

1917 103 2020

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Testing, field hospital sites expand capacity
See page 60

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Jon A. Mukand, MD, PhD

**18 Pain Management Strategies & Therapeutic Options
in the Rehabilitation Setting**

JON A. MUKAND, MD, PhD
GUEST EDITOR

19 Management of Post-Amputation Pain

JACOB M. MODEST, MD
JEREMY E. RADUCHA, MD
EDWARD J. TESTA, MD
CRAIG P. EBERSON, MD

**23 Spinal Cord Stimulation:
The Use of Neuromodulation for Treatment of Chronic Pain**

ALEX HAN, BA, MD'21
ALEXIOS G. CARAYANNOPOULOS, DO, MPH, FAAPMR, FAAOE, FFSMB

**27 Osteoarthritic Pain: A Brief Review of Nonsurgical, Surgical,
and Alternative Treatment Approaches**

SHASHANK DWIVEDI, MD
MICHAEL KUTSCHKE, MD
SEBASTIAN ORMAN, MD
ZAINAB IBRAHIM, MD
ERIC M. COHEN, MD

32 Surgical Management of Rheumatoid Arthritis of the Hand

SHASHANK DWIVEDI, MD
EDWARD J. TESTA, MD
JACOB M. MODEST, MD
ZAINAB IBRAHIM, MD
JOSEPH A. GIL, MD

RHODE  ISLAND
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8 COMMENTARY

Stepping up to the Plate
in the Throes of a Pandemic

WILLIAM BINDER, MD, FACEP

Delayed care-seeking for non-
COVID illnesses in Rhode Island

LUKE MESSAC, MD, PhD

ANITA KNOPOV, MD

MEREDITH HORTON, MD

Addressing Opioid Use
Among Adolescents

ANTHONY BARISANO, ScB'23, MD'27



15 RIMJ AROUND THE WORLD

Quarantine in New York

Rhode Island Blood Center

56 RIMS NEWS

Are you reading *RIMS Notes*?

Working for You

61 SPOTLIGHT

Zoom Talk on "The Great
Influenza" with John M. Barry

Lessons from 1918

MARY KORR

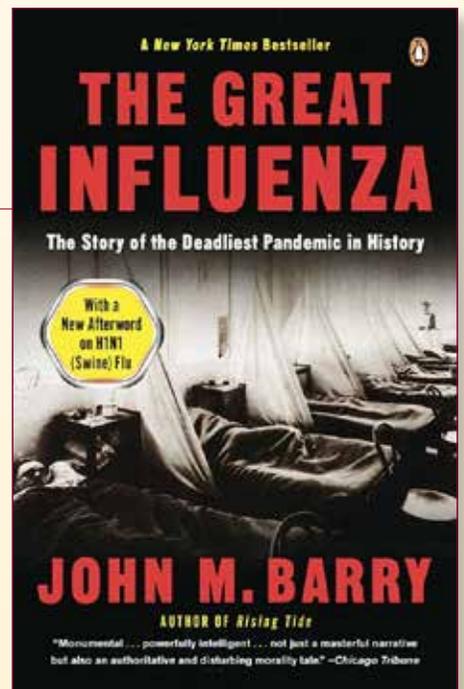
73 HERITAGE

Mary Mallon: First Asymptomatic
Carrier of Typhoid Fever

MARY KORR

The Civil Rights of Mary Mallon

STANLEY M. ARONSON, MD



RHODE ISLAND MEDICAL JOURNAL

IN THE NEWS

CONVENTION CENTER 62
preparing for potential COVID-19 Surge

CARE NEW ENGLAND 64
Covid-19 testing site opens on
Memorial Hospital grounds

DRS. CALIENDO, KURTIS 65
to lead COVID-19 testing
and validation task force

LIFESPAN 65
reports COVID-19 related
financial losses in March

CARE NEW ENGLAND 65
reports operating loss of \$15.2M in March

IMMUNOMIC 66
partners with EpiVax and
PharmaJet on COVID-19 vaccine

66 EPIVAX
Partners with GAIA Vaccine Foundation
to make COVID-19 vaccine license free
to developing countries

67 SOUTHCOAST
ICU opens ahead of schedule
as part of COVID response

68 HERBERT ARONOW, MD, MPH
author of national recommendations
related to cardiovascular care
during COVID-19

68 RIH AND MIRIAM RESEARCHERS
interviewed people who use opioids to
explore the relationships they have with dealers

69 RI AIR QUALITY
worsened for ozone pollution, finds
2020 'State of the Air' Report



PEOPLE/PLACES



ATHENA POPPAS, MD 70
named president of the
American College
of Cardiology



ANITRA L. GALMORE 70
named VP, CNO/COO
at South County Health

71 MATT COLLINS, MD
named 2020 Career Achiever by PBN

72 OBITUARIES
Arthur G. Bonivart, MD
Alfred F. Parisi, MD

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RHODE ISLAND MEDICAL JOURNAL

CONTRIBUTIONS

37 Preconception Marijuana Use in Rhode Island: Rates, Demographics, and Psychosocial Correlates

KIRA A. BROMWICH, BA
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MEAGHAN MCCALLUM, PhD
CYNTHIA NGUYEN, BA
ERIKA F. WERNER, MD, MS
KRISTEN A. MATTESON, MD, MPH
CHRYSTAL VERGARA-LOPEZ, PhD
LAURA R. STROUD, PhD

42 Interdepartmental Collaboration for Simulation-based Education: Obstetric Emergencies for Emergency Medicine

ANDREW MUSITS, MD, MS
ROBYN WING, MD, MPH
MEERA SIMOES, MD
MICHELE STYLE, MD
GIANNA PETRONE, DO
NICK MUSISCA, MD
LINDA BROWN, MD, MSCE

46 Review of Rhode Island Physician Loss-of-Licensure Cases, 2009–2019

LUKE BARRE, MD, MPH
ANGELA PHENGSAVATDY, BS
MARGARET BENSON
JAMES V. McDONALD, MD, MPH

IMAGES IN MEDICINE

50 Contained Free Wall Rupture after Myocardial Infarction

BABAK TEHRANI, MD
NEEL BELANI, MD

CASE REPORT

52 Spinal Epidural Hematoma after Attempted Catheter Thrombectomy of a Large Iliofemoral Deep Venous Thrombosis: A Case Report

KONRAD WALEK, BS
RAHUL SASTRY, MD
STEVEN TOMS, MD, MPH

PUBLIC HEALTH

55 Vital Statistics

ROSEANN GIORGIANNI, DEPUTY STATE REGISTRAR

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Stepping up to the Plate in the Throes of a Pandemic

WILLIAM BINDER, MD, FACEP

WHEN ED FELLER AND I were appointed Co-editors-in-Chief of the *Rhode Island Medical Journal* (RIMJ), a question was raised regarding the relevance of both the Journal and the Rhode Island Medical Society (RIMS), its publisher. This disquieting question has gnawed at me for the past year. In



a world of blogs, Instagram, Facebook, advanced publication of manuscripts, and the Internet's dissatisfying and often indistinguishable amalgamation of opinion and fact, what are the roles of RIMJ and RIMS?

From a historical standpoint, RIMS and RIMJ are part of the living fabric of Rhode Island's medical community. The Rhode Island Medical Society, chartered in 1812, is the eighth oldest medical society in the United States. At one point, RIMS consisted of seven different local societies; the leading local society, the Providence Medical Association, began publishing the *Providence Medical Journal* in 1900. In 1917, RIMS assumed full ownership of the bimonthly publication, and the *Rhode Island Medical Journal* was born. From its inception, RIMJ has always been topical. In the first year of the Journal, Dr. Richard C. Cabot advertised The Fisk Hospital in Brookline, Ma., "for the cure of the morphine habit," as addiction was of singular concern toward the end of World War I.^{1,2}

More than a century later, RIMJ continues to publish research regarding the latest data on the opioid epidemic.

While history and traditions are important and reflect continuity and evoke feelings of nostalgia, current events remind me that the significance of RIMJ and RIMS extends

far beyond a connection to our past. Today, we are faced with an existential crisis as we battle a pandemic that threatens Rhode Island's population, strains our health services, and afflicts the entire nation and world. In 1918 the influenza pandemic resulted in more than 2,000 deaths in Rhode Island; similar numbers, or more, are projected in 2020.³ RIMJ has published early papers reporting on atypical presentations of COVID-19 as well as co-existence of respiratory viruses with the SARS-CoV-2 virus. Additional manuscripts examining other aspects of the pandemic are both in press and planned. Importantly, statistics, research, and case studies pertinent to the health of Rhode Islanders and southern New Englanders are regularly published in RIMJ. The Journal's far reaching impact is evident – it is read in more than 100 countries, receives approximately 15,000 unique views annually, and has had approximately

30,000 pages viewed over the past year. We have been quoted in the *New York Times* and in other media outlets.⁴ Additionally, RIMJ plays a crucial role in the education and academic development of medical students, residents, and fellows in Rhode Island. During the past year more than 200 students, residents, fellows, and faculty were cited in RIMJ.

As Paul Starr noted in *The Social Transformation of American Medicine*, medical societies, including RIMS,

While history and traditions are important and reflect continuity and evoke feelings of nostalgia, current events remind me that the significance of RIMJ and RIMS extends far beyond a connection to our past.

have helped consolidate medicine's increasingly consequential role in 20th-century society. RIMS' successes have been many; the medical society contributed to public health advances, improvements in medical education, and boosted surgical innovation during the 20th century. Unfortunately, in the late 20th and early 21st century, the Rhode Island Medical Society, like many local and national medical societies, suffered an erosion of support. This has mirrored the degradation of our most important and valued American institutions, especially during the past four years. Indeed, the Centers for Disease Control (CDC) has not acquitted itself well during the SARS-CoV-2 pandemic

– at least, initially – and many state departments of health found themselves inadequately prepared and underfunded for our current challenges.

Yet, the current pandemic has created opportunities for local leadership. The Rhode Island Department of Health, hamstrung by a national shortage of testing for COVID-19, has responded vigorously to the crisis. The Rhode Island Medical Society has also stepped up to the plate. RIMS has always supported its membership with physician wellness initiatives, defended physicians affected by poor user interface with electronic medical records, and now, during the pandemic, the Society continues to advocate for physicians as we prepare for our surge, leading to an executive

order limiting liability for physicians and health care workers. The Society has also taken an active role in telehealth expansion, supported license reciprocity, and championed COVID-19 as a work-related illness for providers.

None of this happens in a vacuum. Physician advocacy and leadership has resulted in a new and profound relevance for our local medical society. Now, more than ever, it is important to affirm an institution that has provided continuity within our community for more than 200 years, and which continues to support both its constituency and the citizens of Rhode Island. No one else is looking out for us. It is again time to renew support for RIMS and the *Rhode Island Medical Journal*. ❖

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Delayed care-seeking for non-COVID illnesses in Rhode Island

LUKE MESSAC, MD, PhD; ANITA KNOPOV, MD; MEREDITH HORTON, MD

IN APRIL 2020, EMERGENCY DEPARTMENT PHYSICIANS AT Rhode Island Hospital and The Miriam Hospital noted unusually delayed presentations of acute illnesses. Below are three such cases:

A 41-year-old male with insulin-dependent diabetes presented with three weeks of severe, constant lower abdominal pain with associated chills, with an exam notable for generalized abdominal tenderness and tachycardia. A CT demonstrated perforated appendicitis complicated by a large abdominal wall abscess, which required VIR placement of a drain and prolonged hospitalization.

A 75 year-old male with a history of coronary artery disease presented with one month of progressive urinary hesitancy, progressing to anuria three days prior to presentation. When asked why he waited so long to present, he said he wanted to avoid the hospital for fear of contracting COVID-19. His laboratory studies were notable for a creatinine of 10 (increased from a baseline of 0.8). CT demonstrated bilateral hydronephrosis and a distended bladder, likely due to prostatic enlargement. A Foley catheter was placed, and the patient admitted, with subsequent improvement in kidney function.

A 55-year-old male with a history of hypertension, hyperlipidemia and diabetes presented to the emergency department with intermittent substernal chest pain for the past nine days, with associated left arm discomfort and diaphoresis. The episodes of chest pain occurred daily, lasting approximately one hour, and were not uniformly associated with meals or exertion. When he finally presented to an urgent care just prior to transfer to the emergency department, the ECG revealed an anterolateral STEMI. Cardiac catheterization revealed two-vessel coronary artery disease, and the patient underwent angioplasty and stenting of the left anterior descending and left circumflex arteries.

Delayed presentations of serious illness are not uncommon in normal times, and these are case reports rather than cohort analyses. However, the relative frequency of such cases over the first few weeks of community spread of COVID-19 in Rhode Island is in line with a worrying trend emerging throughout the United States and Europe. An analysis in the *Journal of the American College of Cardiology* compared STEMI activations

at 9 high-volume cardiac catheterization laboratories in the United States in the two months prior to March 1, 2020 (before large-scale outbreaks of COVID in much of the United States) with the month following this date. The analysis showed a 38 percent reduction in monthly STEMI activations.¹ Similar declines were noted in multi-center analyses in Spain (40 percent decline in STEMI activations)² and Austria (39.4 percent reduction in admissions for acute coronary syndrome).³ Stroke centers across the United States have reported declines in patient presentations and admissions.⁴

More generally, emergency departments have seen precipitous declines in patient attendances. This, too, is both a local and international phenomenon. Between early March and early April 2020, daily emergency department attendances across Lifespan hospitals (Newport, Hasbro, The Miriam, and Rhode Island Hospital) fell by approximately 50 percent. Meanwhile, in England, NHS accident and emergency attendance fell 30 percent during March.⁵

The reasons for this decrease in patient presentations in emergency departments have been the focus of preliminary speculation among physicians and public health professionals. Some of the decrease is attributable to decreased pathology. For instance, one logical effect of social distancing measures and massive business closures is a decrease in motor vehicle collisions, a major cause of traumatic injury. However, while social and behavioral changes may play a role in the decline in patients with stroke and MI, there are almost certainly many patients who, like the three patients above, are staying home for days despite worrying symptoms. Some patients admit that they feared coming to the hospital because they worried they might contract COVID-19. Indeed, a Gallup poll conducted between March 28 and April 2 found that among people with heart disease, 86 percent of respondents said they would be “very concerned” or “moderately concerned” about exposure to the coronavirus if they needed urgent medical treatment.⁶

It is also possible that patients might delay their own presentations for more altruistic reasons; namely, that they do not wish to further burden a health-care system that they fear

is struggling to deal with COVID-19 patients. Another possible explanation is that massive unemployment and the accompanying loss of health insurance is discouraging patients from seeking care for fear of hospital bills. However, given that similar decreases in patient presentations have been seen in countries with universal health insurance, this is less likely to be the most important cause.

Hospitals in Rhode Island, as well as across the country, have used the media to stress the safety of their facilities, and the need to seek medical attention for worrisome symptoms, such as chest pain or new weakness. Each of the three patients described above survived their delayed presentations, but other patients have not been so fortunate. Across the United States, epidemiologists have estimated tens of thousands of excess deaths since the start of the COVID-19 pandemic.⁷ While a large portion of these deaths may be attributable directly to the novel coronavirus itself, at least some are likely casualties of this phenomenon of patients with serious illness remaining at home. While we encourage the general public to practice social distancing and stay at home, we must also ensure that they know that our emergency departments remain ready to provide care to all who are sick in our community, whether they are affected by COVID-19 or not. ❖

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Addressing Opioid Use Among Adolescents

ANTHONY BARISANO, ScB'23, MD'27

"HE WAS BLUE AND NAKED on the floor when I got there," the paramedic said. "It was a code for unconsciousness. I gave him Narcan [naloxone] as initial treatment. He woke up but was angry, even though he was blue and seconds away from cardiac arrest and death. He was mad we killed his high; he couldn't control it. We had to sedate and intubate him to help with his breathing because he had aspirated his vomit."



The patient he was describing could have been one of the 47,600 Americans who died as a result of an opioid overdose in 2017.¹ On average, that is more than 130 people overdosing every day.¹ Opioid overdose is a killer pervading our society; in fact, it has reduced overall life expectancy in the United States.² What is true nationally is an even worse problem on Long Island, where I grew up. Described as a "ground zero for the heroin and opiate epidemic," drug overdoses account for 32% of all deaths recorded in Nassau County in the 15–44 age group.³ Furthermore, overdoses and poisonings are the leading causes of death for those between 18 and 35, according to the Nassau County Health and Assessment Report.⁴

This is one of the reasons that, as soon as I graduated from high school, I enrolled in an Emergency Medical Technician (EMT) class. Upon freshly turning 18 (the age required by regulation to be an EMT), I was the only person of my age in the class. I wanted to have the tools necessary to respond to

an emergency and a drug overdose. I was driven by the fact that these were my peers that not only needed immediate help, but someone who could advocate for them. I now know how to recognize the signs of opioid usage and an opioid overdose and what to do to save a life. I have been trained to administer Narcan, insert an airway adjunct,

use a Bag Valve Mask (BMV), and perform CPR. But I also know that none of these things are nearly enough to solve the problem. Now, attending Brown University, joining Brown EMS, and looking at ambulance crews in New York during the summer, the question for me is not whether I will have to respond to an opioid overdose, but how many times a week will I spray Narcan into someone's nose.

Opioids are not a new problem, but there may be a glimmer of hope. After three decades of escalating deaths, total drug overdose mortality dropped 4.6% in 2018 according to the Centers for Disease Control (CDC).⁵ Some credit the drop to a combination of changes in prescribing that have tightened the supply of opioids and wider access to naloxone. Although this is very positive news, it is not yet a trend. This small drop should give us hope that we can break the downward spiral but not lull us into a false sense of security. A lot still needs to be done. New approaches need to be put into action.

According to a 2018 national study by the Department of Pediatrics at the Yale School of Medicine, nearly 9,000 children and adolescents died between 1999 and 2016 from opioid poisonings.⁶ Over that time frame, there has been an increase in the mortality rate of 268.2%, a staggering amount.⁶ The researchers concluded that "the opioid epidemic is likely to remain a growing public health problem in the young unless legislators, public health officials, clinicians, and parents take a wider view of the opioid crisis

Now, attending Brown University, joining Brown EMS, and looking at ambulance crews in New York during the summer, the question for me is not whether I will have to respond to an opioid overdose, but how many times a week will I spray Narcan into someone's nose.

and implement protective measures that are pediatric specific and family centered."⁶

In Rhode Island, from 2006 to 2018, adolescent opioid overdoses increased 70%.⁷

"I have shown up to a call for an adolescent and the kid had altered mental status. The parent had no clue what was going on and couldn't believe he had a drug problem. We gave him some Narcan and he comes around but the parent is still in denial, refusing to acknowledge there is a problem that needs to be addressed," said the paramedic who works in Long Island and New York City.

Over 90% of those with dependence on opioids and other substances start using before the age of 18 and half

started before the age of 15.⁸ We know from research that the rates of opioid misuse and attitudes towards drugs of abuse are highly malleable and subject to change during adolescence.

Programs to address adolescent usage

The Strengthening Families Program has been associated with decreased prescription opioid misuse up to age 25, 13 years after the intervention.⁹ The Strengthening Families Program is an evidence-based family skills training program that aims to improve parenting skills and family relationships and improve social competencies and school performance. You can read more about it at strengtheningfamiliesprogram.org.

Life Skills Training (which teaches drug awareness and social, self-management, and resistance skills) has significantly reduced prescription opioid misuse among middle and high school students when they received classroom intervention in seventh grade;¹⁰ learn more at lifeskillstraining.com. Likewise, the Promoting School-Community-University Partnerships to Enhance Resilience (PROSPER) has

been associated with reductions in nonmedical use of prescription drugs in sixth- and seventh-graders;¹¹ read more on helpingkidsprosper.org.

The direct impact of adolescent opioid use is largely understudied. We need government funding and driven researchers for studies to replicate and verify the results we have. Rhode Island Governor Gina Raimondo has made fighting the opioid addiction a strong priority.¹¹ Part of the Governor's Action Plan is "Prevention," which, as of the 2019 updates, includes creating "community-driven prevention resources" and creating a "Family-Focused Recovery Specialist Model."¹² With dedication to fighting addiction so strong in Rhode Island already, now is the time to implement already verified evidence-based prevention models in The Action Plan. These practices can serve as a blueprint for the rest of the nation on both a local and federal level.

I think of the young man we started with who ended up spending a week in the hospital for aspiration pneumonia. I think that his story could have been different; that if he had received

targeted, evidence-based prevention as a kid, he could have been rescued from that path a long time ago. What is clear to me at my age is how much a culture of use and complete disregard of caution is present in schools and young communities surrounding substance use. Adolescents either think it will never affect them or it gets to a point much like the young man, where the high is more important than life.

The United States has been going at its "War on Drugs" since 1971 with little avail. Having been accepted into Brown's Alpert Medical School as an aspiring physician, I hope to do more to combat this problem in the future, but I know we can do more now. As an 18-year-old EMT, who grew up in an epicenter of the opioid crisis, we need fresh strategies to address the problem and curb addiction at its roots before the next generation gets trapped in its cycle. ❖

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A close-up photograph of two hands, one appearing to be from an older person and the other from a younger person, clasped together in a supportive grip. The background is dark and out of focus.

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SELF-QUARANTINE IN NEW YORK

Anthony Barisano, ScB'23, MD'27, (above) a student in the Brown University Program in Liberal Medical Education, who contributed a commentary in this month's edition of RIMJ, pauses from his remote studies to read the Journal during self-quarantine in Nassau County, New York.

Alex Han, BA, MD'21, (left) a student at the Alpert Medical School, read some recent issues of RIMJ in New York while in self-quarantine due to COVID-19. He has contributed to the current issue of RIMJ's special section on Pain Management in Rehabilitation.

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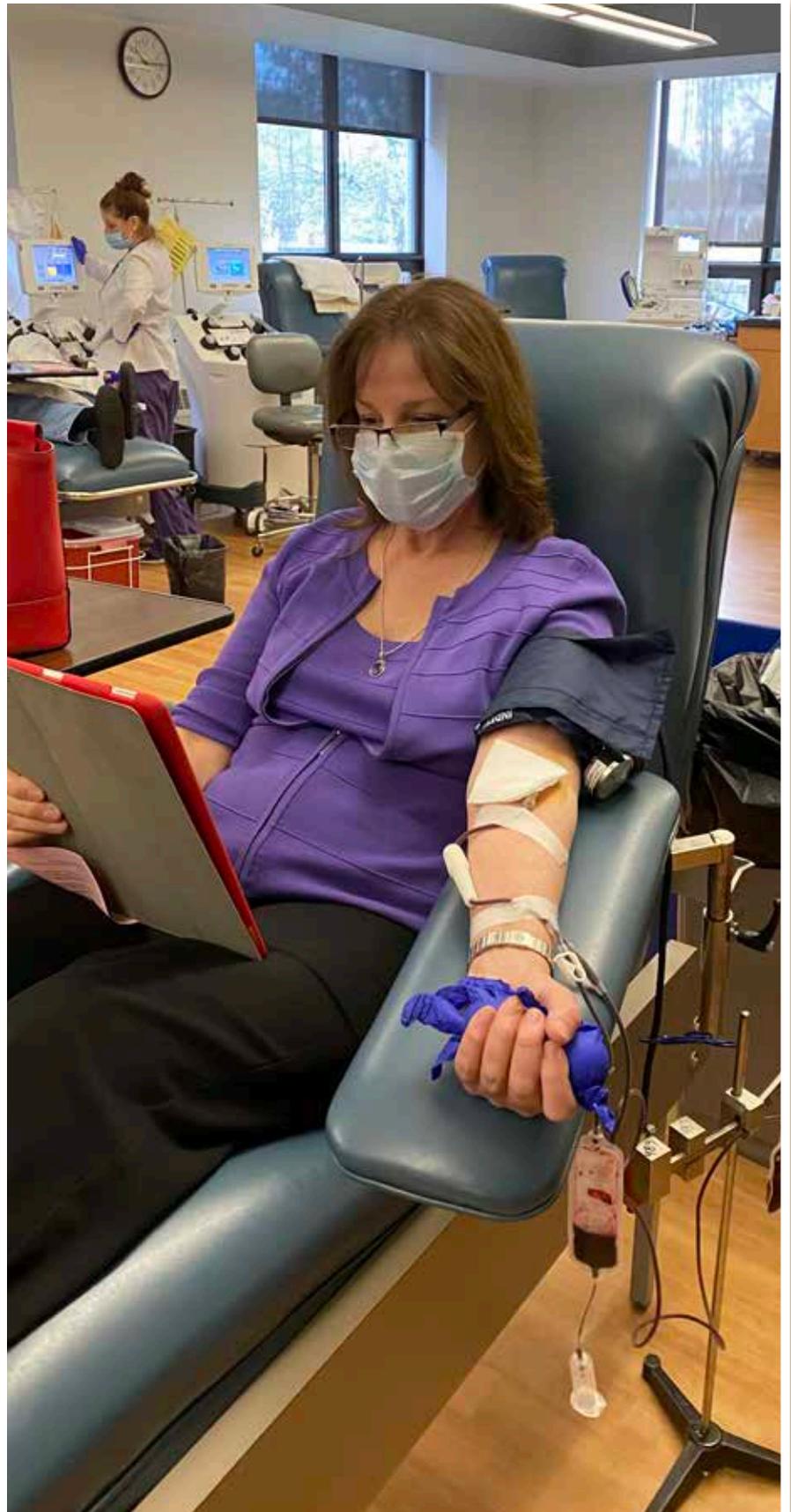
In response to a recent call by the Rhode Island Blood Center (RIBC) for healthy blood and platelet donors to help strengthen the region's blood supply, RIMJ Graphic Designer **Marianne Migliori** answered the call to donate in April.

Fifty percent of blood donations in our region comes from blood drives that are hosted by schools, organizations and businesses. As these groups began to take precautions in response to the coronavirus (COVID-19) outbreak and cancel mobile blood drives, RIBC moved its operations to the six donor centers where they can control the environment and flow of donors.

"Every donation at every one of our centers is critical," said Beau Tompkins, Senior Executive Director of RIBC. "As healthy, eligible donors, we have a responsibility to ourselves, our families and our communities to keep the blood supply safe and robust. A resilient healthcare system is more important than ever, and we're counting on everyone to help maintain that."

RIBC is seeking to double the blood reserves now so that it can prevent shortages if coronavirus cancellations continue.

RIBC provides life-saving blood to nearly every hospital in Rhode Island and many hospitals throughout New England and is responsible for ensuring that our region has a safe and reliable blood supply. It only takes one hour to donate, and a single donation can be used to save multiple lives. About one in seven hospital admissions requires a blood transfusion, and nearly 250 donations are needed each day to meet the needs of the hospitals and patients RIBC serves.





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Pain Management Strategies & Therapeutic Options in the Rehabilitation Setting

JON A. MUKAND, MD, PhD
GUEST EDITOR

A variety of neurological and musculoskeletal conditions are treated in the rehabilitation setting, and people with disabilities are vulnerable to myriad causes of pain. Musculoskeletal structures (bone, ligaments, tendons) are often damaged in weight-bearing joints affected by osteoarthritis and in small joints of the hand and wrist in rheumatoid arthritis. Amputations often result in pain at the residual limb (due to neuromas and skin problems) as well as phantom pain in the part of the limb that has been removed. Disc disease of the spine can compromise small joints in the spinal column and also compress nerve roots. Patients with brain injuries are vulnerable to headaches. After a stroke, patients are at risk of the “hemiplegic shoulder” as well as painful contractures. These and other painful conditions lead to problems with function, sleep, and depression as well as a general decline in quality of life.

Treating pain in the rehabilitation setting often requires a combination of approaches: modalities such as ice, heat, electrical stimulation, and ultrasound; oral, topical, or intra-articular pharmacotherapy; neuromodulation with implanted neural stimulators; and referral for surgical procedures such as arthroscopies and arthroplasties. The authors who have contributed to this special issue of the *Rhode Island Medical Journal* provide a wide range of therapeutic options for pain management to help patients with disabilities. As we contend with the opioid epidemic, these options for optimal pain therapies need to be fully explored.

DR. JACOB MODEST and his co-authors note that the prevalence of post-amputation pain is rising, and almost all people with amputations experience residual limb and/or phantom pain. They discuss the mechanisms and review medication options (tricyclic antidepressants, gabapentin, opioids – with precautions, ketamine, local anesthetics); rehabilitation therapies including mirror visual feedback; cognitive behavioral therapy; and surgical approaches such as neuromodulation and surgery for neuromas.

ALEX HAN (Brown University medical student) and **DR. ALEXIOS G. CARAYANNOPOULOS** review spinal cord stimulators for chronic neuropathic pain disorders, including failed back surgery syndrome (FBSS), complex regional pain syndrome, neuropathy, and radiculopathy. A growing body of literature supports these minimally-invasive stimulators as a safe therapeutic option that can reduce pain and disability, especially in difficult cases of neuropathic pain that are complicated by medication side effects, drug tolerance, or the risks of re-operation.

DR. SHASHANK DWIVEDI and his co-authors (residents and attendings in Orthopedic Surgery at Rhode Island Hospital) have contributed articles on surgical approaches for osteoarthritis and rheumatoid arthritis. Both articles describe the mechanism of damage to joints and surrounding connective tissue structures, which sets the stage for a variety of surgical treatments. The wide-ranging article on osteoarthritis discusses therapeutic options including aerobic exercise, resistance training, weight loss, nonsteroidal anti-inflammatory drugs (NSAIDs, both oral and topical), and tramadol. In addition, Dr. Dwivedi and his co-authors did a literature search and found evidence that suggests a lack of efficacy for glucosamine, chondroitin sulfate, hyaluronic acid, acupuncture, and lateral wedge insoles. This information will help with educating patients about the scientific basis for various remedies that often turn up in internet searches. The article on rheumatoid arthritis focuses on surgical treatment and methodically explores options (tendon transfers, arthroplasty, arthrodesis) for joint damage at the wrist, metacarpophalangeal joints, and inter-phalangeal joints.

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Management of Post-Amputation Pain

JACOB M. MODEST, MD; JEREMY E. RADUCHA, MD; EDWARD J. TESTA, MD; CRAIG P. EBERSON, MD

ABSTRACT

INTRODUCTION: The prevalence of amputation and post-amputation pain (PAP) is rising. There are two main types of PAP: residual limb pain (RLP) and phantom limb pain (PLP), with an estimated 95% of people with amputations experiencing one or both.

MEDICAL MANAGEMENT: The majority of chronic PAP is due to phantom limb pain, which is neurogenic in nature. Common medications used include tricyclic antidepressants, gabapentin, and opioids. Newer studies are evaluating alternative drugs such as ketamine and local anesthetics.

REHABILITATION MANAGEMENT: Mirror visual feedback and cognitive behavioral therapy are often effective adjunct therapies and have minimal adverse effects.

SURGICAL MANAGEMENT: Neuromodulatory treatment and surgery for neuromas have been found to help select patients with PAP.

CONCLUSION: PAP is a complex condition with mechanisms that can be located at the residual limb, spinal cord, and brain — or a combination. This complex pain can be difficult to treat. The mainstays of treatment are largely medical, but several surgical options are also being studied.

KEYWORDS: post-amputation pain, phantom limb pain, residual limb pain, amputation

INTRODUCTION

Limb amputations cause a major physical, economic, and psychological burden to patients and can result in chronic, often debilitating post-amputation pain (PAP). The most common causes of an amputation include diabetes, peripheral vascular disease, and trauma.¹ Amputation is a common operation; the prevalence of lower extremity amputation in the United States in 2005 was 1.6 million people, with projections of 3.6 million people by 2050.² Diabetic patients have an over thirty-fold increased risk of an amputation compared to non-diabetic patients, at a cost of \$4.3 billion annually in the U.S.³ While there are many detrimental effects of amputation including post-operative surgical site

infection, the need for revision amputation, economic cost, and physical disability, one of the most debilitating results is chronic PAP. Comorbid conditions such as fibromyalgia, migraines, irritable bowel syndrome, irritable bladder, and Raynaud syndrome have all been associated with chronic PAP.⁴ The management of PAP is primarily medical, but several surgical options also exist.

PATHOPHYSIOLOGY

There are several methods to categorize PAP. Acute post-amputation limb pain lasts less than two months and chronic post-amputation limb pain lasts more than two months.⁵ Residual limb pain (RLP), often unfortunately referred to as “stump” pain, is pain at the surgical site or proximal remaining extremity. Phantom limb pain (PLP) is described as pain localized distal to the amputation level.⁶ Ephraim et al. looked at 914 patients with limb loss and found that 95% had either RLP or PLP, and there was also a significant relationship with depression symptoms.⁷

While both types of pain may coexist, RLP is most common in the acute post-operative setting, while PLP may present later and with great chronicity. RLP is due to a variety of reasons including incisional pain, scar formation, poor prosthetic fit, or neuroma formation. While RLP has a more acute onset after surgery, it also improves more over time than PLP does.⁸

PLP is usually described as burning, aching, or stabbing and it can occur in the first postoperative week in as many as 25% of patients.⁵ A study of 96 people with upper limb amputations found that there were two peaks for the development of phantom limb pain: acutely within 1 month and at 12 months after amputation.⁸ Risk factors for phantom limb pain include female sex, upper extremity amputation, presence of pre-amputation pain, residual limb pain, and time after amputation.⁹

The mechanism for PLP is thought to be due to cortical reorganization of the somatosensory cortex that serves the sensation of the amputated limb. MRI studies of patients with hand amputations have shown that the cortical area corresponding to the amputated hand is activated and influenced by forearm movements.¹⁰ Another clear mechanism of pain is from nerve damage, as treatment with lidocaine injection or nerve stimulation has been effective in certain

cases. A confounding issue with many cases of PAP is that a significant percentage of patients with amputations have underlying diabetes and diabetic neuropathy.

MANAGEMENT OF POST-AMPUTATION PAIN

Initial and General Approach

After evaluating for anatomic, vascular, infectious, or other pathologic conditions of the residual limb, nonsurgical management is the preferred initial approach to treat PAP. A wide variety of strategies have been studied for the treatment of chronic phantom limb pain. Given that chronic PLP is a type of neuropathic pain, these investigated modalities are often similar to those used to treat other neuropathic pain conditions. These range from pharmacologic, behavioral and rehabilitative therapies to nerve stimulation. The evidence for favoring one medication or modality above another is lacking, and trial data for most studies are based on small numbers of patients. Treatment decisions are often based on patient characteristics and co-morbidities such as depression, as well as side effect profiles. Coupling pharmacologic therapy with other therapies is often practiced. Here, we will review the various non-operative strategies employed for the management of PAP.

PHARMACOLOGIC TREATMENTS

Several classes of medications have been explored as possible management options in chronic phantom limb pain, including antidepressants, anticonvulsants, N-methyl-D-Aspartate (NMDA) antagonists, calcitonin, calcium channel blockers, beta blockers, and local anesthetics. (Table 1)

Antidepressants are a commonly employed class of medications for the treatment of neuropathic pain. The tricyclic antidepressant amitriptyline has been evaluated in the treatment of phantom limb pain. A placebo-controlled study did not show any improvement in analgesia after six weeks of treatment, while a 2005 study reported positive results in controlling PAP with daily amitriptyline.^{11,12} However, amitriptyline was shown to produce undesirable side effects including drowsiness and dry mouth, making it a less desirable pharmacotherapeutic.¹¹ Urinary retention and weight gain are other problematic side effects of amitriptyline. Limited case reports and case series have also documented possible benefit with the use of mirtazapine and duloxetine. The advantages of duloxetine (Cymbalta) are that it is FDA-approved for both depression and neuropathic pain which are associated with diabetes.

Gabapentin is an anticonvulsant that is often used for the management of neuropathic pain, and it has also been

Table 1. Medical options for treating post-amputation pain

Medication	Mechanism of Action	Benefit	Adverse Effects
NMDA-antagonists			
Ketamine	Blocking hyperexcitability and sensitization via NMDA-receptors	Short-term benefit	Mood derangements, hallucinations, abusable
Dextromethorphan		Possible benefit, evidence insufficient	Well-tolerated; may cause abdominal symptoms, confusion
Memantine		Possible benefit, evidence insufficient	Well-tolerated
Antidepressants			
Amitriptyline	Serotonin and norepinephrine reuptake inhibitor	Possible benefit	Anti-cholinergic side effects: dry mouth, sedation
Opioids			
Morphine	Opioid receptor agonist	Beneficial	Dependency, respiratory depression
Injections			
Botulinum Toxin A	Transient focal nerve blockade	Short-term benefit	Low incidence of systemic toxicity, injection site reactions
Anticonvulsants			
Gabapentin	Voltage-dependent calcium ion channel inhibition	Likely beneficial	Good safety profile; may cause sedation
Hormone			
Salmon Calcitonin	Inhibition of centrally firing neurons	Possible benefit, evidence insufficient	Good safety profile; may cause nausea, abdominal pain, diarrhea
Antihypertensives			
Nifedipine	Calcium channel blocker	Possible benefit, evidence insufficient	Hypotension, flushing, peripheral edema
Propranolol	Beta blocker		Sedation, hypotension, bradycardia
Clonidine	Alpha2-adrenergic agonist		Sedation, syncope, hypotension, rebound hypertension

employed to control pain after amputations. The current literature is mixed as to the effectiveness of gabapentin in the treatment of PAP, and it has been associated with significant side effects in this population.¹²

The misuse of opioids continues to pose a nationwide problem, but they can be a useful tool in the management of acute pain, as they blunt the somatosensory cortical reorganization that is thought to lead to the phantom limb sensation.¹¹ Opioids such as high-dose morphine sulfate have shown a positive effect in improving PAP, but patients should be made aware of the risks of opioid dependence and tolerance.^{6,13} Opioids do not represent a long-term solution for patients with PAP wishing to return to their pre-amputation lifestyles. Consequently, they are best suited for the acute management of PAP, along with stool softeners to prevent constipation. Patients should be advised of their short-term use and ideally opioids should be tapered off in the acute hospital or inpatient rehabilitation setting.

NMDA receptor antagonists evaluated for PAP include ketamine, memantine, and the over-the-counter drug dextromethorphan. These medications are thought to block the hyper-excitability and sensitization mechanisms of PAP.^{14,15} Intravenous ketamine has been shown to improve such pain in the short-term, while a small case series has also demonstrated potential benefit for the use of oral ketamine.¹⁶ It is important to note that ketamine has side effects ranging from alterations in mood to hallucinations, and it is a highly abusable drug.

Several other classes of drugs have been explored in the treatment of post-amputation and phantom limb pain. Salmon calcitonin is a hormone that reduces blood calcium levels; it has also been studied as an analgesic due to its inhibition of the central activation of neurons when they are stimulated peripherally.⁶ Reports are mixed regarding calcitonin's ability to provide adequate analgesia in the setting of PAP. Calcium channel blockers such as nifedipine, beta blockers including propranolol, clonidine (an alpha 2-adrenergic agonist), and etanercept (tumor necrosis factor-inhibitor) are other possible treatments for PAP; however, the evidence to support the use of these agents is insufficient.^{6,17}

REHABILITATIVE AND PSYCHOLOGICAL TREATMENTS

As the pathophysiology of the chronic PAP pathway is proposed to have a significant cortical component, various psychological treatment including hypnosis, biofeedback, cognitive behavioral therapy (CBT), and guided imagery have been investigated.^{6,18} Other interesting interventions include eye movement reprocessing, mirror visual feedback (MVF), and the use of virtual reality.¹⁸ Most of the literature on these topics comes from case series, and larger, long-term studies are required to better evaluate their appropriateness for this indication. They are safe and generally well-tolerated,

however, and may help certain patient populations.

MVF utilizes the contralateral intact extremity to reflect an image in a position so that the patient perceives an intact limb, which may reverse the cortical reorganization proposed as a cause of PAP. This technique has shown short-term effectiveness for pain reduction in small studies.^{6,18}

Various forms of physical therapy including massage, taping, acupuncture and ultrasound have also shown modest relief of post-amputation pain. These low-risk, non-invasive treatment options should be offered before medications and invasive approaches.¹⁸

SURGICAL TREATMENTS

In general, the evidence supporting surgical management for the treatment of chronic PAP is limited, and surgery should only be performed if conservative management has failed. There are numerous procedures described in the literature, further emphasizing the lack of consensus for surgical treatment.^{6,19-21} There are two basic types of surgical intervention, neuromodulatory and reconstructive.

Neuromodulatory procedures target maladaptive neuroplastic changes and are represented by various implantable and transcutaneous stimulators. Transcutaneous electrical stimulation (TENS) is theorized to provide pain relief after amputations by increasing blood flow, reducing muscle spasms, and activating large afferent nerves to block nociceptor neurons in the spinal cord. While small series have demonstrated its value, a recent Cochrane review study reported no appropriate studies to judge its effectiveness.²² Other possible technologies include electric nerve block devices, myoelectric prostheses, residual limb covers, and laser systems.²¹

Deep brain, motor cortex, spinal or peripheral nerve stimulators attempt to modulate the neural pathways thought to be involved in chronic phantom limb pain. There are a few randomized controlled studies supporting their outcomes. As demonstrated by Corbett et al. in their systematic review, however, the evidence at best supports short-term benefits from repetitive transcranial magnetic or direct current stimulation.¹⁹ There is limited evidence for implantable stimulators to treat chronic phantom limb pain, even though spinal cord stimulators are reimbursed by Medicare for this specific purpose.

Reconstructive options include surgery for peripheral mechanisms of pain, e.g. residual limb pain caused by neuromas or heterotopic ossification, which can occur at rates as high as 80% and 63% respectively.⁶ There are many possible procedures for neuromas, but the general consensus is that after resection, the nerve end should be protected and implanted into soft tissues. Another surgical solution that has been investigated is upper extremity targeted muscle reinnervation (TMR), which transfers amputated nerves into remaining muscles in the residual limb in order to improve

myoelectric prosthesis control. A retrospective review showed that of the 15 patients who had post-amputation neuromas prior to the TMR, 14 had complete resolution of symptoms and the remaining patient experienced partial relief.²⁰ This evidence suggests that by altering the amputated nerve environment, perhaps neuroma prevention can produce better outcomes than treatment of problems that develop.

CONCLUSION

The number of people with amputations in the United States is increasing, and non-surgical practitioners will increasingly manage their chronic, residual limb and phantom pain. Post-amputation pain encompasses multiple complex pain syndromes after the amputation of an extremity. Currently, the specific pathophysiology is not well understood and is likely multifactorial, which explains the potential benefit of numerous non-operative and operative treatments. In general, approaches to treating chronic phantom limb pain are similar to those for other types of neuropathic pain, and there is no standard of care or strong evidence to support any particular method. However, there are several promising modalities, and further research on the mechanisms of PAP is likely to yield better evidence for some current treatments and new modalities.

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Spinal Cord Stimulation: The Use of Neuromodulation for Treatment of Chronic Pain

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KEYWORDS: neuromodulation, spinal cord stimulation, chronic pain, neuropathic pain

INTRODUCTION

Chronic Pain and the Role of Neuromodulation

Chronic pain, defined as pain persistent for more than 3–6 months, affects 100 million adults in the United States (US) and impacts all dimensions of health-related quality of life (QOL) and healthcare expenditures.¹ Low back pain is the leading cause of disability, with healthcare expenditures estimated to be as much as \$560–\$635 billion, more than the combined spending on heart disease and diabetes.¹ Despite lack of consistent evidence, rates of spine surgeries have increased, while other forms of chronic pain management, including narcotics, contribute to both adverse medical side effects and the ongoing opioid epidemic.²

As such, additional treatment options for chronic pain are being studied. One promising option is spinal cord stimulation (SCS), a form of neuromodulation used since the 1960s. Recently, a paradigm shift has occurred, with SCS increasingly accepted as a first-line therapy after noninvasive treatment (physical therapy, medications, etc). SCS reduces pain, decreases use of analgesic medication, and improves function. Level I evidence supports the use of SCS for chronic neuropathic pain from failed back surgery syndrome (FBSS), complex regional pain syndrome (CRPS), and painful diabetic peripheral neuropathy (DPN).³ Recent guidelines suggest that appropriately selected patients who have failed conventional medical management (CMM) for neuropathic pain may benefit from SCS.⁴

Neuromodulation involves the application of electricity to the central or peripheral nervous systems for therapeutic benefit. The strengths of this approach include reversibility and a low-risk profile. Furthermore, studies demonstrate improved pain relief, health-related QOL, and functional status.^{5,6} Multiple neuromodulatory techniques exist, including spinal cord stimulation (SCS), peripheral nerve stimulation (PNS), dorsal root ganglion (DRG) stimulation, and deep brain stimulation (DBS). Among these, SCS is most commonly performed in the US, with an estimated 50,000 implants annually, accounting for 70% of

all neuromodulation treatments. The valuation of the SCS marketplace was \$1.3 billion in 2014.⁷

Spinal Cord Stimulation and Mechanisms of Action

Spinal cord stimulation (SCS) involves the application of electricity to the spinal dorsal columns, which modulate pain signals relayed by ascending pain pathways to the brain. Although precise mechanisms are complex and not fully understood, the concept derives from the gate control theory, first described by Melzack and Wall.⁸ This theory describes the presence of a “gate” in the dorsal horn, relaying neuronal signals from sensory afferent fibers to brain centers involved in pain perception. Ab fibers (myelinated) carrying non-nociceptive stimuli and C fibers (non-myelinated) relaying painful stimuli both synapse in the dorsal horn with the spinothalamic tract; the gate theory postulates that stimulating the faster Ab fibers leads to closure of nerve “gates,” blocking the transmission of pain signals by slower C fibers (Figure 1). This theory provides insight into why non-nociceptive stimuli, such as tapping or massaging a painful area, provides temporary relief.

Figure 1. Gate theory of pain postulates that sending electrical current to the dorsal column leads to stimulation of faster, myelinated Ab fibers carrying non-nociceptive stimuli, resulting in closure of nerve “gates” and blocking slower, non-myelinated C fibers from transmitting pain signals via the spinothalamic tract.

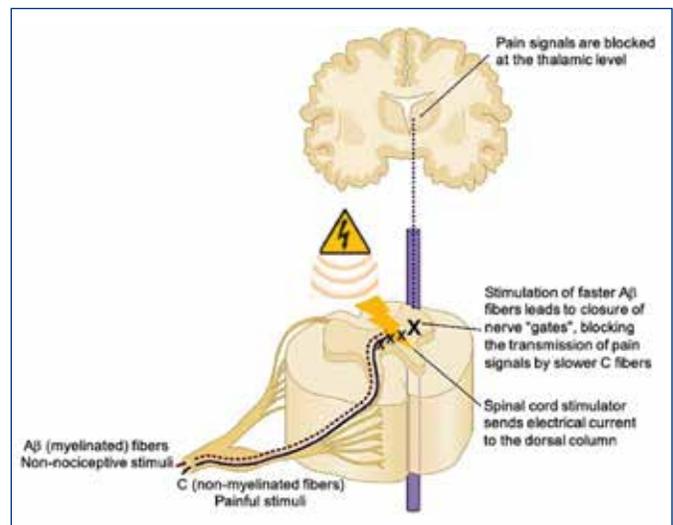
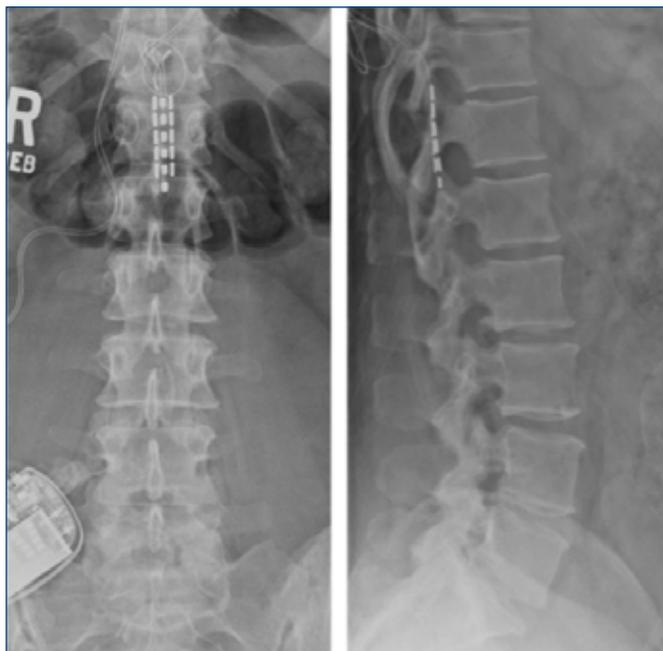


Figure 2. Plain AP and lateral radiographs of spinal cord stimulator implant in place, with pulse generator located within the right buttock subcutaneous tissue and leads placed in the dorsal epidural space at T12.



Source: Stidd et al. (*J Pain Res.* 2014), licensed under Open Access and the Creative Commons Attribution.

In the spinal cord, Ab and C fibers are segregated from motor fibers, making the dorsal column an ideal target for neuromodulation. SCS involves placing electrical leads into the epidural space and sending currents to the dorsal columns (**Figure 2**). Historically, the goal was to replace nociceptive pain signals with more tolerable paresthesias in the distribution of the patient's pain. Recent devices employ higher frequencies, which minimizes paresthesias. Other stimulation paradigms deliver electricity in short bursts, clusters, and via closed-loop feedback.

The exact mechanism for the modulation of neuronal pain in the dorsal columns is probably complex. In animal models, SCS leads to enhancement of inhibitory neurotransmitters such as GABA and the release of acetylcholine, which acts on muscarinic M4 spinal cord receptors involved in analgesia.^{9,10} SCS may also modulate supraspinal pathways to mediate analgesia, as functional MRI demonstrates changes in the thalamus and somatosensory cortex corresponding to altered pain processing.¹¹

Common Indications for Spinal Cord Stimulation

SCS is approved by the Food and Drug Administration (FDA) for chronic neuropathic pain disorders of the trunk and extremities, including failed back surgery syndrome (FBSS), complex regional pain syndrome, neuropathy, and radiculopathy. SCS is also used for refractory angina pectoris, peripheral limb ischemia, and irritable bowel syndrome.¹⁰

SCS has been most widely studied in FBSS, which broadly

encompasses pain that persists despite spine surgery. Randomized controlled trials (RCTs) have studied the efficacy of SCS, particularly in cases of leg-predominant symptoms. A landmark RCT compared patients undergoing SCS with those who had re-operation of the lumbar spine.¹² Significant pain relief, defined as 50% reduction, was achieved in 39% of the SCS group vs. 12% in the re-operation group ($p<0.01$); in addition, there was an 87% reduction in opiate analgesic use with SCS vs. 58% with re-operation ($p=0.025$). Furthermore, after a 6-month post-operative period, 54% of re-operation patients elected to cross-over and undergo SCS, vs. 26% of SCS patients who crossed over from SCS to re-operation ($p=0.02$). A recent review including 2 RCTs and 9 prospective observational trials demonstrated efficacy of SCS for FBBS, with the pooled 1035 observational patients experiencing between 48–77% treatment efficacy at 1-year follow-up.¹³

Evidence also supports the use of SCS in complex regional pain syndrome (CRPS), which involves pain dysregulation and nerve dysfunction in both the sympathetic and central nervous systems, leading to sensory, vasomotor, and sudomotor changes as well as pain and weakness. Management is difficult and symptom-based, with limited structural pathology to target. A systematic review of SCS in CRPS (1 RCT and 25 observational studies) found that in addition to reducing analgesic use and improving QOL, SCS led to a pooled decrease of 47% on the visual analog pain scale.¹⁴

Beyond current FDA-approved indications, RCTs have shown that SCS can benefit ischemic vascular disease, including chronic inoperable limb ischemia and treatment refractory angina.³ The mechanism of action is thought to involve modulation of the sympathetic nervous system, levels of prostaglandin, and nitric oxide production. Compared to CMM, SCS therapy leads to greater pain relief, improved ankle-brachial pressure indices, and higher rates of limb salvage.¹⁵ In patients with treatment refractory angina, no differences were found in exercise function and QOL measures when comparing SCS and coronary artery bypass grafting (CABG), although total mortality was increased in the CABG group at 6-month follow-up.¹⁶ There is also Level I evidence supporting SCS use in peripheral neuropathic pain syndromes, including diabetic and post-chemotherapy neuropathy.^{3,17} Other conditions involving nerve pathology such as post-herpetic neuralgia, post-thoracotomy neuralgia, and phantom-limb pain have been successfully treated with SCS but with less robust evidence.

Complications of Spinal Cord Stimulation and Patient Selection

SCS is widely reported to be a safe procedure, owing to its reversibility and minimal invasiveness.¹⁰ Catastrophic surgical complications are rare, with neurologic injury reported as 0.25% in one review of 44,587 cases.¹⁸ Some causes include formation of epidural hematoma (0.19%) and spinal cord

contusion (0.1%). Minor complications mostly occur within 12 months after implantation and are generally reversible.

The most common mechanical complication is lead migration (14%), which may require revision if it results in loss of targeted stimulation.¹⁹ Lead migration typically occurs within several days of implantation. Post-operative scarring keeps leads in place longitudinally. Migration is mitigated by appropriately anchoring leads. Recently, a lower incidence of migration is attributed to improvements in lead design and anchoring systems. Hardware malfunction or lead fracture necessitating device removal occurs less frequently (7-10%). Subcutaneous implantation of the SCS impulse generator may lead to incisional or pocket pain (10%).

The most common medical complication is infection (3.8%), which is generally superficial and minimized with pre-operative broad-spectrum antibiotic use. There is no evidence supporting routine post-operative antibiotics.¹⁰ Other medical complications are less common (2.5%) and include hematoma, seroma, epidural fibrosis, dural puncture, and neurologic injury.

Appropriate patient selection is crucial for reducing SCS complications and treatment failures.²⁰ SCS candidates should undergo behavioral assessment before a trial of therapy. Untreated depression, major psychiatric illness, and unrealistic expectations lead to less improvement of pain and disability scores. Obesity, younger age, and male gender also predict early failure.²¹

MRI Compatibility and Cost-Effectiveness

Historically, SCS was not compatible with magnetic resonance imaging (MRI). Recent technological advancements allow use of MRI under specific conditions. Although the initial costs of SCS are high, they are offset by improved QOL measures and decreased use of drug and non-drug therapies over time.¹⁹ SCS is particularly cost-effective in long-term studies (>6 months) and for back and leg pain refractory to CMM; SCS was shown to be cost-effective as an adjunct to CMM and when compared to re-operation, with >80% greater likelihood of cost-effectiveness versus CMM and re-operation in predictive models.²² In FBSS patients, SCS decreased annual healthcare costs by an average of 40% over 9-year follow-up compared to CMM.²³ Additionally, newer high-frequency stimulators and rechargeable battery systems have led to increased cost-effectiveness.

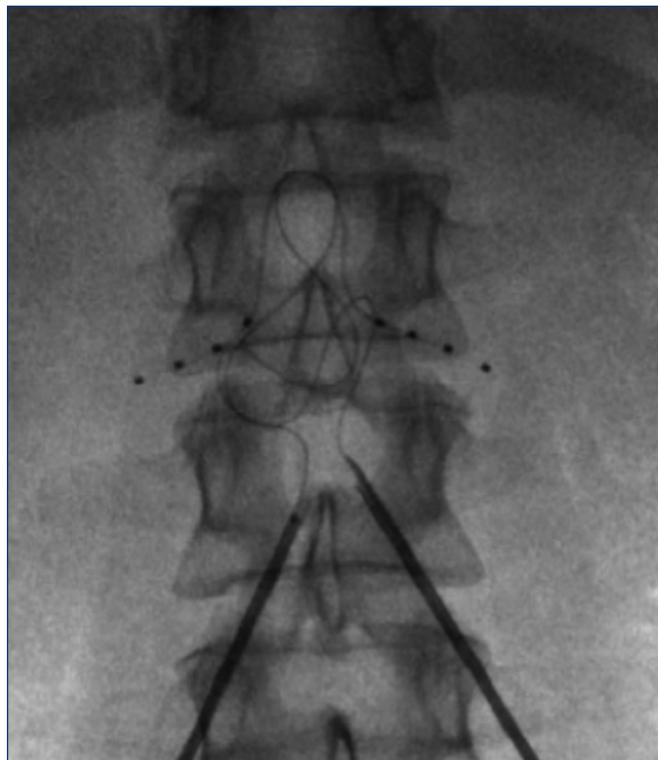
Emerging Approaches in Neuromodulation

Traditionally, SCS stimulates dorsal columns in the 50-100 Hz range, creating perceptible paresthesias in the distribution of the patient's pain. Recently, the application of sub-threshold high-frequency stimulation (HFS) or burst stimuli has reduced or eliminated paresthesias while providing similar or improved pain relief versus traditional SCS.⁷ HFS was FDA-approved in 2015 for chronic refractory trunk and/or limb pain. Its unique waveform at 10kHz preferentially

blocks large-diameter nerve fibers (responsible for paresthesias) while recruiting smaller and medium fibers (involved in vibration and pressure signaling), resulting in paresthesia-free SCS. Burst stimulation delivers higher-frequency stimulation in closely-spaced bursts, rather than constant lower-frequency tonic stimulation used in traditional SCS, which reduces pulse amplitudes and provides subthreshold stimulation with minimal paresthesia. This approach may improve the tachyphylaxis and physiologic tolerance seen with constant stimulation.

Neuromodulation techniques targeting the dorsal root ganglion (DRG) and peripheral nervous system (PNS) allow for greater anatomic specificity. Stimulation of the DRG, which is located at the transition between the spinal cord and peripheral nervous system and contains the primary sensory neuron cell body, can block or reduce painful peripheral signals to the CNS. Anatomically, the vertebral foramina housing the DRG form an ideal enclosure for leads, reducing migration and positional issues seen with SCS (Figure 3). Minimal cerebrospinal fluid at the foramina also allows for lower energy requirements, improving battery longevity. Targeting the DRG of a specific dermatome provides focal pain relief, particularly for refractory CRPS and focal neuralgias that are less effectively treated by traditional SCS, such as the groin and foot.¹⁰

Figure 3. AP fluoroscopic image of bilateral dorsal root ganglion stimulation, with leads in place at L1.



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CONCLUSIONS

Growing Level I evidence supports the use of SCS as a safe and cost-effective therapeutic option for numerous chronic pain conditions. SCS is a minimally-invasive procedure that may be implemented earlier in the treatment continuum to reduce pain and disability, particularly in cases of refractory neuropathic pain complicated by analgesic side effects, drug tolerance, or the need for re-operation. Advancements such as high-frequency, burst, and dorsal root ganglion stimulation have further improved pain relief and patient satisfaction, while mitigating risk and improving outcomes.

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Osteoarthritic Pain: A Brief Review of Nonsurgical, Surgical, and Alternative Treatment Approaches

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KEYWORDS: osteoarthritis, pain, inflammation, arthroplasty, radiofrequency ablation, arthroscopy, alternative medicine

INTRODUCTION

Osteoarthritis (OA) is thought to be the most common chronic joint disease, with the hip, knee, and hand most commonly affected.¹ Although estimates of prevalence vary, 67% of women and 55% of men demonstrated radiographic signs of hand OA in a cohort of nearly 4000 individuals older than 55.² Among those older than 80, 53% of women and 33% of men had radiographic knee OA. It is well known that not all patients with radiographic OA experience pain, and the estimates of the prevalence of osteoarthritic pain are varied. One study reported that 26% of women and 13% of men experienced pain due to OA of the hand, and, in general, 17% and 10% of people experience pain due to OA of the knees and hips, respectively.^{3,4} Pain from OA is known to have a significant effect on quality of life, with women more affected than men.⁵ This effect is modulated negatively by depression and poverty, and positively by education and treatment of underlying disease. Along with back pain, OA accounts for the two most common causes of chronic pain in the US.⁶

The mechanisms of osteoarthritic pain can be generally divided into two pathways, peripheral and central. Early controlled studies demonstrated that pain was correlated with joint space narrowing and other structural abnormalities.⁶ Later studies pointed towards synovium and bone as more likely pain generators, because cartilage lacks nerve endings. It is now understood that the intraarticular milieu of growth factors and cytokines also contributes significantly to the experience of pain. Notably, nerve growth factor (NGF), which promotes axon growth and survival of peripheral neurons, has been implicated in osteoarthritic pain. NGF decreases the firing threshold of vanilloid receptor 1, causing depolarization of nociceptive neurons. Its expression is increased in cartilage in response to mechanical stress and leads to haphazard innervation of previously aneural cartilage with peripheral sensitization to pain. Cytokines such as Tumor Necrosis Factor α (TNF- α) and Interleukin-6 (IL-6) are also upregulated in arthritis, leading to inflammation and pain.⁶

The central mechanism of osteoarthritic pain deals mainly with the spinal cord. Increased glutamate receptor sensitivity leads to the formation of closed synaptic loops, which widens the receptive field for noxious stimuli and enhances both temporal and spatial summation of pain signals. The impairment of descending inhibitory pain pathways further exacerbates pain. Finally, involvement of central pain processing pathways as well as the limbic system, which is responsible for the fear response to pain, also aggravates osteoarthritic pain.⁶

The numerous treatment options for painful OA all involve modulation of these pathways in some manner, although all the effects of some individual treatments are not fully understood.⁶ The purpose of this review is to explore the traditional treatments for painful OA, including nonsurgical and procedural or surgical options, as well as nontraditional methods.

NONSURGICAL MANAGEMENT

There is a robust body of literature describing the nonsurgical management of osteoarthritic pain. In 2013, the American Academy of Orthopaedic Surgeons (AAOS) released updated guidelines for the treatment of the osteoarthritic knee (Table 1).⁷ Current evidence demonstrates that exercise

Table 1. AAOS Consensus Guidelines for Nonsurgical Management of Knee Osteoarthritis⁷

Recommendations For	Strength
Self-directed exercise and strengthening program	Strong
NSAIDs and Tramadol	Strong
Weight loss	Moderate
Recommendations Against	Strength
Acupuncture	Strong
Glucosamine and chondroitin	Strong
Lateral wedge insoles	Moderate
Electrotherapy (e.g. TENS, etc.)	Inconclusive
Manual Therapy (e.g. chiropractic therapy, myofascial release)	Inconclusive
Medial compartment unloader brace	Inconclusive
Acetaminophen, opioids, pain patches	Inconclusive

is strongly associated with decreased pain and self-reported disability in patients with knee arthritis.⁷ A systematic review of 13 randomized controlled trials compared aerobic exercise with resistance training and found that both modes of exercise produced significant improvements in pain and disability, with no difference between the two.⁸ Patients may be encouraged to choose their preferred mode of exercise in order to maximize adherence, which is a key predictor of good outcomes.⁸ Home-based and clinic-based physical therapy are equally effective at producing clinically significant improvement in pain, although previous studies have found that clinic-based therapy can lower medication utilization and increase patient satisfaction.⁹

Another common treatment measure with moderate evidence is weight loss for obese patients.⁷ These patients have excess adipose and muscle tissue and their strength is generally inadequate to bear the load placed through their joints; contributing to this lack of strength is intramuscular fat deposition, which is associated with a 10-fold increase in systemic pro-inflammatory cytokines.¹⁰ Together, these changes alter the composition of cartilage and likely contribute to osteoarthritic progression and worsening pain. Studies have demonstrated significant pain reduction in the hip, knee, ankle, spine, neck, shoulder, elbow, wrist, and hand after weight loss in obese individuals.¹⁰ Weight-loss options include exercise, FDA-approved medications like Orlistat and Sibutramine, and bariatric surgery in the form of laparoscopic gastric banding, sleeve gastrectomy, and vertical banded gastroplasty.¹⁰

There is strong evidence for the use of NSAIDs (oral and topical) and tramadol for arthritic pain in the knee.⁷ Topical NSAIDs such as diclofenac and ketoprofen are associated with a 50% pain reduction in 60% of OA patients, with the benefit of avoiding gastrointestinal side effects, while several placebo-controlled trials also demonstrated good efficacy of oral NSAIDs.¹¹ There is strong evidence in support of tramadol,⁷ but a direct comparison showed that NSAIDs produced a superior analgesic effect¹¹ (and lack the former drug's risk of dependence).

On the other hand, there is inconclusive evidence in support of acetaminophen, opioids, pain patches, and corticosteroid injections.⁷ Intra-articular steroid injections are frequently utilized for their anti-inflammatory and analgesic effects, with effects lasting anywhere from 1 week to 24 weeks.¹¹ Despite their widespread use, more research is necessary to validate their role in the treatment of osteoarthritic pain. Other treatments with inconclusive evidence include growth factors, platelet-rich plasma, stem-cell injections, electrotherapeutic modalities, manual therapies like joint manipulation and chiropractic therapy, and valgus-directed force braces.⁷ Treatments with evidence suggesting a lack of efficacy include acupuncture, glucosamine, chondroitin sulfate, hyaluronic acid, and lateral wedge insoles.⁷

SURGICAL MANAGEMENT

Surgical management plays an important and well-established role in the treatment of osteoarthritis when non-surgical modalities have failed. Among all joints treated for osteoarthritis, hip and knee arthroplasty remain the most prevalent. There is a preponderance of data demonstrating success in reducing pain and improving function in the short- and long-term, with the most significant improvement within the first three months.¹² Certain predictive factors have been shown to affect post-surgical outcomes in surgical candidates. In a comprehensive study of patient-reported outcomes¹³ after total hip (THA) and knee arthroplasty (TKA), age and gender did not have any predictive value, whereas high expectations of pain relief had a positive effect in both hip and knee patients. Interestingly, severe radiographic evidence of OA had a positive predictive effect for TKA patients, but no predictive effect for THA patients.

Resurfacing operations for hip osteoarthritis have also been studied. Unlike total hip arthroplasty, in which the femoral head is removed, resurfacing techniques for hip arthritis involve reshaping the femoral head in order to fit a metal cap. The acetabulum is trimmed to accept a metal shell with which the femoral cap articulates. This technique preserves bone compared to, and may be easier to revise than, total hip arthroplasty. It has a decreased risk of dislocation and leads to more normal walking patterns than total hip arthroplasty as well, and was initially developed for younger and more active patients with hip arthritis. However, disadvantages of hip resurfacing include a greater risk of femoral neck fracture and adverse local tissue reactions related to metal-on-metal wear and the resulting buildup of metal ions in the local tissues, followed by lymphocytic inflammation and pain.¹⁴ Hip resurfacing remains less frequently performed when compared to total hip arthroplasty in part due to this complication profile.¹⁴

Unfortunately, some patients are poor candidates for arthroplasty for various reasons, including medical comorbidities. An alternative to arthroplasty in patients with hip and knee osteoarthritis is radiofrequency peripheral nerve ablation. Radiofrequency ablation (RFA) is a two-step procedure that is typically performed under light sedation, and is also used in the treatment of lumbar facet pain. In the treatment of knee arthritis, the genicular nerves are targeted for ablation. The first step is a diagnostic anesthetic injection to the peripheral extraarticular sensory branches of the genicular nerves. If this trial provides significant pain relief, then a radiofrequency probe is used to apply thermal energy to ablate the peripheral nerve endings. In a double-blind, randomized controlled trial¹⁵ comparing radiofrequency genicular neurotomy to sham surgery, the neurotomy group showed significant improvement in both visual analog (VAS) and Oxford Knee Scores (OKS). Nearly 60% of all patients reported at least 50% pain reduction at 1, 4, and 12 weeks. Similarly, a prospective observational study¹⁶ demonstrated

significant improvement in VAS and Western Ontario and McMaster Universities Arthritis Index (WOMAC) scores following radiofrequency genicular neurotomy. Although the therapeutic effect declined after 6 months, 32% of patients reported at least 50% improvement in pretreatment VAS scores after 1 year.

Patients with hip osteoarthritis may also benefit from radiofrequency ablation of articular branches of the obturator nerve, femoral nerve, or sciatic nerve dependent on the location of pain. Reported techniques are similar to those for treatment of knee arthritis, with a diagnostic anesthetic injection followed by application of thermal energy to ablate the targeted nerve endings. A recent systematic review reported pain relief ranging from 30% to 90% from baseline scores, although the durability of this effect remains unclear, with some studies reporting recurrence of pain within 1–2 years.¹⁷

Complications following radiofrequency ablation are rare. Kumar et al. described loss of cutaneous sensation in the distribution of the lateral femoral cutaneous nerve in a small number of patients treated with RF ablation for hip arthritis.¹⁷ In a recently published systematic review of RF ablation for knee arthritis, Jamison et al. discovered no major adverse complications reported in the literature, although they refer to unpublished cases of skin burns in some patients with nerve branches in near proximity to the skin.¹⁸ Strand et al. recently published a case report of medial thigh hematoma after RF ablation for knee arthritis.¹⁹ Longer-term follow-up studies are required to better characterize the role of nerve ablation in treating pain associated with OA.

Arthroscopy is an alternative to arthroplasty and nerve ablation, especially for the treatment of knee osteoarthritic pain. The mechanism of pain improvement after arthroscopy of the knee is thought to be related to lavage as well as removal of debris. Lavage of the knee decreases the concentration of inflammatory cytokines and degradative enzymes in the synovial fluid, leading to diminished inflammation of the cartilage and surrounding synovium. Removal of tissue debris, inflamed synovium, and damaged cartilage and meniscus also removes sources of synovial and cartilage inflammation, which is thought to improve pain.²⁰ Although arthroscopy was previously used more widely in the treatment of OA, it has received more scrutiny in recent years. A review of arthroscopic management of osteoarthritis found that it tends to benefit young, active patients with mild to moderate arthritic changes without deformity.²¹ Thus, arthroscopy may play a role in the management of early OA in select patients. However, a paucity of high-quality studies makes it difficult to produce thorough guidelines with respect to the treatment of OA with arthroscopy.

ALTERNATIVE TREATMENTS

A number of alternative therapies have tried to address osteoarthritic pain (Table 2). These include practices that have a

Table 2. Alternative Therapies for Treatment of Symptomatic Knee Osteoarthritis⁷

Alternative Therapy	AAOS Recommendation	Rationale
Yoga (Hatha or Chair)	For; Strong	Improved WOMAC and SF-36 Physical Functioning and Bodily Pain Subscales in yoga + physical therapy treatment group when compared to physical therapy alone
Acupuncture	Against; Strong	Based on evidence of lack of efficacy rather than evidence of harm
Glucosamine/Chondroitin	Against; Strong	Based on evidence of lack of efficacy rather than evidence of harm

rich tradition in other cultures, like acupuncture and yoga, as well as nontraditional pharmacological interventions. OA frequently leads to a sedentary lifestyle, which further exacerbates joint stiffening, pain, and muscle weakness.²²

Hatha yoga (HA) is a form of yoga that reduces pain and stiffness in OA patients by realigning the skeleton, strengthening muscles around joints, and stretching out joints.²³ For patients unable to perform HA, chair yoga is an option. A significant reduction in pain was appreciated in patients with lower extremity OA who performed yoga for 3 months.²² Regardless of the specific form, yoga has been shown to increase sleep quality and decrease sleep disturbances in patients with OA.²² Coupled with breathing and relaxation, yoga can help patients cope with the reactive aspects of chronic pain.²³

Similarly, acupuncture has been shown in some studies to help patients with OA pain. The proposed mechanism is that small diameter muscular afferent nerves are stimulated to send impulses to the spinal cord to release endorphins and monoamines involved in the pain messaging pathway.²⁴ Studies examining the immediate effects of electroacupuncture and manual acupuncture on pain and mobility in patients with knee OA have demonstrated a significant reduction in pain intensity and time-to-run test scores in both groups compared to controls.²⁵ Acupuncture has consistently been shown to be an effective treatment modality for pain and dysfunction associated with knee OA.²⁴

Alternative pharmacologic interventions, such as glucosamine, chondroitin, capsaicin, and cannabidiol, are gaining popularity among patients with painful OA. While both glucosamine and chondroitin are over-the-counter supplements in the United States, they are registered as medications in Europe.²⁶ In-vitro models suggest that chondroitin sulfate and glucosamine sulfate exert a beneficial effect on the metabolism of synovial joint cells, including chondrocytes, synoviocytes, and cells from subchondral bone.²⁶ They increase the expression of type II collagen and stimulate proteoglycan synthesis in human articular chondrocytes while

reducing the production of pro-inflammatory cytokines and proteases.²⁶ Studies using MRI have demonstrated that these supplements reduce the loss of cartilage volume and associated joint space narrowing.²⁶ The Osteoarthritis Research Society International (OARSI) considers glucosamine and chondroitin to be low-risk medications with a moderate to high effect. There is a favorable risk/benefit ratio for the treatment of older patients with OA and co-morbidities, in contrast to the long-term administration of drugs like NSAIDs and acetaminophen.²⁶ It should be noted, however, that the 2013 AAOS consensus guidelines for the treatment of knee osteoarthritis recommend against the use of acupuncture or glucosamine/chondroitin due to lack of efficacy, although they do not conclude that either treatment modality is harmful.

Capsaicin, a highly lipid-soluble compound available in topical formulations, is thought to help alleviate osteoarthritic pain through the “dysfunctionalization” of nociceptive nerve fibers, a process that involves temporary loss of membrane potential, inability to transport neurotrophic factors, and a reversible retraction of epidermal and dermal nerve fiber terminals. According to the 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Management of Osteoarthritis of the Hand, Hip, and Knee,²⁷ capsaicin is conditionally recommended for the treatment of osteoarthritic knee pain due to low effect sizes in the available literature, and conditionally recommended against in terms of its use in osteoarthritic hand pain due to lack of available literature in hand OA.

Finally, the effects of cannabidiol on the treatment of osteoarthritic pain are poorly studied. Cannabidiol is the most abundant non-psychoactive compound in extracts of the *Cannabis sativa* plant, and various cannabinoids have been shown to have anti-inflammatory, anti-tumorigenic, and analgesic effects through action on a variety of receptors, but mainly cannabinoid receptors 1 and 2 (CB1, CB2). In animal models cannabinoids have shown to modulate OA pain manifestations and stress-related responses, and CB2 receptor activation has been shown to attenuate the development of pain and sensitization in an OA rat model.^{28,29} However, the only known study to assess the effects of cannabidiol on human articular chondrocytes demonstrated that exposure to high levels of cannabidiol induces apoptosis in chondrocytes in-vitro.²⁸ No clinical trials exist studying the effects of cannabidiol in the treatment of osteoarthritis in humans.

CONCLUSION

Osteoarthritic pain is relatively common and is mediated by both peripheral and central pain mechanisms. Treatment options for osteoarthritic pain are numerous and include non-surgical treatments such as in-home or clinic-based physical therapy, NSAIDs, and tramadol. Joint arthroplasty for appropriate patients is a durable and successful surgical treatment

option. Other surgical options such as radiofrequency genicular nerve ablation and arthroscopy have also shown to be beneficial in certain patient populations. Finally, alternative treatment options such as yoga, acupuncture, and over-the-counter supplements like chondroitin and glucosamine have also shown benefits in the treatment of OA pain.

Although the literature surrounding arthroplasty and traditional nonsurgical treatment options is robust and continues to grow, the research surrounding alternative treatments is relatively sparse. Future research is needed in this field as many patients with either cultural preferences or those with contraindications to traditional approaches could benefit from alternative treatments. Osteoarthritis (OA) is a common cause of disability and pain. A patient-centered approach to the treatment of osteoarthritis is necessary as there are myriad nonoperative and operative treatment options for osteoarthritic pain.

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Surgical Management of Rheumatoid Arthritis of the Hand

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KEYWORDS: rheumatoid arthritis, hand, pain, surgery, deformity, arthroplasty, arthrodesis

INTRODUCTION

Rheumatoid arthritis (RA) is a painful autoimmune disease that affects about 1% of the population.¹ A comprehensive epidemiological study of global disease burden in 2015 found that the prevalence of RA was about 25 million individuals, with an overall increase by 23.8% from 2005.² RA usually causes bilateral joint pain, stiffness, and swelling, which is typically worse after periods of inactivity or in the morning. While RA is characterized by joint involvement, other inflammatory manifestations include fever, anemia of chronic disease, pericarditis, and pulmonary fibrosis. RA can also be associated with other autoimmune diseases, including systemic lupus erythematosus and psoriatic arthritis.

The disease process of RA is a Type III hypersensitivity reaction that involves autoimmune cellular activation and immune complex formation in joints. These deposits lead to thickening of joint capsules, cartilage and bone damage due to inflammatory cascades, and rupture of tendons and ligaments. Chronic RA can lead to pannus formation, due to inflammation and proliferation of the joint synovium.³ Damage to ligaments and tendons in the hands causes deformities such as boutonniere, swan neck, and ulnar deviation of the fingers as well as tendon ruptures affecting the ulnar digits.⁴

Rheumatoid arthritis has a multivariable inheritance pattern, and environmental factors influence the severity of the disease. Risk factors associated with RA include female sex and family history while environmental factors include exposures to cigarette smoke and silica dust.¹

The diagnosis of rheumatoid arthritis is both clinical and serological. RA can be classified as a seropositive disease process with rheumatoid factor (RF), an autoantibody against the Fc portion of IgG, or as a seronegative form. Other autoantibodies in RA include anti-citrullinated protein antigens (ACPAs) as well as antinuclear antibody (ANA) and other, less specific antibodies. While RF was classically associated with the disease, newer data show that ACPA is the most specific antibody for RA.⁵ Serological markers may be present before clinical symptoms; there is a group of patients in

Definitions	
Synovectomy	Surgical resection of inflamed and hypertrophied synovial tissue within a joint. This is generally performed through an open or arthroscopic approach.
Arthrodesis	A surgical procedure on a joint in which the bones comprising the joint are fused. This is generally accomplished through removal of the articular cartilage of the joint, resection of cortical bone on all sides of the joint, and the application of surgical hardware to apply compression across the prepared joint for a period of time.
Arthroplasty	A broadly defined surgical procedure on a joint in which the joint is reconstructed or replaced in order to maintain function while treating pain. This may be accomplished through implanting an artificial prosthesis or resecting the joint with or without interposing a biological or artificial spacer

whom RF is not present in the early stages of the disease but does develop later, so its sensitivity for early detection is somewhat limited.⁶

There are multiple classification systems for RA, and the most recent one (2010) defines “definite RA” based on a score generated by four domains: number and site of joint involvement, serological markers, elevated acute-phase response, and duration of symptoms.⁷

Involvement of the hands in patients with RA can lead to pain, significant limitations in function, and concerns about cosmesis. Every joint can be affected, from the wrist to the individual interphalangeal joints. Although medical management may be appropriate for many, some patients may not tolerate medications or be treated until their joint deformities are advanced. In these patients, surgical treatment may be beneficial. The purpose of this article is to describe the manifestations and surgical treatment options for painful rheumatoid arthritis of the hand.

WRIST

The wrist is affected in approximately 80% of patients with RA.⁹ All three articulations of the wrist (distal radioulnar (DRUJ), radiocarpal, and midcarpal joints) can be affected by RA, with the DRUJ being the most commonly involved

(Figure 1). The surgical goals for the rheumatoid wrist are to reduce pain, improve function, and prevent progressive deformity.

Synovial hyperproliferation characterizes early rheumatoid disease and is therefore a primary surgical target. Synovectomy and tenosynovectomy are indicated in relatively early disease in which wrist motion and radiocarpal joint space are preserved, but absolutely contraindicated in advanced degenerative disease.¹⁰ These procedures reduce wrist pain through denervation of nociceptive nerve fibers,

but do not slow the overall disease process.¹¹ Synovectomy can be performed via open or arthroscopic approaches, with comparable pain relief, but a higher risk of recurrence and radiographic progression after the arthroscopic technique.¹²

Following early synovitis, RA frequently involves the ligamentous structures of the distal ulna. When the synovial-lined ulnar carpal ligaments and other stabilizers of the distal radial ulnar joint (DRUJ) are affected, patients may experience dorsal subluxation and eventual dislocation of the distal ulna ("caput ulna syndrome"). In these patients,

various surgical interventions to treat the DRUJ may be considered. A common surgery is the resection of the ulnar head, or Darrach procedure, but this may be complicated by excessive ulnar translation of the carpus. To prevent this complication, the Suave-Kapanji procedure creates a radioulnar fusion (arthrodesis) following partial ostectomy of the ulna just proximal to the DRUJ.⁹ Ulnar head replacement (arthroplasty) has also been used in the RA wrist. It can confer improved stability and function compared to ulnar head resection and can also salvage a failed Darrach procedure.¹³ While good outcomes have been reported in small case series, larger studies with longer follow-up are necessary to determine its long-term efficacy and safety.¹⁰

With progressive degenerative changes of the wrist, patients may experience involvement of midcarpal and radiocarpal joints. Surgical options include partial arthrodesis, complete arthrodesis, and

Figure 1. Wrist involvement in the Rheumatoid Hand

PA and lateral radiographs of the wrist in a 91-year-old patient with largely untreated rheumatoid arthritis. Note the extensive joint space destruction in the radiocarpal, ulnocarpal, and distal radioulnar joints, as well as auto-fusion of the carpus.

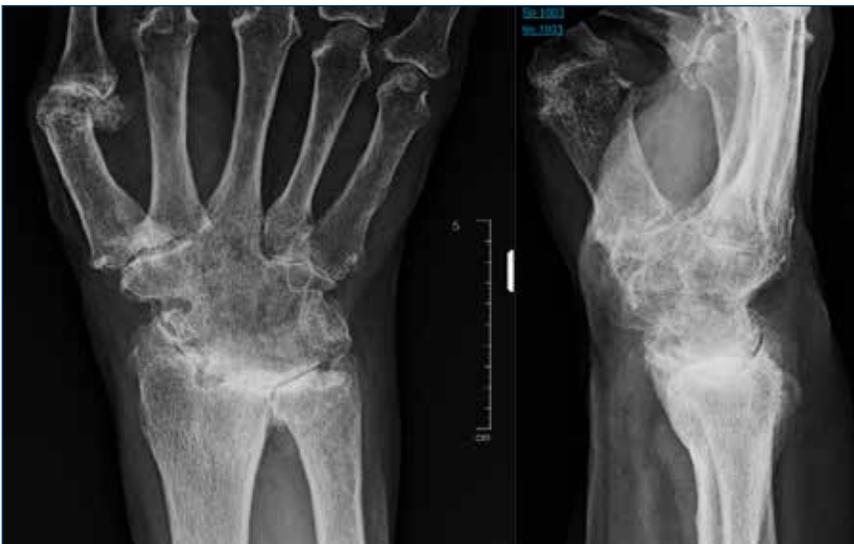


Figure 2. Treatment Options for End-Stage Wrist Arthritis

Left: Total wrist arthroplasty. Right: Total wrist arthrodesis.



arthroplasty. Partial arthrodesis of the radiolunate joint prevents ulnar drift of the wrist and digits. Results are promising, with reports of decreased pain, improved stabilization, and grip strength; however, destruction of the midcarpal joint may persist. Other partial fusions can be attempted, depending on the specific joints involved, such as radioscapulohumeral arthrodesis for radioscapoid arthritis. In cases of severe destruction of the wrist joint, total arthrodesis is the preferred treatment.¹⁴ Complications of arthrodesis surgeries are not uncommon, and in the case of total wrist arthrodesis may be as high as 29%, with a 4.4% rate of nonunion. Among these, major complications, such as deep infection, carpal tunnel syndrome, symptomatic hardware, extensor tenosynovitis, and ulnocarpal impaction may occur in 19% of wrists.¹ Total wrist arthroplasty can also be considered for carefully selected patients with an end-stage rheumatoid wrist (**Figure 2**). This treatment option may be used for low-demand patients with good bone stock for distal fixation, who require maintenance of wrist range of motion. Patients must be well educated on the lifelong restrictions related to joint arthroplasty, as well as the potential complications including infection, implant failure, and requirement for fusion in the future.¹⁵

METACARPOPHALANGEAL JOINT

Although the wrist is frequently involved, the most common deformity affecting the rheumatoid hand involves the metacarpophalangeal (MCP) joint; volar and ulnar subluxation of the proximal phalanx on the metacarpal causes ulnar displacement of the finger (**Figure 3**).¹⁶ Early theories, which have mostly been discounted, attributed this ulnar

deformity to the effect of gravity on patients with hands held in the neutral position during rest, atrophy of the interossei leading to muscle imbalance, and pain-related flexor muscle spasm.¹⁷ The current understanding of ulnar drift at the MCP joint is that chronic synovitis damages the radial fibers of the MCP capsule and sagittal bands of the extensor hood leading to ulnar extensor subluxation, radial joint laxity, and radial forces with functional activities.¹⁷

Ulnar drift is more than a cosmetic deformity, although aesthetic considerations are indeed important to patients. Functional limitations include difficulties with gripping large objects and performing tip-to-tip pinch. In addition, extensor tendon subluxation leads to weakness with digit extension.¹⁶

Treatment of the MCP joint in patients with RA is challenging. Unlike the distal interphalangeal joint, for example, fusion is not commonly performed due to the significant loss in range of motion. In the early stages of disease with comparatively less deformity, synovectomy and/or crossed-intrinsic transfer may be beneficial. As rheumatoid arthritis is a disease of the synovium, the rationale behind synovectomy involves reducing the burden of inflammatory cells and tissue, thereby also treating pain. Crossed intrinsic transfer involves detaching the intrinsic muscle tendons at the ulnar aspect of each digit and rerouting them to the radial proximal phalanx of the adjacent ulnar digit, thereby providing a radially deviating force to restore position of each digit. This treatment is not ideal for patients in whom the disease is not well controlled medically, as further synovitis and joint destruction can stress the repaired connective tissues and predispose the patient to recurrent deformity.¹⁸

In patients with more advanced disease or more rigid deformities, arthroplasty is a treatment option. The main advantages to arthroplasty are maintenance of joint range of motion and shortening of the joint, which relaxes deforming tendon stresses and allows for easier joint repositioning. As in other hand joints, silicone implants are commonly used and have been well studied in the literature. A longitudinal analysis of 325 silicone arthroplasty cases with an average 7-year follow-up demonstrated good short-term outcomes and 95% revision-free survival at 15 years. Although recurrent coronal plane deformity > 10 degrees and implant fracture were common at 15 years, neither was associated with diminished function or the need for revision.¹⁹

Figure 3. Ulnar Deviation of Digits in the Rheumatoid Hand

PA radiographs of bilateral hands in a patient with rheumatoid arthritis demonstrating the characteristic ulnar deviation deformity at the metacarpophalangeal joints along with extensive joint destruction in the digits and wrist.



As in other joints, pyrocarbon implants have been studied for RA of the wrist. Pyrocarbon refers to high-strength graphite substrates with hydrocarbon coatings. Their mechanical properties are intermediate between diamond and carbon, and their elastic modulus is similar to cortical bone. Cook et al. reported a 68% revision or dislocation-free survival at 16-year follow-up, with an average final arc of motion at the MCP joint of 52 degrees.²⁰

DIGITAL INTERPHALANGEAL JOINT

Interphalangeal joint involvement is also common in patients with RA, and often leads to swan neck or boutonnière deformities. Swan neck deformities involve proximal interphalangeal joint (PIP) extension and distal interphalangeal joint (DIP) flexion. PIP hyperextension occurs due to the tightness of the intrinsic hand musculature and weakness of the volar plate of the PIP joint. DIP flexion occurs due to chronic inflammation at DIP joint along with extensor tendon damage and subluxation. A boutonnière deformity, characterized by PIP flexion and DIP hyperextension, results from injury to the central slip at the dorsal PIP joint; volar subluxation of the lateral bands causes a flexion force at the joint. Up to half of patients with RA develop a boutonnière deformity in at least one digit.

As with other joints, surgical treatment of the rheumatoid finger is indicated for painful synovitis, loss of power-grip or pinch, or concerns about the appearance of the hand. The specific surgical approach to finger deformities depends mainly on whether they are flexible (passively corrected) or rigid. Flexible deformities are generally managed through soft tissue reconstruction while rigid deformities require either arthrodesis or arthroplasty.²¹

For a flexible boutonnière deformity, the treatment is PIP joint synovectomy, tightening of the stretched central slip, and relocation of the lateral bands dorsally. This restoration of force vectors along the extensor mechanism improves PIP extension and hyperextension at the DIP joint. The aim of surgeries for a flexible swan neck deformity is to prevent a fixed extension deformity.²² Flexible swan neck deformities may be treated through dermodesis, flexor tendon tenodesis,

spiral oblique retinacular ligament reconstruction, and lateral band tenodesis. A review of these options reported generally good outcomes with all procedures.²²

The mainstays of surgery for rigid IP deformities are arthrodesis and arthroplasty, with either silicone, polyethylene, titanium, or pyrocarbon components. The treatment depends on the joint involved.¹⁸ If the thumb is affected, the IP joint is fused to provide stability for gripping. With the PIP joint, the lack of ligamentous support and tendon imbalance make arthroplasty an unfavorable option.¹⁸ While arthroplasty can improve mobility and the deformity, Ghattas et al. demonstrated a trend towards a relapse of symptoms and prosthetic fracture.²³ Arthrodesis is preferred unless the patient has adequate ligamentous support.¹⁸ The distal IP joint is typically treated with fusion because the tip of the finger requires stability.¹⁸ Even with advances in surgical interventions, the role of specific surgeries continues to be a source of controversy.⁸

CONCLUSION

Rheumatoid arthritis affects all the joints of the hand, from the wrist to the MCP joints to individual IP joints. Not only does the disease lead to chronic pain in these patients but also to progressive deformity, which can compromise both function and appearance. Treatment for the wrist usually addresses the affected DRUJ and can range from arthroplasty procedures to partial or complete fusion. Total wrist arthroplasty is also an option for certain patients. For the MCP joint, treatment goals are to correct ulnar drift of the digits, and options range from soft tissue procedures like crossed-intrinsic transfer to arthroplasty with silicone or pyrocarbon implants. In the IP joints, swan-neck and boutonnière deformities are treated based on whether they are flexible or rigid, with connective tissue procedures for the former and fusion or arthroplasty for the latter. For deformities of the distal IP joint, fusion is the preferred procedure. Although pharmacologic and rehabilitation treatments play an important role in the initial management of RA, the progression of pain and deformities often necessitate surgical treatment (**Table 1**).

Table 1. Summary of Surgical Treatment Options for the Rheumatoid Hand

	Wrist	MCP	PIP	DIP
Early/ Flexible	Synovectomy, Tenosynovectomy	Synovectomy, crossed intrinsic transfer	Boutonnière: central slip repair, lateral band relocation Swan neck: Dermodesis, flexor tendon tenodesis, spiral oblique retinacular ligament repair, lateral band tenodesis	Symptomatic treatment
Late/ Rigid	DRUJ: Ulnar head resection (Darrach), partial ulnar ostectomy, radioulnar fusion (Sauve-Kapandji), or arthroplasty Radiocarpal/midcarpal joints: limited wrist arthrodesis, total wrist arthrodesis, or total wrist arthroplasty	Arthroplasty: silicone, pyrocarbon, polyethylene, or titanium	Arthrodesis or Arthroplasty: silicone, pyrocarbon, polyethylene, titanium	Arthrodesis

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Preconception Marijuana Use in Rhode Island: Rates, Demographics, and Psychosocial Correlates

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ABSTRACT

INTRODUCTION: Rates of marijuana use in Rhode Island (RI) exceed the national average; prevalence during preconception and characteristics of users remain unknown.

METHODS: Prevalence of marijuana use in the 3 months preconception was assessed by a RI-based telephone survey of a diverse, low-income sample of pregnant women ($n=1683$). Sociodemographic characteristics, substance use, and mental health were compared between preconception marijuana users, tobacco users and non-users.

RESULTS: 25.1% of respondents reported using marijuana during preconception. Marijuana users were younger, poorer, and less educated than non-users ($ps<0.001$) and more likely to report alcohol use and mental illness ($ps<0.001$). Marijuana users were younger with fewer children than tobacco-only users ($ps<0.001$).

CONCLUSIONS: Rates of preconception marijuana use in RI exceed national rates of prenatal use. Preconception marijuana users have a distinct sociodemographic profile, with higher rates of concurrent mental health conditions and alcohol use. Understanding this characterization enables targeted screening and interventions.

KEYWORDS: pregnancy, marijuana, cannabis, tobacco

INTRODUCTION

Rates of marijuana use in RI climbed to 20.7% in 2018 (from 15.8% in 2002), exceeding national averages.¹ Increasing prevalence has paralleled a transformation in socio-political and medical acceptability of the drug.² Medical marijuana was legalized in RI in 2005, and the changing local landscape, including legalization of recreational marijuana in Massachusetts in 2016, raises the possibility of future change.^{3,4} RI Governor Gina Raimondo's budget proposal for Fiscal Year 2020 provides for the establishment of "a strictly-regulated legal market for adult use marijuana."⁵

Research has shown that between 48–60% of marijuana users continue use during pregnancy.⁶ Thus, as general rates of use have risen, rates during pregnancy have also increased.⁶ National data showed past-month marijuana use

among pregnant women in their first trimester has increased from 5.7% to 12.1% from 2002–2017.⁷ This is alarming, given associations between prenatal exposure to marijuana and low birthweight,⁸ hypertensive disorders of pregnancy,⁹ spontaneous preterm birth,⁹ and offspring cognitive and behavioral problems.¹⁰

Little is known about the rates and correlates of marijuana use during preconception in RI. The present study aimed to address this gap in the literature. Our aims were 1) to determine rates of preconception marijuana use among low-income pregnant women in the greater RI area; 2) to identify sociodemographic, mental health, and other health characteristics of women who used marijuana in the preconception period; and 3) to examine group differences related to sociodemographic and health characteristics between preconception marijuana users, tobacco users, and controls.

MATERIALS AND METHODS

Sample

This is a secondary analysis of telephone surveys performed as part of two larger studies investigating associations between maternal cigarette smoking and infant neurodevelopment. All women were English-speaking and pregnant. In total, 1691 pregnant women participated in the phone interview between 2014 and 2017. To be included in this secondary analysis, women had to respond to questions about preconception marijuana use.

Procedures

Telephone Survey

Participants were recruited into the parent studies at a comprehensive outpatient reproductive health and maternity services center that serves a diverse population of women in Rhode Island, as well as other clinics throughout Southern New England. All interested women were then verbally consented for the telephone survey, which included items pertaining to substance use, mental health, prenatal care, and demographics. Alcohol and tobacco use were assessed during preconception and pregnancy. Due to local reporting requirements, marijuana use was only assessed during preconception, defined as the three months prior to pregnancy. The study was approved by the Women and Infants Hospital Institutional Review Board.

Women were categorized into three groups: marijuana users, tobacco only users, and controls. Women who reported any marijuana use during the preconception period, regardless of their tobacco use, were considered marijuana users. Women who reported any tobacco product use during preconception or pregnancy but did not report preconception marijuana use were considered tobacco users. Women who reported neither marijuana nor tobacco use were considered controls.

Measures

All measures were self-reported.

Demographics and obstetric factors

Demographic variables included maternal age, number of people in the household, number of children, income, education, and race/ethnicity. Obstetrical factors included estimated gestational age (EGA) at the time of presentation to prenatal care. Respondents self-reported race/ethnicity. Household income, race/ethnicity, and education were analyzed as dichotomous variables (<\$30,000 vs. ≥\$30,000 per year; non-Hispanic White vs. other race/ethnicity; and high school education/GED or less vs. greater than high school education/GED, respectively).

Marijuana use

Survey respondents were asked, *In the three months prior to this pregnancy, did you use marijuana?* Those who reported use were asked, *Approximately how much did you use (equivalent in joints)? How often? How many people shared, including yourself?* Responses were categorized for frequency, method, and mode of use. Frequency of use was categorized as: daily, two or more uses per week but less than daily, between 1 and 2 uses per week, and use once monthly or less. Method of use was categorized as: smoked vs. edible consumption, as no other modes of consumption (e.g. vaping) were reported during this time period. Finally, mode of use for marijuana was categorized as: edibles, joints, blunts, bowls, cigarillos, or other.

Tobacco product use

To assess conventional cigarette use before and during pregnancy, respondents were first asked, *Do you smoke cigarettes?* Respondents who did not report current smoking were asked, *Did you smoke at all during this pregnancy or in the 3 months prior to pregnancy?* Those who reported cigarette use were asked how many cigarettes they smoked per day. To assess for other nicotine or tobacco use, respondents were asked, *Are you currently using any of the following tobacco or nicotine products?* and were prompted to select products used from a comprehensive list. Participants were then asked, *Did you use any of those products listed during this pregnancy or 3 months prior to pregnancy?* followed by a presentation of the same options.

Other health problems, including mental health

Women were categorized as having symptoms of depression during pregnancy if they responded yes to both questions: *During your pregnancy, did you ever feel depressed or down or sad or irritable or lost pleasure in things you usually enjoy?* and *Did you feel like this most of the day, nearly every day, for 2 weeks or more?* Women were also asked if they had ever been diagnosed with bipolar disorder, schizophrenia, schizoaffective disorder, or psychosis; those responding “yes” were categorized as having a severe mental health condition.

Alcohol use

Respondents were considered to have used alcohol during their pregnancy if they responded “yes” to the question, *Have you drunk any alcohol during this pregnancy, including the weeks before you found out?* Those who responded “yes” were asked, *How many drinks per week on average?*

Statistical Analyses

Overall sample and study group characteristics were examined using Stata Version 15. Marijuana users were compared to tobacco users and controls. For continuous variables with normal distributions, independent samples *t* tests were used to compare group means. For count variables, independent samples Mann-Whitney U tests were used. This method was chosen due to skewed distributions for ease of interpretation. We conducted χ^2 tests to examine associations with categorical variables.

RESULTS

Sample rates, sociodemographic characteristics, mental health, and substance use

Of the 1691 women who completed phone interviews, 8 women did not complete the questions regarding marijuana use and were excluded from this analysis, yielding a final sample of 1683 women. A majority of participants were non-white (64.0%), and low-income (66.6%), and reported high rates of mental health concerns and alcohol use (**Table 1**). One quarter of our sample was categorized as preconception marijuana users ($n=423$); 21% were categorized as tobacco users only ($n=353$); 54% were considered controls ($n=907$). More than half (51.7%; $n=216$) of preconception marijuana users reported daily use. Nearly all participants who gave a method of marijuana use reported smoking marijuana ($n=347$, 99.1%) via joint ($n=192$, 45.4%), blunt ($n=128$, 30.3%), or bowl ($n=21$, 5.0%). The remainder used edibles ($n=3$, 0.7%), cigarillos ($n=1$, 0.2%), or other ($n=63$, 17.2%). The majority of marijuana users (58.2%, $n=246$) reported tobacco co-use.

Sociodemographic Characteristics

Women who reported preconception marijuana use were significantly younger ($M=25.8$) compared to controls ($M=27.3$)

Table 1. Sociodemographic and other characteristics of marijuana users, tobacco users, and controls

	Marijuana use (n=423)	Tobacco use (n=353)	Control (n=907)	Total (N=1683)	Marijuana v. controls	Marijuana v. tobacco
	n (%)				p	
White	148 (35.6)	146 (42.1)	298 (33.7)	592 (36)	0.52	0.07
≤ HS Degree	305 (73.5)	263 (75.6)	514 (58.9)	1082 (66.2)	< .001	0.51
Income ≥ \$30,000/year	88 (24.0)	67 (21.46)	347 (42.2)	502 (33.4)	< .001	0.43
Depression symptoms during pregnancy	70 (21.6)	47 (17.3)	59 (8.3)	176 (13.5)	< .001	0.19
Serious mental health conditions	39 (11.6)	34 (12.1)	21 (3.0)	94 (7.1)	< .001	0.86
Alcohol during pregnancy	111 (33.3)	85 (30.9)	122 (17.2)	318 (24.1)	< .001	0.52
Child protective services involvement	33 (9.9)	24 (8.5)	30 (4.2)	87 (5.2)	< .001	0.57
	Mean (SD)				p	
Maternal age (years)	25.8 (5.17)	27.32 (5.29)	27.3 (5.18)	26.92 (5.24)	< .001	< .001
Cigarettes per day [§]	6.29 (5.05)	6.71 (5.44)	0.00 (0.00)	6.55 (5.28)	—	0.55
Number of children	0.81 (1.15)	1.38 (1.49)	1.12 (1.15)	1.10 (1.24)	< .001	< .001
Number of people in household	3.23 (1.44)	3.45 (1.77)	3.26 (1.30)	3.29 (1.45)	0.78	0.09
Gestational age presented to prenatal care (weeks)	8.90 (3.73)	9.11 (4.75)	8.76 (3.57)	8.87 (3.89)	0.58	0.54
Drinks per week [§]	4.09 (7.42)	2.83 (3.54)	1.92 (2.14)	2.92 (5.01)	0.06	0.95

* Preconception is defined as the 3 months prior to pregnancy

[§] Cigarettes per day and Drinks per week analyses included only participants who reported any cigarette before or during pregnancy and any alcohol use during pregnancy, respectively.

and tobacco users ($M=27.3$) ($p<0.001$). Relative to controls, preconception marijuana users were also more likely to report low income (76.0% vs. 57.8%) ($p<0.001$) and a high school education or less (26.5% vs 41.1%, $p<0.001$) (Table 1).

Concurrent Mental Health Conditions and Substance Use

Women who reported preconception marijuana use were more likely than controls to report symptoms of depression during pregnancy (21.6% vs 8.3%, $p<0.001$) and other serious mental health conditions (11.6% vs 3.0%, $p<0.001$). Preconception marijuana users were also more likely than controls to consume alcohol during their pregnancies (33.3% vs 17.2%, $p<0.001$)

DISCUSSION

This study investigated rates of preconception marijuana use and associated demographics in a large convenience sample ($n=1683$) of low-income pregnant women in the greater RI area. In this study which occurred between 2014 and 2017, 25% of pregnant women reported marijuana use in the three months prior to pregnancy, with more than 50% reporting daily use. Relative to controls, users were significantly younger, less educated, and had lower incomes. They were more likely to report alcohol use during pregnancy, symptoms of perinatal depression, and serious mental health problems. The majority of preconception marijuana users were poly substance users, with 58.2% endorsing tobacco use during pregnancy, and 33.3% endorsing alcohol during

pregnancy. Nearly all (99.1%) women who used marijuana reported use of combusted marijuana.

Our study's reported prevalence of preconception marijuana use far exceeds the overall national prevalence¹¹, overall prevalence in RI¹², and prevalence during pregnancy reported in prior studies.^{7,11} Though our data are restricted to the preconception period, research has indicated that 48% to 60% of marijuana users continue their use during pregnancy.¹³ Furthermore, the high percentage of daily users in our study is consistent with prior studies.^{7,11} Given the risks posed to the fetus by prenatal marijuana use⁸⁻¹⁰ and the evolving legality of marijuana in the region^{3,4}, it is vital that interventions are initiated to reduce prenatal use.

Our findings are consistent with national survey data showing that pregnant marijuana users are younger, with lower incomes than non-users.^{14,15} Increased knowledge of sociodemographic characteristics of preconception users may be an important means of identifying high-risk groups for intervention.

An association between preconception marijuana use and mental health conditions is consistent with prior studies, which have indicated a link between prenatal marijuana use and mood and personality disorders.¹⁶ Previous research has also established an association between marijuana use and other substance use in pregnancy.^{15,17} Enhanced understanding of comorbid psychiatric conditions and concurrent substance use among pregnant marijuana users is critical to developing screening and prevention tools for this population. As studies have demonstrated synergistic effects of

multiple substances on fetal development, reaching these co-users will be essential.¹³

Marijuana users only differed significantly from tobacco users in age (marijuana users significantly younger) and number of children (marijuana users had fewer children); though a large percentage of marijuana users used tobacco as well, the general lack of differences between the two groups is still striking. There have been several campaigns to reduce cigarette smoking during pregnancy.¹⁸ Future studies should further investigate the overlap between preconception marijuana and tobacco users and analyze whether existing tobacco interventions may be adapted to reach pregnant marijuana users.

Future studies should develop screening and intervention tools to reduce use among pregnant women. Determining the current recommendations of local dispensaries and healthcare providers is fundamental to understand the messaging reaching pregnant users. Indeed, a 2019 study found that 70% of Colorado marijuana dispensaries recommended cannabis products to treat nausea in first trimester pregnant women.¹⁹ Finally, previous studies combining urine toxicology and self-report have found increased prevalence of marijuana use. Future research should include biochemical indicators in analyses of marijuana prevalence.

We highlight three limitations to the current study. First, this study does not provide an index for prevalence rate of marijuana during pregnancy. Instead, we documented high levels of marijuana use in the three months prior to pregnancy. However, given the high rates of women using marijuana during the preconception period who continue into the pregnancy, these values serve as a useful indicator.¹³ Second, the study used a convenience sample, raising the possibility of sampling bias and misrepresentation of the RI community and the surrounding area. However, the sample's diversity and race/ethnicity distribution closely aligns the source population.²⁰ Third, due to the tobacco focus of the parent studies, there was oversampling of tobacco users.

CONCLUSION

In a large convenience sample of low-income pregnant women, we found that the prevalence of preconception marijuana use is 25%. Preconception marijuana use was associated with younger age, lower annual household income, less education, and fewer children living at home compared to women who reported no tobacco or marijuana use. In addition, preconception marijuana users were more likely to engage in concurrent alcohol use and to have depression and other mental health diagnoses. Increased understanding of the rates, demographics, and mental health correlates of this population provides a framework for the development of strategies to engage RI women on the subject of preconception and prenatal marijuana use and implement preventative strategies.

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Interdepartmental Collaboration for Simulation-based Education: Obstetric Emergencies for Emergency Medicine

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ABSTRACT

BACKGROUND: Simulation in medical education is a well-accepted educational modality that allows for practice of high risk, low frequency events. The Obstetric Emergencies for Emergency Medicine course was developed to prepare trainees for challenging scenarios.

METHODS: Six clinical scenarios were chosen: spontaneous vaginal delivery, neonatal resuscitation, preeclampsia, neonatal resuscitation with cardiopulmonary resuscitation (CPR), shoulder dystocia and postpartum hemorrhage. Development and facilitation was an interdepartmental effort with contributions from Emergency Medicine, Obstetrics and Gynecology, and Pediatric Emergency Medicine. Each case was allotted 35 minutes, including debriefing. Participants completed an evaluation survey for each scenario.

RESULTS: All participants responded yes to the question "Would you recommend this simulation become part of the standard curriculum." The means of ratings for "scenario overall" and "relevance to training/duties" ranged from 4.95-5 out of 5 across all simulation groups.

CONCLUSION: An interdepartmental and collaborative approach can optimize the success of a simulation educational program.

KEYWORDS: medical education, simulation, obstetric emergencies, neonatal emergencies

INTRODUCTION

The use of simulation for training was first reported in the aviation industry in 1929 when a basic flight simulator was developed, and has since become an important tool for educating healthcare providers. The first human patient simulator was created in 1966 as a method to train anesthesiology residents in endotracheal intubation. Over the past 20 years, simulation has become increasingly utilized across healthcare and thoroughly researched as a method to educate learners in procedural skills, teamwork, communication, and critical thinking.^{1,2} It is uniquely suited to train individuals and teams in the assessment and management of low frequency, high acuity events in a safe setting, allowing

practice without direct patient contact. With the use of high-fidelity simulators, healthcare providers can experience real-time feedback on their decisions and interventions in the form of changes in patient responsiveness, respiratory effort, and vital signs. Recently, there is growing evidence that training with simulation for procedures, such as for ultrasound-guided central line placement, can not only improve success rates but can also improve quality of care for patients.^{3,4}

The Rhode Island Hospital Medical Simulation Center began operation in May 2002 and was created in part with funding from a United States Department of Defense project aimed at transferring the lessons learned from Army aviation to medical teams working in emergency departments.⁵ The center was renamed the Lifespan Medical Simulation Center in 2012 and has become nationally recognized for innovative acute care simulations, teamwork training expertise, continuing medical education courses, and quality improvement programs ranging from office-based preparedness sessions to EMS training and inpatient interprofessional simulations. It is located one-third of a mile from the main Rhode Island Hospital/Hasbro Children's Hospital campus and blocks away from The Warren Alpert Medical School of Brown University, in the newly evolving "knowledge district" of Providence.

The delivery of a newborn in the emergency department is an uncommon, but potentially life-threatening emergency that emergency providers are expected to manage. The Accreditation Council for Graduate Medical Education (ACGME) states that the required training for an Emergency Medicine resident is 10 vaginal deliveries by the end of their training. There are no specific requirements stated for complicated deliveries. Resident training experiences in the clinical setting vary and, therefore, some standardization of educational experiences in this area is beneficial to ensure adequate and comprehensive training.

The Obstetrics Emergencies for Emergency Medicine course is one part of the larger Emergency Medicine (EM) resident simulation curriculum for Brown EM residents hosted at the Lifespan Medical Simulation Center. This curriculum is designed to provide training around high risk, low frequency events that EM trainees must be capable of handling upon graduation. It incorporates both tactile procedural skills, clinical decision making, and leadership skills.

The Brown EM residents have 5 hours per month of this simulation-based educational training as part of their standard curriculum.

METHODS

Curriculum

The goal of the Obstetrics Emergencies for Emergency Medicine course is to prepare EM residents for time-sensitive obstetric emergencies when immediate assistance from consultants is not available. The obstetric emergencies curriculum was designed specifically for EM providers. Cases were written and developed by simulation trained EM and Pediatric Emergency Medicine (PEM) faculty in collaboration with faculty from the department of Obstetrics and Gynecology (OB-GYN), who served as subject matter experts. The case scenarios developed represent low frequency, emergent and time-sensitive patient presentations.

Six clinical scenarios were chosen as simulation cases: normal spontaneous vaginal delivery, neonatal resuscitation, pre-eclamptic seizure, neonatal resuscitation with CPR, shoulder dystocia, and postpartum hemorrhage. Each case was developed with specific learning objectives and critical actions pertaining to the appropriate medical management of the clinical presentation.

The Obstetrical Emergencies for Emergency Medicine course was incorporated into the monthly EM resident simulation curriculum as a dedicated obstetrical simulation session. The total time for the session was approximately five hours including a brief introduction and a concluding meta-debriefing. Residents were divided into three groups of roughly ten participants. Each case was allotted a total of 35 minutes with approximately 20 minutes designated for the scenario followed by 15 minutes for debriefing. To successfully implement this simulation-based curriculum, the right mix of people, technology, and resources was required.

People

The Obstetrics Emergencies for Emergency Medicine team was multidisciplinary and interdepartmental, composed of subject matter experts, medical education and simulation experts, and simulation operations specialists. Our medical experts included two obstetricians, two pediatricians (specializing in pediatric emergency medicine and certified in neonatal resuscitation) and four emergency medicine physicians. This team of content experts worked together to ensure that the cases presented had sound medical knowledge and were realistic to those encountered in patient care. The medical education and simulation experts worked with the subject

matter experts to write cases with clear goals and learning objectives including structured debriefing guides. Other team members critical for success included two simulation operations specialists. These individuals worked with the team to develop this high-fidelity simulation program, prepared the simulation environment for realistic staging of the cases, and directed control room activities of the manikins and audio-visual equipment during the course.

Technology

Technology based simulators enhance the educational experience by adding realism and real-time feedback to learners. The PROMPT Flex Advanced Birthing Simulator™ was used for the normal delivery and shoulder dystocia scenarios. The simulator comes with a fully articulating neonate with a flexible head and clavicles and an accompanying placenta with detachable umbilical cord to provide realism for the delivery. It is ideally suited to simulate shoulder dystocia because of the articulating hips and flexible vaginal wall and perineum which allows learners to perform standard maneuvers such as McRobert's, Zavanelli & posterior arm delivery. The neonate is Bluetooth-enabled so the instructor can monitor force applied to the baby during management of a shoulder dystocia.

For the neonatal resuscitation cases, Laerdal Sim NewB® was used. (Figure 1) This simulator responds to provider actions by changing vital signs, breath sounds, and pulses. Procedures including CPR, intubation, and umbilical vein catheterization can be performed. A similar adult version, Laerdal SimMan 3G®, was used for the postpartum hemorrhage case. While not a specific OB simulator, this simulator allows the focus of the case to be on resuscitation of the postpartum mother. Like Sim NewB®, this simulator responds

Figure 1. Sim NewB®

Sim NewB®, a life-sized anatomical manikin manufactured by Laerdal, allows medical students and residents along with providers to practice early assessment, diagnosis, and intervention in the Lifespan Medical Simulation Center.

[PHOTO COURTESY OF ALAN SOUSA, LIFESPAN MEDICAL SIMULATION SPECIALIST]



to provider actions and allows for multiple procedures related to resuscitation including IV insertion, intubation and intraosseous line placement.

For the pre-eclamptic seizure case, a standardized patient (SP) was used. While use of an SP is low technology, it allows for high fidelity regarding patient interviewing and changes in mental status. An earpiece allowed faculty to coach the standardized patient from the control room as necessary.

Indeed, other simulator options exist from a variety of manufacturers. There are some low technology wearable models that provide basic feedback, consisting of a rudimentary outlet to serve as a vagina and an inflatable neonate for delivery. Conversely, there are more expensive models that can provide even more sophisticated feedback. Such features include assessing fetal head position relative to the pelvis, information on progress of birth, medication administration to progress delivery, and incorporated software to provide the learner tocography and partograms. However, the specific simulators used worked well to meet our educational objectives and demonstrate a variety of options and technology available.

Evaluation

Participants were asked to evaluate each scenario they participated in during the course using the standard simulation evaluation form EM residents routinely complete after participating in simulation training exercises at the Lifespan Medical Simulation Center. Participants rated the simulation experience across three domains and space for free text comments was provided. This evaluation form was administered through Qualtrics® using a mobile friendly format to collect the anonymous responses.

RESULTS

Participants in the simulations included EM residents, advanced practice providers, medical students, and faculty. The largest participant category was residents with 16 (84.21%) attending the shoulder dystocia simulation, 12 (70.59%) attending the normal vaginal delivery simulation, 15 (83.33%) attending the postpartum hemorrhage simulation, 11 (73.33%) attending the preeclampsia simulation, 15 (78.95%) attending the neonatal resuscitation, and 15 (78.95%) attending the neonatal resuscitation with CPR simulation. One advanced practice provider, one medical student, and one faculty member participated in each simulation with the exception of the normal vaginal delivery simulation that had 3 faculty participants; the preeclampsia simulation that had two medical student participants, and both neonatal resuscitation simulations had two faculty participants.

Table 1. Participant feedback by scenario. Scale from 1 "Poor" to 5 "Excellent". Std dev =Standard deviation

Scenario		Scenario Overall	Relevance to training/ Duties Mean	Faculty effectiveness at facilitation and debriefing
Spontaneous vaginal delivery (n=17)	Min, Max	5, 5	5, 5	5, 5
	Mean (Std dev)	5 (0.00)	5 (0.00)	5 (0.00)
Shoulder dystocia (n=19)	Min, Max	5, 5	4, 5	4, 5
	Mean (Std dev)	5 (0.00)	4.95 (0.22)	4.95 (0.22)
Neonatal resuscitation (n=15)	Min, Max	4, 5	4, 5	4, 5
	Mean (Std dev)	4.87 (0.34)	4.93 (0.25)	4.87 (0.34)
Neonatal resuscitation with CPR (n=19)	Min, Max	4, 5	4, 5	4, 5
	Mean (Std dev)	4.95 (0.22)	4.95 (0.22)	4.95 (0.22)
Pre-eclamptic seizure (n=15)	Min, Max	5, 5	5, 5	4, 5
	Mean (Std dev)	5 (0.00)	5 (0.00)	4.93 (0.25)
Post-partum hemorrhage (n=18)	Min, Max	5, 5	5, 5	5, 5
	Mean (Std dev)	5 (0.00)	5 (0.00)	5 (0.00)

Across the six simulations, all participants agreed with the statement that "Learning objectives for this simulation were clearly identified" and responded yes to the question "Would you recommend this simulation become part of the standard curriculum?"

At the end of the simulation, participants were asked to rate the simulation in three categories (scenario overall, relevance to training/duties, and faculty effectiveness at facilitation and debriefing) using a scale from 1 to 5 with 1 being "poor" and 5 being "excellent". (Table 1)

Anecdotal free text comments reported on the feedback form included:

- "This was one of the best, if not the best, simulation experiences that I have ever had."
- "It was really helpful to have the OB-GYN attendings – really great to learn from the perspective of a different specialty."
- "Great review of something that is very scary for many graduating residents. This should definitely be made part of our standard curriculum."
- "The entire sim day should be part of the core rotation. It was great and very high yield stuff we don't see, do, or talk about often."
- "Faculty would benefit from this as well."

Formal thematic analysis of free text responses was beyond the scope of this project.

DISCUSSION

Simulation holds a respected place in graduate and continuing medical education. Best practices in simulation, including clear learning objectives, deliberate practice, and debriefing, were incorporated into this project.⁶ Indeed, the success of a simulation course is dependent on many factors. Based on the experience described, it is suggested that an interdepartmental, collaborative model of simulation development and implementation optimizes the success of the simulation educational program.

The process of creating this curriculum involved multiple preparation meetings including OB-GYN, PEM, and EM faculty. The coordination across departments was key to creating a meaningful learning experience. For example, scenario choice and design was a collaborative effort. OB-GYN faculty identified that maternal morbidity and mortality in the United States stems mainly from obstetric hemorrhage and hypertensive disorders of pregnancy. EM faculty agreed these topics were low frequency, high stakes encounters in the emergency department.

The faculty practiced with the models in advance to get a feel for the capabilities of the simulators and the force of the shoulder dystocia. There was also a briefing with the standardized patient who participated as the patient with preeclampsia. The overall timeline was six months. This lead time was required to keep the day free from clinical commitments for all of the faculty and prepare for the resident experience. It also allowed for adequate scheduling of the simulation space and the preparation by the simulation operations team to secure the necessary materials and simulator programming.

An interesting by-product of this interdepartmental collaborative effort was the conversations started between faculty and residents in different disciplines. It was quickly apparent that the perspective and treatment patterns varied between OB-GYN and EM. This is likely due to the different practice environments, resources, patient population, educational backgrounds, training, and common literature experienced by these two groups. Sharing these perspectives broadens everyone's education and helps break down departmental silos.

Many elements coalesce in the formation of a successful simulation-based educational event. The right mix of people, curriculum, technology, and simulation space creates the recipe for success. When an interdepartmental, collaborative approach is added into the mix, the stage is set for knowledge and perspective sharing of all involved.

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Disclosures

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Review of Rhode Island Physician Loss-of-Licensure Cases, 2009–2019

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ABSTRACT

Disciplinary actions against physicians are uncommon, and loss of license is less common. This unmatched, case-control, and descriptive study reviews disciplinary actions involving physician loss-of-license cases from January 1, 2009, to December 31, 2019. There were 82 physician loss-of-license cases involving 66 physicians, which were categorized by age, sex, and specialty and were compared to 4,347 non-disciplined controls. In this study, males (OR 4.69, $p < 0.001$) were associated with an increased risk of loss of license; age was a separate risk factor (OR 1.24, $p < 0.05$). Preventive strategies are discussed to reduce future physician loss of license.

INTRODUCTION

The practice of medicine, perhaps unlike any other profession, is predicated on the establishment and sustainability of trust. Physicians provide an altruistic service to the community they serve and in exchange, are allowed the privilege of self-regulation.¹ Physicians, as mediators of this trust, are held to high standards of character, competence, and integrity in their professional practice.

The mission of the Rhode Island Board of Medical Licensure and Discipline (BMLD) is to protect the public through enforcement of standards for medical licensure and ongoing clinical competence.² Carrying out this mission requires the BMLD, like other state medical boards, to protect the public through investigation of complaints about physicians regarding allegations of professional misconduct. When these allegations are substantiated or there is a violation of a rule, regulation, or law, there will be a disciplinary action and rarely, loss of license.^{3,4} The removal of a physician's license is the most serious action and may bring finality to a career or set the stage for reinstatement after remediation.

There is significant investment to train new physicians, and individual physicians generally sacrifice a great deal in order to attain a license; however, there is little published information regarding characteristics of disciplined physicians. This case-control study seeks to describe the characteristics of disciplined physicians and to describe preventive measures available to at-risk physicians to mitigate their risk.

METHODS

Cases of physician disciplinary action were extracted from the publicly available list on the Rhode Island Department of Health's (RIDOH) website.⁵ Data were categorized by physician loss-of-license cases for the specific time period of January 1, 2009, to December 31, 2019 and compiled for review. Licensing information regarding physician age, specialty, and sex was compiled from RIDOH's physician licensing database, and the main reason for disciplinary action was summarized. The control group, chosen from physicians with active licenses in 2017 in Rhode Island, was limited to 4,347 physicians where demographic information, including age, sex, and self-reported specialty was available.

Mean age of disciplined and non-disciplined physicians was analyzed using the t test. Multivariate logistic regression was done to evaluate the relationship between age, sex, specialty, and disciplinary status. Stata version 14 was used for the reported analyses.

To increase statistical power, specialties representing less than 5% of the physician population were grouped with larger similar specialties, and all other specialties without a larger similar category were grouped together as other specialties. The resulting categories used for analysis were emergency medicine, internal medicine, family medicine, pediatrics, psychiatry, radiology, surgical specialties, and other specialties. Internal medicine was used as reference, as it was the largest category.

Data were also categorized by number of cases in a year, average age of loss of licensure individuals in years, and time (in months) for physician reinstatement for repeat offenders. Application from RIDOH's Institutional Review Board (IRB) occurred on October 15, 2019, for expedited review, and approval was received on October 30, 2019.

RESULTS

A review of disciplinary actions from 2009 to 2019 revealed 82 physician loss-of-license cases, involving 66 physicians. Ten of the physicians lost their license more than once.

The highest number of loss-of-license cases adjudicated by the full Board was in 2013. The rate of physician loss of licensure in 2013 was 4.5 of every 1,000 physicians licensed in Rhode Island. The lowest rate of loss of licensure, in 2015, was 0.7 out of every 1,000 physicians. **Figure 1** illustrates the number of loss-of-license cases per year.

Of these 82 losses of license cases, 30 were primarily related to improper controlled substance prescribing, 18 were primarily related to physician impairment, and 11 were due to noncompliance with existing consent orders. Seven licenses were lost because of criminal activity, including criminal activities related to narcotics, sexual assault, and other sex offenses. Boundary violations accounted for 8 loss-of-license cases, and were primarily made up of inappropriate relationships with patients, including inappropriate romantic relationships, and sexual misconduct. **Figure 2** illustrates the main reason for loss of license.

Loss of license varied by type of disciplinary action. During the 10-year period, there were 18 license surrenders/voluntary agreements not to practice medicine (VANTPM) and 22 Summary Suspensions (**Figure 3**). License surrenders/VANTPM represent an action where a physician voluntarily surrendered a license, whereas a summary suspension represents an emergency action of the Director of Health to protect the public.

The current license status of the 66 unique physicians involved in these 82 actions is that 21 were reinstated. **Table 1** illustrates the percentage of physician licenses reinstated, after loss of license, for some of the more common reasons for loss of license.

Disciplinary action resulting in loss of license was taken against 60 males and 6 females between 2009–2019. Ninety-one (91%) were male physicians; the difference was statistically significant. Disciplined physicians were older, with an average age of 59 years old versus 55 years old among controls.

Using the logistic regression model adjusted for sex, age, and specialty, only age and sex remained a statistically significant risk for disciplinary action with an odds ratio of 1.24 and 4.69, respectively.

DISCUSSION

Twenty-one (21) out of 60 physicians were able to reinstate their license after additional training and remediation of the underlying cause. Although it is a rare event, loss of a license protects the public from further physician misconduct, and remediation is often achieved via an agreement between the physician and the BMLD. Objective, third-party observers are included in remediation through monitoring

Figure 1. Number of Physician Lose-of-License Cases, Rhode Island, 2009–2019

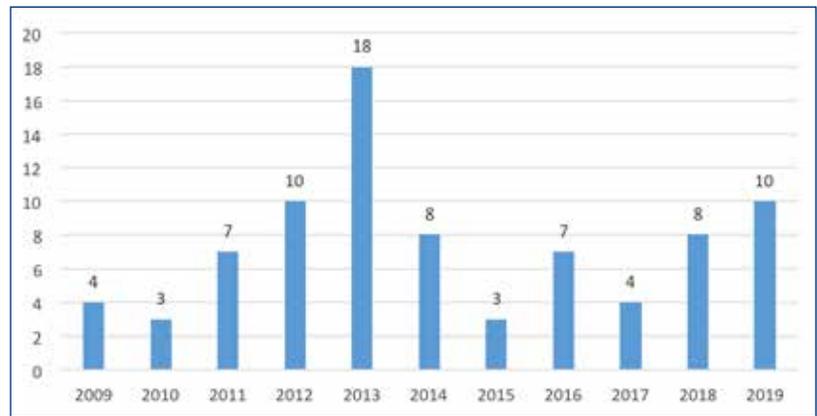


Figure 2. Primary Reason for Physician Loss of License, Rhode Island, 2009–2019

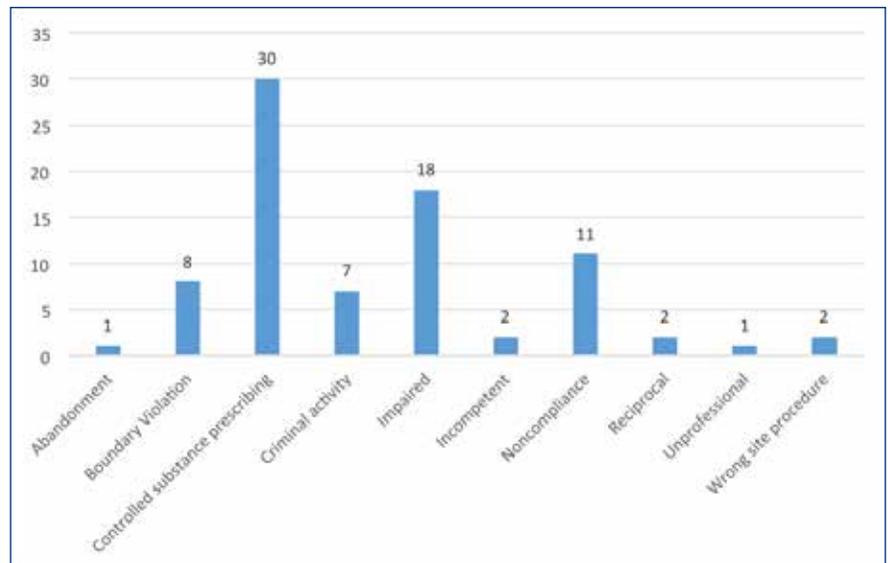


Figure 3. Specific Disciplinary Action for Loss of License, Rhode Island, 2009–2019

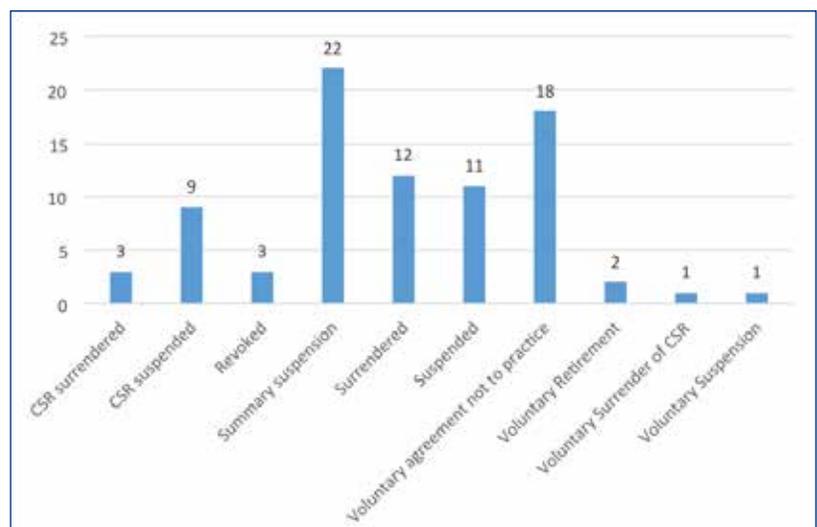


Table 1. Percentage of Physician Licenses Reinstated, Rhode Island, 2009–2019

Reason for Loss of License	Definition	Number of Cases	Percent reinstated
Controlled Substance Registration (CSR) Summary Suspension	CSR is suspended for an indefinite period of time without completely affording due process. Imminent harm is needed to be shown by Director of Health.	9	67%
CSR Surrendered	CSR is surrendered. Imminent harm is not needed to be shown by Director of Health.	3	33%
Summary Suspension	License is suspended for an indefinite period of time, without completely affording due process. Imminent harm is needed to be shown by Director of Health	22	14%
Suspension	License is suspended for a defined or indefinite period of time, while completely affording due process. Imminent harm is not needed to be shown by Director of Health	11	45%
Revocation	License is no longer active due to a disciplinary reason and is considered terminated. (The physician may reapply for licensure in five years.)	3	33%
Surrender	An agreement from the respondent to give up their license because of a disciplinary action.	12	8%
Voluntary Agreement Not to Practice Medicine	An agreement from the respondent to give up their license because of a disciplinary action.	18	28%
Stayed Suspension	A license is suspended for a period of time, yet the suspension is not in effect as long as certain conditions are met. If a condition is not met, the license becomes suspended as agreed upon in the original consent order for a specified period of time.	N/A	

Table 2. Sex and Self-Reported Specialty Distribution for Physician Loss of Licensure, Rhode Island, 2009–2019

Specialty	Number of loss-of-license cases	Number/1000	Number of male physicians disciplined	Number of female physicians disciplined	Number of physicians in specialty (2017)
Internal Medicine	17	17	16	1	1019
Family Practice	11	32	10	1	348
Psychiatry	8	31	6	2	259
Emergency Medicine	6	23	5	1	257
Surgical specialties	12	20	12	0	612
Other specialties	7	6	6	1	1,153
Radiology	4	11	4	0	349
Pediatrics	1	3	1	0	350
Total	66		60	6	4,347

*2017 is baseline for rates.

Table 3. Odds Ratios from the Logistic Regression Model

Variable	Odds Ratio (95% confidence interval)	P value
Males	4.58 (1.98-11.09)	<0.01
Age, by decade	1.24 (1.01-1.40)	0.04
Emergency Medicine	1.34 (0.52-3.43)	0.560
Family Medicine	2.14 (0.99-4.65)	0.052
Pediatrics	0.23 (0.03-1.76)	0.157
Psychiatry	1.84 (0.78-4.34)	0.157
Radiology	0.61 (0.20-1.82)	0.374
Surgical specialties	0.82 (0.37-1.81)	0.622
Other specialties	0.39 (0.17-0.83)	0.028

actions and educational efforts to ensure that remediation is occurring and the physician is fit to return to the practice of medicine.

The year with the highest number of loss of licenses cases was 2013, which reflected a RIDOH emphasis on addressing overprescribing of opioids and coincided with previously vacant Board leadership positions being filled. The remainder of this 10-year period does not reflect any significant variation.

The most common reason for a loss of license during the 10-year period was related to controlled substance prescribing. This does reflect the larger public health concern of the opioid epidemic and the potential harm to the public if controlled substances are overprescribed.

The second most common reason for loss of license was an impaired physician. A physician can be classified as impaired for a variety of reasons, including inability to practice effectively due to age, substance misuse, or other impairment. It should be emphasized that had these physicians first come to the attention of the Rhode Island Medical Society's (RIMS) Physicians Health Program (PHP), disciplinary action could be avoided, as the BMLD recognizes the value of a physician demonstrating insight and following the recommendations of the PHP. Physicians that self-recognize issues regarding their practice of medicine that may result from an impairment can seek help from the PHP before an issue arises with the BMLD. The BMLD is not notified of a physician's voluntary attendance in a PHP because the PHP evaluates each physician confidentially and coordinates appropriate treatment. Physicians who self-report to the PHP can enter into a private agreement with the PHP not to practice medicine while they undergo treatment.

There were 11 physicians whose loss of license occurred due to noncompliance with an existing consent order. These physicians had previously agreed to disciplinary action via a consent order that was intended to bring their practice back into compliance with accepted standards. A consent order is an agreement with the BMLD, and it stipulates facts of the complaint, violations of relevant statutes, and agreed-upon sanctions. Physicians agree to consent orders to avoid the uncertainty of an administrative hearing and to avoid the risk of a more severe sanction than what would be agreed upon in a consent order. As part of the terms of all consent orders with the BMLD, if physicians do not comply with their consent order, they agree that the Director may suspend their license.

Our logistic regression model looked at age, sex, and specialty against license status. An increased risk association with age and prior disciplinary action has been previously described, and other analyses have suggested this may be more directly related to years out of training. Our analysis, adjusted for sex and specialty, showed a small but statistically significant increased risk with increasing age. It is not clear from the current review why male physicians are at increased risk for disciplinary action when adjusted for age and specialty, yet a prior RIDOH study⁶ regarding controlled substance disciplinary actions also showed males to be more commonly affected.

Prior analysis has shown specialty may be a risk for disciplinary actions.⁷ This study did not demonstrate any significant difference by specialty, likely because of the relatively smaller sample size of 66 physicians disciplined in the period observed.

Physician loss of license is largely preventable throughout one's career. One of the benefits of rules and regulations is there is an established, agreed-upon standard to follow. Adhering to the Pain Management regulations⁸ is a sensible way to prevent misconduct relevant to the highest risk

area, controlled substance prescribing. Physicians are also reminded that reaching out to the PHP (<https://www.rimedicalsociety.org/physician-health-program.html>),⁹ prior to an allegation of professional misconduct, is wise to protect the physician's career and the patients' health and wellbeing.

The BMLD is comprised of 13 members, 7 physicians and 6 public members appointed by the Governor. Anyone interested in opportunities to be considered for appointment to the BMLD should contact RIDOH.

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Contained Free Wall Rupture after Myocardial Infarction

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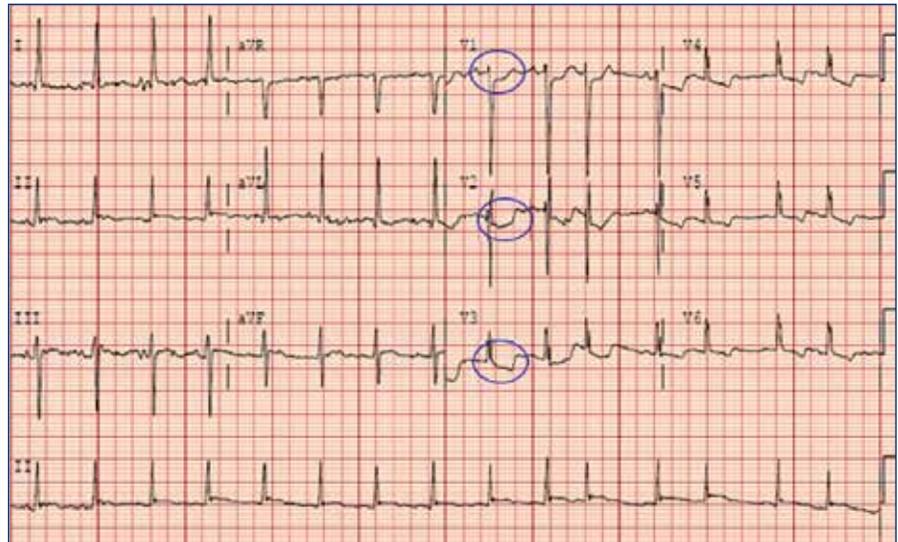
CASE SUMMARY

A 78-year-old man with Alzheimer's disease, coronary artery disease and anteroapical infarction 18 years prior resulting in triple-vessel Coronary Artery Bypass Grafting (CABG), presented via ambulance after his wife had found him stumbling in his bathroom. His only complaint leading up to this episode was right-shoulder pain. Initially vital signs were stable, but over the course of four hours he developed tachypnea and hypoxia. Electrocardiogram demonstrated new ST-depressions in precordial leads V1-3 (Figure 1). Troponin was elevated to 15.18 ng/mL. Patient was administered loading doses of both aspirin and ticagrelor given concern for posterior wall infarction. On Bipap, patient became hypotensive to 84/61. The patient's hemodynamic deterioration prompted an urgent bedside echocardiogram. A contained left ventricular free wall rupture was visualized (Figure 2).

DISCUSSION

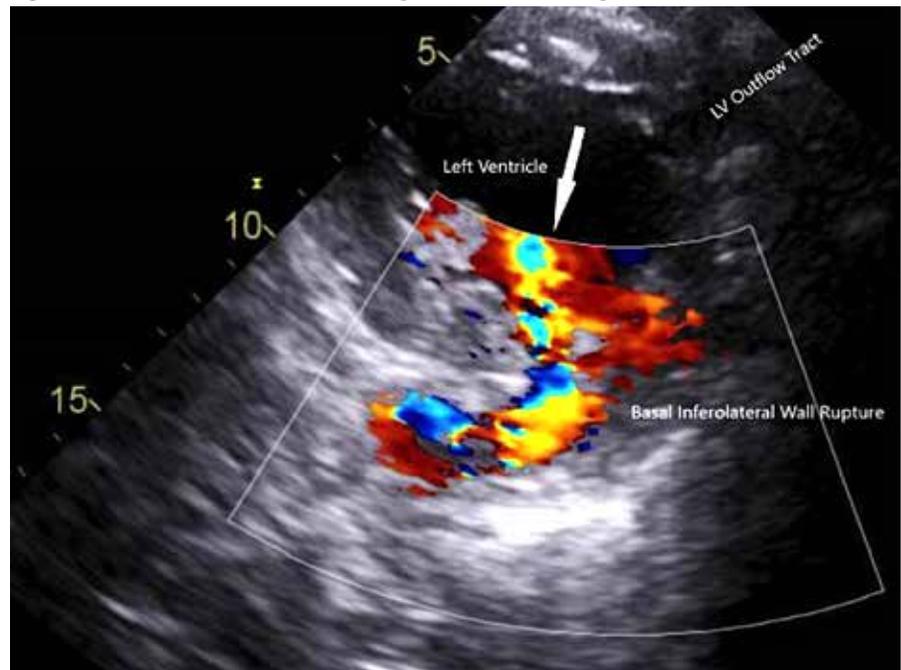
Free wall rupture is one of the more feared complications of myocardial infarction (MI), occurring classically within the first week of MI. A pseudoaneurysm forms when the rupture is contained by pericardium or scar tissue. Pseudoaneurysms can also be caused by trauma or surgery. However, MI is reported as the etiology more than half of the time.¹ When infarction is the culprit, the inferior or posterolateral wall are the most common areas for pseudoaneurysm formation.² If a pseudoaneurysm forms following an MI, it generally has a narrow neck with an abrupt disfiguration of the left ventricle.³

Figure 1. EKG on Presentation



*New ST-depressions in the precordial anterior leads (V1-V3), circled in blue

Figure 2. Bedside Transthoracic Echocardiogram, Parasternal Long Axis



*Left ventricular wall rupture with significant structures labeled. White arrow indicating ventricular wall defect and direction of flow.

Figure 2 fits the discussed descriptors for pseudoaneurysm formation following an MI. The rupture opening is narrow at the basal inferolateral wall causing compression of the left ventricle and obscuring normal landmarks. Our patient most likely experienced a silent MI in the week leading to his presentation. Surgical management of ventricular rupture following infarction is complicated because the defect is difficult to reach at the base of the heart and is surrounded by necrotic tissue. This patient had been loaded with dual antiplatelet therapy (DAPT) making any surgical intervention more hazardous. Given recent administration of dual antiplatelet therapy, his progressive Alzheimer's disease, and the overall high risk for surgical mortality, immediate surgical management was not recommended. The patient and his family decided to pursue comfort measures only with no further escalation of care.

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Spinal Epidural Hematoma After Attempted Catheter Thrombectomy of a Large Iliofemoral Deep Venous Thrombosis: A Case Report

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ABSTRACT

The authors report the case of an 82-year-old woman with a spinal epidural hematoma following attempted catheter-directed thrombolysis of a large femoral-popliteal deep venous thrombosis. The patient rapidly developed acute motor and sensory paralysis below the level of T7 within hours of the thrombectomy procedure. Computed tomography imaging revealed that the catheter had perforated the wall of the right inferior vena cava and magnetic resonance imaging subsequently demonstrated an extensive T1-S1 dorsal epidural hematoma with compression of the thoracic spinal cord, conus medullaris, and cauda equina. Given the extent of cord infarction and the risks of extensive thoracolumbar laminectomy, decompression was not performed. The incidence, diagnosis, and management of anticoagulation-associated spinal epidural hematoma as well as the indications for catheter-directed thrombolysis of acute deep venous thrombosis are reviewed.

KEYWORDS: epidural hematoma, spinal epidural hematoma, spinal cord injury, DVT, PE, thrombectomy, thrombolytic

INTRODUCTION

Spinal epidural hematoma (SEH) is rare but has been reported as a sequela of thrombolytic therapy.^{1,2} It is usually localized, most commonly occurring in the T12-L1 region and producing neurological symptoms 12–24 hours following the typical initial presentation of severe focal back pain.^{1,2} Up to one-third of SEH is associated with anticoagulant therapy,^{2,3,4,5} which is commonly used to treat a variety of conditions including atrial fibrillation, deep venous thromboembolism (DVT), and pulmonary embolism. Catheter-directed thrombolysis (CDT), which involves percutaneous placement of a venous catheter in the vicinity of the thrombus for the local delivery of thrombolytic agents, is a treatment modality primarily indicated for the acute management of life-threatening proximal iliofemoral DVT.⁶ Compared to intravenous anticoagulation alone, CDT contributes to better complete thrombolysis and prevention of venous obstruction but does not significantly reduce

mortality or risk of recurrent DVT; furthermore, CDT has also been associated with significantly higher risk of major bleeding.⁶ In this report, we review the case of an 82-year-old female who suffered a large SEH after CDT.

CASE REPORT

An 82-year-old female with prior history of multiple intracranial meningiomas treated with stereotactic radiosurgery presented to an outside hospital with a 3-day history of left lower extremity (LLE) swelling and was found on ultrasound to have an acute occlusive left deep venous thrombus (DVT) from the common femoral vein to the popliteal vein. Her laboratory evaluation was notable for a mild creatinine elevation and troponin I elevation (0.153 ng/mL). She was started on a continuous heparin infusion and intravenous fluids. Three days later, she developed acute midthoracic back pain without associated neurological symptoms. Two days later, given the patient's improved but incompletely resolved LLE pain and swelling, she underwent attempted ultrasound-augmented catheter-directed (CDT) tissue plasminogen activator (tPA) thrombolysis with the EKOS EndoWave Infusion Catheter System (EKOS Corporation, Bothell, WA). Immediately following the procedure, she quickly developed bilateral lower extremity paraplegia. tPA was held. Duplex ultrasounds of the lower extremities were unremarkable. CT imaging of the brain, abdomen, and pelvis was negative for intracranial hemorrhage, stroke, and retroperitoneal hemorrhage; however, new foci of air in the right retroperitoneal space adjacent to the IVC were noted. tPA was then restarted and the patient transferred to our center. Examination at that time was notable for complete loss of motor and sensory function below the T10 level, consistent with an American Spinal Injury Association (ASIA) Grade A spinal cord injury.

Repeat CT imaging of the abdomen and pelvis demonstrated perforation of the IVC wall by the catheter at the level of the right renal vein; in retrospect, these findings are consistent with the identification of right-sided retroperitoneal air on the previous CT scan (**Figure 1**). The patient was urgently taken to interventional radiology for removal of the EKOS catheter and IVC filter placement. Subsequent spine MRI revealed a dorsal epidural hematoma extending from T1-S1 with compression of the thoracic spinal cord, conus

Figure 1. Abdominal imaging demonstrating perforation of the right renal vein by EKOS catheter. **(A)** Coronal CT showing catheter tip (yellow arrow) extending beyond the wall of the right renal vein. **(B)** Venogram following EKOS catheter removal. Sequential frames showing leakage (yellow arrows) of contrast into the retroperitoneal space above the junction of the right renal vein and inferior vena cava.

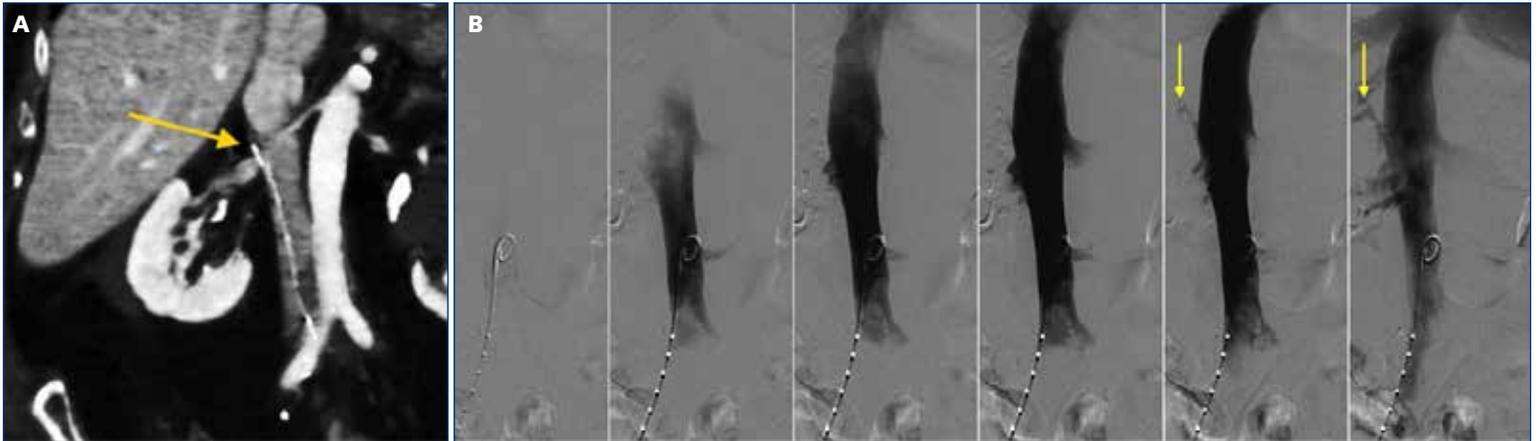


Figure 2. MRI imaging of patient's spinal epidural hematoma. Midsagittal T2 STIR images of **(A)** thoracic spine and **(B)** lumbar spine, demonstrating hematoma extending from T1-S1 with marked compression of the thoracic cord. **(C)** Transverse axial images of the thoracic spine demonstrating T2-hyperintense signal of the ventral horn (yellow arrows), suggesting acute ischemic infarction in the vascular distribution of the anterior spinal artery.



medullaris, and cauda equina with acute ischemic infarction in the vascular distribution of the anterior spinal artery (**Figure 2**). Given the risks of surgical intervention and limited potential benefits of surgery, the patient and family declined decompressive surgery. The patient was ultimately discharged to rehabilitation – at that time, she was still plegic in her bilateral lower extremities. She has since passed away.

DISCUSSION

Outcomes of SEH are variable.² Of the cases reported in the literature, SEH is usually localized, most commonly occurring in the T12-L1 region and not producing neurological symptoms until 12–24 hours following the typical initial presentation of severe focal back pain.^{2,3} In one case, a patient with a left leg DVT was treated with catheter-directed urokinase thrombolysis and a venous stent and several hours after the procedure developed severe lower back pain followed by bilateral lower extremity paraplegia, which

resolved after evacuation of a T11-L2 spinal epidural hematoma revealed by MRI.⁷ In another case, a 43-year-old male patient receiving tPA and heparin for treatment of acute myocardial infarction developed a C6-T5 SEH 18 hours after administration, and did not regain neurological function after decompression.⁸

In this case, the patient's complaint of acute onset back pain could have indicated an SEH,^{1,2} however, other causes of sudden-onset atraumatic back pain, including osteoporotic or pathologic compression fracture or spinal epidural abscess, were also on the differential. Although the patient was neurologically intact, severe atraumatic back pain in the context of therapeutic anticoagulation should have prompted urgent evaluation with MRI. Epidural hematoma was likely inappropriately ruled out by the primary team on the basis of CT imaging, which is insensitive for SEH, alone. Given the patient's midthoracic back pain after 4 days of heparin, it is also possible that a minor heparin-associated spinal epidural hematoma was catastrophically amplified by the release of retroperitoneal tPA, which may have entered into spinal veins or radicular arteries.

Low-molecular-weight heparin remains the mainstay of both immediate and long-term anticoagulation for venous thromboembolic disease in the setting of malignancy.⁷ Although renal impairment is a contraindication to initiation of enoxaparin, this patient's mild acute kidney injury on presentation (GFR 47 mL/min) should not have necessitated the use of unfractionated heparin. Furthermore, guidelines from the American College of Chest Physicians do not recommend the routine use of CDT, which has been associated with increased bleeding risk without mortality benefit, in the management of DVT. Currently, the strongest relative indication for CDT is for patients with acute (<14 days from onset) ileo-femoral DVT with impending venous gangrene, good functional status, and no contraindications to thrombolytic therapy. As previously noted, this patient's DVT did not extend to the iliac vein. Furthermore, as per the most recent CHEST guidelines, the patient's advanced age and female gender have both been associated with increased risk of hemorrhagic complication after thrombolysis and are considered relative contraindications to thrombolytic therapy.

In our opinion, the patient and her family reasonably declined surgical treatment. Although extrapolated in this case, data from the traumatic spinal cord injury literature suggest a greater than 60% 1-year mortality for geriatric patients (age > 70) with ASIA A spinal cord injury.⁹

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VITAL STATISTICS

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 DIRECTOR, RHODE ISLAND DEPARTMENT OF HEALTH
 COMPILED BY ROSEANN GIORGIANNI, DEPUTY STATE REGISTRAR

Rhode Island Monthly Vital Statistics Report

Provisional Occurrence Data from the Division of Vital Records

VITAL EVENTS	REPORTING PERIOD		
	NOVEMBER 2019	12 MONTHS ENDING WITH NOVEMBER 2019	
	Number	Number	Rates
Live Births	842	11,080	10.5*
Deaths	873	10,583	10.0*
Infant Deaths	6	59	5.6#
Neonatal Deaths	6	45	4.2#
Marriages	424	6,548	6.2*
Divorces	—	2,900	2.8*

* Rates per 1,000 estimated population

Rates per 1,000 live births

Underlying Cause of Death Category	REPORTING PERIOD			
	MAY 2019	12 MONTHS ENDING WITH MAY 2019		
	Number (a)	Number (a)	Rates (b)	YPLL (c)
Diseases of the Heart	198	2,458	232.0	3,057.0
Malignant Neoplasms	182	2,264	213.7	5,057.0
Cerebrovascular Disease	42	454	42.9	372.5
Injuries (Accident/Suicide/Homicide)	86	930	87.8	12,757.0
COPD	46	495	46.7	435.0

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

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

(c) Years of Potential Life Lost (YPLL).

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.

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RIMS NOTES: NEWS YOU CAN USE

This issue sponsored by

Welcome to the current issue of *RIMS Notes*, your concise, bi-weekly bulletin to keep RIMS members up to date on RIMS, the legislature, and highlights of our advocacy efforts.

Volume 1 - Number 21

For more information about our Sponsors, please visit [here](#).

What's New

On October 14 CMS published its Final Rule for implementing MACRA. All physicians must take careful note of the momentous changes in how Medicare will pay starting in little more than 2 months. On October 20, AMA released two new documents to help physicians understand the Final Rule and what it means for their practices. AMA's new [chart](#) provides an outline, while AMA's new [summary document](#) provides detail of MACRA. The Final Rule incorporates a number of improvements that AMA fought for to ease the transition for doctors.

Membership Activities

The Medical Society's new website debuted September 22, 2016. The URL is unchanged: www.rimed.org, but everything else has been rebuilt from the ground up in fulfillment of strategic planning and consulting done last winter. You will like what you see.

December 1 Back by popular demand! [Paint and Wine](#) at the Muse Paint Bar, 117 North Main Street, Providence. Register through the [Member Portal](#) on RIMS' website. Unleash your inner artist.

Keeping You Posted: Opioids

New Prescription Limits are in Effect! By state law effective June 28, 2016, initial opioid prescriptions for outpatient adults shall entail no more than 30 morphine milligram equivalents (MMEs) or 20 total dosages. Review the impact of these important new laws [here](#).

Co-prescribing FDA now requires strong warnings for combined use of opioid analgesics, prescription opioid cough products, and benzodiazepines. The action is part of a national effort led by Rhode Island Director of Health, Nicole Alexander-Scott, MD, MPH, to highlight the dangers of co-prescribing.

Surgeon General to physicians: Take the pledge! Vivek H. Murthy, MD, MBA, calls on America's doctors to [Turn the Tide](#) on the opioid crisis. Read his [letter](#). Take the pledge.

This Date In History - 23 Years Ago

October 21 is National Mammography Day, and October is Breast Cancer Awareness Month. President Bill Clinton designated the third Friday of October as Mammography Day in 1993.

RHODE ISLAND MEDICAL SOCIETY, 405 PROMENADE STREET, SUITE A, PROVIDENCE RI 02908-4811
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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



RI-ACEP President **Otis Warren, MD**, models PPE donated from the public. RIMS is serving as a collection and distribution center for this effort initiated by RI-ACEP.

April 1, Wednesday

Blue Cross conference call regarding telemedicine coverage issues
Department of Health providers conference call regarding clinical issues

April 2, Thursday

American Tort Reform Association (ATRA) webinar *COVID-19: The Legislative Response* (via teleconference)

April 3, Friday

Blue Cross conference call regarding telemedicine coverage issues
Conference call with American Nurses Association-RI, RI Academy of Physician Assistants, and the Hospital Association of RI regarding provider issues

April 4, Saturday

RIMS goes live as a collection site for donated PPE in collaboration with the Rhode Island Chapter of the American College of Emergency Physicians

April 6, Monday

AMA federal legislation update call
RIMS Council: Christine Brousseau, MD, MPH, President; James McDonald, MD, MPH, Medical Director RI Department of Health, guest (via teleconference)

April 7, Tuesday

RIMS Physician Health Committee: Herbert Rakatansky, MD, Chair (via teleconference)

April 8, Wednesday

Governor's Overdose Opioid Overdose Intervention and Prevention Task Force (via teleconference)
RIMS goes live as the collection site for donated iPads as a partner in "COVID Connectors," an action initiated by Rory Merritt, MD, and Kaya Suner, to enable isolated patients to maintain contact with loved ones

April 9, Thursday

AMA conference call with state medical societies, Patrice Harris, MD, MPH, AMA President

April 10, Friday

RIMS Notes production
Governor Raimondo issues Executive Order 20-21 conferring liability immunity upon health care professionals and institutions during the emergency. The Governor acted in response to RIMS' March 30 call for such immunity

April 14, Tuesday

Governor's Overdose Task Force Harm Reduction Working Group (via teleconference)
Conference call with U.S. Senator Sheldon Whitehouse and staff: Peter A. Hollmann, MD, Chair of the Board; Christine Brousseau, MD, MPH, President; Catherine A. Cummings, MD, President-elect; Michael Migliori, MD, Chair, Public Laws Committee; and staff

April 15, Wednesday

Department of Health Primary Care Provider Advisory Committee (via teleconference)

April 16, Thursday

American Tort Reform Association (ATRA) webinar *COVID-19: Legislative Recommendations to Curb the Coming Legislative Surge* (via teleconference)
Call with state medical society public health leads – COVID-19 (via teleconference)

April 17, Friday

AMA federal legislation update call
World Diabetes Day (WDD) planning meeting – Department of Health (DOH)
Call with Department of Health (DOH) regarding federal grant application for dementia funding

April 18, Saturday

Bi-Annual *11th Hour CME Event*, (via webinar)

April 21, Tuesday

American Medical Association (AMA) Advocacy Resource Center (ARC) Executive Committee Conference Call

April 22, Wednesday

RI Medical Repertory Charter School Board of Directors Call: Bradley Collins, MD, RIMS Staff

April 24, Friday

RIMS Notes production
World Diabetes Day (WDD) planning meeting – Department of Health (DOH)

April 28, Tuesday

Conference call with Congressman Cicilline and staff: Peter A. Hollmann, MD, Chair of the Board; Christine Brousseau, MD, MPH, President; Catherine A. Cummings, MD, President-elect; Michael Migliori, MD, Chair, Public Laws Committee; and staff

April 30, Thursday

Health Professional Loan Repayment Board/Department of Health: Steve DeToy, Board Member (via teleconference)
New England Delegation (NED) to the American Medical Association (AMA) conference call: Peter Hollmann, MD, Chair



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 expanding its Affinity Program to allow for more of our colleagues in health-care 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.

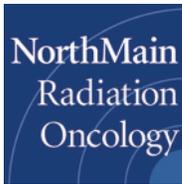


www.ripccpc.com

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.



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Zoom Talk on “The Great Influenza” with John M. Barry

Lessons from 1918

MARY KORR
RIMJ MANAGING EDITOR

On April 20th, the *Rhode Island Medical Journal* (RIMJ) and other media outlets participated in a National Press Foundation (NPF) Zoom book talk with Providence native **JOHN M. BARRY**, author of “The Great Influenza: The Story of the Deadliest Pandemic in History,” which was named the National Academy of Sciences’ outstanding book on science or medicine in 2004. The book returned to the *New York Times* bestseller list recently. Barry is currently a professor at the Tulane University School of Public Health and Tropical Medicine.

In the hour-long discussion, it was evident that the lessons from the past resonate today in the current COVID-19 pandemic. Barry, who spoke from his home in New Orleans, gave a shout-out to his home state when responding to a question from RIMJ. “Hello, Providence. I went to Classical High School and Brown University. My mother still lives there; she’s 102 years old and still kicking.”

During his talk and in the Q&A period, he gave an overview of the emergence of the influenza of 1918 and public response. He offered his two key takeaways presented in his book:

1. Failure to tell the truth killed people.
2. Well-established social distancing measures work, but you need to get compliance from the public; the public needs to believe the message from government. Ultimately society’s response is based on trust.

In 1918, the public heard from officials that the flu in 1918 was like any other flu, “an ordinary influenza by another name. There was no Tony Fauci in 1918,” he said wryly. Complicating matters was World War I. He said government officials and public figures as well as newspapers felt pressured to maintain wartime morale, and as a result the truth suffered, as well as trust in government.

The first influenza wave was mild, Barry said, but described the second wave in the fall of 1918 as “lethal.” He quoted Dr. Victor Vaughn, who was the Dean of the University of Michigan Medical School, and who served as head of communicable diseases for the US Army during that period, and who was dispatched to Army camps to investigate when thousands of troops became ill. Vaughn said: “If the epidemic continues its mathematical rate of acceleration, civilization could easily disappear from the face of the earth.”

By the time the epidemic ran its course, over a million troops were afflicted with influenza, and 30,000 of them died; 675,000 people died in the United States as a whole. Barry said industrial Pittsburgh had one of the highest mortality rates and that statistics from Metropolitan Life showed that the younger people were the most susceptible, with the peak age of death at 28 years and two-thirds of the deaths in the 18–45 age range. “18% of all factory workers died in a compressed time frame from 6 to 8 weeks.”



John M. Barry (bottom) during a Zoom Book Talk from his New Orleans home. **Chris Adams**, top, of the National Press Foundation, moderated the event.

Barry noted there was a third influenza wave in 1919 and arguably a seasonal wave in 1920 but that the most lethal was in the second wave of 1918. He said the source of the influenza, whose natural reservoir is birds, still remains definitive; at first it was thought to be from a small corner of Kansas, transmitted then to an Army encampment, but that it could also have come from overseas, or New York. “We will never really know,” he said.

Most of the victims, he related, died of bacterial pneumonia or acute respiratory distress syndrome (ARDS). In response to another question, he stated that as the influenza of 1918 started to ebb, people wanted to get back to normal and cities opened up shuttered saloons, restaurants, and theaters and allowed large gatherings, such as parades. But, one city had to shut down three times when the virus returned “with a vengeance.”

In response to the question RIMJ asked: “The influenza pandemic also catalyzed a dramatic evolution in American medicine. Are there similar paradigm changes in medicine that we are likely to see from the current pandemic?” he answered he thought COVID-19 has served as a catalyst for unprecedented cooperation among competing scientists and the scientific community that hopefully will result in expedited vaccines and a broad spectrum of antivirals.

“This is not the only virus in the wild that can jump species. In fact, this is an event that a lot of people predicted. There will be more in the future,” he said. ❖

Preparing for Potential COVID-19 Surge

Convention Center, two other field hospitals ready if needed

MARY KORR
RIMJ MANAGING EDITOR

The motto of the State of Rhode Island is “Hope.” And everyone in the state is hoping the plans announced this week by Governor Gina Raimondo at her daily press briefing on Monday, to phase in a gradual re-opening on May 9th, will occur.



John Murphy, MD, Executive Vice President of Physician Affairs, Lifespan and Interim President, Rhode Island Hospital, in patient room.

“We have started to plateau and if social mobility remains down, maybe we will even see a decline in positive COVID cases in a couple of weeks,” she said. The hospitalization number has remained relatively flat for about two weeks now. “Overall, it is a very stable picture,” the governor said.

Later on Monday, **JEREMIAH SCHUUR, MD**, Chair of the Department of Emergency Medicine at the Alpert

Medical School, spoke during a Brown webinar on preparing for a surge during a pandemic. Acknowledging a flattening of the curve, he spoke on reviewing preparedness for a surge beyond existing hospital structures, one component of disaster preparedness.

Planning to account for models of patient surge, requested by Rhode Island officials, began in March, and within a month, the Rhode Island Convention Center facility, operated by Lifespan, was ready to go with a capacity of up to 600 beds to care for lower acuity patients or patients transitioning out of hospital. That effort was directed by **SELIM SUNER, MD, MS**, on the staff at Rhode Island Hospital, and the Director of Disaster Medicine and Emergency Preparedness in the Department of Emergency Medicine, and **CATHY DUQUETTE, PhD, RN**, Chief Nursing Executive for Lifespan.

In addition to the Convention Center site, there are two other surge facilities available should they become



Selim Suner, MD, MS, Director of Disaster Medicine and Emergency Preparedness in the Department of Emergency Medicine at Rhode Island Hospital.

necessary: at the former Citizens Bank facility at Sockanosset Cross Road in Cranston, and at the former Lowe’s warehouse in the Quonset Business Park in North Kingston. If necessary, the three facilities could provide more than 1,500 additional hospital beds. Care New England is managing the



Cathy Duquette, PhD, RN, Chief Nursing Executive for Lifespan, in resuscitation room.

[Photos: Rhode Island Medical Journal]



Donald McKaig, RPh, Lifespan's pharmacy manager, in pharmacy area.

At the Rhode Island Convention Center, capacity ranges from 546 beds to 594. The convention center's main display space has been transformed into four wards comprised of 28 pods, each with 24 beds; walls and a curtain separate each individual "unit."

An architect suggested adding Rhode Island street signs, such as Hope Street on the East Side and Nayatt Road in Barrington, along the corridors.



A network of metal ducts provides negative pressure to ensure safe airflow.

Citizens Bank and Lowe's facilities.

"We have not been overwhelmed like New York," Dr. Schuur said. "At this point it does not look like we will need them, but an essential part of preparations in a pandemic have included field hospitals. The best evidence was they would be used in some capacity. Had we not done this and it was needed, there would have been a tremendous amount of suffering."

He noted the two important steps he sees in the resumption of normal hospital operations are having rapid, accurate point-of-care testing and isolating COVID-19 patients when the spread is under control. "I don't see COVID going completely away," he said. ❖



New CNE Covid-19 testing site opens on Memorial Hospital grounds

Care New England's President and CEO **DR. JAMES FANALE**, Pawtucket Mayor **DONALD R. GREBIEN**, and Central Falls Mayor **JAMES A. DIOSSA** announced the opening of a multilingual coronavirus testing site that

has more than tripled the capacity of existing test sites in the Blackstone Valley, in addition to the respiratory clinic already provided on the site by Care New England.

The site opened on April 22 at the former Memorial Hospital property, as part of CFP Beat COVID-19, a broad community collaboration aimed at stopping the spread of coronavirus in these two communities.

The launching of the site to provide accessible testing to the Blackstone Valley was a collaborative effort between Care New England, Pawtucket and

Central Falls, the Rhode Island Department of Health, and the Rhode Island National Guard.

The coronavirus testing site is staffed by CNE medical professionals Monday-Friday from 8 a.m. to 5 p.m. ❖



[PHOTOS: RIMJ]



Drs. Caliendo, Kurtis to lead COVID-19 testing and validation task force

On April 24th, Governor Gina Raimondo announced at her daily press briefing the formation of a COVID-19 testing and validation task force, to be headed by **ANGELA CALIENDO, MD, PhD**, and **JONATHAN "JAKE" KURTIS, MD, PhD**.



She said the state has received 20,000 antibody tests which will be used to obtain a random sampling throughout the state to assess the prevalence of COVID-19. The task force will analyze and draw conclusions from the tests. She said it would be "weeks, not days" before the state would be able to share results.

She also noted that Rhode Island has had the highest number of COVID-19 tests performed per capita in the nation, now nearing about 3,000 tests per day.

Plans for hospital to re-start procedures

She also announced she has asked Rhode Island hospitals to provide her and the Department of Health with a plan to re-start non-critical surgeries and procedures, which will be evaluated over the next few weeks. "We now need to get back in the business of allowing hospitals to do these. This is a key source of revenue for hospital systems. After we see and evaluate plans they will be given a date to incrementally bring back these procedures," Governor Raimondo said. ❖

Lifespan reports COVID-19 related financial losses in March roughly equivalent to last year's total losses

On Monday April 20th, Lifespan reported an operating loss of \$23.8 million for the month of March related to the COVID-19 crisis. The losses were primarily due to the canceling of elective surgeries, closing of ambulatory sites, and a significant reduction in office and emergency room visits. In addition to lost revenue from declining patient volumes and revenue, there were significant increases in expenses associated with our preparedness efforts including maintaining as many staff as possible on the payroll, expenses associated with procuring personal protective equipment and additional testing and lab expenses. After factoring in \$8.9 million for restructuring expenses unrelated to COVID-19, the Lifespan operating loss for the month of March 2020 is \$32.7 million. Investment losses included in nonoperating gains/losses of \$41.1 million will result in a one month overall net loss of \$75.7 million.

For the entire fiscal year of 2019, Lifespan reported an operating loss of \$23 million and a net loss of \$34.9 million – their worst loss in more than a decade.

"From a purely financial standpoint, this crisis could not have come at a worse time for Lifespan since we were beginning to reap the financial benefits of our restructuring efforts that began at the end of last year. As we recently reported, operating losses shrunk to \$2.6 million for the first quarter of fiscal year 2020 (October 1, 2019–December 31, 2019)," said **DR. TIMOTHY BABINEAU**, Lifespan's President and CEO. "Unfortunately, we anticipate that April and May will be even worse, and we could approach \$100 million in operating losses for the time period March-May. We are working around the clock developing plans to mitigate these losses while working hard to keep as many Lifespan staff employed as possible. We sincerely hope the state and federal government will provide enough financial relief to ensure that Lifespan can be here when our citizens need us the most. Recently, we received approximately \$25 million in federal relief. Certainly, a help, but much more needs to be done."

In a partial response to these financial challenges Dr. Babineau, Lifespan's president and CEO, stopped drawing any salary as of April 1, 2020. ❖

After factoring in \$8.9 million for restructuring expenses unrelated to COVID-19, the Lifespan operating loss for the month of March 2020 is \$32.7 million. Investment losses included in nonoperating gains/losses of \$41.1 million will result in a one month overall net loss of \$75.7 million.

CNE reports operating loss of \$15.2M in March

Care New England had an operating loss of \$15.2 million for just the month of March, plus non-operating losses of \$29.3 million largely tied to investments.

Care New England already received \$8.7 million in additional federal aid from the \$2.2 trillion CARES Act that Congress passed earlier.

"At some point, elective [surgeries] will open up – probably sooner than later. But remember – I don't think it's all going to come back right away. If everything came back in May, we'll struggle through a couple months – even though they're devastating losses in March and April. But I don't think it's going to come back right away. It's going to be slow," said CNE President & CEO **DR. JAMES FANALE**. ❖

Immunomic partners with EpiVax and PharmaJet on COVID-19 vaccine

ROCKVILLE, MD, PROVIDENCE, RI, AND GOLDEN, CO – Immunomic Therapeutics, Inc., a privately held clinical stage biotechnology company pioneering the study of nucleic acid immunotherapy platforms, announced in April that it is developing a nucleic acid vaccine candidate against COVID-19 leveraging its investigational UNITE platform for prevention of the novel coronavirus disease caused by SARS-Cov-2 coronavirus.

Immunomic will work with leaders from EpiVax and PharmaJet, who have a wealth of immunology and vaccine delivery expertise, to rapidly develop its COVID-19 vaccine. Immunomic's UNITE platform has been widely applied to create vaccine candidates for rabies, yellow fever, dengue fever, hepatitis C and SARS, a relative to the SARS-Cov-2 coronavirus.

"COVID-19 is a global pandemic and fighting this will take a major global effort investigating many prevention therapies, treatment options and new modalities. We believe that our UNITE platform, which has shown promising results in infectious disease applications, is well-suited to develop novel vaccines for coronaviruses," said **DR. WILLIAM HEARL**, CEO of Immunomic Therapeutics. "To rapidly advance our COVID-19 program, we are excited to collaborate with EpiVax, PharmaJet and our academic and strategic partners to explore ways to flatten the curve and prevent the spread of this deadly virus."

EpiVax CEO, **DR. ANNIE DE GROOT**, said "My company is thrilled to partner with ITI and PharmaJet on this important project. We believe that the UNITE platform, combined with epitopes that have been carefully triaged by EpiVax's advanced computational tools, will generate a highly effective immune response against the pathogen that causes COVID-19, while reducing off-target effects."

"We are pleased to be collaborating with Immunomic and EpiVax on this important program," said **CHRIS CAPPELLO**, President and CEO of PharmaJet, Inc. "The PharmaJet Tropis intradermal Needle-free Injection System has had great success in clinical studies as well as improved the immune response of multiple nucleic acid based (DNA and RNA) vaccines."

This collaboration will combine leading technologies from all three companies: Immunomic's UNITE platform, EpiVax's in silico T cell epitope prediction tool, and PharmaJet's well established Tropis® Needle-free Injection System that precisely targets delivery to the intradermal tissue layer. By bringing these companies' and their technologies together, Immunomic aims to create a vaccine against COVID-19 that produces broad and potent immune responses, is feasible for rapid-responses, scalable, thermostable, safe and easy to administer by healthcare professionals. In addition to working with EpiVax and PharmaJet, Immunomic plans to explore grant initiatives through the U.S. government, other companies and institutions, non-profit organizations, and investigators in the infectious disease field to advance its efforts against COVID-19. ❖

EpiVax Partners with GAIA Vaccine Foundation to make COVID-19 vaccine license free to developing countries

PROVIDENCE – EpiVax, Inc., is using advanced computational tools to accelerate a COVID-19 vaccine candidate (EPV-CoV19) for healthcare workers (HCW) into clinical trials in 6 months. Recently EpiVax announced its partnership with GAIA Vaccine Foundation ("GVF") to crowd-source funds for the project and its pledge to make a free license available to developing countries who qualify, in the context of this partnership.

EPV-CoV19 is a peptide-based, epitope-driven vaccine that can be rapidly and safely produced in most countries. Applying EpiVax's expertise enabled the selection of sequences representing all circulating SARS-CoV-2 genomes that will drive a T cell-mediated immune response, providing HCW with immune system "body armor", reducing their risk of morbidity and mortality. EPV-CoV19 will enter US clinical trials once funds have been raised (\$1.75M).

GVF, a 501(c)(3) nonprofit organization, will enable private citizens and foundations to contribute to development of EPV-CoV19. GVF's mission is to reduce incidence of infectious diseases that disproportionately affect the under-served and promote the development of globally relevant, accessible vaccines that can be distributed on a not-for-profit basis in the developing world. **ANNIE DE GROOT, MD**, EpiVax CEO/CSO, said, "The soul of each company will be revealed during this crisis. Personally, I do not believe this is the time to become a billionaire. Each of us should do what we do best to reduce the impact of COVID-19 globally."

As it is the mission of EpiVax to "improve human health everywhere," the company has granted GVF a cost-free, royalty-free license to the EPV-CoV19 design for use in countries that can produce and test the vaccine candidate on the Least Developed Countries list published by the United Nations. Collaborators and a clinical trial site in West Africa have been identified.

Donations to the GVF COVID-19 vaccine fund will be entirely dedicated to the preclinical and clinical development phases of EPV-CoV19.

For more information or to make a donation to the program, visit <http://www.gaiavaccine.org/covid19>. ❖

About EpiVax: EpiVax is a biotechnology company with a broad portfolio of projects, including vaccines and immunotherapies for infectious diseases, autoimmunity and cancer. www.epivax.com

About GVF: GVF is a 501(c)(3) organization that supports activities to advance healthcare accessibility and educational programs to inform the public about diseases, including HIV, and the importance of vaccines in West Africa. www.gaiavaccine.org

New Southcoast ICU opens ahead of schedule as part of COVID response

St. Luke's adds 16 beds, doubles size of previous unit, which will remain in operation



From left, **Keith Hovan**, President and CEO of Southcoast Health, **Maria Tassoni, RN**, Nurse Manager, and **Dr. Michael Barretti**, Medical Director for the new ICU at the abbreviated ribbon-cutting ceremony for the new ICU.

NEW BEDFORD – Southcoast Health's \$14 million, state-of-the-art intensive care unit at St. Luke's was slated to open soon – just not quite this soon.

But the not-for-profit health system opted to accelerate the project's completion as part of its preparation for and response to the COVID-19 pandemic's potential impact in the region, Southcoast officials said recently during a "virtual ribbon cutting" featuring physically distanced administrative and clinical leaders. The timeline was moved up by as much as a month in anticipation of a projected surge, they said.

At 16,000 square feet, the new ICU, built on the fourth floor of St. Luke's, more than doubles the size of the previous unit, which itself will remain in operation to handle increased patient volume related to the coronavirus. At a later date to be determined, the space will be repurposed for medical/surgical patients.

"The fact that this investment in our community could be up and running at such a crucial time is a remarkable achievement on the part of our staff and a testament to the trades and small businesses who stayed on the job to see the project through ahead of schedule," said **KEITH HOVAN**, President and CEO of Southcoast Health. "Amid so much uncertainty right now, these frontline health care heroes and amazing essential workers are a source of confidence who inspire enduring gratitude and hope."

Hovan also thanked the Commonwealth of Massachusetts, the local legislative delegation, and the City of New

Bedford for working closely with Southcoast throughout the process.

The new ICU will add 16 beds in 440-square-foot rooms to the hospital's capacity. Other features include an advanced video system for monitoring and safe patient-nurse communication, transitional screening windows for privacy, and images of the region created by local artists to promote a calming, healing environment.

"This new ICU is important for our trauma and critical care patients and staff," said **MARIA TASSONI, RN**, Nurse Manager. "It's more modern, more spacious, and more accessible. We're thankful to everyone who has worked on this project. It's been a group effort, and all involved have been tremendous."

Officials said the new ICU also aligns with Southcoast Health's process to establish St. Luke's as a Level II Trauma Center, meaning patients along the 195 corridor can receive critical care without necessarily needing transport to Providence or Boston during the moments that matter most.

"The Level II Trauma Center required a state of the art medical ICU with enhanced surgical capability, and that's what we have here now to provide our patients with the best possible care," said **DR. MICHAEL BARRETTI**, Medical Director for the new ICU. "The technology and comfort, along with the negative pressure rooms for airborne precautions and upgrades in safety and monitoring features, make this an incredible opportunity and honor for me and our entire staff." ❖



Herbert Aronow, MD, MPH, is author of national recommendations related to cardiovascular care during COVID-19

HERBERT ARONOW, MD, MPH, director of interventional cardiology and of the cardiac catheterization labs at Rhode Island and The Miriam Hospitals, is one of the authors of national recommendations for interventional cardiac procedures during COVID-19. The article, which was accepted for rapid publica-

tion by both the American College of Cardiology and the Society for Cardiovascular Angiography and Interventions, examines:

- How preexisting cardiovascular disease affects severity of COVID-19 infection

- the cardiovascular complications that can arise from infection
- the cardiovascular side effects of therapies under investigation
- How the rapid triage of non-COVID cardiovascular patients may be affected by the response to COVID-19
- How the provision of cardiovascular care may make health care workers vulnerable to infection

The group reviewed peer-reviewed and preprint literature pertaining to cardiovascular considerations and COVID-19, and highlighted gaps in knowledge that require further study. ❖

Researchers at Rhode Island Hospital and The Miriam Hospital interviewed people who use opioids to explore the relationships they have with dealers

PROVIDENCE – A study led by researchers at Rhode Island Hospital and The Miriam Hospital suggests that that one strategy for addressing opioid overdoses and deaths may involve the relationships between people who use illicit drugs and their dealers.

The study, which involved surveys and interviews with Providence residents who use drugs, found that many of them seek to protect themselves from harm by acquiring drugs from dealers whom they know and who either refuse to sell drugs that they know contain fentanyl or test their supply for the dangerous synthetic narcotic.

This new study, published in the *International Journal of Drug Policy*, was paid for by both The Miriam Hospital and the Center of Biomedical Research Excellence (COBRE) on Opioids and Overdoses at Rhode Island Hospital – with funding from the National Institutes of Health.

The same trio of researchers published a similar study in the *International Journal of Drug Policy* in 2017, which demonstrated that most people who use drugs in Providence do not seek out drugs containing fentanyl and struggle to control the contents and quality of the drugs they purchase – pushing back on early suspicions that fentanyl was entering the U.S. drug

market as a result of user demand for “the ultimate high.” This study adds new depth to those earlier findings: while it is certain that fentanyl is being added to the drug supply somewhere in the supply chain, users can better protect themselves from fentanyl overdose by purchasing opioids directly from dealers who are known to them.

“The conventional wisdom that ‘we cannot arrest our way out of this’ is generally well accepted when we talk about people who are living with a substance use disorder. Our study found that we may be able to save more lives if we apply that logic to people who sell and trade drugs as well,” said lead author **JENNIFER CARROLL, PhD, MPH**, a fellow at The Miriam at the time of the research. “Our data shows that arresting someone for drug dealing can immediately increase the risk of overdose faced by the people they regularly sell to., who then may have to buy from a dealer with whom they have no relationship. In other words, our data suggest that enhanced criminal justice responses to drug distribution may actually cause harm rather than reducing the risks posed by substance use.”

Carroll, an adjunct assistant professor of medicine at the Warren Alpert School of Medicine of Brown University and on the faculty of Elon

University, co-authored the paper with two prominent Lifespan opioid research experts. They are **JOSIAH RICH, MD**, an infectious disease physician at The Miriam Hospital and co-director of its Center for Prisoner Health and Human Rights, and **TRACI GREEN, PhD, MSc**, an epidemiologist with Rhode Island Hospital and on the faculty at Brown and Brandeis universities. Rich and Green are co-directors of the COBRE on Opioids and Overdose, which was established at Rhode Island Hospital in 2018 with an \$11.8 million grant from the NIH.

The study involved surveying and interviewing 92 individuals from 2016 to 2017. Of those, 51 discussed their relationships with drug suppliers and indicated that their experience with them was a key part of their strategy to avoid fentanyl. The just-published paper includes excerpts of interviews of anonymous drug users recounting their experiences in Rhode Island.

“This research gives important insight into the nature of the street-level drug market,” said Green. “It suggests taking an approach that considers dealer relationships and the social network, possibly as something to intervene on with prevention and harm reduction, rather than just as something to disrupt and dismantle. ❖

Rhode Island's air quality worsened for ozone pollution, finds 2020 'State of the Air' Report

PROVIDENCE – The American Lung Association's 2020 "State of the Air" report found counties in the State of Rhode Island maintained failing grades for ozone pollution with both Providence and Kent recording more unhealthy days than in last year's report. In contrast, all three reporting counties did report less short-term particle pollution, and only Kent reported a slight increase in long term particles – with all continuing to meet the national standard.

The Lung Association's annual air quality "report card" tracks Americans' exposure to unhealthy levels of particle pollution and ozone during a three-year period. As the country continues to grapple with the COVID-19 pandemic, improving air quality is more important than ever – as studies have shown air pollution harms lung health, and emerging research links long-term exposure to particle pollution to increases in the death rate among COVID-19 patients. Once again, the report found that nearly half of all Americans were exposed to unhealthy air in 2016–2018. In Rhode Island, ozone pollution placed the health of its residents at risk, including those who are more vulnerable to the effects of air pollution such as older adults, children and those with a lung disease.

"For many Americans, the COVID-19 pandemic has illustrated just how important lung health really is," said **DR. TERRANCE HEALEY**, Director of Thoracic Radiology at Rhode Island Hospital. "There is no short cut, no alternative to breathing. We must do more to protect our lungs from anything that puts our ability to breathe at risk, be it a virus, tobacco smoke, or air pollution."

"This year marks the 50th anniversary of the Clean Air Act, which has been responsible for dramatic improvements in air quality. However, Rhode Island residents are breathing more unhealthy air driven by extreme heat as a result of climate change, placing our

health and lives at risk," said **JENNIFER WALL**, Director of Advocacy for the American Lung Association in Rhode Island. "Furthermore, with nearly half of Americans breathing unhealthy air, our 'State of the Air' report shows that nationally, because of climate change, the nation is heading in the wrong direction when it comes to protecting public health."

Each year the "State of the Air" provides a report card on the two most widespread outdoor air pollutants, ozone pollution, also known as smog, and particle pollution, also called soot.

This year's report covers 2016, 2017 and 2018, the years with the most recent quality-assured data available collected by states, cities, counties, tribes and federal agencies. Notably, those three years were among the five hottest recorded in global history. Rising temperatures lead to increased levels of ozone pollution. Changing climate patterns also fuel wildfires and their dangerous smoke, which increase particle pollution. Ozone and particle pollution threaten everyone, especially children, older adults and people living with a lung disease. Although this report does not cover data from 2020, amid the COVID-19 pandemic, the impact of air pollution on lung health is of heightened concern.

Ozone Pollution

Compared to the 2019 report, the Boston-Worcester-Providence metro area, which includes the counties of Bristol, Kent, Newport, Providence, and Washington, worsened for the second year in a row, ranking 38th most polluted metro area for ozone, and showing an increase in unhealthy days. Both Kent and Providence followed suit with increased unhealthy days, and while Washington slowed a slight improvement, all three maintained their failing grades for ozone.

"Ozone pollution can harm even healthy people, but is particularly dangerous for children, older adults and

people with lung diseases like COPD or asthma," said Healey. "Breathing ozone-polluted air can trigger asthma attacks in both adults and children with asthma, which can land them in the doctor's office or the emergency room. Ozone can even shorten people's lives."

This report documents that warmer temperatures brought by climate change are making ozone more likely to form and harder to clean up. Significantly more people suffered unhealthy ozone pollution in the 2020 report than in the last three "State of the Air" reports.

Particle Pollution

"State of the Air" 2020 found that year-round particle pollution levels in Providence were slightly improved, although it continues to be the most polluted county for year-round particles in the Boston-Worcester-Providence metro area. Washington County showed improvement, whereas Kent slightly worsened. Both continue to pass national standards.

"Particle pollution can lodge deep in the lungs and can even enter the bloodstream. It can trigger asthma attacks, heart attacks and strokes and cause lung cancer," said Healey. Particle pollution comes from coal-fired power plants, diesel emissions, wildfires and wood-burning devices.

"State of the Air" 2020 also tracked short-term spikes in particle pollution, which can be extremely dangerous and even lethal. The report found that Providence had fewer days when short-term particle pollution reached unhealthy levels, raising its grade from a B to an A.

While the report examined data from 2016–2018, this 21st annual report also provides air pollution trends back to the first report. Learn more about air quality across Rhode Island and the nation, in the 2020 "State of the Air" report at Lung.org/sota. ❖

Appointments



Athena Poppas, MD, named president of the American College of Cardiology

ATHENA POPPAS, MD, FACC, is the new president of the American College of Cardiology. Her term officially began March 30th.

Poppas has been a long-standing leader of the College throughout her more than 20 years of membership. She previously served as president of the Rhode Island chapter,

holding a seat on the ACC Board of Governors. She also served as Annual Scientific Session chair for ACC.15 where she led the scientific program planning for the conference's 13,000 professional attendees.

As a member of the Governance Committee, she helped spearhead the restructuring of the ACC's governance structure and process to ensure the ability of the College to be nimble, strategic, accountable and inclusive of the diverse needs of the global cardiovascular community. She's also held positions on the Cardiometabolic Strategic Work Group, Clinical Quality Committee and Women in Cardiology Council.

Poppas has been a member of the ACC Board of Trustees since 2010, most recently serving as vice president.

"I am honored to be serving as president and helping to advance the mission and vision of the College," Poppas said. "I'm particularly focused on continuing to expand our efforts in diversity and inclusion, clinician well-being and global expansion of education, science and quality."

Poppas is a professor of medicine at The Warren Alpert Medical School of Brown University and chief of cardiology and director of the Lifespan Cardiovascular Institute at Rhode Island, The Miriam and Newport hospitals.

She received a Bachelor of Science from Brown University and a Doctor of Medicine from the University of Wisconsin Medical School. Poppas completed her residencies in internal medicine at University of Wisconsin Hospital and Clinics and in cardiovascular medicine at University of Chicago Hospitals.

Poppas specializes in valvular heart disease, heart disease in women, and echocardiography and heart disease in pregnancy and focuses her research on echocardiography and heart disease in women and the elderly.

Other ACC officers for 2020–2021 are Vice President Dipti Itchhaporia, MD, FACC; Board of Governors Chair Daniel Philbin, MD, FACC; and Treasurer Howard T. Walpole Jr., MD, MBA, FACC. ❖

Anitra L. Galmore named VP, CNO/COO at South County Health



South County Health has named **ANITRA L. GALMORE, RN, BSN, MS, NEA-BC**, as Vice President & Chief Nursing Officer/Chief Operating Officer. She joined the health system on April 6.

In this capacity, Anitra will oversee and lead South County Health system in its continuing efforts to improve patient care and operational efficiencies.

Prior to joining South County Health, Anitra was Vice President of Nursing/CNQ at SSM Health St. Joseph and Wentzville Hospitals in St. Charles, MO.

She earned a Bachelor of Nursing from Webster University and a Master's in Health Administration from Lindenwood University. She holds Advanced Nurse Executive Certification and Bronze and Silver Certifications in Lean Methodology.

Anitra is currently enrolled in the Doctoral program at St. Louis University.

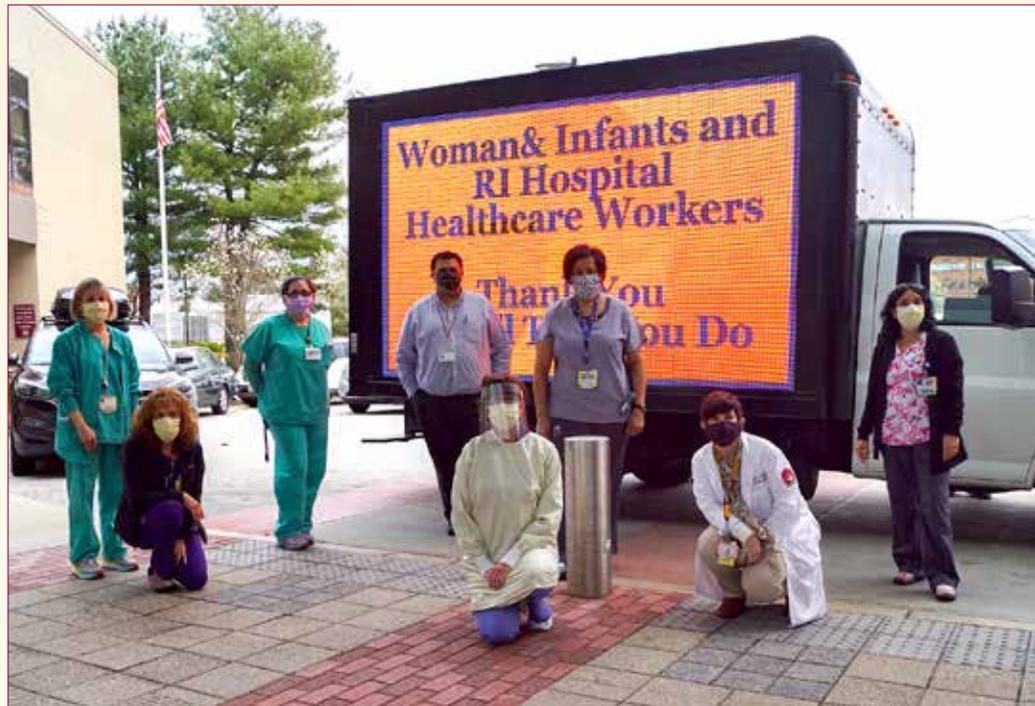
"Anitra brings 20 years of diverse experience as a healthcare executive to this role and will contribute greatly to sustain our reputation of healthcare excellence," said Aaron Robinson, President and CEO of South County Health. "We welcome the leadership experience she brings as it aligns with our mission, vision, and values." ❖

Recognition

Matt Collins, MD, named 2020 Career Achiever by PBN

PROVIDENCE – Providence Business News recently announced its winners for the 2020 C-Suite Awards, honoring top C-level executives in the public, private and nonprofit sectors for their efforts as innovators, trailblazers, role models and leaders in the community.

MATT COLLINS, MD, MBA, executive vice president and chief medical officer for Blue Cross & Blue Shield of Rhode Island, has been named the 2020 Career Achiever by PBN. Collins' career at Blue Cross began in 2015 as its vice president of clinical integration and, among other tasks, leads Blue Cross's efforts to help Rhode Islanders connect with a primary-care practice to help ensure health care affordability. Collins also serves as a clinical assistant professor at The Warren Alpert Medical School at Brown University and is a member of Gov. Gina M. Raimondo's Overdose Prevention and Intervention Task Force. ❖



In April, representatives from the Laborers Union New England region drove by Women & Infants Hospital with a large truck, showcasing a message of appreciation to the doctors, nurses and staff at Women & Infants Hospital, who are working diligently during the COVID-19 pandemic.

Obituaries



ARTHUR G. BONIVART, MD, died at home on March 19, 2020. He was 94 years young.

He was the husband of Elizabeth L. (Stewart) Bonivart and the devoted father of Jennifer E. Bonivart.

He was born in Tiszagyuláháza, Hungary in 1925. Following its revolution, he chose to leave his native country in 1956; emigrating first to Ontario, Canada, then finding permanence in the United States in 1959.

He held a private surgical practice in Pawtucket for many years before retiring in 1990. He was affiliated with Memorial Hospital, Miriam Hospital and Notre Dame. He was a longtime member of the Rhode Island Medical Society.

Arthur loved sports – especially tennis, skiing and swimming. He travelled widely and enjoyed reading, learning languages and gardening in his yard. He savored peaches, a good port wine and the services of the U.S. Postal Office. He jogged and rode his bicycle around Slater Park regularly. Finally, he walked in his neighborhood, a late private practice he cherished fully.

Along with his wife and daughter, he leaves behind four siblings: Adel Scholtz of Grand Junction, Colorado; Erwin Bonivart of Windsor, Ontario, Canada; Laszlo Bonivart of Örnköldsvik, Sweden; and Istvan Bonivart of Budapest, Hungary. He also leaves his brother-in-law, Laszlo Ujvary of Windsor, Ontario, Canada along with many nieces, nephews and great nieces who were dear to him. Arthur was also brother to the late Vali Ujvary and his late older brother Antal (Tony) Bonivart.

A celebration of his life will be held once this pandemic is over. ❖



ALFRED F. PARISI, MD, 82, passed away on April 15, 2020. He is survived by wife Susan Ferriman Jenkins and his children, Mark A Parisi and wife Lydia, Christy (Parisi) McLean and husband Robert, and John F. Parisi. He was predeceased by his former wives, Joan S. Parisi and Anna Albrecht.

He received his undergraduate degree at Georgetown University where he served as president of Alpha



Sigma Nu honor society. He subsequently attended Cornell University Medical College in New York City where he was elected to the Alpha Omega Alpha honor society. After military service in the US Air Force as Major (1969–1971) in San Antonio Texas, Dr. Parisi pursued a distinguished career as an academic teacher, clinician and researcher.

Early in his career, he was an Associate Professor of Medicine at the University of Maryland School of Medicine and Chief of Cardiology VA Hospital, Baltimore Maryland (1971–1974). He moved to Boston in 1974 as Senior Associate in Medicine at Peter Bent Brigham Hospital (now Brigham and Women's Hospital) and advanced to Associate Professor of Medicine at Harvard Medical School in 1977. As Chief of Cardiology at the West Roxbury VA Medical Center (1974–1988), he directed a cardiology training program considered by many to be the leading independent program in the VA. He later moved to Providence, as Professor of Medicine at Brown University School of Medicine and Chief of Cardiology of the Brown University Hospitals (1988–2002).

He was the former President of the American Society of Echocardiography. He earned a national reputation as an innovative researcher. His extensive research publications helped to advance clinical practice in the field of echocardiography.

He was also an outstanding teacher. In addition to being awarded Teacher of the Year while at Brown University, he mentored scores of cardiologists. He was admired and respected by those who were fortunate enough to be trained by him. He was also selected on more than one occasion by his peers to be included in *The Best Doctors in America*.

In his later years he enjoyed watching baseball, good food and conversation. He especially treasured living on Cape Cod and spending time with his beloved wife, Susan, and dog Caz, family, and friends.

An early summer memorial is planned at our Lady of Victory Church in Centerville, Massachusetts. Please check Our Lady of Victory website for future details. A funeral service will be held at Gate of Heaven Cemetery in Hawthorne, New York at a later date.

In lieu of flowers, please send donations to The Miriam Hospital Foundation (Development Office PO Box H Providence, RI 02901), the Weill Cornell Medical College (1300 York Ave, Box 314 New York, NY 10065) or the American College of Cardiology. ❖

Mary Mallon: First Asymptomatic Carrier of Typhoid Fever

MARY KORR
RIMJ MANAGING EDITOR

Mary Mallon (1869–1938), dubbed by the tabloids of the day as “Typhoid Mary,” was an Irish cook who immigrated to New York from Northern Ireland as a teenager, and was the first person in the United States identified as an asymptomatic carrier of the disease.



Mary Mallon, photographed in Riverside Hospital, North Brother Island, New York, where she was forcibly quarantined as a carrier of typhoid fever in 1907 for three years, and then again from 1915 until her death in 1938.

[WIKIMEDIA, CREATIVE COMMONS]

By reading various newspaper reports of the day, she decried this label, and claimed she felt she was being treated “like a leper,” forced into quarantine on North Brother Island in the East River without due process. Lab tests showed the presence of the pathogen in samples; however, she exhibited no symptoms of the disease.

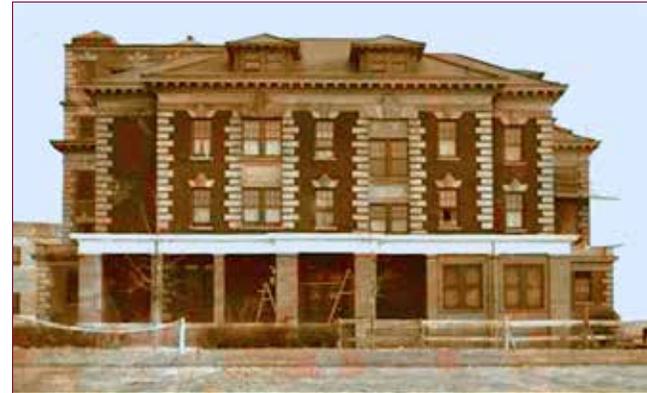
A young Irish lawyer, E.F. O’Neill, took up her case, only to lose in the New York State Supreme Court, when the judges weighed individual liberties versus the safety of the public.

However, she was released after three years on the island when she agreed to never work as a cook again and report to

the state health department every three months. She promptly disappeared, resuming her job as cook in various capacities, and infecting more people. When she was found by happenstance, as a result of an infectious outbreak of typhoid fever at a hospital for women, she was forced back into quarantine on North Brother Island. Here she lived out the remainder of her days. Eventually, Mallon was employed as a helper in the island’s hospital laboratory, but was not allowed to cook or share meals with anyone.

For most of her quarantine, Mallon lived in a cottage on the island with a dog, a fox terrier, as her only companion. One could speculate that the canine was the first therapy dog.

The late **Dr. Stanley M. Aronson’s** article, “The Civil Rights of Mary Mallon,” published in 1995 in the *Rhode Island Medical Journal* on the following pages, relates in great detail the story of Mallon and the sanitary engineer who was instrumental



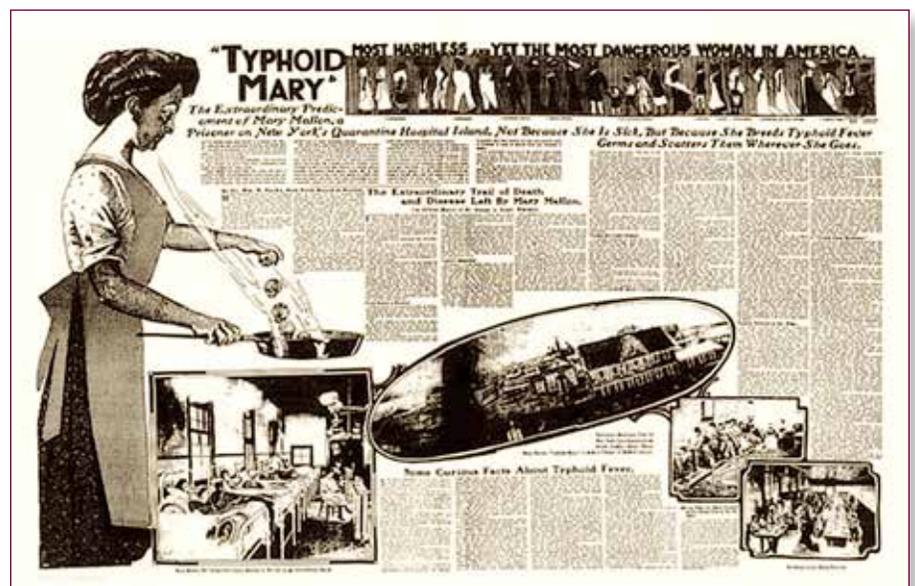
Photograph of the hospital facility on North Brother Island in 1937. [THE NEW YORK PUBLIC LIBRARY DIGITAL COLLECTIONS]



For most of her quarantine, Mary Mallon lived in this cottage on North Brother Island.

[NEW YORK CITY MUNICIPAL ARCHIVES]

in tracking down the source of the outbreaks, **Dr. George A. Soper**. ❖



Cover of the June 20, 1909 issue of The New York American. [WIKIMEDIA, CREATIVE COMMONS]

The Civil Rights of Mary Mallon

STANLEY M. ARONSON, MD

No one disputes the events after August 1906; the facts prior to this date, however, remain conjectural. Gen. William Henry Warren, a prominent New York City banker, rented a summer house for his family of three in Oyster Bay, Long Island. In July 1906 they moved in, bringing with them a complement of seven live-in servants. On August 27, one of the servants became acutely ill with typhoid fever, and by September 3, five more cases of typhoid had arisen within the household, including the general's wife and daughter. There were no further cases but the owner of the home, fearing that the value of her property was now in jeopardy, recruited an established epidemiologist and sanitarian, Dr. George A. Soper, to seek out the origins of the contagion. He quickly eliminated the usual sources of enteric fever (faulty privies, deteriorating sewer systems, contaminated water supply), leaving him with the uneasy likelihood that a healthy human might be the carrier of the pathogen. By bacteriologic assays, he eliminated from suspicion Mr. Warren and six of the seven servants. The seventh, a Mary Mallon, had quietly resigned her job as the family cook shortly after the first case of typhoid had emerged and had then disappeared. She was described by her fellow house servants as remote, unfriendly, at times violently hostile and a "rather dirty person."

Soper felt obliged to pursue his one remaining lead and he sought out a Mrs. Stricker whose employment agency in Manhattan had originally recruited Mary Mallon as the family cook. Slowly and deliberately Soper reconstructed Mallon's employment history as a family cook, going back many years. He then interviewed most of these families. Beginning in 1900 there had been a household in Mamaroneck,

then several in Manhattan, then one in Maine, then Sands Point in Long Island, then Tuxedo Park, New York. In each instance, one or more individuals in the household had developed typhoid, and in each instance, Mallon was said to have discretely departed to seek employment elsewhere. In the seven households investigated, Soper identified 53 cases of acute typhoid fever (with three deaths), all temporarily associated with Mallon's employment as cook. Soper readily admitted that these statistics were quite conservative since many of Mallon's known places of previous employment could no longer be investigated and not all of her tours of duty had been obtained through the Stricker employment agency. Furthermore, Soper counted only those primary cases of typhoid ascribable to direct contact with Mallon's food preparations while not considering the many secondary cases stemming from the momentum of the initial outbreaks. Soper fully acknowledged that the true number most likely exceeded 1,000.

Armed with circumstantial evidence of a compelling association between Mallon's cooking and multiple outbreaks of typhoid, Soper tracked her finally to a new sight of employment, confronted her with the epidemiologic data and requested her voluntary cooperation in verifying her carrier state. Mallon's pathologic temper was amply demonstrated and he barely escaped her wrath. Undeterred however, he appealed to the New York Department of Health and eventually Mallon was arrested, but only after a violent struggle in which two policemen suffered injuries, one losing most of one ear. Mallon was kept in an isolation ward

at Willard Parker Hospital where she exhibited no ill health, but repeated stool cultures nevertheless demonstrated an abundance of *S. Typhi*. By order of the health authorities, she was then remanded to a small bungalow next to Riverside Hospital on North Brother Island in the East River. Her cottage was provided with all necessary amenities and she was free to roam the island and use its facilities, including the local chapel.

Mary Mallon's story became widely publicized and the June 20, 1909 edition of William Randolph Hearst's *New York American* vividly elaborated on the morbid events, labeling her as "...the most dangerous woman in America." The newspaper also provided her with a new name: "Typhoid Mary."

In 1908, G.F. O'Neill, a local attorney, took on her case as an instance of imprisonment without due process of law, without legal representation, indeed, without even a trial. The judge dismissed a request for release, pointing to a 1905 Supreme Court judgment regarding compulsory vaccination, which declared that prudent measures undertaken to protect the public were a legitimate exercise of the state police powers. By this time Mary Mallon's story became widely publicized and the June 20, 1909 edition of William Randolph Hearst's *New York American* vividly elaborated on the morbid events, labeling her as "...the most dangerous woman in America." The newspaper also provided her with a new name: "Typhoid Mary."

In February 1910, after 35 months of isolation (during which time she repeatedly asserted her innocence claiming that her imprisonment was a British plot to suppress her activities

on behalf of Irish independence) Mallon was offered her freedom on two conditions: that she refrain from any employment requiring direct contact with food and that she report to the Department of Health at three-month intervals.

She was then released and promptly broke both promises, disappearing into the urban sprawl of municipal New York. For the next five years she held various cooking posts at numerous homes and in restaurants, under a number of aliases, producing a further series of typhoid fever outbreaks.

In 1915, there was an unexplained cluster 20 cases of typhoid among the patients at the Sloane Hospital for Women. Soper was called, and he immediately recognized the chef as Mary Mallon, now under the assumed name of Brown. She was promptly remanded to the same East River cottage. Some 17 years later, on Christmas morning 1932, Mallon suffered a severe stroke, remaining in a semicomatose state for another six years, ultimately dying on November 11, 1938. In what some regarded as undue haste, she was buried in a Bronx cemetery within hours of her death.

These, then, are the accepted details in the tragic life of Mary Mallon.

Civil liberties vs. population safety

The New York Department of Health had been accused of abridging Mallon's civil liberties; indeed, banishing her without trial to life imprisonment. Many claimed that a mere quirk of microbial happenstance, ultimately beyond her control, had somehow converted her into an unwilling chronic carrier. The department, on the other hand, pointed to as many attempts to work out some sort of compromise with Mallon; it insisted, nevertheless, that it could never abdicate its obligation to protect the health of the larger community. It claimed that all society represents an uneasy equilibrium between private autonomy and the needs of the community and that no system of government can prevail for

long without some visible authority in matters of health and social stability. (Plato describes an important trial in Athens: "The judges: Tell us Socrates, do you suppose a city can exist and not be overthrown, in which the decisions of law are powerless, set aside and trampled upon by individuals?")

The debate regarding the civil liberties of the innocent carrier may have obscured yet another area of contention. The arrival to the shores of some 36 million immigrants between 1880 and 1920 was greeted with varied emotions, particularly so since most newcomers were poor, under-educated and with a greater vulnerability to such infectious diseases as cholera, typhoid, tuberculosis and poliomyelitis. The waves of arriving Irish that, for example, coincided with major outbreaks of cholera and typhoid in East Coast cities, and nativist hostilities to the new immigrants, were translated readily to blanket accusations that the Irish were the cause of these outbreaks. These complaints ignored the fact that the Irish were the chief victims of these contagions, which had been spread exclusively by contaminated water supplies. The spread of poliomyelitis, between 1910 in 1920, was similarly blamed upon immigrant Italians and Jews.

Newspaper reports invariably mentioned Mary Mallon's Irishness, as well as her alleged temper, suggesting that a Celtic heritage and a confronting personality were somehow the necessary preludes to the carrier state. Epidemiologists, on the other hand, concluded that at least five percent of those exposed to the typhoid bacillus became chronic carriers, meaning that they were at least 20,000 carriers of all ages and persuasions wandering the streets and country roads of the United States in 1906. Yet only Mary Mallon's name crops up as the evil exemplar of the carrier state.

Some further observations need to be offered: without any help from carrier immigrants, typhoid fever had continued to flourish throughout the United States, including those heartland cities

where few if any immigrants had ventured. Indeed, in the United States Army of 1898 to 1900 with approximately 107,000 officers and men, most of whom were native-born, there were 20,738 cases of typhoid, with 1,580 deaths.

Even if all immigrants had somehow been excluded from this nation, typhoid would nevertheless have continued to exert its toll until American society could instill better personal hygiene habits in its residents and until local communities were sufficiently motivated to establish water supplies free of fecal contamination. ❖

[Editor's Note: This article, written by the late Stanley M. Aronson, MD, founding dean of Brown's medical school and a former editor-in-chief of the *Rhode Island Medical Journal*, first appeared in RIMJ's November 1995 edition.]