine deformity. He received his undergraduate degree from the University of Florida, graduating summa cum laude. He graduated from the University of Florida College of Medicine with Honors. He completed an Orthopedic Surgery residency at Brown University and Rhode Island/Miriam Hospitals.

Dr. Kleinhenz completed a Spine Surgery fellowship at Brown University and Rhode Island Hospital. He is a board-eligible orthopedic surgeon with the American Board of Orthopaedic Surgery. •



# Lifespan acquires da Vinci Xi's for Miriam, RIH to expand robotic-assisted, minimally invasive procedures

PROVIDENCE – Lifespan has expanded and enhanced its minimally invasive surgical programs by acquiring two da Vinci Xi's – the latest generation surgical system for performing robotassisted procedures.

In the hands of skilled and experienced surgeons, robotic surgical systems can perform procedures through tiny incisions and contribute to better outcomes for patients, including reduced pain and blood loss, quicker recovery, minimal scarring and fewer complications. The Xi offers additional capabilities that allow for robotassisted surgeries for some of the most complicated cases.

One da Vinci Xi has been delivered to The Miriam Hospital, which was the first hospital in Rhode Island and Southeastern New England to acquire a da Vinci surgical system in 2006 and whose urologic program was ranked in the top 2 percent in the nation by *U.S. News & World Report*. Surgeons with the hospital's Minimally Invasive Urology Institute use a da Vinci robot for an array of routine and complex kidney, bladder and prostate operations. The addition of a second robot at The Miriam will allow the hospital and its surgeons to substantially increase the volume of robot-assisted cases for not only urologic procedures, but also for colorectal cases and general surgery. The Miriam's new robot went into service on January 13.

A second da Vinci Xi was acquired for Rhode Island Hospital and went into service on December 19. The unit, which replaces an older generation da Vinci, is used there for thoracic, gynecologic, pediatric urologic, and general surgery. Like the unit acquired at The Miriam, the one at Rhode Island Hospital includes dual surgeon consoles.

These allow residents and fellows to gain experience in robot-assisted surgery while under the supervision of the attending surgeon performing the procedure. This strengthens the hospitals' ability to cultivate talent and promote progress while enhancing one of the key missions of both institutions, which serve as teaching hospitals for the Warren Alpert Medical School of Brown University.

At both Lifespan hospitals, surgeons are performing robot-assisted procedures that are not offered anywhere else in the region. It's expected that in the near future other procedures will be performed in Rhode Island for the first time using the Xi's at the two Lifespan hospitals.

Urologic surgeon **DRAGAN GOLIJA-NIN, MD**, co-director of the Minimally Invasive Urology Institute and director of genitourinary oncology, helped spearhead the initiative to acquire the new robot for The Miriam and performs some of the most complex robot-assisted kidney, prostate and bladder procedures in the region.

"Acquiring the Xi means that my urologist colleagues and I are able to further expand our surgical capabilities. Our Institute is by far the most experienced in the region, offering superior outcomes," Dr. Golijanin said. "With the addition of the Xi, we are pleased to further expand our capacity and capabilities, offering additional types of robot-assisted surgeries to more men and women throughout New England."

WILLIAM CIOFFI, MD, surgeon-inchief at The Rhode Island and Miriam hospitals, said, "Investing in such cutting edge technology as the da Vinci robot enhances the capabilities of our outstanding surgeons across many specialties so that our patients can receive the best care close to home."

The da Vinci series of surgical systems is manufactured by Intuitive. ❖



Photo taken from a video filmed by Randy Beever (MarComm Video Team) of da Vinci Xi during a surgical procedure.

### Providence VA Medical Center holds ribbon cuttings for new ICU, garage



Dr. Satish Sharma, VA Providence Healthcare System chief of medical staff, cuts the ribbon on a new Intensive Care Unit at the medical center in Providence on February 5th with Ryan Lilly, director of the VA New England HCS, far left; Erin Clare Sears, acting director of the VA Providence HCS, second from right; Matt Goulet, associate director for patient care, and Leslie Pierson, acting associate director for operations. One of several recent improvements at the Providence VA Medical Center, the new ICU is a significant clinical improvement from the former facility.

The \$8 million, 10,000 square-foot ICU provides state-of-the-art equipment, a location adjacent to the surgical suite, and additional space for patients and staff. It incorporates nine inpatient care units, modern nurse stations, and a family consultation room. ICU patients now have individual rooms with enhanced privacy and ample space for visitors. [PROVIDENCE VA HEALTHCARE SYSTEM PHOTOS BY WINFIELD DANIELSON]



Cutting the ribbon on a new parking garage at the Providence VA Medical Center on Feb. 5th were from left to right, **E.J. McQuade**, director of the VA Providence Regional Benefits Office; **Matt Goulet**, associate director for patient care at the VA Providence Healthcare System; **Ryan Lilly**, director of the VA New England Healthcare System; from the VA Providence HCS, **Erin Clare Sears**, acting director, **Dr. Satish Sharma**, chief of medical staff, and **Leslie Pierson**, acting associate director for operations; and **Kasim Yarn**, director of the Rhode Island Office of Veterans Services.

The new garage will park 450 cars, benefiting Veterans, visitors, employees and volunteers alike. As an urban campus with no other multi-story parking facility, parking at the Providence VAMC has been a serious challenge, as the medical center has experienced an increase in the number of Veteran outpatient appointments in recent years. Funding for the 18-month, \$16 million project came through Section 255 of the Consolidated Appropriations Act, 2018. This was the first project awarded under the act's increased minor construction project threshold of \$20 million.



## **Appointments**

### Jonathan Friedman joins University Gastroenterology as COO

PROVIDENCE – University Gastroenterology recently announced **JONATHAN FRIEDMAN** is joining the organization as Chief Operating Officer.

"It's an exciting time for University Gastroenterology and we couldn't be more excited to have Jonathan on board. His focus on not only the day-to-day operations but also long-term goals will enable our doctors to spend quality time with their patients instead of on administrative duties," said **DR. ERIC P. BERTHIAUME**, UGI president. "His proven track record of growing practices, running

them in a fiscally prudent manner while managing diverse workforces is exactly what our growing practice needs."



For 14 years, Friedman served as COO of Somnia, growing the practice from seven to more than 350 physicians operating in 17 states. Most recently, he served as COO at Integrated Medical Partners in Milwaukee, WI. He received his undergraduate degree in accounting at the University at Albany and his MBA in Healthcare Administration at Baruch College's Mt. Sinai School of Medicine.

"The entire staff at UGI provides care that is second-to-none. I am just honored to be able to help this well-renowned practice continue to ful-

fill its mission of providing cutting-edge, compassionate care to the people of Southern New England."  $\diamondsuit$ 

### Rebecca Boss joins CODAC as COO

PROVIDENCE – CODAC Behavioral Healthcare announced that **REBECCA BOSS**, former Director of the Rhode Island Department of Behavioral Healthcare, Developmental Disabilities and Hospitals (BHDDH), has accepted the new position of Chief Operating Officer & Vice President of Strategic Development. Boss, who served over 15 years as BHDDH director and achieved national recognition, will be working to develop a new division of service for CODAC.

Boss will lead strategic development initiatives to further the organizational mission beyond state borders, specifically Massachusetts, for service delivery and nationally for consultation and training. In her new position, Boss will oversee overall strategic development and will be responsible for implementing programing and supervising the clinical and operational aspects of the organization. Boss joins the executive leadership team with CODAC CEO Linda Hurley to establish a national consulting center.

"I am so excited that Rebecca is coming back home to CODAC," said Linda Hurley, President & CEO of CODAC Behavioral Healthcare, who was referring to Boss' previous tenure at CODAC in

2004 as a program director. "We could see early on at CODAC that Rebecca was remarkably committed to her patients. She provided cutting edge and creative programming that would follow her to BHDDH, where she would develop the BH Link as well as other nationally recognized programs that connected people with recovery and establish peer recovery in emergency departments."

During her time as the Director of BHDDH, Boss was a highly regarded leader of behavioral healthcare and developmental disabilities services with special expertise in addiction and recovery solutions. She was responsible for the management, design and delivery of statewide efforts for Medication Assisted Treatment (MAT) expansion, developing national behavioral health integrated care models, and expanding recovery outreach programs. A published national speaker and presenter, Boss delivered Congressional testimony to the U.S. House of Representatives and U.S. Senate subcommittees in 2017, and oversaw a \$500 million state budget.

"I am excited about the opportunity to rejoin CODAC to continue to ensure access to quality, community-based behavioral healthcare services. CODAC has continually demonstrated a commitment to its mission, the people served, and our community for nearly 50 years. Having worked with CODAC, I believe we can take our experience to a national level to have an even greater impact," Boss said.

Honored for her service, she received several awards including the Advocate Award for outstanding support of the Tune In & Tune Up RI Musicians Health Awareness Program and the Karen Rosene Montella Spark Award for Innovation in Women's Health in Rhode Island.

She also earned the "Service Award" from the National Association of State Alcohol and Drug Abuse Directors (NA-SADAD) for outstanding service in the field of substance use disorder treatment and prevention in 2018 as well as the National Treatment Network Representative of the Year in 2016.

A resident of Harmony, RI, Boss received her MA in Counseling and Educational Psychology from Rhode Island College and her BA in Psychology from the University of Rhode Island. ❖



## Recognition

### Integra Community Care Network #2 in overall quality score in national ranking of 'Next Generation ACOs'

PROVIDENCE – Integra Community Care Network is the second-highest-rated accountable care organization (ACO) in the country, according to data recently released by the U.S. Centers for Medicare and Medicaid Services (CMS).

Integra, a local care network comprised of a collaboration between Care New England, South County Health and the Rhode Island Primary Care Physicians Corporation, was one of just 49 ACOs in the country to be included in CMS's Next Generation ACO Model, a three-year program that recognizes ACOs "that are experienced in coordinating care for populations of patients" and "allows these provider groups to assume higher level of financial risk and reward" than are available under other programs.

CMS recently released its Financial and Quality report from 2018, the third year of the Next Generation ACO Model. Integra's "Quality Score," graded on a scale of 100, was reported at 98.59 – the second-highest score reported in the nation and well above the average score of 92.98.

CMS measures participating ACOs' Quality Scores by analyzing four primary categories of value-based care: patient/caregiver experience, care coordination and patient safety; preventive health; and serving at-risk populations.

"We take great pride in our proven ability to provide the best possible patient experience, a more efficient and effective approach to health care delivery, and – most importantly – the opportunity to achieve optimal health and wellbeing for our more than 120,000 members across Rhode Island," said JOHN MINICHIELLO, president, Integra Community Care Network. "The quality scores reflected in this report are a testament to our network of dedicated care providers, and to our highly coordinated approach to value-based care. We are proud of these results, and we look forward to continue building on this success in 2020 and beyond."

Since its launch in 2015, Integra Community Care Network has closed every fiscal year with a surplus, distributing significant shared savings to its participating primary care physicians and reducing the cost of care for its Medicare members by more than \$15 million. •

### Southcoast Health awarded AHA Gold for workplace health

FALL RIVER – The American Heart Association's Workplace Health Achievement Index has awarded Gold to Southcoast Health for building a culture of wellness within the organization. It is the third consecutive year in which Southcoast has earned the highest level of recognition for employers.

The American Heart Association has defined best practices for employers to use to build a culture of health for their employees in the workplace.



Southcoast Health
System's employees
were the recipients
of the AHA Gold
recognition for
workplace wellness
and celebrated this
achievement in
February.
[PHOTO:
SOUTHCOAST]

The Workplace Health Achievement Index measures the extent to which a company has implemented those workplace health best practices.

The AHA's Workplace Health Achievement Index assessment is grounded in data-driven science and a quality improvement framework. Companies recognized at the Gold level have achieved an Index score of 175 to 217 out of a maximum 217 points. The Index scores organizations on 55 individual best practices in seven categories: leadership, engagement, programs, policies and environment, partnerships, communications and reporting outcomes.

The framework of the Index was built so that organizations would continue to strive to improve the health of their workplace and their workforce from one year to the next. KRIS AIMONE, Southcoast Health Wellbeing Program Manager, cited the hard work and effectiveness of Southcoast Health's Wellbeing Committee and the support the group receives from leadership for the continued success.

The Index was called for and tested by the AHA's CEO Roundtable to provide employers with best practices to evaluate the quality and effectiveness of workplace health programs.

"We are honored to be recognized as a Gold Level recipient for the third year in a row," said Southcoast Health President and CEO **KEITH HOVAN**. "This achievement reflects our commitment to employee health and wellbeing, as well as the dedication of our staff to participating actively in our wellness programs. With our system's emphasis on preventative care and addressing social influencers of health in the region, I commend the Southcoast community – more than 7,500 employees strong – for setting a positive example."

**LAUREN DE SIMON JOHNSON**, Southcoast Health Senior Vice President and Chief Human Resources Officer, agreed.

"The Gold Level designation is a very special acknowledgment of the amazing work we have all done together to ensure that workplace health is front and center at Southcoast," she said. .\*



## Recognition

### Lindsay Orchowski, PhD, earns Selya Award for Excellence in Research

Psychologist LINDSAY ORCHOWSKI, PhD, was honored at Lifespan's most recent annual meeting with the 2019 Bruce M. Selya Award for Excellence in Research, an honor created to recognize rising stars in their fields of medical research.

Dr. Orchowski is a member of the Lifespan Physician Group and a staff psychologist in the Rhode Island Hospital adult outpatient division. She was recently promoted to associate professor of research in the department of psychiatry and human behavior at The Warren Alpert Medical School of Brown University, and also serves as the medical school's deputy Title IX coordinator. She was nominated by JODY UNDERWOOD, MD, psychiatrist-in-chief at Rhode Island Hospital, The Miriam Hospital and Lifespan Physician Group, and clinical associate professor at Brown.

Dr. Orchowski has distinguished herself nationally in the fields of alcohol abuse, sexual assault and domestic violence, with her current work dedicated to sexual assault prevention. Her research program has garnered more than \$6.7 million in funding to advance the development and evaluation of sexual assault prevention programs for middle school, high school, college and military populations. She's earned this impressive funding in the span of less than a decade, and as the principal investigator on four federally funded projects. Her work is supported by the National Institute of Alcohol Abuse and Alcoholism, the Centers for Disease Control and Prevention, the Department of Defense and the Department of Education.

In her nomination letter, Dr. Underwood notes

that, "Dr. Orchowski's work is not only known for its theoretically-driven, methodologically rigorous approach, but also for its emphasis on leveraging community partnerships for maximum impact and sustainability... Her research has tremendous potential to contribute not only to our scientific understanding of 'what works' in real communities, but also to reduce the rates of sexual assault among adolescents throughout the state."

The results of her work, says Dr. Underwood, will likely serve as an exemplar for other states, and taken to scale across the country.

Dr. Orchowski holds posts as associate editor for Psychology of Women Quarterly and consulting editor for Psychology of Violence. She has published more than 75 peer-reviewed scientific papers and chapters, and has given over 225 presentations at regional, national and international conferences. Most recently, she published the book, "Sexual Assault Risk



Reduction and Resistance: Theory Research and Practice," and is the co-editor of a forthcoming volume addressing men's role in sexual assault prevention.

Dr. Orchowski earned her undergraduate degree at Dartmouth College, then completed her PhD in clinical psychology at Ohio Uni-

versity in the Laboratory for the Study and Prevention of Sexual Assault, concurrently earning a graduate certificate in women's studies. She completed her psychology residency at Brown University, and a NIAAA T32 fellowship at the Center for Alcohol and Addiction Studies at Brown. At the completion of her training in 2012, she was hired onto the Brown faculty and at Lifespan.

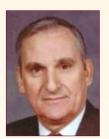
The Lifespan Board instituted the award in 1999 to honor Judge Selya, chairman of the Lifespan Board from the creation of Lifespan in 1994 until 1999. Lifespan recognizes Judge Selya's "steadfast commitment to academic medicine and his keen insight concerning the importance of academic programs to quality health care at Lifespan." The award is intended to recognize a rising star in research, an independent investigator who has demonstrated excellence through a record of high-quality peer-reviewed publication and ability to attract research funding. .



### **Obituaries**

**VINCENT A. DECONTI, MD**, 90, of North Providence, passed away on Feb. 1st after a brief illness.

He was a graduate of Classical High School and received an A.B. degree from Brown University, completed post-graduate studies in biology at Georgetown University and was a gradu-



ate of the University of Bologna School of Medicine. Upon graduation, he completed an internship at St. Joseph Hospital, Providence, and was a resident at Rhode Island Hospital and V.A. hospitals in Providence and West Roxbury, MA.

He served in the U.S. Army during the Korean War for two years.

Dr. DeConti entered private practice in July 1964 and served on the medical staff at St. Joseph Hospital, Providence and Our Lady of Fatima Hospital, North Providence until his retirement in 1994. He served as Director of the Department of Medicine at St. Joseph and Our Lady of Fatima Hospitals from 1986 until 1994.

He was known among his patients and nursing staff alike as the consummate professional with a warm, compassionate, personal touch. He will be remembered among his colleagues as one who never compromised his ideals in the area of quality and who was truly the "physician's physician."

Dr. DeConti was the recipient of the Unitam Award for Outstanding Contribution to Mankind in 1992. He was a member of the Rhode Island Medical Society, Providence Medical Association, American Medical Association, RI Heart Association, Brown University Medical Association, American and RI Society of Internal Medicine, and the American College of Physicians.

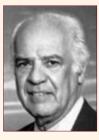
He was a Diplomat of the American Board of Internal Medicine and was board-certified in internal medicine and a Fellow of the American College of Physicians.

He was the loving husband for 64 years of Ann (Giovine) DeConti, whom he met while both were students at Classical High School. He was the beloved father of Linda A. DeConti and Brenda M. Coutu (Robert), and was the adored grandfather of Robert Coutu Jr., John Coutu, and Alexandra Coutu. He is also survived by many cousins, nieces, and nephews.

Memorial contributions may be made to St. Edward Food and Wellness Center, 1001 Branch Ave., Providence, RI 02904. ❖

ALCEU L. PEDREIRA, MD, of Tiverton, RI, formerly of Westport, MA, died on Jan. 16th. He is survived by his wife of 26 years. Martha W. Pedreira. Dr. Pedreira was born in Corumba, Brazil, on May 14, 1933.

He attended secondary school in Rio De Janeiro, Brazil, and received a bachelor of science degree from La Fayette College and his doctor of medicine degree from



the University of Brazil, Rio de Janeiro. Prior to moving to the United States, he served in the Brazilian Navy. Upon arrival in the US, he interned at Edward W. Sparrow Hospital at Michigan State University, Lansing, MI, and did his residency in cardio-vascular and thoracic surgery at Rush-Presbyterian-St. Luke's Medical Center in Chicago.

He practiced thoracic and cardiovascular surgery at the Truesdale Clinic, Charlton Memorial Hospital and at St. Anne's Hospital in Fall River, MA. He was the chief of the division of surgery at Charlton Memorial Hospital from 1990 until his retirement.

He is survived by his children, Patricia Pedreira of North Bennington, VT; Paul Pedreira of Portland, OR; Susan Pedreira of Westport, MA and his grandson, Maxwell Perry-Pedreira of North Bennington, VT. He is also survived by his stepdaughter, Elizabeth Hearn and her husband Kevin Hearn, and three step-grand-children, William, Charles and Andrew Hearn of Wheatfield, NY. Donations may be made in his memory to the Visiting Nurse Home & Hospice, 1184 East Main Rd., Portsmouth, RI 02871.



**JACOB Y. SCHINAZI, MD**, 87, passed away Jan. 29th. He was the beloved husband of Helen Schinazi, MD, for 56 years.

Born in Cairo, Egypt, he earned his medical degree from Cairo University, with post-graduate degrees and training in England and the United States. He was in private practice for many years, and an assistant professor at Brown University and

Boston University. He served as president to the New England Ophthalmological Society (NEOS), as well as of the Rhode Island Ophthalmological Society. During his tenure at NEOS he created the Educational Trust Fund, one of his proudest contributions to the future of the field.

An old-school physician, his profession was the gift of sight, yet his true gift was making each patient feel truly seen.

Known for his calming presence, and welcoming, gentle soul, he was always an entirely present listener, rich with meaningful pearls shared at the right moment. Loved by all who knew him, he will be dearly missed.

Besides his wife, he is survived by his sons, Alan Schinazi and his wife Bre Goldsmith, and Robert Schinazi and his wife Lauren DeRosset; sister Laurette Galapo and grandson Robert Jacob Schinazi.

Contributions in his memory may be made to The New England Ophthalmological Society's Educational Trust Fund, http://www.neos-eyes.org/Donations.



## Aboard the Adriatic, Bound for Alexandria Letters to the Editor from Dr. F.T. Rogers, 1922

Adriatic steamed away at

noon yesterday for Egypt and

H.G. Wells.

principal Mediterranean ports..."

Dr. Rogers, a longtime practitioner

in Westerly, (Figure 1), wrote letters

to RIMJ about the voyage, which

appeared in the spring issues. On January 22, he noted the presence of

MARY KORR RIMJ MANAGING EDITOR

On January 7, 1922, DR. FREDERICK T. ROGERS, 63, associate editor of the Rhode Island Medical Journal (RIMJ), an ophthalmologist and otolaryngologist from Westerly, boarded the steamship RMS Adriatic in New York City on a six-week Mediterranean voyage. The following day the New York Times reported:

### ADRIATIC OFF WITH NOTABLES TO EGYPT

Thousands Crowd Liner to Bid Adieu to Friends Sailing to Mediterranean Ports.

H.G. WELLS IS ON BOARD Departs for Spain to Write a Book

- He Praises Disarmament Conference.



Figure 1. Dr. Frederick T. Rogers [PHOTO: RHODE ISLAND MEDICAL SOCIETY, PAST PRESIDENTS]

Figure 2. Vintage postcard shows the Adriatic, one of the largest commercial and passenger ships of the White Star Line. Launched in 1906, in Belfast, Northern Ireland, it sailed the North Atlantic and Mediterranean.

SOURCE: COMMONS WIKIMEDIA.ORG]



Figure 3. Author H.G. Wells on board

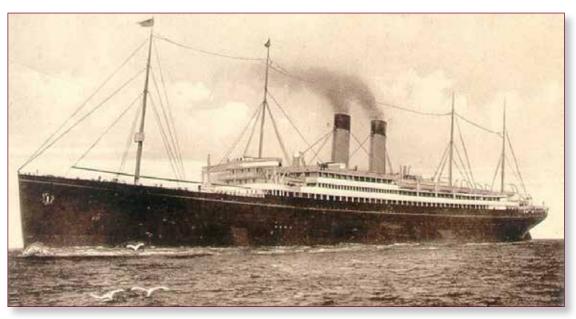
[PHOTO: LIBRARY OF CONGRESS]

"On the Adriatic (Figure 2) there are types of all sorts. There is the woman (usually who knows the celebrities of art and literature) who bores us with her imaginary reminiscences. One on board said while she was in Washington as the guest of Secretary Hughes she had the entrée of the Conference and had so many interesting talks with Mr. Wells, the famous author. Mr. H.G. Wells (**Figure 3**) happens to be on board and failed to recognize his quondam friend."

Wells was on his way to Gibraltar, and when asked by the Times reporter about the Disarmament Conference he had attended in Washington, D.C., he replied: "America has

come to the front and taken a great interest in European affairs for the first time in her history and I trust that she will continue to do so and never return to her shell."

Also among the 609 first-class passengers were composer Irving Berlin, New York Times' publisher Adolph S. Ochs, and European and Asian delegates to the Disarmament Conference.







**Figure 4.** The *Adriatic's* reading and writing room. [SOURCE: COMMONS.WIKIMEDIA.ORG]

"We have passed the Messina Straits and are in the Adriatic bound for Athens. In two days we should be at Alexandria. This letter is but an attempt to keep my word to Dr. Brown that I would send a letter to the Journal. Pardon the effort; when I get back from Assuam I hope I shall have more interesting material.

"Of course, there are possibilities; there are already rumors on board that Cairo is under martial law, an epidemic of flu is raging at Alexandria and one of the Nile boats has been sunk by the rebels. However, we shall see what we shall see."

### Adriatic Amenities, Services

The RMS *Adriatic (II)* was billed as one of the largest and most luxurious cruise ships of the era with the latest technology. According to a White Line brochure: "This steamer is fitted with Marconi's system of wireless telegraphy and also submarine signaling apparatus." The ship's four masts supported the telegraphy cables.

The ship featured a glass-roofed dining room, reading and writing room (**Figure 4**), smoking room, a covered promenade, Turkish bath and indoor pool.

Dr. Rogers writes of spending many hours in the ship's library with its thousands of volumes on history and antiquity. No doubt he ran into H.G. Wells there, who published "A Short History of the World" in 1922.

However, the "trip on the *Adriatic* was not an entire success," he wrote, and enumerated some of the woes he encountered, such as "white fleas" in his cabin. And then there was the ship's arrival in Naples:

"We were lined up at the gangway when an officer appeared and stopped us, and there we stood at first patiently, and then expectantly and finally wrathfully for hours...six hundred of us packed in so we could scarcely move, with women fainting, children crying and men swearing...

"See Naples and die," someone once said, and I don't wonder at it.

### On the bumpy road

Dr. Rogers' travel observations were interspersed with Ocean State innuendos. Once in Italy, he described the road driving to Pompeii:

"Multiply the famous East Greenwich detours of some years ago by the number of rough cobbles on lower Weybosset Street and it will approximate the number of bumps we bumped."

Back on board and headed for Greece, he referred to unstable conditions rumored to be occurring in Egypt.

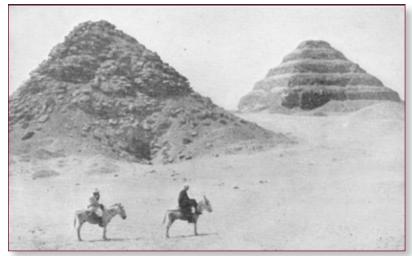
### In Egypt

He did not report any unrest in his travelogue, and reverted to medical observations and amusing asides. On February 7, Dr. Rogers described walking the streets of Cairo and a donkey ride in the desert:

"Trachoma in its varying stages is so common. One meets scores of blind and sees hundreds of children with swollen, purulent lids..."

"The antiquities offered for sale had the flavor of Attleboro, so I bought none..."

"Donkey ride in the desert to see the ruins of the old city of Memphis, of Sakkara and the tomb of Ti. Some five thousand years have elapsed since there was any life in the city or the tombs. We had four donkeys, named Black Diamond, Whiskey, Telephone and Maria...it was an enjoyable five miles into the desert, nothing but sand, not a vestige of green, passing on the way a camp of Bedouins, with their picturesque gaily colored tents..." (Figure 5)



**Figure 5.** A photo of the Sakkara pyramids which appeared in H.G. Wells' "A Short History of the World," published in 1922.



[SOURCE: PROJECT GUTENBERG]

### The Nile

Dr. Rogers was most impressed by the Nile and its vessels.

"Of more interest to me are the boats. Photographs only can adequately describe them, the feluccas, with their peculiar lateen sails, their curious up-turned bows, wide gunwales on which they stand to pole the boat upstream, slowly drifting on the placid waters of the Nile, the green of the fertile planes, the yellowish brown of the surrounding mountains and above all the wonderful blue of the sky, at sunset changing to the hues of the rainbow form a picture of the Nile never to be forgotten...the wondrous, the glorious Nile." (Figure 6)

The *Adriatic* returned to New York on February 13th and remained in operation for 12 more years, until the Cunard Line and White Star Line merged in 1934. The following year, the ship was broken up for scrap in Japan.

Dr. Rogers, a graduate of Union College, and the New York Medical College (1882), passed away in 1932. He left behind a trove of written material, including a history of the medical community in Washington County, and numerous letters to the editor on his travels around the globe. He is buried among the notables in Swan Point Cemetery. •



Figure 6. The Felucca by Joseph Turner.

[SOURCE: MATTHEW IMMS, 'THE FELUCCA C.1824 BY JOSEPH MALLORD WILLIAM TURNER', CATALOGUE ENTRY, MAY 2006, IN DAVID BLAYNEY BROWN (ED.), J.M.W. TURNER: SKETCHBOOKS, DRAWINGS AND WATERCOLOURS, TATE RESEARCH PUBLICATION, DECEMBER 2012, HTTPS://WWW.TATE.ORG.UK/ART/RESEARCH-PUBLICATIONS/JMW-TURNER/JOSEPH-MALLORD-WILLIAM-TURNER-THE-FELUCCA-R1131781, ACCESSED 18 JANUARY 2020.]