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Why don’t people wear masks?

EDWARD FELLER, MD, FACP, FACG

The vast majority of scientists believe that masking and social distancing confer some protection against COVID-19 infection. Yet, despite violating mandates, guidelines or common sense, many Americans continue to increase the risk of contagion by flocking unmasked to crowded political rallies, bars or large parties.

We all know that many non-maskers oppose social distancing mandates, guidelines or community pressure as attacks on personal autonomy, abrogation of embedded constitutional rights, unbridled government control of individual behavior as well as challenging self-control of one’s life. Some critics of non-maskers decry this behavior as selfish, reckless, impulsive denials of science and a failure of civic responsibility. Many commentators oversimplify this controversy as a partisan political issue exemplified by the report that as few as one third of conservative-leaning Fox viewers always wear masks in public compared to two-thirds of liberal-leaning MSNBC/CNN viewers. But, it’s more complicated and nuanced.

There is danger in accepting the stereotype of a “Blue state versus Red state” mentality, an assessment which exaggerates the magnitude to which specific party affiliation determines adherence to masking and social distancing. What other influences help explain masking behavior?

How do we decide if a risk is acceptable?
We live in a risky, uncertain world complicated by a harmful national controversy about COVID-19-related risks. Risk perception reflects a subjective interpretation of the world. Individual tolerance for both risk and uncertainty vary widely. Non-maskers may believe that danger from COVID-19 is lower than maskers do and that the threat is exaggerated, sometimes purposefully. Thus, non-maskers are not uncaring or ignoring their civic duty; they may conclude that the virus is less threatening or that mask protection is ineffective, thus, giving users a false sense of security. Also, many Americans support opening the economy as more important than any public health consequences of not masking or social distancing. Previously innocent actions, such as a meal at a crowded eatery with friends, are difficult to abandon. “COVID fatigue” from prolonged adaptation to the complex new normal of isolation, quarantine and contagion may decrease compliance with preventive measures.

Personal risk-taking perception may be a common component in decisions about distancing behavior. Risk perceptions can align poorly with actual, real-world risk, which may be unclear, misunderstood, controversial or manipulated. Sudden or dramatic increases in rates of infection or personal experience with infected persons may induce us to overestimate risk. Some non-maskers may downplay social distancing because their personal costs of lost revenue or connections to others are greater or the perceived advantages of distancing are lower. Other influences, including group affiliations, affect risk perception. It is important to note that existing beliefs tend to be resistant to change.

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What factors influence “following the crowd”? Risk has a social context. Masking is a collective choice as well as an individual one. Our self-identity is linked to the social groups and values with which we align. Shared solidarity in crowds such as at sports events can satisfy a human wish for closeness, belonging, camaraderie and trust. In crowds, we tend to feel less vulnerable to disease when we identify strongly with fellow attendees. In social settings, data suggests that potential COVID-19-related threats arising from in-group members will be rated as less risky and tend to elicit enhanced risk-taking behavior compared to potential threats from non-group members.

Herd behavior in groups tends to homogenize attitudes or actions. Thus, non-masking and rejection of social distancing may satisfy a human drive for consensus, collaboration, inclusiveness as well as avoidance of rejection, stigma and loss of status when one’s group identity is impaired or threatened. A strong group identity reinforces the subjective assumption that in-group members will act in principled, safe ways and are thus less likely to be COVID-infected. A bystander effect in large groups may inhibit active, individual choice- the more people present, the less likely an individual will make an active decision, believing that “Someone else will do it!”

Why do those we trust sometimes pose the greatest risk? “I’m less at risk if maskless with kindred spirits” is a dangerous belief which may lead to increased risk-taking behavior with friends or colleagues. Groupthink, a cognitive bias where pressure from oneself, peers, or leaders to achieve consensus may interfere with choices because potential dissenters self-censor, revise or suppress a contrary opinion or evidence despite underlying disagreement. Adherence to unhealthy “Wisdom of the Crowd” beliefs (smoking, non-masking) increases the probability of bad outcomes. Examples from experimental studies include widespread beliefs that risk of a car crash is lower when driven home by a friend who drank too much vs. a stranger and there is less risk shaking hands with a co-worker with dirt on her hand if she's a member of our political party. Of course, experimental studies may create artificial distinctions rather than mirror real-life behavior.

Conclusion The COVID-19 pandemic has spawned an infodemic of disagreement, information and misinformation. Controversy about personal and community prevention has challenged
our ability to make effective, reasoned choices – including masking and social distancing decisions. These preventive interventions remain contentious and unresolved despite the weight of robust evidence supporting them.

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When Ruth Bader Ginsburg was nominated by President Bill Clinton to the Supreme Court in 1993, he described her as the “Thurgood Marshall of gender-equity law.” In her ensuing 27 years on the Court, she would become an ardent champion of health equity, reproductive rights, Americans with disabilities, and challenges to the 2010 Patient Protection and Affordable Care Act [ACA].

Her recent passing and the debate over her successor brought to mind memories of an event I covered as Assistant Editor of The Jewish Voice & Herald, where she was the keynote speaker. August 22, 2004 was a balmy and beautiful Sunday in Newport. The Touro Synagogue was filled to capacity, eager to welcome Justice Ginsburg, accompanied by her husband, Marty, to the annual reading of the 1790 George Washington Letter to the Hebrew congregation in Newport, which reads, most notably:

…the Government of the United States gives to bigotry no sanction, to persecution no assistance, requires only that they who live under its protection should demean themselves as good citizens, in giving it on all occasions their effectual support.

The Letter reading coincided with a celebration of 350 years of Jewish life in America. Sunlight shone through the balcony synagogue windows on Justice Ginsburg, a diminutive figure on the podium below, who was introduced as the “fulfillment of the American Dream.” While she spoke about the legal profession, spotlighting the history of Jewish justices of the Court, I noted lighter moments in my article. At one point she asked, “What is the difference between a New York City garment district bookkeeper and a Supreme Court Justice? Just one generation. My life bears witness, the difference between opportunities open to my mother, a bookkeeper, and those open to me. Where else but in the USA could that happen?”

Her mother, Celia Amster Bader, passed away from cancer the year her daughter graduated from James Madison High School in Brooklyn. Described by Justice Ginsburg as a brilliant and determined woman, her mother would no doubt be proud of her daughter’s opinions and dissents during her career,
both before and while sitting on the highest Supreme court in the land. The following Supreme Court cases, from 1999 to 2016, illustrate Justice Ginsburg’s jurisprudence in the healthcare arena.

**Americans with Disabilities**

On June 22, 1999, the Court ruled 6-3 on a landmark case1 which focused on the rights of people with mental health issues to have appropriate care in community centers where they lived, rather than be institutionalized. The case involved two women who were voluntarily admitted to the psychiatric unit of a state-run Georgia hospital, but were then held there in isolation for several years, despite receiving medical clearance for transfer of care to a community-based facility.

The Court voted in favor of the women and Justice Ginsburg wrote the majority opinion, stating that, “Recognition that unjustified institutional isolation of persons with disabilities is a form of discrimination…” The Opinion referred to Title II of the Americans with Disabilities Act (ADA): “States are required to provide community-based treatment for persons with mental disabilities when the State’s treatment professionals determine that such placement is appropriate, the affected persons do not oppose such treatment, and the placement can be reasonably accommodated, taking into account the resources available to the State and the needs of others with mental disabilities.”1

**ACA Challenges**

Challenges to the ACA and the individual mandate have come before the Court, with Justice Ginsburg concurring in rulings to maintain it. On June 28, 2012, the Court upheld most of the ACA, including the individual mandate, which required that most Americans maintain “minimum essential” health insurance coverage, either through their employer, a government program or through a private plan. Beginning in 2014, those who did not comply with the mandate must make a “[s]hared responsibility payment” to the Federal Government.2 The Court ruled 5-4 that the individual mandate is constitutional under Congress’s taxing authority.

Ultimately, Congress repealed the individual mandate penalty as part of the Tax Cuts and Jobs Act of 2017. Challenges to the ACA continue. On November 10, one week after the upcoming Presidential election, the Court will hear oral arguments on two consolidated ACA cases, California v. Texas and Texas v. California, which pose the question whether the law’s individual insurance mandate is unconstitutional without a tax penalty and, if so, whether the rest of the law can remain standing.

**Reproductive rights**

In 2016, the Supreme Court struck down a contentious Texas law which imposed severe restrictions on the delivery of services at abortion clinics. Justice Ginsburg filed a concurring opinion on June 27, 2016, and did not mince words. She stated: “The Texas law called H.B.2 inevitably will reduce the number of clinics and doctors allowed to provide abortion services. Texas argues that H.B.2’s restrictions are constitutional because they protect the health of women who experience complications from abortions. In truth, complications from an abortion are both rare and rarely dangerous. “It is beyond rational belief that H.B.2 could genuinely protect the health of women, and certain that the law would simply make it more difficult for them to obtain abortions. When a State severely limits access to safe and legal procedures, women in desperate circumstances may resort to unlicensed rogue practitioners, faute de mieux, at great risk to their health and safety.”

**Farewell remarks**

I will conclude this commentary with Justice Ginsburg’s final remarks in 2004 at Touro, which seem to me to resonate in today’s turbulent times. She said: “Just as we draw inspiration from the letter exchange between this Congress and George Washington, may I conclude these remarks with counsel a wise woman of that age, Abigail Adams, gave to her then young son, future President John Quincy Adams.

“These are the times in which a genius would wish to live. It is not in the still calm of life, or the repose of a pacific station, that great characters are formed. The habits of a vigorous mind are formed in contending with difficulties.”

**References**


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Emergency Mail-in Voting in Rhode Island: Protecting Civic Participation During COVID-19 and Beyond

NICOLE M. BURNS, BS’23; KEYANA ZAHIRI, BS’23; REETAM GANGULI, BS’23; GIOVANNI KOZEL, BS’23; SABA PARACHA, BS’23; KEVIN P. TANG, BS’24; OLIVER Y. TANG, MD’23; KELLY E. WONG, MD

ABSTRACT
The COVID-19 pandemic challenges safe and equitable voting in the United States’ 2020 elections, and in response, several states including Rhode Island (RI) have made significant changes to election policy. In addition to increasing accessibility of mail-in voting by mailing applications to all registered voters, RI has suspended their notary/witness requirement for both the primary and general election. However, RI’s “emergency” voting process still plays a crucial role in allowing voters who missed the mail-in ballot application deadline, such as those unexpectedly hospitalized in the days leading up to the election, to still cast their ballot. COVID-19 has also forced RI to modify its emergency voting procedures, most notably allowing healthcare workers to serve on bipartisan ballot delivery teams. This commentary highlights these salient updates to voting procedures and serves as a primer as to how interested health care workers may navigate this process alongside patients and lead in the arena of patient voting rights.

KEYWORDS: COVID-19, public health, patient advocacy, health policy, patient voting

Introduction
The COVID-19 pandemic has strained the United States health care system, taking 190,262 lives nationally as of this writing and more than 1,000 in Rhode Island (RI) alone.1,2 With upcoming elections at both the state and federal levels, COVID-19 also presents additional public health challenges. Recent research has suggested an increased risk of viral transmission at crowded election polls, such as one study demonstrating a statistically significant link between voting in April’s Wisconsin primary and increases in COVID-19 cases in the state.3,4 In addition to unsafe conditions potentially deterring voters from in-person voting (particularly frontline workers and vulnerable populations), the virus also magnifies accessibility issues for hospitalized patients.

More than 52,503 patients nationwide have been hospitalized for COVID-19, the overwhelming majority being 18 and older.5 Significant racial disparities have also been observed in the pandemic, with hospitalization rates for Native Americans, Blacks, and Hispanics/Latinos being 4–5x that of white Americans.5 Amidst several studies suggesting that voters who are hospitalized, ill, or face a disability are underrepresented in the general voting populace,6,7 the pandemic may exacerbate these existing inequities in voter participation.

Given these concerning trends, national dialogue surrounding safe and accessible voting has focused on expanding mail-in voting availability. Eligibility requirements, deadlines, and procedures for absentee voting vary greatly between states, but RI is one of many no-excuse absentee states, where anyone can request an absentee ballot for any reason. Additionally, due to COVID-19, RI has joined a small collection of states in sending mail-in applications to all registered voters for the primary and general elections.8 However, a more specialized process, used in almost 40 states, is emergency absentee voting, wherein voters experiencing an unexpected hospitalization or medical emergency after the normal absentee ballot request deadline may still apply to receive an absentee ballot (Table).9 In several states including RI, emergency absentee voting processes have also been altered by election process changes spurred by COVID-19. Emergency voting procedures remain essential to protecting voting rights for patients who miss RI’s 10/13/20 mail-in ballot application deadline – such as those intending on voting in-person but experiencing an unexpected hospitalization – as well as voters separated from their mail-in ballots due to unexpected hospitalization. Accordingly, the goals of this commentary are threefold: to highlight election changes made within RI due to COVID-19, to describe RI’s emergency absentee process, and to provide a primer as to how interested health care workers may navigate this process alongside patients and lead in the arena of patient voting rights.

How has COVID-19 impacted RI election processes?
COVID-19 introduced several notable changes for the 2020 elections. For RI’s presidential primary, delayed from 4/28/20 to 6/2/20, the state mailed absentee ballot applications to all registered voters and suspended the notary or witness requirement.10 For the general election, the state once again mailed absentee ballot applications to all registered voters and continued the suspension of a notary or witness requirement.8 The mail-in ballot application deadline remains 10/13/20, three weeks before election day. Additionally,
although RI normally delivers emergency ballots to patients in hospitals or other long-term care facilities (e.g., nursing homes) using bipartisan teams sent by the local Board of Canvassers, infection control-minded restrictions in hospital visitation have compelled the RI Board of Elections to grant health care workers (HCWs), also working in bipartisan pairs, the ability to be sworn in to assist with these responsibilities for all 2020 elections, including the general election. These policy changes will impact the safety of voting from both the home and the hospital come November.

**How does emergency mail-in voting in RI work?**

For the general election, RI’s “emergency mail ballot” is a process designed for voters experiencing a medical emergency who were unable to submit an absentee ballot application by the regular deadline of 4:00 pm EST on 10/13/20 (Table).11 Beginning on 10/14/20, hospitalized patients have until 11/2/20 at 4:00 pm EST to fill out and submit an emergency mail ballot application. Applications are available for download (https://elections.ri.gov/voting/emergency.php) when the emergency period begins. Voters can submit their application through an “agent” or by mail. Agents are personal representatives designated by the voter, such as a family member, to carry out in-person document delivery between the voter and their local Board of Canvassers. If approved, a hospitalized voter would obtain their ballot through personal ballot delivery via a bipartisan in-person team sent from their local Board of Canvassers, who would be assisted by hospital employees for 2020 elections due to COVID-19. This team would also automatically handle returning the voter’s filled-out ballot to be counted. Additionally, a voter who has been discharged from the hospital after the regular absentee deadline whose mobility continues to be reduced may obtain their emergency ballot by their agent or mail and have until 8:00 pm EST on 11/3/20 to return it to the State Board of Elections (Cranston, RI), similarly by agent or mail (time of delivery, not postmark).11 Within RI’s guidelines, health care workers and family members of loved ones affected by medical emergencies may also utilize this emergency absentee mail ballot process, if prevented from voting in-person on election day. No physician affidavit is required for the emergency application, as is the case in other states.

**How can health care workers navigate this process?**

Several studies elucidating the link between public policy and health outcomes have advocated for health care workers (HCWs) to improve political participation among their patients.12-16 Emergency absentee voting represents a promising, non-partisan way to achieve this. Approaching election day, interested HCWs may offer information on emergency voting processes to patients, especially those expressing concerns about being able to vote. This should be approached akin to consenting patients for a procedure, respecting patients who decline and are not interested in voting. For
interested patients, hospitals can take several steps to make this process as convenient as possible, such as printing readily available emergency mail ballot applications or potentially serving as agents for patients without family to do so. Additionally, serving as their facility's volunteers to facilitate bipartisan ballot delivery teams represent another tangible way for HCWs to assist in emergency voting processes. Due to low patient awareness of emergency absentee processes, HCWs serve an integral role in improving general public knowledge of these procedures through the provision of informational pamphlets or flyers with the guidelines and deadline reminders, which may also benefit colleagues and caregivers of hospitalized patients qualifying for these processes in RI. Finally, to allay potential concerns over the process, HCWs may benefit from staying up-to-date with the evidence surrounding mail-in voting, which has been shown to have near-zero risk for fraud and no biased impact on partisan turnout.\textsuperscript{7,16}

Several voting organizations within RI, such as Common Cause RI and the American Civil Liberties Union of Rhode Island, are actively leading efforts to advocate for voter rights and improve turnout. Another such example is Patient Voting, a non-partisan organization to increase voter rights and improve turnout. Another such example is Patient Voting, a non-partisan organization to increase voter rights and improve turnout. Its website (https://www.patientvoting.com) serves as a centralized resource for patients who are projected to be hospitalized on election day. Patient Voting was initially founded in Rhode Island by Dr. Kelly Wong, an emergency medicine resident at Brown University, and the authors of this commentary are volunteers. Its website (https://www.patientvoting.com) serves as a centralized resource for protocols in all 50 states, due to variable availability of this information online. Given the necessity in certain states of making several back-and-forth trips between a hospital and local elections office for these processes, Patient Voting also connects patients to ballot delivery options and coordinates volunteers to serve as a patient’s agent, in states where these apply. For the November election, Patient Voting plans to implement similar efforts in RI hospitals, such as the provision of informational flyers and readily available emergency ballot applications.

Dr. Donald Berwick, a former Administrator of the Centers for Medicare and Medicaid Services and President emeritus of the Institute for Healthcare Improvement, contended in a recent commentary on a “morally guided campaign for better health” that “restoring order, dignity, and equity to US democratic institutions” may be a moral prerogative for HCWs.\textsuperscript{19} Because our patients’ wellness is influenced by a myriad of environmental and socioeconomic factors outside of medical care, safeguarding their ability to reshape these factors through the ballot box – especially amidst a pandemic that has already posed challenges to voting systems nationwide – may function as another way to serve their health. ◀

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Confidentiality in Sexual Healthcare for Adolescents and Young Adults: Addressing Disclosure in the Explanation of Benefits

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KEYWORDS: adolescents, young adults, confidentiality, sexual healthcare, explanation of benefits

Introduction
Health insurance claims documents such as Explanations of Benefits (EOBs) are sent by insurers to inform policyholders of their – and their covered dependents’ – medical visits and services to promote transparency and prevent healthcare fraud. However, EOBs, which typically identify the individual who received care, the healthcare provider, and what type of care was received, may lead to unintended consequences by causing a breach of patient confidentiality. Patients, such as adolescents and young adults (AYA), may be unaware of the potential for such disclosures. In this commentary, we describe confidentiality concerns related to EOBs and how this may affect AYA when seeking sexual healthcare services. We conclude with potential policy solutions that can aid AYA and others in such situations.

Case study – access to PrEP for adolescents and young adults
In April 2019, the Rhode Island General Assembly held hearings in the Senate and House to review S.580/H.5556, a bill to address confidentiality breaches that occur with EOBs. One of the testimonies included a college student’s experience with taking pre-exposure prophylaxis (PrEP), a medication preventing HIV transmission. Prior to starting PrEP, he was cautioned by healthcare providers that his parents, the primary insurance policyholders, would likely be notified about his medical visit. His parents supported his being on PrEP, but he was troubled by the lack of confidentiality involved in his sexual healthcare. In his role as a sexual health educator, he also heard from peers who opted against seeking sensitive services due to fear their personal health information would be disclosed to their parents via EOBs.

Adverse effects of explanation of benefit forms on the health of adolescents and young adults
While EOBs are designed to promote transparency, disclosure of health information to policyholders who are not the patient, in some situations, can do more harm than good. As clinical researchers and providers, we have repeatedly encountered situations where AYA, covered by parents’ health insurance, are deterred from taking PrEP, or pursuing other important healthcare, due to confidentiality concerns related to the EOB. In addition to leading AYA to delay or forego care, inadvertent disclosure of healthcare information through EOBs may lead to negative mental and physical health outcomes. Care that may be affected by breaches in EOBs includes sexual and reproductive health services, substance use treatment, mental health diagnosis or treatment, and domestic violence-related care.

Regarding consent for sexual health services in all 50 states, minors under 18 may independently consent to testing and treatment for sexually transmitted infections (STIs), and adults may consent to any healthcare independently. In some states, there is a minimum age for such consent such as 12 or 14 years; RI does not have a minimum age. RI law also allows minors to consent for outpatient substance abuse treatment if disclosure could harm the patient; for consent for pregnant teens of any age; and for consent for routine healthcare for adolescents age 16 and older. Confidentiality violations with EOBs can lead to a chilling effect on AYA utilizing these rights to consent and seek healthcare. Providing AYA with confidential healthcare is critical to improve their health outcomes.

Sexual health issues and insurance coverage among adolescents and young adults
Twenty percent of the United States (U.S.) population are ages 10 to 24. AYA have distinct healthcare needs including sexual and behavioral health. Currently, AYA bear a disproportionate burden of new HIV and other STI infections in the U.S. In 2017, AYA ages 13 to 24 accounted for 21% of all new HIV diagnoses, most of whom were ages 20 to 24. Half of the 20 million new STIs each year in the U.S. are among those ages 15 to 24 years.

After the 2010 Patient Protection and Affordable Care Act (ACA) was enacted, millions of children and young adults gained health insurance, primarily through Medicaid expansion and a provision allowing young adults to remain on their parents’ plans until age 26. An estimated 2.8 million children from birth to age 18 years and 6.1 million young adults ages 19 to 25 gained coverage by 2016. Compared to all other age groups, young adults ages 19 to 25 had the largest gains in coverage, with an 18% decrease in uninsured young adults from 2010 to 2018. However, with
Addressing confidentiality and explanations of benefits through state policy change

The Health Insurance Portability and Accountability Act (HIPAA) states that an individual can receive confidential communications “by alternative means or locations” if potential disclosure “could endanger the individual.” However, confidentiality practices regarding EOBs vary across states and may not adequately ensure that vulnerable patients are not endangered. Several states, though, have introduced legislation to address confidentiality breaches from EOBs. In 2015, California passed a law allowing patients to make a Confidential Communications Request (CCR) to redirect the EOB to a location of their choice [www.myhealthmyinfo.org]. In 2018, Massachusetts passed the Protect Access to Confidential Health Care Information (PATCH) Act, mandating changes including A) using general terms on EOBs like “office visit” to describe sensitive services, B) allowing members to redirect EOBs to an alternate physical or electronic address, and C) allowing patients to suppress EOBs if no cost-sharing of the visit or the service occurred. Other states have implemented additional policies protecting minor confidentiality and consent, including specific consent laws for minors to access PrEP.

In 2018, we formed the Rhode Island Health and Privacy Alliance (RIHPA) to address this issue. This coalition began by reviewing existing literature, partnering with key stakeholders, communicating with insurance companies and the state health insurance commissioner’s office, and identifying prior efforts within and outside RI to address EOBs and confidentiality. RIHPA includes health professionals and medical societies, college health groups, and advocacy organizations working on domestic violence, reproductive health, and substance abuse issues. During the 2019 RI legislative session, as noted in the case study above, RIHPA supported legislation similar to the PATCH Act, with lead sponsors of Senator Gayle Goldin in the Senate and Representative Susan Donovan in the House. The bill did not pass, but a Senate resolution was passed recommending that the core tenets be implemented as regulation. In 2020, a new bill focusing on preventing breaches of confidentiality with EOBs was proposed in the Senate. However, the legislative session was curtailed by the COVID-19 pandemic and this legislation has not progressed.

We heard alternative perspectives about EOBs and confidentiality during this process. Some insurers argued that mechanisms for redirecting and suppressing EOBs already existed. However, utilizing such mechanisms requires AYA to 1) understand EOBs and 2) have the ability to request changes. Even adult patients may not have such knowledge. Healthcare providers might be considered natural educators about EOBs; however, many are unaware of these issues as well. Additionally, insurers may not comply with requests in a timely manner without state-level policy change. Furthermore, some argued during hearings that parents should be aware of all of their minor children’s healthcare. We agree that parents should be involved in children’s care when possible; however, the standard of care is to provide confidentiality for AYA in sensitive situations.

Conclusion

Evidence and our experiences suggest AYA and other vulnerable populations have been deterred from care based on EOB concerns, and their health has been put at risk from privacy breaches. More research is needed to determine the full scope of these breaches and adverse outcomes, given that occurrences are likely underreported. In addition, more work must be done to identify and mitigate other threats to patient confidentiality, such as pharmacy refill reminders and online patient portals. Policies and protocols to prevent potential disclosure through EOBs should be integrated systematically at the insurance and provider level. Patient education about their rights to confidential healthcare, and education for healthcare providers, also are important for
implementation efforts. Rhode Island has an opportunity to implement such changes to strengthen access to confidential healthcare and improve overall health outcomes for adolescents, young adults, and others impacted.

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Implied Yet Unproven: The Digital Pill – Present and Future

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KEYWORDS: digital medicine, medical device, medical ethics, health policy, patient medication adherence

On November 13, 2017, Otsuka Pharmaceutical received approval of a New Drug Application (NDA) for the use of its antipsychotic medication, aripiprazole (Abilify), with Proteus Digital Health’s ingestible sensor technology. This sensor, composed of copper, magnesium, and silicon [ingredients found in food], is embedded within Abilify and sends an electrical signal to an adhesive patch on the abdomen once the sensor mixes with stomach acid. The medication provides real time data on patient medication adherence to both patient and provider with most ingestions detected within 30 minutes, while 97% of ingestions are detected within 2 hours. The goal of this technology is to improve patient medication adherence. Proteus’ sensor technology has now been paired with over 40 different medications for a variety of diseases like hepatitis C, diabetes, hypertension, and cancer. While Proteus does not outwardly claim improved adherence rates, scientific articles and lay reviews alike tout the medical benefits of the digital pill. Before Abilify MyCite can be widely adopted though, the path to its approval and its effects on treatment adherence must be better understood. It is the purpose of this article to analyze the regulatory approval process for the technology and to review the current body of literature of the device.

It is essential to fully understand the approval process of Proteus’ technology before the efficacy and safety data of the combination therapy can be discussed. On February 7, 2014, the Food and Drug Administration (FDA) approved Proteus Digital Health’s sensor as a medical device via the 510(k) premarket notification route (this route assures that a Class I, II, or III medical device intended for human use is at least as safe and effective as a legally marketed medical device). The approval enabled Proteus to market the patch, including an ingestible sensor (also included was a mobile application). Proteus, Otsuka and the Center for Drug Evaluation and Research then discussed using the technology with Abilify. After communications between the parties, the FDA provided the applicant (Otsuka) with parameters for the NDA for the combined product: a human validation study would need to be performed with 36 patients from three different diagnostic groups (schizophrenia, major depressive disorder, and bipolar 1 disorder). The FDA agreed that the applicant would not need to submit any new safety data as the combination of Abilify and Proteus’ sensor, named Abilify MyCite, was presumed to have similar adverse side effects compared to Abilify without the sensor technology.

Since the safety and efficacy profile of Abilify Mycicte was already presumed to be comparable to traditional Abilify, no controlled clinical trials or integrated summary of safety were required. The company’s original review, performed with placebo, was rejected as the technology was unreliably able to detect ingestion at 30 minutes and there was an overall variability in transmission times. The FDA then instructed the applicant to design a trial that tested the Abilify MyCite combination in real-world conditions. The company submitted clinical trials that showed that the technology was able to sense medication ingestion. As stated in the FDA clinical review, “the most accurate statement regarding Abilify MyCite’s capabilities is that ‘Abilify MyCite successfully tracks ingestion of Abilify with embedded sensor.’” However, there was no difference in rates of adherence in the submitted trials. Furthermore, scant safety data was submitted on the drug device combination as the FDA relied upon previous safety data from when the drug Abilify itself was first approved. Cosgrove and colleagues reviewed the clinical trials submitted to the FDA, finding that there was no evidence of improved quality of life, reduction of symptoms, nor improved adherence over the non-digital version of Abilify. Additionally, the group found that there are no prospective, double-blind randomized clinical trials that have compared the non-digital formulation of Abilify against the digital Abilify MyCite or a placebo. The trials submitted to the FDA were comprised of open label, single arm studies that contained 20–60 patients focused on usability, adverse reactions from the adhesive patch and the latency period between ingestion and tracking the devices ingestion. Since approval, limited evidence suggests that the
technology actually accomplishes what it set out to do – improve medication adherence. Researchers reviewed the current literature on the device published subsequent to the 501(k) approval in 2014 and noted that medication adherence was infrequently the primary objective of the completed studies. Instead, the primary objectives were health outcomes and potential health savings the technology might provide. However, adherence was usually tracked, and while studies showed increased adherence rates, they were conducted on small sample sizes, took place over a short period of time, and were largely funded by Proteus. Heretofore, the current research that addresses the digital pill is limited to only a handful of peer-reviewed studies, and there is a need for large scale, investigator initiated, rigorous clinical trials that focus on safety, adherence, and patient outcomes.

Despite a majority of scientific articles demonstrating benefit of the Abilify MyCite formulation, the FDA received no evidence that Abilify MyCite is better than traditional Abilify. Additionally, Otsuka and Proteus supplied limited safety information about the combination therapy. Subsequent to Abilify MyCite’s approval, few clinical trials have been published that suggest the new technology is an improvement over the non-digital Abilify. However, this did not stop Virginia Medicaid authorities from approving coverage for Abilify MyCite at a price almost 30 times higher than generic Abilify. Nonetheless, the Abilify MyCite, and Proteus’ digital pill technology is a novel approach to improve medication adherence rates. In March of 2019, the Durham VA Medical Center and Otsuka began a study looking at the difference between adherence and all cause healthcare use between traditional Abilify and Abilify MyCite. The trial is currently enrolling patients and is expected to have 300 enrollees. Additionally, a recent trial looked at the Proteus sensor used as a replacement for directly observed therapy (DOT) finding that the patients preferred the technology over DOT and had adherence rates comparable to that of DOT.

Trials like these could provide insight into the potential for more honest communication between patient and provider, increased patient engagement in their own healthcare, and improved adherence rates. These factors, coupled with a conceivable improvement in patient outcomes is promising as healthcare looks for ways to make patients healthier and lower healthcare spending. Despite Proteus’ financial difficulties and recent Chapter 11 Bankruptcy filing, this technology could improve on already existing, low-tech mechanisms of enhancing medication adherence such as self-reported medication diaries, and weekly pillbox. However, more safety and efficacy evidence in the form of robust, blinded clinical trials need to be addressed before the technology can be ubiquitously adopted.

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The novel coronavirus disease 2019 (COVID-19) outbreak, first reported on December 8, 2019 in Wuhan, China, was designated as a pandemic by the World Health Organization (WHO) on March 11, 2020. This disease, recognized as an infection by a new severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), spread quickly throughout the world. As of August 23, 2020, over 23 million laboratory-confirmed cases had been documented globally, with more than 800,000 deaths worldwide. The mortality rates vary significantly among studies from 0.3% to 10%, partially reflecting the differences in local policy, access to diagnostic testing, and health care resources and response.

Clinical presentations of COVID-19 can range from asymptomatic infection, self-limited influenza-like symptoms, acute pneumonia to severe respiratory failure. COVID-19 has life-threatening effects far beyond its respiratory manifestations. SARS-CoV-2 binds to the angiotensin-converting enzyme 2 receptor, which is highly expressed in the kidney, providing a route for direct infection. Coupled with vascular injury and inflammatory insult, acute kidney injury (AKI) has been found in COVID-19 with cumulative incidences ranging from 0.9% to 29%. However, the epidemiology, management, and associated outcomes have varied greatly between studies and the pathophysiology remains unclear.

Besides AKI, there is a paucity of data on the risk factors and outcome of SARS-CoV-2 infected patients with underlying kidney disease, including those receiving dialysis or underwent kidney transplantation. These groups of patients are unique in view of their immunosuppressed status.

The ongoing COVID-19 pandemic carries serious medical, psychosocial, and economic consequences. Understanding its pathophysiology, clinical course, management strategy and therapeutic response are of paramount importance. Here, we will synthesize the current literature on COVID-19 and provide reviews on COVID-19 testing, acute kidney injury, SARS-CoV-2 infection in patients with end-stage kidney disease, and those who received a kidney transplant.
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ABSTRACT
The rampant COVID-19 pandemic has strained the testing capabilities of healthcare centers across the country. Several nucleic acid and serologic assays are available or currently being developed to meet the growing demand for large-scale testing. This review summarizes the developments of commonly used testing methods and their strategic use in clinical diagnosis and epidemiologic surveillance. This review will cover the basic virology of SARS-CoV-2, nucleic acid amplification testing, serology, antigen testing, as well as newer testing methods such as CRISPR-based assays.

KEYWORDS: COVID-19, RT-PCR, serology testing

INTRODUCTION AND VIROLOGY OF SARS-COV-2
In December of 2019, an unknown pneumonia outbreak started in the Wuhan province, later determined to be caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus. Later named Coronavirus Disease-19 (COVID-19), widespread human-to-human transmission led to over 21.7 million confirmed cases and 775,937 deaths among over 200 countries as of August 17, 2020. The novel disease has and continues to spread rapidly throughout many countries including the United States.

Coronaviruses are separated into four main sub-groups: alpha, beta, gamma, and delta. Only seven alpha and beta coronaviruses are known to infect humans. These are positive-sense single-stranded RNA viruses. Four of the most common types (229E, NL63, OC43, and HKU1) are endemic globally and usually cause mild to moderate upper-respiratory tract illness, accounting for 10–30% of all such infections in adults. Three other coronavirus strains, known as severe acute respiratory syndrome coronavirus (SARS-CoV), Middle East respiratory syndrome coronavirus (MERS-CoV), and SARS-CoV-2, are associated with epidemiological outbreaks and have a much higher mortality rate.

SARS-CoV-2 is estimated to have a basic reproduction number (R0) of about 2.5, with a global estimate displaying a 1.2%–13.9% case fatality rate (CFR) at the time of writing. In comparison, SARS-CoV has an R0 value of 3 with a CFR of 15% and MERS-CoV has an R0 value of 1 with a CFR of 35%.

These three coronavirus strains have some distinguishing characteristics which account for their increased virulence compared to the endemic coronavirus strains. The spike glycoprotein (S protein) of MERS-CoV binds to cell surface receptor dipeptidyl peptidase 4 (DPP4), while the S protein of SARS-CoV and SARS-CoV-2 binds to angiotensin-converting enzyme 2 (ACE2) on their host cells. Notably, SARS-CoV-2 displays a 10- to 20-fold greater binding affinity compared to SARS-CoV – a characteristic that is explained by some unique genetic inserts in its spike glycoprotein.

NUCLEIC ACID AMPLIFICATION TESTS (NAATS) OF SARS-COV-2
Overview
Similar to many RNA virus detection assays, SARS-CoV-2 NAATs use reverse transcription-polymerase chain reaction (RT-PCR) to detect viral genomes with high sensitivity and rapid turnaround times. NAATs target conserved regions located in the open reading frame-1ab (ORF1ab) gene as well as the genes of envelope (E), spike (S), and nucleocapsid (N) proteins. NAATs are widely available and remain the primary methods of diagnosing COVID-19 disease.

Specimen Types
Several specimen types have received Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA). The most frequently used are the nasopharyngeal [NP] swab, nasal swab, and oral pharyngeal [OP] swab. Recently, saliva-based PCR testing also received FDA EUA approval.

NP swabs are samples collected along the posterior wall of the nasopharynx and are the most appropriate sample type due to the location of the virus within the upper respiratory tract. However, its use is limited due to the requirement of special training in collection technique. Nasal swabs, on the other hand, can be self-collected by the patient, eliminating the need for contact with a healthcare provider. Nevertheless, tests with these samples are subject to a slight decrease in sensitivity due to their suboptimal sample location. OP swabs are directed towards the rear of the oropharynx and are used as an alternative site when an NP or nasal swab cannot be obtained. Saliva is the easiest to obtain and has been gaining popularity in massive testing plans despite claims of such samples having a lower yield. In addition to
upper respiratory tract specimens, lower respiratory tract specimens from bronchoalveolar lavage (BAL) have provided the best yield, but the bronchoscopy procedure is considered to be rather invasive.

**Testing Turnaround Time**
The turnaround time is the time it takes from collecting a sample to reporting a result. Many factors should be considered, such as location and method of collection, testing method being used, and the location where the test is being performed. The vast majority of the NAATs are performed in an off-site location located away from the patient due to the requirement of high complexity laboratories to perform the NAATs. The exceedingly large volume for diagnosis and screening frequently leads to increased turnaround time in many labs. Where there is a high test volume but a limited number of certified labs, one solution is to use pooled testing.

Pooled testing aims to increase the efficiency of identifying positive cases while minimizing the number of tests needed to screen a population. Pooled testing involves combining several samples into a pool and testing them all at once. If the pool result is negative, all samples included are presumed to be negative. If the pool test is positive, then each sample will be re-tested to identify individual positive samples. Pooled testing takes two steps to identify positives but is efficient when the prevalence of the virus is low because the majority of the samples will be negative. It allows for a great number of individuals to be screened using far fewer testing resources.

**Assay Sensitivity and Specificity**
Despite having high analytical sensitivity and specificity values, NAATs have a few limitations. Notably, the detectability of the SARS-CoV-2 genome may vary depending on the disease stage. The current consensus is that NAAT assays are the most sensitive during the acute stage of infection. The timing of the test is critical, as testing in the early phase of the incubation period and during the later stages of infection will lead to significant false negatives. When used appropriately, these tests have a very high sensitivity, being able to detect as few as 10–100 copies of viral RNA per milliliter in a sample. They also have a high specificity in that they do not cross-react with other coronaviruses. While these values vary depending on the specific test and manufacturer used, all such assays have comparable performances in terms of their accuracy.

**Utility**
The overall benefit of NAATs is that they amplify a small amount of viral target RNA to a detectable level. They are more sensitive than an antigen-based test and much faster and safer than performing viral culture. However, a significant drawback is that they can detect viral RNA shedding for an extended period in some patients, even after they are no longer symptomatic and presumed no longer infectious.

**SARS-COV-2 TESTING – SEROLOGY TESTING**

**Overview**
Serological tests detect antibodies present in the blood and thus can reveal any current or previous infection. Antibody tests must be specific enough to prevent cross-reaction with antibodies against other pathogens. For SARS-CoV-2, antibodies against S and N proteins are commonly tested, where the antibodies against two subunits S1 and S2 of the S protein can be tested individually or together. The antibody isotypes in SARS-CoV-2 tests are IgM, IgG, and IgA, although IgM and IgG antibodies are generally tested individually or together as total antibodies.

Antibody responses generally occur between 10 to 21 days after infection, with mild cases potentially taking upwards of four weeks. In a recently published study, COVID-19 specific IgM and IgG antibodies were first detectible 3–4 and 5–6 days post-symptom onset, respectively, with a marked increase in antibody detectability and test sensitivity 14 days post-symptom onset. Therefore, such tests are not useful for early screening or initial patient visits.

It is unknown how long COVID-19 specific antibodies remain detectable and whether they correlate to any long-term protection. A recently published study suggests that most patients showed sharp declines of COVID-19 specific IgG antibodies within two to three months after infection onset. A possible new area of inquiry is the study of cellular immunity. A study on medRxiv done by Staines et al. has found that a small percentage of infected patients do not develop COVID-19 antibodies at all, suggesting that the immune response in these patients could be through separate antigens or mediated through T cells.

**Testing Platforms**
Of the few dozen serology tests currently in the market, four particular testing platforms are currently being used to analyze SARS-CoV-2: the lateral flow assay (LFA), the enzyme-linked immunosorbent assay (ELISA), the chemiluminescent assay (CLIA), and the cyclic enhanced fluorescence assay (CEFA).

LFAs prioritize speed and ease of use, offering a flexible and cost-effective method of obtaining a result. Nevertheless, limitations of LFAs include the difficulty to perform large-volume testing and multiple analyte testing. ELISA tests provide standard antibody titers, however, the tests are rather labor-intensive, if not assisted by automation. As opposed to other immunoassays, CLIAs measure photons of light to discern a result, leading to its high sensitivity and specificity. While these tests require expensive instruments and highly purified reagents, the high sensitivity permits the use of very small reagent volumes per test, keeping the
assay cost-effective. The main advantage of CEFA tests lies in the cyclic amplification of the fluorescence signals to detect antibodies sensitively and specifically, and have shown promising clinical utility in evaluating the immune response in infected and convalescent patients.

While current serology testing serves as an excellent indicator of prior or current infection, they do not directly assess the neutralizing capabilities of the antibodies. For this purpose, neutralizing antibody assays aim to identify antibodies that recognize the SARS-CoV-2 virus and block its host cell entry.

There are two recognized types of neutralizing antibody tests: virus neutralization test (VNT) and pseudovirus neutralization test (pVNT). VNTs utilize SARS-CoV-2 viruses from clinical isolates and can only be performed in a Biosafety Level 3 laboratory by highly trained personnel. Alternatively, pVNTs use recombinant pseudoviruses that express the S protein of SAS-CoV-2 to construct the spikes on the viral surface. A specific example is the pseudovirus luciferase assay (PVLAX), where the inhibition of viral entry into cells by the neutralizing antibody correlates to the decreased luciferase signals in the cells. pVNTs are safer, simpler, and more accurate than conventional assays.

Utility
Serologic testing is primarily used to detect the presence of antibodies specific to a given virus and is therefore not a good indicator of current infection, as a positive result indicates that a patient is either in the late phase of the disease or he/she may have been infected in the past. Nevertheless, using a serological test alongside a NAAT has proven effective in providing more accurate diagnoses.

Serologic testing is frequently used for disease surveillance and is thus an integral part of policymaking, both on the governmental and communal level. It is also utilized in transfusion medicine (e.g., with the convalescent plasma treatment) to determine the antibody titer in the unit. Finally, serologic testing will be useful in verifying whether or not a vaccine incites the desired immune response. Distinguishing the immune response to the vaccine from that to the real infection will be challenging in individuals inoculated by inactivated virus-based vaccines, but the presence of RBD or S-protein antibodies and absence of N-protein antibodies should be sufficient to identify an immune response to the S-protein based vaccines.

Other Assays
Currently, NAAT and serologic tests are the most prevalent assays used to diagnose or screen COVID-19. But due to the continued shortage of available tests, there has been a continued push to utilize existing and novel methods for viral detection.

Antigen-based tests are diagnostic tests designed to detect fragments of viral proteins. They utilize similar technology to some serology tests, such as the LFA and the ELISA. The advantage of antigen tests is that they can be performed near the patient without the need for a high-complexity laboratory, and a large number of tests can be manufactured and widely distributed due to their simpler design. However, they do suffer from a lack of sensitivity and specificity compared to NAATs. For the first time, the CRISPR-based technology has been authorized under the FDA EAU for direct patient use. The assay uses the SHERLOCK (Specific High-sensitivity Enzymatic Reporter unLOCKing) method to program a CRISPR molecule to specifically detect the presence of a specific SARS-CoV-2 genetic signature. The advantage of this technology is that it is faster than RT-PCR and can potentially be scaled up to test a large volume of samples. Finally, there are increasing in the development of simple, daily COVID-19 tests. One such test is the paper-strip test, in which a sample of spit in a saline solution would be tested with a strip of paper embedded with protein. Such tests have shown promise and can potentially circumvent some of the issues surrounding the current testing strategies such as cost and testing availability.

Closing Remarks
As it stands, personal hygiene and social distancing procedures are the most effective preventative measures against SARS-CoV-2. When it comes to testing, NAAT and serology testing are the mainstays in clinics and hospitals. In the competitive market of COVID-19 testing, more and more assays are becoming available and being authorized by the regulatory agencies. All the current and emerging assays will keep being used under specific medical and epidemiologic circumstances until the global population reaches herd immunity either by the virus or by the vaccine. The swift response of the medical diagnostic industry to the pandemic highlights the importance of basic biomedical research which is constantly providing scientific and technological knowledge for the health care industry to develop advanced tools and agents to fight diseases and safeguard our population.


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COVID-19 and Kidney Injury

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ABSTRACT

BACKGROUND: Acute kidney injury (AKI) has been reported as a complication of COVID-19. However, the epidemiology, management, and associated outcomes have varied greatly between studies. The pathophysiology remains unclear.

SUMMARY: The etiology of AKI in the setting of COVID-19 appears multifactorial. Systemic effects of sepsis, inflammation, and vascular injury likely play some role. Furthermore, SARS-CoV-2 binds to the angiotensin-converting enzyme 2 receptor, highly expressed in the kidney, providing a route for direct infection. Older age, baseline comorbidities, and respiratory failure are strong risk factors for the development of AKI. Regardless of etiology, AKI carries a significantly increased risk for in-hospital mortality, especially in those with critical illness. Currently, management of AKI in patients with COVID-19 remains supportive.

KEY MESSAGES: AKI is common in patients with COVID-19. Future studies are needed to examine the response to anti-viral treatment as well as long-term renal outcomes in patients with AKI.

KEYWORDS: acute kidney injury, COVID-19, ACE2

INTRODUCTION

The novel coronavirus disease 2019 (COVID-19) outbreak, first reported on December 8, 2019 in Wuhan, China, was designated as a pandemic by the World Health Organization (WHO) on March 11, 2020. This disease, recognized as an infection by a new severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), spread quickly throughout the world. As of August 4, 2020, close to 18 million laboratory-confirmed cases had been documented globally, with nearly 700,000 deaths worldwide. The mortality rates vary significantly among studies from 0.3% to 10%, partially reflecting the differences in local policy, access to diagnostic testing, and health care resources and response. Clinical presentations of COVID-19 can range from asymptomatic infection, self-limited influenza-like symptoms, acute pneumonia to severe respiratory failure.

The ongoing COVID-19 pandemic carries serious medical, psychosocial, and economic consequences. Understanding its pathophysiology, clinical course, management strategy and therapeutic response are of paramount importance. Here, we will synthesize the current literature on the acute kidney injury (AKI) in COVID-19, and discuss its epidemiology, pathogenesis, clinical features, outcomes, and management strategies.
renal replacement therapy. Independent predictors of severe illness. Of those with AKI in the ICU, 34% received renal replacement therapy (rrT), and the vast majority (96.8%) were on ventilators. Risk factors for AKI included older age, DM, cardiovascular disease, black race, hypertension, and need for ventilation and vasopressor support. For patients who developed AKI and survived to hospital discharge, the median peak serum creatinine was 2.34 mg/dL with a range of 1.44–6.39 mg/dL. In ventilated patients vs. non-ventilated patients, the incidence of AKI was 10% vs. 0.2%, respectively, with rates of rrT use ranging from 5.6% to 23.1% with a pooled rate of 13%. These studies reiterate that the risk of AKI and need for RRT were much higher in COVID-19 patients who were critically ill.

In addition to AKI from acute tubular necrosis, the possibility of glomerular disease from COVID-19 has been suggested with the presence of hematuria and proteinuria. In the Chinese cohort by Cheng, et al, 44% of patients had proteinuria and 27% had hematuria at presentation. In the US cohort by Hirsch et al, 42% had proteinuria and 46% had hematuria.

AKI in this cohort included CKD, higher systolic blood pressure, and potassium at baseline.

In a meta-analysis of nine studies (eight from China, one from United States) of hospitalized patients with COVID-19, two of the studies included only patients admitted to the intensive care unit. In an overall hospital setting, the incidence rates of AKI varied from 0% to 14.7%, with a pooled incidence rate of 7%. In the six studies that reported RRT use, 0.5%–7.3% of patients required RRT, with a pooled RRT incidence rate of 2%. Four studies reported the incidence of AKI in the ICU setting, with rates ranging from 8.3% to 28.8% and a pooled incidence rate of 19%. Only three studies reported RRT use in an ICU setting, with rates of RRT use ranging from 5.6% to 23.1% with a pooled rate of 13%. These studies reiterate that the risk of AKI and need for RRT were much higher in COVID-19 patients who were critically ill.

Table 1. Summary of published studies on AKI in patients with COVID-19

<table>
<thead>
<tr>
<th>Studies</th>
<th>Origin</th>
<th>N</th>
<th>Age (years)</th>
<th>DM (%)</th>
<th>HTN (%)</th>
<th>CKD (%)</th>
<th>ICU (%)</th>
<th>AKI (%)</th>
<th>Mortality (overall)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cheng et al</td>
<td>China</td>
<td>701</td>
<td>63 (50–71)</td>
<td>100</td>
<td>233</td>
<td>14</td>
<td>73</td>
<td>36</td>
<td>113 (16%)</td>
</tr>
<tr>
<td>Wang et al</td>
<td>China</td>
<td>138</td>
<td>56 (42–68)</td>
<td>10</td>
<td>43</td>
<td>4</td>
<td>36</td>
<td>5</td>
<td>6 (4%)</td>
</tr>
<tr>
<td>Guan et al</td>
<td>China</td>
<td>1099</td>
<td>47 (35–58)</td>
<td>81</td>
<td>165</td>
<td>8</td>
<td>55</td>
<td>6</td>
<td>15 (1%)</td>
</tr>
<tr>
<td>Hirsch et al</td>
<td>USA</td>
<td>5449</td>
<td>64 (52–75)</td>
<td>1797</td>
<td>3037</td>
<td>N/A</td>
<td>1395</td>
<td>1993</td>
<td>888 (16%)</td>
</tr>
<tr>
<td>Yang et al</td>
<td>China</td>
<td>52</td>
<td>60 (13)</td>
<td>9</td>
<td>N/A</td>
<td>N/A</td>
<td>52</td>
<td>15</td>
<td>32 (62%)</td>
</tr>
<tr>
<td>Chan et al</td>
<td>USA</td>
<td>3235</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>815</td>
<td>1406</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Data was reported as median (IQR), mean (SD) or number (%)

AKI was seen in COVID-19 patients with respiratory failure (23.2% in ventilated patients vs. 0.2% in non-ventilated patients). Of patients who required ventilation and developed AKI, 52.2% had the onset of AKI within 24 hours of intubation. Among patients with AKI, 14.3% received renal replacement therapy (rrT), and the vast majority (96.8%) were on ventilators. Risk factors for AKI included older age, DM, cardiovascular disease, black race, hypertension, and need for ventilation and vasopressor support. For patients who developed AKI and survived to hospital discharge, the median peak serum creatinine was 2.34 mg/dL with a median of 1.70 mg/dL at discharge. In another large cohort of 3,235 hospitalized COVID-19 patients from New York, AKI occurred in 46% patients with 20% requiring RRT. The cumulative incidence of AKI (admission plus new cases) in patients admitted to the intensive care unit was 68%. In the entire cohort with AKI, the proportion with stages 1, 2, and 3 AKI were 35%, 20%, 45%, respectively. In those needing intensive care, the respective proportions were 20%, 17%, 63%, suggesting an association between severe AKI and severe illness. Of those with AKI in the ICU, 34% received renal replacement therapy. Independent predictors of severe AKI included CKD, higher systolic blood pressure, and potassium at baseline.

In a meta-analysis of nine studies (eight from China, one from United States) of hospitalized patients with COVID-19, two of the studies included only patients admitted to the intensive care unit. In an overall hospital setting, the incidence rates of AKI varied from 0% to 14.7%, with a pooled incidence rate of 7%. In the six studies that reported RRT use, 0.5%–7.3% of patients required RRT, with a pooled RRT incidence rate of 2%. Four studies reported the incidence of AKI in the ICU setting, with rates ranging from 8.3% to 28.8% and a pooled incidence rate of 19%. Only three studies reported RRT use in an ICU setting, with rates of RRT use ranging from 5.6% to 23.1% with a pooled rate of 13%. These studies reiterate that the risk of AKI and need for RRT were much higher in COVID-19 patients who were critically ill.

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Table 2. Summary of COVID-19 related kidney pathological findings in patients with acute kidney injury. Summarized from 9–11.

<table>
<thead>
<tr>
<th>Tubulointerstitial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Tubular Injury</td>
</tr>
<tr>
<td>Vascular</td>
</tr>
<tr>
<td>Cortical infarction</td>
</tr>
<tr>
<td>Microthrombi</td>
</tr>
<tr>
<td>Glomerular</td>
</tr>
<tr>
<td>Anti-Glomerular Basement Membrane Nephritis</td>
</tr>
<tr>
<td>Collaborative Focal and Segemental Glomerulosclerosis</td>
</tr>
<tr>
<td>Membranous Nephropathy</td>
</tr>
<tr>
<td>Minimal Change Disease</td>
</tr>
</tbody>
</table>
scattered subepithelial deposits were noted in another case. Both patients did not have evidence of bacterial infections, suggesting a direct association with SARS-CoV-2 infection. No other diagnostic electron-dense deposits were detected.

Two separate biopsy series taken from patients in the United States who developed AKI in the setting of COVID infection has found new-onset immune-mediated glomerular disease and the presence of collapsing focal and segmental glomerulosclerosis in patients with two apolipoprotein L1 risk variant genes. No intracellular viral particles were observed in these cases.

**PATHOGENESIS**

The causes of AKI are likely multifactorial. In addition to common processes related to systemic infection including poor renal perfusion from volume depletion or blood flow shunting, direct cytopathic viral infection, severe inflammation and cytokine storm resulting from SARS-CoV2 infection have all been implicated. The contribution of each of these entities to tubular injury remains under investigation. As noted above, the vast majority of cases are caused by ATN, although some glomerular pathologies have been found. In the cases of glomerular involvement, the absence of viral particles in these series suggests cytokine-mediated kidney damage as the likely etiology, but further investigation to confirm this is required. Lastly, COVID-19 has been shown to cause endothelial injury and is associated with hypercoagulable state, thus renal thrombotic microangiopathy (TMA) or microvascular thrombosis can also contribute to the development of AKI.

**DIRECT VIRAL INFECTION OF KIDNEY**

Similar to SARS-CoV, the spike (S) protein of SARS-CoV-2 binds to angiotensin-converting enzyme 2 (ACE2), its host cell target for direct invasion. The viral entry into the host cells also require viral S protein priming by cellular proteases, the TMPRSS family, which entails S protein cleavage and allows fusion of viral and cellular membranes. ACE2 is highly expressed in the kidney, similar to the epithelial cells of lung and gastrointestinal (GI) tract, indicating kidney as a potential target organ. Via single-cell transcriptome analysis, Pan et al demonstrated that both ACE2 and TMPRSS genes were significantly co-expressed in podocytes and renal proximal tubules, and the levels of expression were higher than that of lung tissue and GI tract.

The more direct evidence of viral kidney infection came from an autopsy series in Wuhan, China. Su et al reported pathologic findings in the kidneys from 26 patients died of SARS-CoV-2 infection. Nine of the 26 had clinical evidence of kidney involvement with increased serum creatinine and/or new-onset proteinuria. Electron microscopic examination revealed clusters of coronavirus particles with distinctive spikes in the tubular epithelial cells and podocytes. The immunostaining for SARS-CoV-2 nucleoprotein was positive in renal tubules, as well. There was also strong focal viral staining in parietal epithelial cells as well as occasional weaker staining in podocytes. As expected, the expression of ACE2, the receptor of SARS-CoV-2, was found to be upregulated in these patients infected with COVID-19. Compared with non-COVID-19 infected control, ACE2 expression was prominent in proximal tubular cells, particularly in areas with severe tubular injury.

**CYTOKINE STORM AND INFLAMMATION**

Induction of an inflammatory response is a known trigger for AKI, and it is initiated through both pathogenic and non-pathogenic processes. During inflammation, pathogen-associated molecular patterns (PAMPs) and/or damage-associated molecular patterns (DAMPs) bind to Pattern Recognition Receptors (PRRs) expressed in cells of multiple organs, including renal tubular epithelial cells, and induce cell damage. As a matter of fact, there is a strong association between cytokine levels (interleukin (IL)-6, IL-10, and macrophage migration inhibitory factor) and the development of sepsis-induced AKI.

An inflammatory cytokine profile resembling hemophagocytic lymphohistiocytosis has been found in severe cases of COVID-19, characterized by increased IL-2, IL-7, granulocyte-colony stimulating factor, interferon-γ inducible protein 10, monocyte chemoattractant protein 1, macrophage inflammatory protein 1-α, and tumor necrosis factor-α. According to a retrospective study of 150 COVID-19 cases in Wuhan, China, elevated levels of inflammatory markers such as ferritin, C-reactive protein and IL-6 were present in severe COVID-19 cases and predicted fatality, suggesting...
an important and detrimental role of virally driven hyperinflammation and cytokine storm in SARS-CoV-2 infection. The higher risk and severity of AKI seen in severe SARS-CoV-2 infections supports the role of inflammation in the pathogenesis of AKI.

VASCULAR INSULT AND COAGULATION DISORDER

Cardiovascular complications are rapidly emerging as a key threat in COVID-19. Direct endothelial cell infection and endothelitis have been demonstrated in SARS-CoV2 infected patients. Recruitment of immune cells, either by direct viral infection of the endothelium or immune-mediated, can result in widespread endothelial dysfunction. Injured endothelial cells produce a decreased quantity of vasodilators, such as nitric oxide, resulting in a more pronounced response to vasoconstrictors. This leads to a redistribution of blood flow. The imbalance between vasoconstrictors, vasodilators and oxidative stress at the endothelial level is believed to be a major contributor to the development of AKI.

The development of coagulopathy in the forms of deep venous thrombosis and pulmonary embolism are well-recognized features of COVID-19, and is one of the most significant poor prognostic factors. Therefore, augmented vasoconstriction, small vessel occlusion due to activated endothelial cells and activation of the coagulation system can result in renal TMA and compromised microvascular perfusion. Lastly, patients with severe COVID-19 who experienced abnormal clotting have been shown to carry positive antiphospholipid antibodies, suggesting secondary anti-phospholipid syndrome might also account for COVID-19-associated thrombotic events.

MANAGEMENT OF AKI IN THE SETTING OF COVID-19

To date, there are limited data to guide the clinical treatment strategies for COVID-19 and its renal complications. For COVID-19, the general approaches include controlling the source of infection, use of personal protective equipment to reduce the risk of transmission, early diagnosis/isolation, and symptomatic supportive care for affected patients. Antibacterial agents are ineffective, and no antiviral agents have been clearly proven to be beneficial for treating COVID-19.

In those with AKI, early detection and adoption of kidney protective measures are important to reduce mortality and improve prognosis. Strategies have been applied including hemodynamic support, avoidance of nephrotoxic drugs, aggressive management of electrolyte and acid-base derangements, and renal replacement therapy whenever it is indicated.

For patients who require dialysis, clinicians can decide to provide either intermittent hemodialysis, continuous renal replacement therapy (CRRT) or acute peritoneal dialysis based on a patient’s clinical status and the facility’s resources. Increased thrombosis of catheters or extracorporeal filters during CRRT has been recognized and specific anticoagulation protocols have been developed to mitigate the hypercoagulable state.

PROGNOSIS OF COVID-19 PATIENTS WITH AKI

AKI has a major impact on survival among hospitalized COVID-19 patients. In a large cohort from New York, in-hospital mortality among patients with AKI was 41%, the rate increased to 52% in those admitted into intensive care with AKI. The adjusted odds ratio for mortality associated with AKI was 9 overall and 20.9 in patients receiving intensive care.

In another cohort from New York, among 1,993 patients who developed AKI during the hospitalization, 26% of patients were discharged and 35% died. Of those with AKI, risk of death and prolonged hospital stay was related to severity of AKI: 57% with stage 1 AKI died or were still hospitalized during the study period as compared with 80% with stage 2 and 94% with stage 3. Among the 285 patients who required RRT, 157 died and only 9 were discharged from the hospital. Another 119 were still undergoing treatment in the hospital, with 108 still on RRT (90.8%).

Outside United States, Cheng et al examined 701 hospitalized COVID-19 patients in Wuhan, China, and found AKI carried a significantly increased risk for in-hospital mortality. Cox proportional hazard regression confirmed that baseline CKD, AKI, proteinuria and hematuria were all independent risk factors for in-hospital death after adjusting for age, sex, disease severity, comorbidity and leukocyte count. Therefore, both baseline CKD and AKI during hospitalization in patients with COVID-19 is clearly associated with higher in-hospital mortality.

CONCLUSION AND FUTURE PERSPECTIVES

The COVID-19 pandemic is far from over with millions of cases reported worldwide, and over 200,000 new cases reported daily. The pathogenesis of AKI has not been clearly established in this patient population. The therapeutic responses of patients with AKI to various medications under clinical investigation are unclear. The impact of AKI on disease duration, viral clearance, risk of CKD and long-term survival are also unclear. As the healthcare system and resources become overwhelmed by COVID-19 pandemic, the access to routine CKD care and kidney transplantation can be negatively affected and its short-term and long-term impact warrants further investigation. Lastly, an evidence-based comprehensive management guideline is desperately needed to win this battle.
References


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COVID-19 and ESKD, A Rapid Review
ANKUR D. SHAH, MD; NATHAN CALABRO-KAILUKAITIS, MD

ABSTRACT
In 2020, the COVID-19 pandemic has ravaged the world. Individuals with end-stage kidney disease (ESKD) are at higher risk due to impaired immunity, comorbid conditions, and dependence on travel to medical care settings. We review the salient features of COVID-19 in this population, including the risk of infection, disease course, changes in dialysis unit management, use of investigatory medications, access considerations, home dialysis, and capacity planning.

KEYWORDS: coronavirus, COVID-19, end-stage kidney disease, dialysis

INTRODUCTION
The COVID-19 pandemic, caused by the novel severe acute respiratory syndrome coronavirus 2 (SARS-COV-2), has devastated the United States and the world in 2020. Patients with end-stage kidney disease (ESKD) are at particular risk, owing to both dysfunction of innate and adaptive immunity and a significant burden of comorbid conditions. Management of this vulnerable population is complex, and in this paper, we review key aspects including risk of infection, risk of mortality, changes in operations including medications and access, and contingency planning.

RISK OF INFECTION
The Centers for Disease Control (CDC) guidance states that while everyone is at risk of COVID-19, certain populations have increased risk for severe illness, including older adults, individuals with chronic kidney disease, individuals with chronic obstructive pulmonary disease, solid organ transplant recipients, those with obesity, cardiac conditions, sickle cell disease, and type 2 diabetes mellitus. Patients on dialysis have weakened immune systems and high rates of cardiac conditions and type 2 diabetes mellitus in addition to their own kidney dysfunction.

A preliminary Medicare COVID-19 snapshot of claims and encounter data from services rendered through May 16, 2020 with claims received by June 11, 2020 found the highest burden of COVID-19 in patients with ESKD. 2,614 cases were found per 100,000 beneficiaries compared to the general population rate of 518 cases per 100,000. Burden increased further to 3,953 per 100,000 in those with dual Medicare and Medicaid eligibility. 51.3% required hospitalization. Individual centers have published their experience as well, with significant heterogeneity. Dialysis Clinic, Inc. (DCI), a non-profit dialysis organization caring for approximately 15,000 patients in outpatient dialysis units, noted as of July 5, 2020, 566 (3.7%) patients in outpatient clinics had tested positive for COVID. 51.3% of cases were from group homes. The majority of new cases were reported in April, 2020; however, there was a recent increase in the trend of incident cases.

CLINICAL FEATURES AND MORTALITY
Early in the pandemic it was theorized that the clinical course could either be more exaggerated than the general population due to high rates of comorbid conditions and the basal mortality of the ESKD population or that the immunocompromised state may attenuate the inflammatory response of COVID-19 and thus provide a milder syndrome. The literature is currently rapidly evolving to better delineate the course.

Three hospitals in New York, Columbia University Irving Medical Center, Moses Hospital, and Weiler Hospital, have reported outcomes of patients admitted with end stage kidney disease. Pooled mortality was 28.9% in a total of 173 hospitalized patients, the majority of whom dialyzed via in center hemodialysis. Symptoms of cough, fever, and dyspnea were present in less than fifty percent of patients. Risk factors for mortality reported by the groups included greater age, higher comorbidity index, degree of lymphopenia, C-reactive protein elevation, LDH elevation, IL-6 elevation, and ferritin elevation. Mortality was 86.7% in those requiring intensive care unit level of care.

While these single center reports provide granular detail, they are limited by the nature of the pandemic as different areas of the US have had different experiences. The DCI COVID-19 cohort, a national cohort, reported 21.3% mortality. Amongst those living in group homes, mortality was higher at 25.7%. Notably the population from which this cohort is derived is outpatient dialysis units, while the population of the above cohort was hospitalized dialysis patients, which accounts for the variability in mortality.
The international experience has been described as well in an early report from Wuhan, China demonstrating the tenuous state of dialysis patients with COVID-19. During a 2-month study period, 42 of 230 hemodialysis patients were diagnosed with COVID-19, 10 of the 42 died during the epidemic. Only 2 deaths were associated with respiratory failure, with the main causes of death being cardiovascular events and hyperkalemia, highlighting to the nephrology community the risk of underdialysis in reaction to COVID-19. This was followed by a more comprehensive analysis from Wuhan, China in which 154 of 7154 maintenance hemodialysis patients were reported to test positive for COVID-19 from January to March 10, 2020. Of the 154 patients diagnosed with COVID-19, 23 did not consent to analysis of their data. Fever, cough, and dyspnea were only present in 51.9%, 37.4%, and 26% of patients respectively. 82.1% presented with ground glass opacities on computerized tomography of the chest. 13.8% progressed to develop acute respiratory distress syndrome. Mortality was 31.2% amongst 131 patients.

Four Italian centers in the Brescia Renal COVID Task Force have also shared their experience, reporting the outcomes of 643 hemodialysis patients. 94 (15%) patients were positive for COVID-19. 39% required hospitalization. Treatments attempted included antivirals, hydroxychloroquine, glucocorticoids, and tocilizumab. Mortality was 25.5% in the cohort. History of fever, cough and a C-reactive protein higher than 50 mg/l at presentation were associated with the risk of death.

### CHANGES IN DAY-TO-DAY OPERATIONS

The need to care for COVID-19 patients who do not require hospitalization has presented a challenge for dialysis units. Dialysis units are congregate settings in which in-person encounters are necessary. Considerations that must be taken into account during the COVID-19 pandemic include the safety of this vulnerable group of patients as well the need to maintain a healthy staff of highly trained personnel including technicians, nurses, and physicians to provide continued dialysis care. In addition to the Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 (COVID-19) in Healthcare Settings, the CDC has released guidance for outpatient hemodialysis units.

Broadly, the CDC recommendations have addressed topics

<table>
<thead>
<tr>
<th>Key Area</th>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Universal Face Covering</td>
<td>Mask for health care personnel, cloth face covering or mask for patients</td>
</tr>
</tbody>
</table>
| Early Recognition and Isolation of Individuals with suspected or known COVID-19 | Non-punitive sick leave policies  
Awareness of the possibility of asymptomatic transmission (highlighting importance of universal face mask policy and application of prevention practices to all patients (hand hygiene, surface decontamination, and distancing)  
Identification of patients with fever or symptoms of COVID-19 before entrance into treatment area  
Patients should call ahead if they have fever or symptoms of COVID-19  
Facility should provide instruction regarding maintaining a distance of at least 6 feet from all other persons, hand hygiene, use of face covering, cough etiquette.  
Facility should post signs at clinic entrances with instruction for patient with fever or symptoms of COVID-19 to alert staff  
Facilities should position supplies (tissues, no-touch receptacles, and hand hygiene supplies close to dialysis chairs and nursing |
| Placement of Patients                         | Facilities should have space in waiting areas for patients to sit separated by at least 6 feet from other patients.  
Bring patients with known or suspected COVID-19 to treatment area as soon as possible to minimize time in the waiting area.  
Dialyze patients with known or suspected COVID-19 in a separate room. If not possible, patients with known or suspected COVID-19 should be dialyzed in an end-of-row or corner station.  
Patients with known or suspected COVID-19 should be separated by at least 6 feet from the nearest patient station.  
If more than one patient is suspected of having or confirmed to have COVID-19 consideration should be given to cohorting these patients and HCP providing care for them to a section of the unit and/or to the same shift. |
| Personal Protective Equipment                 | HCP caring for patients with suspected or confirmed COVID-19 should use an N-95 or higher level respirator if available.  
If a shortage exists, respirators should be reserved for situations when respiratory protection is most important (i.e. performance of aerosol generating procedure).  
Gloves  
Eye protection  
Isolation gown |
| Disinfecting                                  | Current procedures for routine disinfection and cleaning of dialysis stations are acceptable for patients with COVID-19 (though important to validate activity of surface disinfectant is active against SARS CoV-2).  
Staff should be trained and have competency assessed for cleaning and disinfection procedures. |
including masking, early recognition of individuals with suspected or confirmed COVID-19, placement of patients, personal protective equipment (PPE), and disinfecting. A summary of the CDC guidance can be found in Table 1.

Similarly, The American Society of Nephrology (ASN) has also provided information for screening for and management of COVID-19 in the outpatient dialysis facility closely based on the CDC guidance.

The experiences of several international dialysis centers have been described. In Lombardy, Italy, 18 hemodialysis patients were infected then isolated immediately and treated in a dialysis ward, separate from the main dialysis ward. None of the health care staff had been infected at the time of reporting, nor had any of the other, approximately 200 total hemodialysis patients developed known infection. In a second center, four of 170 patients were infected and after isolation no other case had been diagnosed in staff or another patient. Testing was done in symptomatic cases and following the first positive case, all patients were required to wear surgical masks.12

A second later report from a hemodialysis center in Lombardy Italy suggested that preventive measures were helpful in preventing the spread of SARS-CoV-2. 33 of 188 HD patients in the outpatient centers had positive nasopharyngeal swab for SARS-CoV-2. Prior to results, SARS-CoV-2 positive patients received HD treatments in rooms with patients who had had a negative swab. After receiving swab results, cohorting of patients was implemented. The results were no additional symptomatic infections in patients who had previously had negative swabs and none in the health care staff.13

A multi-center study conducted in Korea investigated HD with cohort isolation for close contacts of patients with COVID-19 on the prevention of secondary transmission of the SARS-CoV-2 in HD units. 11 patients on HD and seven health care workers from 11 HD centers were diagnosed with COVID-19. 302 close contacts based on the epidemiologic investigation were enrolled and cohort isolation HD was performed among all close contacts in seven centers for a median of 14 days. During cohort isolation, only two health care workers and no patients were diagnosed with SARS-CoV-2.14

In terms of de-isolation, fourteen days may not be an appropriate threshold. Dudreuilh et al reported the deisolation experience of a single center in the NHS trust in London. 14 of 34 patients [41%] of COVID-19 positive patients did not clear the virus by day 15. Five patients cleared the virus later [median of 18 days], and 9 patients had had only one negative swab at the end of follow-up or had remained positive.15 Notably prolonged viral shedding may not represent an infectious individual as it is unclear if individuals with prolonged shedding are shedding inactive viral particles or functional virions.

**EXPERIMENTAL MEDICATION CONSIDERATIONS**

Several medications have been and are being studied as anti-viral and anti-inflammatory agents in the management of COVID-19. Agents such as remdesivir, hydroxychloroquine, glucocorticoids, and tocilizumab have all been the focus of recent or active randomized controlled trials.

Remdesivir, a prodrug initially developed for treatment of ebolavirus that inhibits viral replication, has been studied in the management of COVID-19 based on in-vitro and in-vivo animal studies showing activity against coronaviridae. The FDA emergency use authorization recommends consideration of potential risks and benefits in individuals with estimated glomerular filtration rate less than 30 milliliters per minute. Intravenous remdesivir is delivered with an excipient, sulfobutylether-β-cyclodextrin (SBEC), due to its water insolubility. Animal studies have shown that SBEC accumulation when delivered in doses 50-100 times the dose from a 5-10 day course of remdesivir can be nephrotoxic. SBEC is also the excipient of intravenous voriconazole, a setting in which short term use has been found to be safe. SBEC is cleared by hemodialysis as well. Consideration of risk-benefit should be given prior to withholding remdesivir in patients with ESKD.16,17

Hydroxychloroquine, an antimalarial commonly used for its anti-inflammatory properties, has been the subject of great debate in COVID-19. It is highly protein bound, with hepatic metabolism and renal clearance accounts for only fifteen to twenty five percent of excretion. Dialytic clearance is minimal and supplemental dosing is not necessary.17 Dexamethasone, a long acting glucocorticoid with potent anti-inflammatory properties, was found to reduce mortality in the Randomized Evaluation of Covid-19 Therapy trial.18 Dexamethasone is hepatically metabolized with minimal urinary excretion. Safety has been demonstrated in individuals receiving renal replacement therapy and dose adjustments or supplementary doses are not required in dialysis patients.17

Tocilizumab, an antagonist of the interleukin-6 receptor leads to a reduction in cytokine production and is used frequently in cytokine release syndrome from T-Cell therapy. Efficacy and safety have not been demonstrated in individuals with moderate to severe kidney impairment. It is not believed that clearance is influenced by kidney function and dose adjustments are not typically needed.17

**VASCULAR ACCESS CONSIDERATIONS**

Establishing vascular access in preparation for chronic hemodialysis remains essential during the COVID-19 pandemic. Early in the pandemic, CMS released guidance recommending delay of any non-essential surgeries. The American Society of Diagnostic and Interventional Nephrology and the Vascular Access Society of the Americas have issued a joint statement excluding dialysis accesses are the “lifeline” for
patients with ESKD and suggested that lack of access would lead to complications and demise.\textsuperscript{19}

In response to feedback regarding difficulty scheduling placement or repair of arteriovenous fistulas, arteriovenous grafts, and intravascular catheters, CMS clarified their stance and deemed establishment of vascular access essential to receiving hemodialysis noting the risk of morbidity, mortality, and infection that would be expected with temporary hemodialysis catheters.

**FUTURE CONTINGENCY PLANS AND HOME DIALYSIS**

The data presented previously highlights the opportunity to lower the risk of COVID-19 infection amongst the vulnerable ESRD patient population. Home dialysis therapies including peritoneal dialysis (PD) and home hemodialysis (HHD) offer the potential advantage of minimizing interpersonal contact and transmission of COVID-19 as compared to in-center hemodialysis (HD). However, in 2017, home therapies constituted less than 10% of treatment for ESRD. 62.7% of all prevalent ESRD patients in 2017 were receiving HD therapy. Only 2.0% of these patients used HHD. 7.1% of ESRD patients in the same year were being treated with PD.\textsuperscript{3}

Snapshot data on infection rates in the Veneto region and Vicenza referral area of Italy in April, 2020 showed a lower percentage of COVID-19 positive peritoneal dialysis (PD) patients compared to hemodialysis patients. Aggregate data showed four of 627 (0.64%) of PD patients were positive for COVID-19 while 36 of the 1,991 hemodialysis patients showed four of 627 (0.64%) of PD patients were positive for COVID-19 while 36 of the 1,991 hemodialysis patients. Aggregate data showed four of 627 (0.64%) of PD patients were positive for COVID-19 while 36 of the 1,991 hemodialysis patients (1.81%) were positive for COVID-19. Noteworthy was that one of the COVID-19 positive PD patients was thought to have acquired the infection from a daughter who worked in a nursing home.\textsuperscript{20}

The COVID-19 pandemic has prompted the use of telehealth in the management of home dialysis patients. Telehealth offers the obvious advantage of limiting physical congregation as compared to traditional medical visits. In March 2020, CMS released a toolkit for ESKD providers to help with the establishment and operation of telehealth programs.

Telehealth has been successfully used during the COVID-19 pandemic as a substitute for in-person monthly clinic visits for home dialysis patients. The Rogosin Institute is an independent dialysis provider affiliated with New York Presbyterian Hospital and had a home dialysis population of 210 patients (150 on PD and 60 on HHD). All patients were offered telehealth visits for their monthly visit from March 1, 2020. 78 telehealth monthly visits were performed. Anecdotally the institute’s home dialysis patients were satisfied with telehealth as a tool to potentially reduce COVID-19 exposure though no formal survey was conducted, nor any clinical outcome data reported.\textsuperscript{21}

While the evidence is clearly limited thus far, a commentary in the Journal of the international Society for Peritoneal Dialysis recommended consideration of PD as a preferred option for individuals with advanced kidney disease.\textsuperscript{22}

**CONCLUSION**

ESKD and COVID-19 are both conditions with significant morbidity and mortality. Patients on maintenance dialysis are unique in the frequency in which they encounter healthcare settings. They are at the highest risk of contracting COVID-19 and have high mortality from the disease. Many changes have been made to their care in consideration of this.

**References**


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The views expressed in this article are those of the authors and do not necessarily reflect the position or policy of the United States Department of Veterans Affairs or the United States government.

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Kidney Transplantation and COVID-19

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KEYWORDS: kidney transplantation, COVID-19, immunosuppression

INTRODUCTION

Kidney transplantation is the treatment of choice for patients with advanced chronic kidney disease or end stage kidney disease. More than 1,500,000 people live with a transplanted organ worldwide. In the United States, approximately 40,000 patients received an organ transplant in 2019 with almost 60% of those receiving a kidney transplant. Generally, kidney transplant recipients receive induction therapy (antithymocyte globulin, basiliximab or alemtuzumab) at the time of transplant, followed by a maintenance immunosuppressive protocol consisting of prednisone, a calcineurin inhibitor (tacrolimus or cyclosporine) or mTOR inhibitor (sirolimus), and an antimetabolite (mycophenolic acid, azathioprine). Long-term immunosuppression is associated with an increased risk of infectious complications and specifically, transplant recipients are more susceptible to infections resulting from ribonucleic acid respiratory viruses.

The enduring epidemic outbreak originating in Wuhan, China in December 2019 caused by the 2019 novel coronavirus (COVID-19) or the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has created a dangerous and deadly public health disaster of international proportions. Although this outbreak has raised great concern among the general population, its specific impact on transplant recipients is unknown. The Centers for Disease Control and Prevention (CDC) lists immunocompromised patients, including those requiring immunosuppression following renal transplantation, as at high-risk for developing severe disease from COVID-19.

WHY KIDNEY TRANSPLANTATION SLOWED DOWN OR STOPPED DURING THE PANDEMIC

Due to the “uncertainty” of patient outcomes within the transplant community, transplantation volumes declined during the early period of the COVID-19 pandemic. In early April of this year, the United Network for Organ Sharing (UNOS) released data showing that transplantation rates in the US dropped sharply coincident with the timing of stringent infection control measures. There was a 51.1% reduction in deceased donor kidney transplantation and 71.8% of centers placed a complete suspension of live donor kidney transplantation. Furthermore, 84% of transplant centers added stringent restrictions included transplanting only highly sensitized patients, those with a negative cross-match, higher acuity patients and those without dialysis access. Some centers reported transplanting only healthier recipients with the best quality organs and with the lowest risk of delayed graft function because of fears of overwhelming the health-care system that was already being stretched thin by the pandemic. Because of concerns of the sensitivity of the RT-PCR test and the fear of transmitting COVID-19 from the donor to the recipient, the decision to proceed with transplantation was made on a case-by-case basis, after careful assessment of the risks and benefits of transplantation. For this reason, rates of deceased donor discard and waiting list inactivation increased dramatically while the rate of new additions to the waiting list decreased during the pandemic. Using data from the National Organ Procurement Agency in France and the UNOS in USA, Loupy et al. showed that the trend in declining transplant rates accelerated over time from February 2020 until April 2020, with the reduction driven primarily by kidney transplantation. There was a 90.6% overall reduction in deceased donor kidney transplantation in France and 51.1% in the USA during this time period, although a substantial negative effect was also seen for heart, lung and liver transplants. An analysis of US registry data showed that between March 15 and April 30, 2020, the numbers of deceased donor and live donor kidney transplant procedures were, respectively, 24% and 87% lower than would be expected based on pre-epidemic data.

HOW TO MANAGE IMMUNOSUPPRESSIVE MEDICATIONS IN KIDNEY TRANSPLANT RECIPIENTS (KTRs) INFECTED WITH COVID-19

Because of their chronically immunosuppressed status, KTRs are at increased risk for infectious complications, accounting for significant morbidity and mortality. Infections rank as the second leading cause of death in these individuals. Additionally, KTRs frequently suffer from medical conditions such as diabetes, hypertension, cardiovascular disease and chronic kidney disease that have been identified...
early reports of outcomes in kidney transplant patients with COVID-19 originated in Europe since the pandemic spread from Wuhan to this continent before spreading to the rest of the world. These are limited predominantly to case series and single-center studies and are lacking in control groups of non-transplant patients. Regardless, observational studies can provide useful early insights into effective treatment strategies. Alberici et al9 described the early experience of COVID-19 infections among 20 Italian KTRs. Management consisted of the withdrawal of all immunosuppression followed by the administration of hydroxychloroquine [95%], lopinavir/ritonavir [79%] and the administration of methylprednisolone [16 mg] in all patients. Additionally, six patients who deteriorated clinically were given tocilizumab. In this limited cohort, the development of COVID pneumonia was associated with a high risk of clinical deterioration. ICU level care was required in 20% of patients accompanied by a high rate of acute allograft injury [30%] and a mortality rate of 25%. The UK experience was summarized by Banerjee et al,9 describing the clinical course of 7 KTRs infected with COVID-19. Modifications in the immunosuppressive regimen consisted of withdrawal of the antimetabolite and reducing the tacrolimus dose, while prednisone was kept unchanged or increased. 57% of patients required ICU admission and were otherwise managed with supportive care alone. In this cohort, older and diabetic patients were at higher risk for poor outcomes, with elevate D-Dimer, ferritin and troponin levels clinically predictive of case severity. In their series, 57% of patients developed acute kidney injury with mortality rate of 14%.

In early March of this year, New York City became the epicenter of the coronavirus pandemic in the United States. At Montefiore Medical Center, Akalin et al10 summarized the course of 36 KTRs with COVID infection during the outbreak in New York City between March 16 and April 1, 2020. Seventy-five percent of affected individuals were recipients of deceased donor kidney transplants and maintenance immunosuppressive regimen consisted of tacrolimus, MMF and prednisone. Most patients suffered from medical comorbidities including hypertension [94%], diabetes [69%], a history of smoking or active smokers [36%] and heart disease [17%]. Management consisted of the withdrawal of the antimetabolite in most patients [86%] and tacrolimus [21%] in severely ill patients. Eighty-six percent of patients received hydroxychloroquine and 2 patients received tocilizumab. Allograft outcomes were poor with 21% of patients requiring renal replacement therapy. The study showed a high early mortality rate of 28% at 3 weeks. In another study from New York during the first three weeks of the outbreak (March 13 to April 3, 2020), Pereira and colleagues described the outcomes of COVID-19 infections in ninety patients with solid organ transplants which included 46 KTRs. Many patients had comorbidities associated with COVID-19 severity, such as obesity, cardiovascular disease, and chronic kidney disease. Seventy-six percent required hospitalization and 35% required mechanical ventilation. As per previous studies, immunosuppressive medications were reduced [88% antimetabolite, 7% steroid and 18% CNI decreased or held]. Ninety-one percent of patients received hydroxychloroquine, 66% azithromycin, 3% remdesivir, 21% tocilizumab, and 24% bolus steroids. The overall mortality rate was 18%. Twenty-four percent of hospitalized patients and 52% of those who were admitted to the intensive care unit died during the 3-week study period.

The outcome of COVID-19 in elderly transplant patients was described by Crespo et al.11 From March 12 until April 4, 2020, COVID-19 was diagnosed in 16 of 324 KT patients aged ≥65 years old [4.9%] in their cohort. Up to 33% showed renal graft dysfunction with short-term fatality rate of 50% at a median time of 3 days following admission. Those who died were more frequently obese, frail, and had underlying heart disease. The study is alarming for the early and high mortality rate among the elderly kidney transplant population infected with COVID-19.

**WHAT IS THE ROLE OF TOCILIZUMAB AND REMDESVIR IN TREATING KTRS WITH COVID-19?**

As the cytokine storm triggered by the coronavirus may be responsible for severe manifestations of COVID-19, immunosuppressive therapy could potentially mitigate some of these effects and reduce the risk of developing complications. Therefore, interleukin-6 (IL-6) targeting therapies have been proposed to manage the acute respiratory distress syndrome and organ dysfunction when present. Perez-Saez et al11 published their multicenter cohort experience using tocilizumab, a monoclonal antibody directed against the IL-6 receptor, in 80 KTRs in Spain with COVID-19. The mortality rate was high at 32.5% with a predilection for older patients [> 60 YO]. Of note, 10% of treated patients developed superimposed bacterial infection after tocilizumab infusion. IL-6 and other inflammatory markers, including LDH, ferritin, and D-dimer increased early after tocilizumab administration and correlated with poor patient survival. CRP was the only marker that decreased with tocilizumab treatment by a median time of 3 days following admission. Those who died were more frequently obese, frail, and had underlying heart disease. The study is alarming for the early and high mortality rate among the elderly kidney transplant population infected with COVID-19.
received tocilizumab more frequently in the intensive care unit. The authors concluded that declining CRP levels after tocilizumab administration together with clinical and radiological response might help to identify patients with favorable outcomes. In contrast, 2 case reports describing the use tocilizumab in 2 KTrs infected with COVID-19 showed rapid resolution of the cytokine storm and favorable clinical course without the need of mechanical ventilation\cite{14,15}, suggesting that earlier treatment in the disease course may be beneficial. Larger randomized controlled trials are clearly needed to confirm the utility and safety of IL-6 inhibition in treating KTrs with COVID-19.

Remdesivir is a nucleoside analogue prodrug that has been shown to have inhibitory effects on pathogenic animal and human coronaviruses, including COVID-19 in vitro. On May 1, 2020, the Food and Drug Administration (FDA) issued an emergency use authorization for this anti-viral agent for treatment of severe COVID-19 patients. The preliminary results of a double-blind, randomized, placebo-controlled trial of intravenous remdesivir in adults hospitalized with COVID-19 have recently been published, documenting faster recovery time (11 vs 15 days) and reduced mortality by 14 days in the treatment arm.\cite{16} To date, no similar trials have been conducted in solid organ recipients and its value in treating COVID-19 in this cohort remains to be determined.

**CASES AT RHODE ISLAND HOSPITAL**

The Transplant Program at Rhode Island Hospital (RIH) experienced 16 kidney transplant recipients infected with COVID-19 between March 1 and May 18, 2020. Of these, three had previously failed their allografts with return to renal replacement therapy, although all remained on immunosuppressive therapy at the time of infection. All three were subsequently taken off their immunosuppression following confirmed infection and did well without hospital admission or additional adjunctive therapy. Of the 13 active KTrs infected with COVID-19, 2 patients transplanted more than 10 years previously were managed as outpatients and 11 KTrs required hospitalized. The median age of the cohort was 54 years with the majority being female (62%). Immunosuppressive medications were reduced in 12 of 13 patients by discontinuation of the antimetabolite followed by a reduction in the calcineurin inhibitor dose. Interestingly, tacrolimus or sirolimus levels were noted to be supratherapeutic in 67% of patients on hospital presentation, which was likely due to increased drug absorption from COVID-induced diarrhea or decreased drug metabolism resulting from hepatic dysfunction. Adjunctive therapy consisted of remdesivir (36%), convalescent plasma (46%) and tocilizumab (27%). IL-6 levels were markedly elevated (>1,000) in 3 KTrs. There was a single mortality, involving the only patient treated with hydroxychloroquine. Of note, hydroxychloroquine was not commonly used at RIH as a treatment regimen while extremely elevated levels of IL-6 were common compared to the other studies. All 3 patients who received tocilizumab survived with one patient developing superimposed bacterial infection with graft pyelonephritis and ESBL bacteremia. Convalescent plasma was well tolerated in the four patients treated and subsequent publications have since shown that convalescent plasma could help patient recovery from COVID-19,\cite{17,19} prompting emergency use approval by the FDA as a potential treatment option.

**CLINICAL OUTCOMES**

Current reports suggest that kidney transplant recipients show similar symptoms but worse outcomes when compared to the general population. Indeed, results from the TANGO International Transplant Consortium from the US, Italy and Spain identified 144 hospitalized adult kidney transplant recipients infected with COVID-19 and showed high rates of acute kidney injury (51%) and mortality (32%) among this cohort with non-survivors being older and having higher IL-6 levels.\cite{20} This outcome is similar to previous single-center reports discussed here, which observed death rates between 14% and 30%. Of note, this and previously published studies focusing on solid organ transplant patients lacked comparison with a control group to ascertain their risk as compared to a general population. To address this knowledge gap, Molnar and colleague compared outcomes in solid organ transplant (SOT) recipients versus non-SOT patients with COVID-19 who were admitted to intensive care units throughout the US, using data from a multicenter cohort study.\cite{21} Using a propensity score-matched cohort, the authors showed that death within 28 days of ICU admission was similar in SOT and non-SOT patients (40 and 43% respectively, respectively) and showed that there was no difference between groups in the duration of ICU length of stay, risk of ARDS, secondary infection, thromboembolic events, or receipt/duration of invasive mechanical ventilation. The authors suggested that the higher use of corticosteroids treatment in SOT compared to non-SOT patients may have contributed to this favorable outcome. Furthermore, they hypothesized that immunosuppressive medications may have mitigated pro-inflammatory cytokine activation in SOT patients, which might result in a lower risk of developing cytokine-release syndrome.

**CONCLUSIONS**

As the COVID-19 pandemic continues to progress, we are likely to see an increasing number of kidney transplant recipients who will be exposed to and subsequently develop a COVID-19 infection. However, the current management of COVID-19 disease in kidney transplant recipients remains ill-defined. No randomized controlled trials have
been conducted to assess how immunosuppression should be managed during acute infection nor how they should be resumed after remission. COVID-19 is associated with a higher mortality rate in KTRs than the general population with particularly poor outcomes noted in elderly kidney transplant population. Given the high mortality rate, transplant clinicians should focus on primary prevention with a careful case-by-case assessment of risk versus benefits of continuing immunosuppression in those infected. It seems rational to reduce the immunosuppressive load with first step being the withdrawal of antimetabolite agents followed by a reduction or discontinuation of the calcineurin inhibitor. Several agents have been used for treating KTRs infected with COVID-19 although none have shown proven efficacy. Ultimately, studies with a larger number of patients and longer follow-up are required to better assess the optimal management, outcomes, and treatment of kidney transplant recipients with COVID-19 infection.

References

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INTRODUCTION
More than 200 million people suffer from osteoporosis with 1 in 3 women over the age of 50 years and 1 in 5 men experiencing osteoporotic fractures in their lifetime.1 Osteoporosis is a condition defined by low bone mass, devastation of bone tissue, and disruption of bone construction that may lead to weakened bone strength and an increase in the risk of vertebral compression fractures in the spine (VCF). Excess mortality is associated with VCFs and kyphosis due to its impact on lung function and resultant abdominal dysfunction.2 Conservative treatment includes pharmacological therapy such as narcotics, acetaminophen, nonsteroidal anti-inflammatory drugs, and calcitonin. In addition, more specialized treatments include physical therapy, nerve root blocks and epidural injections.

Despite medical therapy, patients with severe compression fractures often report intolerable side effects or inadequate pain relief with conservative treatment, and these patients may be candidates for surgical intervention. Kyphoplasty is a common minimally invasive technique performed by pain physicians and spine surgeons to manage symptomatic vertebral compression fractures. The interventional technique involves a balloon catheter that expands the vertebra and injects bone cement into the structure of the collapsed bone. Despite a low complication rate, these minimally invasive procedures come with their share of risks. We present a patient with a history of acute back pain who underwent kyphoplasty treatment complicated by postoperative chest pain, difficulty breathing and acute drop in blood pressure due to hemothorax.

CASE PRESENTATION
A 94-year-old Caucasian female presented to the emergency department with progressively worsening back pain after a mechanical trip and fall several weeks earlier. The patient had attempted medical therapy prior to presentation but now reported her pain as severe, localized to the upper back between her shoulder blades, with radiation to her chest, and exacerbated by movement. She had with tenderness to palpation. A CT scan was negative for aortic dissection but revealed a T11 vertebral compression fracture. After consulting with the spine team, the patient was referred for kyphoplasty of the T11 vertebra. The intraoperative course was without complication. Immediately after the procedure, the patient was transferred to the post anesthesia care unit where the patient started to require blood pressure support and complained of shortness of breath and right-sided chest pain. She was tachycardic and required 14 L/min of supplemental oxygen via nonrebreather. Physical exam revealed tracheal deviation, absent breath sounds in the right chest and dullness to percussion over the anterior and posterior right chest. A chest x-ray was ordered and the post anesthesia care unit (PACU) team then used a point of care ultrasound (POCUS) machine at the bedside, which revealed a large anechoic collection between the chest wall and the lung (Figure 1). A CT image confirmed the diagnosis of a hemothorax (Figure 3). The hemothorax was rapidly decompressed by inserting a 36F chest tube. Seven hundred milliliters drained, providing the patient with immediate relief. The patient was discharged post-op day 4 with no further interventions.

DISCUSSION
Percutaneous vertebral augmenting procedures are relatively safe and effective procedures with success rates as high as 95%, yet still come with risk.3 The most concerning risk is the potential for cement extravasation causing paralysis, neuropathy, or fatal emboli from cement entering unintentional structures. In addition, the procedural complications have included air embolism, vertebral body split fracture, pneumothorax and rib fractures. The incidence of hemothorax is <1% during vertebral augmenting procedures while the success rate of a kyphoplasty provides generous benefits compared to risks.4 Vertebral augmenting procedures are increasingly performed in an off-site ambulatory and office setting where clinical vigilance of the patient’s clinical picture and awareness of potential complications is imperative.4 The potential implications of a hemothorax in the elderly can be fatal with the potential sequelae of an empyema, fibrothorax resulting from fibrin deposition, and eventual lung entrapment from an inflammatory coating within the pleural space.5

The use of ultrasonography is a fast and highly sensitive tool for detecting hemothorax and can confirm the physical findings in emergency situations. Practitioners should monitor patients carefully for postoperative complications and consider other anesthetic methods to maintain patient awareness during kyphoplasty to better identify and manage risks associated with a vital pain-relieving procedure.
References


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Corynebacterium Striatum Bacteremia in End-Stage Renal Disease: A Case Series and Review of Literature

CATHERINE M. GARCIA, MD’21; JACLYN MCKENNA, MD; LENA FAN, MD; ANKUR SHAH, MD

ABSTRACT
Corynebacterium striatum is emerging as an opportunistic pathogen in immunocompromised hosts. End-stage renal disease remains an underappreciated state of immunocompromise. We present a series of individuals with end-stage kidney disease on hemodialysis who developed Corynebacterium striatum bacteremia, which was initially thought to be a contaminant, but eventually recognized as the culprit pathogen. We review the bacteriology of C. striatum, increasing resistance, as well as known cases of C. striatum bacteremia in the setting of end-stage renal disease. These cases highlight the importance of a high index of suspicion when interpreting bacterial cultures in patients with end-stage renal disease.

KEYWORDS: end-stage renal disease, hemodialysis, immunocompromised, Corynebacterium

INTRODUCTION
Corynebacterium striatum [C. striatum], first described by von Besser in 1889, is a common nondiphtherial Corynebacterium.1 It is a non-sporeulating, non-acid fast, gram-positive rod that is facultatively anaerobic and colonizes the skin and upper respiratory tract.2 Nondiphtherial Corynebacterium are usually dismissed as common contaminants when isolated from clinical sample.3 In immunocompromised individuals, C. striatum is emerging as a cause of life-threatening infections, such as bacteremia with unknown focus and infective endocarditis.4

Individuals with end-stage renal disease (ESRD) requiring long-term dialysis have an increased risk of infection, averaging about 5.7 events per 1000 dialysis days.5 The etiology of immunologic dysfunction in patients with ESRD is multifactorial, involving alterations in both the innate and adaptive immune systems.6 For example, ESRD impairs secreted pattern recognition receptors, toll-like receptors and cytokine production.7 ESRD and its complications also causes the malfunction of antigen presenting cells (APCs) and T lymphocytes.8,9 Therefore, ESRD should be considered a state of immunologic dysfunction and here we report two cases in which C. striatum presents an opportunistic infection in patients with ESRD.

CASE 1
A 59-year-old man with ESRD secondary to autosomal dominant polycystic kidney disease on hemodialysis for approximately 10 years via femoral arteriovenous fistula (due to a history of multiple failed fistulas due to recurrent fistula thrombosis), presented to the emergency department with abdominal pain, fever, and chills for one day. The patient reported a sudden onset of sharp, burning epigastric pain associated with nausea and vomiting. Past medical history was significant for heart failure with reduced ejection fraction, atrial fibrillation [not on anticoagulation] and cirrhosis. On admission, vital signs were notable for a temperature of 97.8 F, heart rate of 92 beats per minute, and a blood pressure of 93/57 mmHg. Labs were significant for a sodium of 127 mEq/L, potassium of 5.4 mEq/L, venous lactate of 3.1 mEq/L and white blood cell count of 7.6^9 cells/L with 6% bands. Abdominal exam was notable for diffuse tenderness, distention, and hyperactive bowel sounds. Cardiopulmonary exam did not reveal any abnormalities. Skin exam revealed a decubitus ulcer on his left foot that had been present for over a month. Two sets of blood cultures were obtained and the patient was started empirically on IV vancomycin and piperacillin/tazobactam. Computerized tomography of the abdomen and pelvis with intravenous (IV) contrast revealed cirrhosis, splenomegaly and bilateral changes of polycystic kidney disease, without evidence of an acute inflammatory process to explain the abdominal pain. His abdominal pain spontaneously resolved while in the emergency department. The following day, C. striatum was isolated from both sets of blood cultures. Initially thought to be a contaminant, repeat blood cultures were obtained and C. striatum bacteremia was confirmed. Culture of the decubitus ulcer on his left foot grew C. striatum, Methicillin-Sensitive Staphylococcus aureus, and gram-negative rods. Magnetic resonance imaging (MRI) of the left foot confirmed a small focus of osteomyelitis on the medial aspect of the metatarsal head. He was treated with 6 weeks of IV vancomycin with dialysis with a goal trough of 15-20 mg/mL. Three months after completion of antibiotic use, a repeat MRI was negative for osteomyelitis.
**CASE 2**

A 66-year-old man with ESRD secondary to diabetic nephropathy on hemodialysis via tunneled dialysis catheter, presented to the emergency department with discoloration of all the digits on his left foot, fever (measured at 103.2 °F at home) and chills. The patient had a recent history of a large blister on his left foot that had been recently deroofed. His past medical history was significant for peripheral arterial disease, heart failure with reduced ejection fraction and a sacral decubitus ulcer with chronic osteomyelitis of the coccyx. He had recently completed a 10-day course of levofloxacin for a diabetic wound infection. Vitals were significant for blood pressure 128/72 mmHg, pulse 92 and irregular, temperature 97.7 degrees Fahrenheit, respiratory rate 19, and oxygen saturation 100 percent on room air. Physical examination was notable for purple/black discoloration of multiple toes on the left foot with large areas of lanced blisters on the lateral aspect of the left foot. Cardiopulmonary exam was unremarkable. The exit site of the tunneled catheter was without evidence of infection. X-ray of the left foot was notable for diffuse demineralization with second digit proximal interphalangeal (PIP) joint erosive changes and computerized tomography demonstrated atherosclerotic disease as well as edema around decubitus ulcer. He was empirically started on daptomycin and levofloxacin for diabetic wound infection, based on prior culture data and allergies. On hospital day 3, he was broadened to daptomycin and meropenem for anaerobic coverage. Blood cultures drawn on admission were positive for gram-positive rods which speciated *C. striatum*. This was initially felt to be a contaminant so repeat cultures were drawn and 6 of 9 blood cultures cleared. Sensitivities for the strain he was infected with revealed a daptomycin resistant. He was switched to linezolid and survived. Resistance to fluoroquinolones has also been noted when there is a combination of two mutations in the 

**DISCUSSION**

*C. striatum* is an opportunistic colonizer with low virulence but it is emerging as a nosocomial source of infection. Since it was first reported as the cause of bacteremia and empyema in 1980, *C. striatum* has been recognized as the causative agent of various illnesses. Patients infected with *C. striatum* often have significant underlying disease, and recovery of this organism from culture is often assumed to be a contaminant or incidental finding unless repeated cultures produce the same bacterial species. *C. striatum* is generally isolated from a variety of specimens, such as tissue, wounds, devices and blood cultures. It is commonly co-isolated with *S. aureus*, coagulase-negative staphylococci and *Pseudomonas aeruginosa*. Using matrix-assisted laser desorption/ionization time-of-flight mass spectrometry (MALDI-TOF MS), Kang et al., analyzed 303 gram-positive bacilli isolated from blood cultures of patients and of these 65 (21.7%) were identified as *C. striatum*. They also observed that patients with multiple blood cultures had significantly higher level of biofilm production; suggesting that biofilm phenotype could contribute to the determination of clinical significance of *C. striatum* in patients. *C. striatum* is typically pathogenic in immunocompromised patients, including those with ESRD. A literature search identified six other cases of *C. striatum* infection in patients with ESRD (Table 1). Patient's ranged from 46 to 83 years (average age of 67 years old). Their manifestations included sepsis, endocarditis, mediastinitis and septic arthritis. Hypertension, diabetes mellitus type II and heart failure with reduced ejection fraction were the most common comorbidities similar to our patients, with two patients falling under each category. *C. striatum* was originally considered a contaminant in many of these cases and was only subsequently considered to be the likely culprit. Four patients were started on antibiotic regimens that included vancomycin; two patients survived under these regimens. Two of the eight patients were on an antibiotic regimen that included daptomycin; only one of the patients survived. The second patient that was presented began treatment on daptomycin and levofloxacin but sensitivities for the strain he was infected with revealed a daptomycin resistance. He was switched to linezolid and survived. *C. striatum* is an emerging, multidrug-resistant pathogen among immunocompromised and chronically ill patients. In hospitalized settings, this organism has the potential to acquire vectors containing genes that make it resistant to multiple antimicrobials. *C. striatum* has shown resistance to penicillin, cephalosporins, ciprofloxacin, meropenem, tetracycline, and clindamycin. Aminoglycosides are usually used as second-line treatment of corynebacterium infections and some strains are now highly resistant to them. Daptomycin is usually a last line of defense in the treatment of infections from gram-positive organisms and there is a rapid development of high level of daptomycin resistance. Resistance to fluoroquinolones has also been noted when there is a combination of two mutations in the *gyrA* gene leading to increased MICs of ciprofloxacin and levofloxacin. Transposable elements are associated with macrolide, lincosamide, and aminoglycoside resistances. Vancomycin, linezolid and telavancin have shown good activity against *C. striatum* in vitro.
CASE REPORT

83-year-old female presented to the emergency department after cardiac arrest secondary to aspiration pneumonia. She was found to have acute kidney injury and started on hemodialysis. On hospital day 26, she developed \textit{C. striatum} bacteremia with dialysis catheter felt to be the source.

- CKD
- Hypertensive cardiovascular disease

Treatment: Amoxicillin/Clavulanic acid + Vancomycin

Survival: Expired

Reference: 11

77-year-old male presented with 1 week of worsening right shoulder pain not relieved by opioids. An arthrocentesis was performed and aspirate contained 32,700 nucleated cells/mm³ with no crystals. Cultures grew \textit{C. striatum}. A surgical washout of the glenohumeral joint was performed.

- Bilateral lung transplant for severe COPD on immunosuppressive treatment
- Hemodialysis dependent ESRD
- Hypertension
- Drug-induced Pancytopenia

Empirically on vancomycin and Ceftriaxone. Then narrowed to vancomycin.

Survival: Survived

Reference: 12

46-year-old female presented with fever, chills and chest pain. A month prior, she underwent removal of an infected left femoral graft used to repair a pseudoaneurysm of the left femoral artery. She was found to have \textit{C. striatum} bacteremia with tricuspid valve endocarditis.

- Hemodialysis dependent ESRD

Daptomycin and rifampin

Survived

Reference: 13

80-year-old male presented 15 days after aortic arch replacement with fevers and leukocytosis. There was erythema, tenderness and serous exudate from the wound of the mid-chest. Blood and wound exudate cultures grew out \textit{C. striatum}. He was diagnosed with \textit{Corynebacterium}-associated mediastinitis.

- ESRD

Debridement. Glycopeptide antibiotic

Survived

Reference: 14

56-year-old male presented with 1 week of fever, lethargy, and dyspnea. He previously received two 6-week courses of daptomycin for catheter-related MRSA bacteremia and osteomyelitis. He was found to have native mitral valve endocarditis with cultures positive for \textit{C. striatum}.

- DM II
- ESRD

Mitral valve replacement, daptomycin and IV telavancin

Expired

Reference: 15

69-year-old female presented with acute thrombosis of dialysis fistula in her left arm. She was found to have fevers and a grade I systolic murmur over the cardiac apex. Two sets of blood cultures grew out \textit{C. striatum} and echocardiogram revealed a large vegetation on her mitral valve.

- ANCA-associated vasculitis
- ESRD

Vancomycin

Rifampin

Expired

Reference: 16

59-year-old male presented with a one day history of diffuse abdominal pain, fevers, and chills. Found to have chronic left foot ulcer. MRI depicted a small focus of osteomyelitis on the medial aspect of the metatarsal head of the left foot. Blood and wound cultures grew \textit{C. striatum}.

- ESRD
- Autosomal dominant polycystic kidney disease
- HF with reduced ejection fraction
- Atrial fibrillation
- Cirrhosis

Vancomycin

Survived

Reference: 17

66-year-old male presented with fever, chills, and discoloration of left foot digits. He was found to have \textit{C. striatum} bacteremia. Transmetatarsal amputation was performed revealing acute osteomyelitis with no organism isolated. Bacteremia cleared after removal of tunneled dialysis catheter.

- ESRD
- Peripheral artery disease
- DM II
- HF with reduced EF
- Chronic osteomyelitis of the coccyx

Started on empiric daptomycin and Levofloxacin. Sensitivities for the \textit{C. striatum} revealed Daptomycin resistance and he was transitioned to Linezolid

Survived

Reference: 18

### Table 1. Summary of \textit{Corynebacterium striatum} Cases Associated with ESRD Found in Literature

<table>
<thead>
<tr>
<th>Case Description</th>
<th>Comorbidities</th>
<th>Treatment</th>
<th>Survival</th>
<th>Reference</th>
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<tbody>
<tr>
<td>83-year-old female presented to the emergency department after cardiac arrest secondary to aspiration pneumonia. She was found to have acute kidney injury and started on hemodialysis. On hospital day 26, she developed \textit{C. striatum} bacteremia with dialysis catheter felt to be the source.</td>
<td>• CKD • Hypertensive cardiovascular disease</td>
<td>Amoxicillin/Clavulanic acid + Vancomycin</td>
<td>Expired</td>
<td>11</td>
</tr>
<tr>
<td>77-year-old male presented with 1 week of worsening right shoulder pain not relieved by opioids. An arthrocentesis was performed and aspirate contained 32,700 nucleated cells/mm³ with no crystals. Cultures grew \textit{C. striatum}. A surgical washout of the glenohumeral joint was performed.</td>
<td>• Bilateral lung transplant for severe COPD on immunosuppressive treatment • Hemodialysis dependent ESRD • Hypertension • Drug-induced Pancytopenia</td>
<td>Empirically on vancomycin and Ceftriaxone. Then narrowed to vancomycin.</td>
<td>Survived</td>
<td>12</td>
</tr>
<tr>
<td>46-year-old female presented with fever, chills and chest pain. A month prior, she underwent removal of an infected left femoral graft used to repair a pseudoaneurysm of the left femoral artery. She was found to have \textit{C. striatum} bacteremia with tricuspid valve endocarditis.</td>
<td>• Hemodialysis dependent ESRD</td>
<td>Daptomycin and rifampin</td>
<td>Survived</td>
<td>13</td>
</tr>
<tr>
<td>80-year-old male presented 15 days after aortic arch replacement with fevers and leukocytosis. There was erythema, tenderness and serous exudate from the wound of the mid-chest. Blood and wound exudate cultures grew out \textit{C. striatum}. He was diagnosed with \textit{Corynebacterium}-associated mediastinitis</td>
<td>• ESRD</td>
<td>Debridement. Glycopeptide antibiotic</td>
<td>Survived</td>
<td>14</td>
</tr>
<tr>
<td>56-year-old male presented with 1 week of fever, lethargy, and dyspnea. He previously received two 6-week courses of daptomycin for catheter-related MRSA bacteremia and osteomyelitis. He was found to have native mitral valve endocarditis with cultures positive for \textit{C. striatum}.</td>
<td>• DM II • ESRD</td>
<td>Mitral valve replacement, daptomycin and IV telavancin</td>
<td>Expired</td>
<td>15</td>
</tr>
<tr>
<td>69-year-old female presented with acute thrombosis of dialysis fistula in her left arm. She was found to have fevers and a grade I systolic murmur over the cardiac apex. Two sets of blood cultures grew out \textit{C. striatum} and echocardiogram revealed a large vegetation on her mitral valve.</td>
<td>• ANCA-associated vasculitis • ESRD</td>
<td>Vancomycin</td>
<td>Expired</td>
<td>16</td>
</tr>
<tr>
<td>59-year-old male presented with a one day history of diffuse abdominal pain, fevers, and chills. Found to have chronic left foot ulcer. MRI depicted a small focus of osteomyelitis on the medial aspect of the metatarsal head of the left foot. Blood and wound cultures grew \textit{C. striatum}.</td>
<td>• ESRD • Autosomal dominant polycystic kidney disease • HF with reduced ejection fraction • Atrial fibrillation • Cirrhosis</td>
<td>Vancomycin</td>
<td>Survived</td>
<td></td>
</tr>
<tr>
<td>66-year-old male presented with fever, chills, and discoloration of left foot digits. He was found to have \textit{C. striatum} bacteremia. Transmetatarsal amputation was performed revealing acute osteomyelitis with no organism isolated. Bacteremia cleared after removal of tunneled dialysis catheter.</td>
<td>• ESRD • Peripheral artery disease • DM II • HF with reduced EF • Chronic osteomyelitis of the coccyx</td>
<td>Started on empiric daptomycin and Levofloxacin. Sensitivities for the \textit{C. striatum} revealed Daptomycin resistance and he was transitioned to Linezolid</td>
<td>Survived</td>
<td></td>
</tr>
</tbody>
</table>

**Legend:** chronic kidney disease, CKD; chronic obstructive pulmonary disease, COPD; end-stage renal disease, ESRD; diabetes mellitus type II, DM II; heart failure, HF; ejection fraction, EF
CONCLUSION

Although nondiphtherial Corynebacteria are often dismissed as contaminants due to their low virulence, *C. striatum* is emerging as a multidrug-resistant, opportunistic pathogen. As the organism can be transmitted from person-to-person, once it has been identified as the etiology, universal hygiene measures should be observed to contain the spread of this organism. Failure to follow these measures can pose a threat to vulnerable individuals.

References

17. Roy M, Ahmad S. Rare case of Corynebacterium striatum septic arthritis. *BMJ Case Rep.* 2016;bcr2016216914.

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Conflict of Interest

All authors declare no conflict of interest

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Ectopic Pregnancy after Hysterectomy: A Case Report of Ectopic Pregnancy 7 Years after Postpartum Hysterectomy

NWAMAKA MARY-ANNE ONWUGBENU, MD

ABSTRACT

BACKGROUND: Ectopic pregnancy after hysterectomy is a rare event. There are 81 cases documented in the English medical literature since 1895.

CASE REPORT: 32y/o G2P1011, with baseline history of chronic pelvic pain after abdominal hysterectomy and unilateral salpingectomy, presented with acute pain. Patient was diagnosed with ectopic pregnancy and underwent an urgent laparoscopy.

CONCLUSION: Ectopic pregnancy should be part of the differential diagnosis for women of reproductive age, including women post hysterectomy, who present with abdominal or pelvic pain or vaginal bleeding. Untimely diagnosis increases the risk for morbidity and mortality.

KEYWORDS: ectopic pregnancy, tubal pregnancy, hysterectomy, vaginal-peritoneal fistula

INTRODUCTION

The differential diagnosis for abdominal or pelvic pain in a reproductive age woman after a hysterectomy would routinely include, but is not limited to, adhesive disease, bowel obstruction, appendicitis, diverticulitis, ovarian mass/torsion, hemorrhagic cyst, and cystitis. Ectopic pregnancy tends to be omitted. The presenting symptoms are nonspecific and may make early diagnosis a challenge. Most patients present initially with abdominal or pelvic pain with associated nausea and vomiting; on some occasions, patients have presented with dyspareunia, malaise, vaginal bleeding, mastalgia and loose stools. Any woman of reproductive age with an ovary or bilateral ovaries should be considered at risk for ectopic pregnancy. A delay in diagnosis increases the patient’s risk for morbidity and mortality.

CASE PRESENTATION

We report a 32-year-old G2P1011 woman with a history of an abdominal hysterectomy, partial trachelectomy and right salpingectomy for postpartum hemorrhage after a vaginal delivery for a fetal demise, who presented to the emergency department with acute on chronic abdominal pain. The patient was seen initially at a routine annual gynecological exam in which she complained of increased right-sided lower abdominal pain. She stated her pain resolved with rest and over the counter analgesia. At this visit, her vital signs and physical exam were unremarkable. Sixteen days after her routine visit, she presented to the emergency room via EMS with acute right lower quadrant pain after intercourse. Pain was associated with nausea and vomiting. Her vital signs were stable and physical exam was significant for cervical motion and bilateral adnexal tenderness.

Labs studies were as follows: WBC 9.8x10^9/L, Neutrophils 83%, Hgb 12.1g/dl, Hct 35.2%, Platelet 219x10^9/L, Urinalysis negative, GC/CT negative, Urine pregnancy test positive, and Bhcg 21,000miU/mL. Ultrasound revealed a left adnexal ectopic pregnancy with crown rump length measuring 1.53 cm, consistent with 7w6d pregnancy and fetal heart rate of 165bpm. In addition, there was moderate amount of complex fluid in the cul de sac.

She was taken to the operating room and underwent a diagnostic laparoscopy, left salpingectomy, removal of ectopic pregnancy and evacuation of hemoperitoneum. Intraoperative findings included: omental adhesions to left anterior abdominal wall, the left fallopian tube and ovary moderately adhered to the anterior abdominal and left pelvic side wall, a distended left fallopian tube with ectopic pregnancy extruding from the fimbriated end and 100cc of dark blood in the cul de sac. Bilateral ovaries were normal in appearance. The procedure was uncomplicated, and patient was discharged the same day. Her post-operative course was unremarkable. Final pathology was consistent with tubal ectopic pregnancy.

DISCUSSION

In 1895 Wendeler published the first case of an ectopic pregnancy after a hysterectomy. Since the initial report there have been at least 81 published cases in the English medical literature (Table 1). Ectopic pregnancy after hysterectomy is categorized as early or late presentation. The designation is based on when the diagnosis of the ectopic pregnancy is made in relation to the timing of the hysterectomy. Early presentation ectopic pregnancy occurs when a woman conceives immediately prior to the hysterectomy. Patients usually present with ectopic pregnancy approximately 29 to 96 days post operative. The diagnosis is confounded by the point of care urine
pregnancy test taken prior to the hysterectomy, as it may be negative due to the low levels of the hCG hormone. A positive urine pregnancy test occurs when the fertilized ovum has implanted, which typically occurs 6–12 days after ovulation. With a negative hCG, the hysterectomy is performed, the fertilized ovum is entrapped in the fallopian tube or implanting in the ovary or abdomen; in following weeks to months, the ectopic pregnancy is then diagnosed.

Late presentation is diagnosed months to years after hysterectomy (range 7 months to 12 years). This is the result of a fistulous tract in the vagina allowing communication of sperm and ovum. Fistulas may form due to inadvertent defects in vaginal vault closure, infection or formation of granulation tissue post-operative. Other causes include incorporation of fallopian tube-ovarian complex in the closure of the vaginal cuff, fallopian tube prolapse through the vaginal cuff, or a cervical stump that has not peritonealized. The most common surgical modality of hysterectomy associated with late presentation is vaginal hysterectomy, followed by supracervical hysterectomy (combining scheduled cases and emergent postpartum hysterectomy). Late presentation ectopic pregnancy is less likely to occur with other hysterectomy modalities because the vaginal cuff and the cervical stump closure incorporates the parietal peritoneum allowing repertionalization, this ultimately keeps the vagina and the peritoneal cavity isolated.

Risk-reducing practices should be implemented to decrease the incidence of ectopic pregnancy after hysterectomy. Measures includes attention to proper surgical technique to decrease risk of vaginal cuff infection, hematoma, abscess, and dehiscence and closure of the proximal cervical stump to avoid communication between the vaginal and the peritoneal cavity. Performing bilateral salpingectomy at the time of hysterectomy will not protect against ovarian or abdominal ectopic pregnancy. Consideration should be made to perform total hysterectomy instead of supracervical, if clinically feasible or safe. However, if supracervical hysterectomy has to be performed, it should be standard of care for peritonealization of the cervical stump. Prior to surgery, surgeons should recommend that patient abstain or use reliable form of contraception. Ideally, if a patient is not using contraception, surgeons should try to avoid operating during the postovulatory luteal phase of the menstrual cycle.

Once a post hysterectomy ectopic pregnancy is diagnosed, it is preferably treated surgically. Pharmacologic therapy with methotrexate can resolve the current pregnancy but does not allow implementation of corrective measures to prevent future ectopic pregnancies. There is one known case of a recurrent post hysterectomy ectopic pregnancy reported by McMillan and Dunn in 1921. The case involved an 18-year-old who had an abdominal pregnancy after a subtotal hysterectomy 17 months prior. She underwent a laparotomy and removal of the fetus, then 18 months later patient had another abdominal pregnancy but died from hemorrhage. For this reason, it is strongly recommended to manage post hysterectomy ectopic pregnancies with laparoscopy or laparotomy with removal of ectopic pregnancy and bilateral salpingectomy. After bilateral salpingectomy, there is still a residual risk, albeit a small risk, for recurrent ectopic pregnancy in the ovary or intraabdominal space. After the patient recovers from the removal of the ectopic pregnancy, it may be judicious to have the patient return for a fistulogram to assess and repair the vaginal vault defect.

Any woman of reproductive age with or sans uterus should have ectopic pregnancy on their differential diagnosis. The consequence of a missed diagnosis can be catastrophic; therefore, a female presenting with abdominal pain or pelvic mass should have at least a point of care urine pregnancy test performed.

### References


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Disclaimer
The views expressed herein are solely those of the author and does not necessarily reflect the views of colleagues at Lifespan Physician Group, Rhode Island Hospital and Women & Infants Hospital.

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Concurrent Utilization of Prescription Opioids and Non-opioid Controlled Substances: Rhode Island Prescription Drug Monitoring Program, 2018

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ABSTRACT

OBJECTIVE: To estimate the prevalence of concurrent prescription opioid and non-opioid controlled substance use in Rhode Island (RI).

METHODS: We conducted a cross sectional observational study using data from the RI Prescription Drug Monitoring Program on controlled substance prescriptions dispensed in 2018. We estimated the prevalence of concurrent use of other prescribed controlled substances among adults who received at least one opioid prescription.

RESULTS: In 2018, 142,692 RI adult residents received at least one opioid prescription, of whom 25.1% (99% confidence interval [CI]: 24.8-25.4) were concurrently prescribed at least one other controlled substance, including benzodiazepines (17.0%, 99% CI: 16.8–17.3), medications for insomnia (4.0%, 99% CI: 3.9–4.2), and stimulants (3.8%, 99% CI: 3.6–3.9).

CONCLUSION: The concurrent use of prescription opioids and other prescribed controlled substances is common. Our findings suggest an urgent need to implement focused initiatives to address controlled substance polypharmacy to reduce the risk of overdose.

KEYWORDS: opioids, benzodiazepines, stimulants, controlled substances, Z-drugs

INTRODUCTION

In response to a citizen’s petition submitted by Drs. Leana Wen, Commissioner of Health for the Baltimore City Department of Health, and Nicole Alexander-Scott, Director of the Rhode Island Department of Health, the US Food and Drug Administration (FDA) in 2016 added a black box warning to all opioid and benzodiazepine labels on the risk of respiratory depression and fatal overdose when these agents are used concurrently. The FDA also noted that adverse outcomes are associated with the concurrent use of non-benzodiazepine sedative hypnotics. Despite this warning, from July 2017 through June 2018, approximately one third of all fatal opioid-involved overdoses in the US involved benzodiazepines and, when limited to prescription opioid-involved overdoses specifically, roughly half (49%) involved benzodiazepine use. RI has been significantly impacted by the overdose epidemic. Between 2009 and 2018, 1,197 fatal overdoses involving prescription opioids occurred in RI. As controlled substance polypharmacy increases the risk of fatal and non-fatal opioid overdoses, the objective of our study was to estimate the prevalence of concurrent utilization of prescription opioids and non-opioid controlled substances in RI.

METHODS

We conducted a cross sectional study analyzing data from the RI Prescription Drug Monitoring Program (PDMP) from 2018. The RI PDMP includes controlled substances dispensed by all community pharmacies with a controlled substance registration in RI and includes information on controlled substances dispensed to RI-residents by pharmacies in neighboring states. More details about the RI PDMP are available at the RI Department of Health website. For this analysis we excluded patients who received lozenges and troche forms of fentanyl, and certain suppository and liquid opioid formulations of hydromorphone, meperidine, methadone, morphine, opium, and oxycodone, which are generally prescribed during end-of-life care when the risks and benefits of medication use may be weighed differently than use for acute or chronic pain relief. We also excluded prescriptions that are not known to significantly increase the risk of overdose when co-prescribed with opioids, including: antidiarrheals, anabolic steroids, human growth hormone, and testosterone. We also excluded gel forms of benzodiazepines used to treat seizures. Buprenorphine-containing products were also excluded as this medication is more often prescribed for opioid use disorder than for pain, and we could not determine the indication for use from the available data. In addition, we excluded patients who were not RI residents because the RI PDMP would not have information about all other controlled medications that have been dispensed by pharmacies outside of RI to non-RI residents.

We identified all patients who received at least one opioid prescription during 2018, and then determined if the patient concurrently received benzodiazepines, non-benzodiazepine sedatives (the “Z-drugs” zolpidem, eszopiclone, and zaleplon), stimulants, or a non-opioid controlled substance of any type (other than the types of medications excluded).
We sought to identify all patients with recent access to both opioid and non-opioid controlled medications, irrespective of the number of days of overlap. Therefore, consistent with other work, concurrent utilization was defined as at least one day of medication overlap according to the prescription fill dates and days’ supply of medication, for any quantity dispensed. We calculated 99% confidence intervals (CIs) for prevalence estimates and used a significance threshold of p < 0.01 for Chi-square tests of subgroup comparisons. Multivariable logistic regression was performed to estimate the odds of concurrent use of prescription opioid and non-opioid controlled substances, adjusted for patient sex, age group, payment method, and county of residence. Because it appeared that Medicare Advantage plans were often misclassified as “commercial insurance” in the RI PDMP dataset, a payment type of “commercial insurance” was reclassified as “Medicare” if the patient was age 65 or older. In addition, we dichotomized Medicare payment type by age to determine rates of concurrent use among Medicare beneficiaries under 65 years of age who qualify based on having a long-term disability or end stage renal disease (ESRD). Payment method and county were assigned according to the most recently dispensed opioid prescription. Analyses were performed using SAS version 9.4. The study was approved by the Institutional Review Boards at the RI Department of Health and the University of Rhode Island.

RESULTS

In 2018, there were 142,692 adult RI residents who received at least one opioid prescription dispensed by a RI licensed pharmacy [Table 1]. Women comprised 59% of these residents, and the most frequent payment type was commercial insurance (43.0%), followed by Medicare (27.8%), Medicaid (13.6%) and cash (12.3%). Approximately 30% of subjects were age 65 or older and more than half of patients (56.8%) lived in Providence County.

Table 1. Concurrent Use of Prescription Opioid and Non-Opioid Controlled Substances, Overall and by Patient Characteristics

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Patients with at Least 1 Opioid Dispensing n (%)</th>
<th>Patients with Overlapping Dispensings for Opioid and Non-Opioid Controlled Substance n (%), [99% CI]</th>
<th>Adjusted Odds of Concurrent Use of Prescription Opioid and Non-Opioid Controlled Substances*^</th>
<th>aOR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18–34</td>
<td>20,239</td>
<td>2,743 (13.6%), [12.9%–14.2%]</td>
<td>0.47 (0.45–0.50)</td>
<td></td>
</tr>
<tr>
<td>35–49</td>
<td>28,960</td>
<td>7,356 (25.4%), [24.7%–26.1%]</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>50–64</td>
<td>49,385</td>
<td>14,384 (29.1%), [28.6%–29.7%]</td>
<td>1.20 (1.16–1.24)</td>
<td></td>
</tr>
<tr>
<td>65–74</td>
<td>25,385</td>
<td>7,011 (27.6%), [26.9%–28.3%]</td>
<td>1.12 (1.05–1.20)</td>
<td></td>
</tr>
<tr>
<td>75+</td>
<td>18,723</td>
<td>4,250 (22.7%), [21.9%–23.5%]</td>
<td>0.82 (0.77–0.88)</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>59,174</td>
<td>12,405 (21.0%), [20.5%–21.4%]</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>83,478</td>
<td>23,319 (27.9%), [27.5%–28.3%]</td>
<td>1.54 (1.50–1.58)</td>
<td></td>
</tr>
<tr>
<td>Payment Method</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Commercial Insurance</td>
<td>61,361</td>
<td>13,683 (22.3%), [21.9%–22.7%]</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>Medicaid</td>
<td>19,352</td>
<td>5,135 (26.5%), [25.7%–27.4%]</td>
<td>1.31 (1.26–1.36)</td>
<td></td>
</tr>
<tr>
<td>Medicare&lt;65</td>
<td>9,072</td>
<td>3,747 (41.3%), [40.0%–42.6%]</td>
<td>2.13 (2.04–2.24)</td>
<td></td>
</tr>
<tr>
<td>Medicaid≥65</td>
<td>30,561</td>
<td>8,181 (26.8%), [26.1%–27.4%]</td>
<td>1.25 (1.16–1.33)</td>
<td></td>
</tr>
<tr>
<td>Cash</td>
<td>17,503</td>
<td>3,775 (21.6%), [20.8%–22.4%]</td>
<td>0.98 (0.92–1.03)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>4,843</td>
<td>1,223 (25.3%), [23.6%–26.9%]</td>
<td>1.30 (1.21–1.41)</td>
<td></td>
</tr>
<tr>
<td>County of Residence</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Providence</td>
<td>81,066</td>
<td>19,610 (24.2%), [23.8%–24.6%]</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>Kent</td>
<td>27,499</td>
<td>7,488 (27.3%), [26.6%–28.0%]</td>
<td>1.17 (1.13–1.21)</td>
<td></td>
</tr>
<tr>
<td>Washington</td>
<td>18,239</td>
<td>4,565 (25.0%), [24.2%–25.9%]</td>
<td>1.06 (1.02–1.10)</td>
<td></td>
</tr>
<tr>
<td>Bristol</td>
<td>5,857</td>
<td>1,505 (25.7%), [24.2%–27.2%]</td>
<td>1.10 (1.03–1.17)</td>
<td></td>
</tr>
<tr>
<td>Newport</td>
<td>10,071</td>
<td>2,576 (25.6%), [24.5%–26.7%]</td>
<td>1.05 (1.00–1.11)</td>
<td></td>
</tr>
</tbody>
</table>

One in four patients who received an opioid prescription also received an overlapping prescription for a non-opioid controlled substance (38,150/142,692, 25.1%; 99% CI: 24.8–25.4). Women had a higher prevalence of concurrent use than men: 27.9% [99% CI: 27.5–28.3] versus 21.0% [99% CI: 20.5–21.4], respectively. Patients aged 50 to 64 years of age had the highest prevalence of concurrent utilization of opioids and other controlled substances when compared to other age groups (29.1%, 99% CI: 28.6–29.7). Concurrent use was particularly high among patients younger than 65 years who paid with Medicare insurance at 41.3% [99% CI: 40.4–42.6, n = 3,747]. The non-opioid class with the highest prevalence of concurrent utilization was benzodiazepines, with 17.0% [99% CI: 16.8–17.3] having at least one day overlap with a benzodiazepine and opioid prescription [Table 2]. The
prevalence of concurrent use of opioids and non-opioid controlled substances was lower for Z-drugs for insomnia (4.0%, 99% CI: 3.6–3.9). The multivariable logistic regression analysis identified several factors associated with increased odds of concurrent use of opioid and non-opioid prescribed controlled substances. Patients who paid for their prescription with Medicaid insurance had 31% higher odds of concurrent use, as compared with patients using commercial insurance (adjusted OR [aOR]: 1.31, 95% CI: 1.26–1.36), adjusting for sex, age group, and county of residence. People under 65 years of age who paid with Medicare insurance had more than twice the odds of those using commercial insurance to concurrently utilize prescription opioids and non-opioid controlled substances (aOR: 2.13, 95% CI: 2.04–2.24). Women had 54% higher odds of concurrent use of opioids and other prescribed controlled substances as compared to men (aOR: 1.54, 95% CI: 1.50–1.58).

**DISCUSSION**

One in four adult RI residents (25%) who received a prescription for an opioid medication in 2018 also concurrently received at least one pharmacy-dispensed non-opioid controlled substance, most frequently a benzodiazepine (17%). Even though a smaller percentage of patients concurrently received a sedative-hypnotic “Z-drug” or a stimulant medication (roughly 4% for each category), this represents a substantial number of RI residents utilizing each of these combinations (5,731 and 5,356 patients, respectively). The concurrent utilization observed in our study occurred even with warnings built into electronic prescribing and dispensing systems, and the widespread availability of the PDMP for reviewing patients’ controlled substance prescription history.

Since July 2018, pharmacists and prescribers are required to check patients’ controlled substance prescription history in the PDMP prior to prescribing/dispensing an opioid for the first time and every 3-months for chronic opioid therapy. It is also recommended that the PDMP is checked prior to prescribing/dispensing a benzodiazepine or sedating medication. Our findings suggest that either prescribers and/or pharmacists did not check the PDMP before prescribing/dispensing these controlled substances (i.e., were unaware of the concurrent use), or they considered the benefit of the combination to exceed the substantial risk of morbidity and mortality. The 2018 regulations, which were made aware to all controlled substance prescribers in July of that year, required documentation of this benefit-risk calculation for opioid-benzodiazepine combinations. This documentation, if extant, is retained only within prescriber written or electronic notes, and is not transmitted to the PDMP. Yet a 2019 survey of RI prescribers and pharmacists indicated suboptimal awareness of these requirements.

Several other studies have examined the concurrent utilization of prescription opioids and benzodiazepines, albeit using varied definitions of concurrent use. One analysis using 2015 data from PDMPs in nine states found that 21.6% of patients who received at least one opioid prescription also received a prescription for a benzodiazepine during the calendar year, with 54.9% [11.9% of the study population] having at least 7 days overlap of opioids and benzodiazepines. A cross-sectional study using data from the North Carolina Medicaid program from 2017–2018 found that 19.7% of patients with at least one opioid prescription had at least one day overlap with a benzodiazepine prescription. The concurrent use of prescription opioids and benzodiazepines is also common among older adults. In a study of enrollees of a commercial Medicare supplement plan in 2017, Musich et al. found that 18.4% of patients who received at least two prescriptions for opioids had concurrent use of benzodiazepines for at least 30 days.

While the thresholds for defining prescription overlap differ across published studies, our analysis aligns with other research in finding that prescription opioids and benzodiazepines are often prescribed concurrently despite the increased

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**Table 2. Prescription Controlled Substance Classes with the Highest Prevalence of Concurrent Utilization with Prescription Opioids**

<table>
<thead>
<tr>
<th>Patients with Use of Prescription Opioids (N=142,692) and Concurrent Use of:</th>
<th>Any non-opioid type of prescribed controlled substance</th>
<th>Benzodiazepines</th>
<th>Z-Drugs</th>
<th>Stimulants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Patients with Concurrent Utilization Overall (%)</td>
<td>35,744 (25.1%)</td>
<td>24,279 (17.0%)</td>
<td>5,731 (4.0%)</td>
<td>5,356 (3.8%)</td>
</tr>
<tr>
<td>Age group</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
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<td>27.9%</td>
<td>19.5%</td>
<td>4.3%</td>
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</table>

* Bold indicates a statistically significant higher percentage of concurrent utilization for the subgroup compared with all others, p<0.01
risk of drug-related harm. Among unintentional opioid overdose deaths in RI occurring from July through December 2016, 24.1% had a positive toxicology report for benzodiazepines.\textsuperscript{13} Moreover, an analysis of Medicare Part D claims for 2013–2014 found that patients who were concurrently prescribed opioids and benzodiazepines were more than five times more likely to experience an opioid overdose compared to patients without concurrent use, after adjusting for demographic and clinical characteristics (adjusted hazard ratio: 5.05, 95% CI: 3.68–6.93).\textsuperscript{14} It is encouraging that following the FDA’s alert there was an estimated 18% relative reduction nationally in the concurrent use of prescription opioids and benzodiazepines during the subsequent 16 months,\textsuperscript{15} while in RI, the number of patients who received a prescription for both an opioid and benzodiazepine within a 30-day period declined by 41% from the first quarter of 2017 to the first quarter of 2020, potentially as a result of the July 2018 regulation changes.\textsuperscript{16}

There are fewer published studies regarding the concurrent use of prescription opioids and other types of prescribed controlled substances, such as sedative hypnotics, stimulants and other CNS depressant medications. In the aforementioned study by Musich \textit{et al.}, approximately 6.81% of patients receiving prescription opioids concurrently used non-benzodiazepine sedative hypnotics, which is slightly higher than what we observed in RI in 2018.\textsuperscript{12} Moreover, they reported that among patients with depression or anxiety, the concurrent use of prescription opioids and two or more central nervous system agents resulted in an 18% increased risk of injurious falls or fractures.\textsuperscript{12} Additionally, a retrospective analysis of patients receiving opioid prescriptions in the Washington State Medicaid program found that patients who also received non-benzodiazepine CNS depressants (predominantly Z-drugs) had more than a 3-fold increase in the risk of opioid-related death (adjusted hazard ratio: 3.1, 95% CI: 1.6–6.2).\textsuperscript{17}

We also found that 3.8% of RI adults who received a prescription for an opioid had concurrent utilization of stimulants. Prescription opioid use is not an absolute contraindication among patients who are prescribed stimulants, yet both medication classes have a high risk of physical and psychological dependence\textsuperscript{16,19} and the combination may lead to euphoric effects.\textsuperscript{20} A cross-sectional study of pharmacy data from 29 state Medicaid plans found that 5.4% of adults with attention deficit hyperactivity disorder had concurrently used stimulants and opioids,\textsuperscript{18} while a case-control study conducted of residents of British Columbia for the years 2015–2016 found that patients who were prescribed opioids and experienced an overdose had significantly higher odds of prescription stimulant utilization compared to their controls [OR: 3.63, 95% CI: 2.99–4.39].\textsuperscript{19}

Consistent with the published literature,\textsuperscript{12, 21–23} women in our study had a higher odds of receiving concurrent therapy with opioid and non-opioid prescribed controlled substances when compared to men, which was particularly higher for benzodiazepines (19.5% vs 13.5%, p<0.01). However, this finding is not unexpected as women have a higher prevalence of diagnosed anxiety disorder as compared with men.\textsuperscript{22} The highest prevalence of concurrent utilization of opioids and non-opioid controlled medications was among Medicare patients under the age of 65 (41.3%). The high prevalence of controlled substance polypharmacy in this subgroup merits concern given that these patients have chronic disability or ESRD; however, this finding aligns with prior research. One analysis of Medicare data from 2007 through 2011 found that more than 40% of non-senior beneficiaries received at least one opioid prescription annually.\textsuperscript{24} Another analysis of Medicare Part D claims data from 2015 found that 41.4% of enrollees under the age of 65 who had at least one opioid prescription also had concurrent utilization of either a benzodiazepine or sedative hypnotic, compared to under 24% for enrollees age 65 or older.\textsuperscript{8} Additionally, an analysis of the U.S. Renal Data System (USRDS) database for the calendar year 2014 found that 52.2% of patients had at least one opioid prescription annual, and 17% of patients with an opioid prescription received a benzodiazepine prescription within 1 week of the opioid dispensing.\textsuperscript{25}

There were several limitations to our study. Foremost, the PDMP data contains pharmacy-level information only, and we were unable to determine the indications for medication use. Also, we were unable to assess controlled substance use without prescription, or medication received from outlets other than pharmacies with a RI retail pharmacy license. An additional limitation is that pharmacy dispensing records do not confirm that the medication was consumed by the patient whose name is on the prescription captured within the PDMP data. Patients may have been nonadherent, may have been advised by their provider to stop taking a medication when a concurrent controlled substance was added to their regimen, and/or may have shared their medications with someone else. We also did not determine whether the concurrently used medications were issued from the same prescriber; however, all providers have access to the PDMP to review a patient’s use of other controlled medications before a new prescription is issued. Last, we applied a liberal definition of concurrent use, requiring only 1-day overlap between opioid and non-opioid controlled substance dispensing. This likely resulted in a higher rate of concurrent utilization than what may have been observed if we used a 7-day or 30-day overlap definition.

Further research is needed to determine adverse health outcomes and health care utilization resulting from the combined use of these high-risk medications, to evaluate the prevalence and impact of naloxone co-prescribing to mitigate risk, and to determine if the regulations of 2018 had further impact into 2019 and beyond in reducing controlled substance polypharmacy.
CONCLUSION

Approximately 1 in 4 adult RI residents who received a pharmacy dispensing for an opioid also received a concurrent non-opioid prescription controlled substance, while 1 in 6 had concurrent utilization of prescription opioids and benzodiazepines despite the evidence-based risk of this combination. Our findings suggest an urgent need to implement focused initiatives to address controlled substance polypharmacy to reduce the risk of opioid overdose.

References


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Disclaimer

The views expressed herein are those of the authors and do not necessarily reflect the views of the Rhode Island Department of Health or Healthcentric Advisors.
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Experiences of Rhode Island Assisted Living Facilities in Connecting Residents with Families through Technology During the COVID-19 Pandemic

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ABSTRACT

BACKGROUND AND STUDY OBJECTIVE: The COVID-19 pandemic has forced assisted living facilities (ALF) to implement strict social isolation for residents. Social isolation in the geriatric population is known to negatively impact health. Here, we describe how ALFs in Rhode Island utilized device donations received from Connect for COVID-19, a nationwide nonprofit organization which has mobilized medical students to gather devices for donations to care centers.

METHODS: Rhode Island ALFs were contacted to determine if they were interested in receiving smart device donations. After donations were made, an impact survey was electronically administered.

PRIMARY RESULTS: A total of 11 facilities completed the survey with a response rate of 24% (11/46). The facilities were located throughout all five counties in Rhode Island, with the majority located in Providence County. All but one of the facilities that responded to the survey (n=10, 90.9%) have used the devices to allow residents to video-call their family members. Seven responses (63.6%) indicated that devices were used for more than one purpose.

PRIMARY CONCLUSIONS: Smart devices were well received by Rhode Island ALFs and used for purposes beyond video conference calls. ALFs should consider advertising the need for devices to encourage community donations. Future studies should investigate the direct impact that digital connectivity has had on Rhode Island ALF residents.

KEYWORDS: Assisted Living Facility, COVID-19, digital connectivity, smart devices

INTRODUCTION

The COVID-19 pandemic engendered public health officials to urge social isolation and quarantine as methods to prevent further disease spread given lack of alternative less-restrictive means to control viral spread.1 While social distancing has been vital to mitigate the current pandemic, it is important to recognize the emotional and psychological implications of isolation.2-4
METHODS
Rhode Island community members provided donations to purchase smart tablets. Some devices were directly donated to Connect for COVID-19 for subsequent distribution. Most devices that were obtained were Amazon Fire Tablets and a few were Apple iPads. A team of volunteers prepared the devices with pre-installed software and Zoom accounts in order to minimize onboarding burden to IT departments in ALFs. Following device collection and preparation via donations, Rhode Island ALFs were contacted to gauge their interest in receiving smart devices through direct email, email listservs, telephone communication, and newsletter announcements. ALFs that expressed interest in receiving devices were asked to fill out an online Google form with a formal request.

Device allocation to the facilities was done in multiple rounds, based primarily on the number of beds at each facility. Other factors taken into consideration were the number of devices requested, whether or not the institution had other similar devices in use currently, and WiFi capabilities at the institution, which was required. While the number of devices per bed differed in each allocation due to the number of available devices on hand for donation, there was an attempt to balance consistency with rapid allocation and distribution.

Devices were primarily distributed directly to the facilities by medical student volunteers. For one allocation, there were two afternoon slots during which facilities could pick up their allocated devices from a centralized location in order to minimize volunteer driving. The institutions were provided with the device ID login and password information by email in addition to online instructions for use. Two weeks after the bulk of the devices had been distributed to facilities, an email was sent to the participating institutions with a request for their feedback in an online “Impact Survey” Google form.

RESULTS
The total number of devices donated to Rhode Island ALFs was 254 to 46 facilities. Eleven facilities completed the survey with a response rate of 24% (11/46). Supplemented by information available on each institutions’ webpage, all provided at least one or more services to their patients. The median number of devices donated was 5.45 (range = 2–20) and the most common number of devices donated to a facility was 2 (n=5, 31.2%).

Supplemented by information available on each institutions’ webpage, all provided at least one or more services to their patients. Ten (90.9%) provided two or more services and the average number of services provided by facilities was 4.36 (range = 1-9).

The facilities were located throughout all five counties in Rhode Island, with the majority located in Providence County. All but one of the facilities that responded to the survey (n=10, 90.9%) have used the devices to allow residents to video-call their family members. Of note, 7 responses (63.6%) indicated that devices were used for more than one purpose. Reported uses included patients video-calling their families [10, 90.9%], health workers providing status updates to patients’ families [4, 36.4%], telehealth purposes [4, 36.4%], social services [3, 27.3%], administrative purposes [1, 9.1%], and other [2, 18.2%]/recreational purposes [3, 27.3%]. Per information from the facility contacts, a total of 374 residents were served with these devices and across facilities, on average, each device was used by 14.8 patients (range= 0-40).

DISCUSSION
Rhode Island ALFs responded positively to the receipt of donated devices. We hypothesized that isolation of residents during the COVID-19 pandemic could be mitigated through digital connectivity. Virtually all of the facilities that responded to our survey confirmed that residents used the devices to connect via video conferencing calls with others. In addition, devices were used for educational and entertainment purposes. Our results suggest that technology is a key tool in the context of social isolation during the current pandemic and in other situations.

ALFs may benefit from institution-specific plans to ensure widespread use of smart devices. For example, a designated coordinator such as an activity director could communicate with Information Technology (IT) specialists to create strategies to show residents how to use the devices. Implementing short training sessions for these coordinators could ensure that they become comfortable with the task of helping residents successfully use devices. In addition, besides making use of devices on a one-on-one basis, ALF administrators could consider their use in broader activity-based and social communication sessions with residents.

With the continuity of the current pandemic, it is imperative that ALFs and similar institutions receive assistance...
from the community to protect the mental and emotional wellbeing of their residents. Our findings support the role for technology-based donations to these institutions as one mechanism to ensure that these residents remain connected with their loved ones. ALFs should consider advertising the need for smart devices to inform community members about this need.

**Limitations and Future Studies**

Our investigation is not without limitations. Our low response rate probably reflects the administrative burdens that many ALFs are likely facing in the context of the pandemic. Another limitation to our study is that we received information directly from administrators rather than ALF residents. Therefore, we cannot directly conclude from our survey responses whether ALF residents experienced a greater sense of social connectivity because of these devices. Future research should describe the digital connectivity experiences of ALF residents who have made use of donated devices and investigate whether device utilization is associated with self-reported wellness, cognitive performance, and other indicators of health status.

**References**


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We would like to acknowledge the efforts of all the Connect for COVID-19 volunteers.

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Dental and Oral Health Care in Nursing Homes: Results from Two Multi-Stakeholder Surveys

CHANTAL LEWIS, MPH; SAMUEL R. ZWETCHKENBAUM, DDS, MPH; ROSA R. BAIER, MPH; DANIEL HARRIS, MPH; REBEKAH L. GARDNER, MD

ABSTRACT

STUDY OBJECTIVE: To characterize oral health practices using data from statewide, multi-stakeholder surveys.

STUDY DESIGN AND METHODS: We analyzed data from two Rhode Island surveys. Together, the surveys targeted all nursing homes, residents, and resident representatives in Rhode Island, and asked about staff training on mouth care, frequency of dental provider visits, enrollment in nursing home dental programs, and barriers to oral health.

PRIMARY RESULTS: Responding nursing home administrators reported high levels of commitment to oral health. Among residents enrolled in a nursing home dental care program, 76.1% had a preventive visit in the prior six months, compared to 31.0% of residents not enrolled. The majority of facilities (71.8%) reported that staff received training on routine mouth care at the time of hire.

CONCLUSIONS: Our findings highlight opportunities to better support nursing homes in providing residents with high-quality oral health, including acquiring staff skills to manage care-resistant behaviors, and routinely assessing residents’ ability to provide their own mouth care.

KEYWORDS: oral health, nursing homes, dental care

INTRODUCTION

Oral health is linked to systemic health outcomes and to the quality of life for people of all ages. Poor dentition often causes pain and affects cardiovascular health, immune function, and medication burden. Additionally, individuals with tooth loss, tooth mobility associated with periodontal disease, and dental caries may have diminished ability to chew, which subsequently influences patterns of food consumption and diet quality and may lead to both weight loss and obesity. Older populations are at particular risk for these adverse outcomes because they may be more likely to have untreated oral and dental pathology, less likely to access consistent oral health care and have a relatively high burden of co-morbidities residing in a nursing home magnifies some of these challenges.

Recognizing the importance of oral health care in nursing homes, the Centers for Medicare & Medicaid Services established minimum standards for US nursing homes, stipulating that staff periodically assess residents’ oral health status and assist residents in obtaining both routine and emergency dental care, including making appointments and arranging for transportation. Under these standards, residents are also entitled to basic dental supplies, such as toothbrushes, and denture cleaner. Some states have also disseminated best practices for oral health in their nursing homes, including implementing personalized oral health plans for residents, and actively monitoring oral health program compliance.

Despite regulatory requirements and published best practices, many nursing home residents do not receive adequate oral health care due to a range of barriers. Insufficient training in working with people with dementia, residents’ responsive behavior (such as grabbing onto staff, agitation, resisting care), high workload, and staff burnout are some barriers as perceived by care aides, to providing better oral health care to nursing home residents. Previous studies have additionally reported financial challenges and lower priority of health care as barriers to improving oral health care in nursing homes. In order to improve oral health in this vulnerable population, we need a better understanding of how nursing homes currently provide dental and mouth care to their residents. The few studies that exist were conducted outside the U.S., are older, describe only a limited number of nursing homes, or do not incorporate resident and family perspectives. This study leverages data collected in two statewide, multi-stakeholder quantitative surveys to update and characterize current oral health practices, including routine mouth care and provision of dental care, in a statewide sample of nursing homes, residents, and resident representatives. We aim to 1) identify opportunities to support nursing homes in their delivery of oral health care, 2) inform oral health policy development, and 3) provide a baseline assessment of nursing home dental delivery system that can be used to measure the impact of changes in regulatory and clinical practice.

METHODS

We obtained the data from two statewide surveys in Rhode Island. The first survey was the 2018 Nursing Home Oral Health Survey administered by the Rhode Island Department
of Health [RIDOH] to inform statewide oral health initiatives in nursing homes. This instrument was created by RIDOH in conjunction with Healthcentric Advisors and the Rhode Island Long Term Care Coordinating Council’s Oral Health Subcommittee and administered electronically to all nursing homes [N=84] in Rhode Island, using an online survey platform [SurveyMonkey, Inc]. Questions related to routine mouth care and episodic dental care challenges were adapted from Smith et al.30 Nursing home administrators received a letter via U.S. mail from RIDOH with an URL link to the survey, as well as an email notification with the link and up to three electronic reminders. The survey period was from January 26, 2018, to February 9, 2018. Administrators from 46 nursing homes participated in the 2018 Nursing Home Oral Health Survey (response rate: 54.8%).

The second survey was the 2017 Rhode Island Nursing Home Satisfaction Survey, which is administered annually by RIDOH as part of the state’s legislatively mandated Healthcare Quality Reporting Program. The 2017 survey period ran from October 30 through November 27, and the survey was administered to all eligible 3,320 long-stay nursing home residents [101 days or more in the nursing home] and to all eligible 5,203 long-stay resident representatives. A resident representative was defined as an individual chosen by the resident or authorized by law to act on their behalf.31 To be eligible for this mandatory survey, residents were required to be cognitively intact [cognitive impairment was determined by individual facilities]; resident representatives were eligible irrespective of the resident’s cognitive status. Paper copies of the surveys were mailed to each facility. Facilities then distributed surveys to eligible residents and their representatives, and completed surveys were returned via U.S. mail. The survey received 2,417 resident responses [response rate: 72.8%] and 1,524 resident representative responses [response rate: 29.3%] to the 2017 Rhode Island Nursing Home Satisfaction Survey. Of the respondents, 94.3% of residents [n=2,280] and 88.5% of resident representatives [n=1,348] completed the one question related to oral health care: “How often do staff assist you with brushing your teeth or dentures and cleaning your mouth?” Answer choices included “Never,” “Sometimes,” “Usually,” “Always,” or “I do not need this type of assistance.” The question was modified for resident representatives to ask how often nursing home staff assisted the resident. No compensation was provided for completing either survey. For both surveys, all measures were self-reported.

We obtained data on resident and facility characteristics from the Nursing Home Oral Health Survey. We included residents’ type of dentition [natural teeth only, natural teeth and dentures, or dentures only] and the following facility characteristics: number of beds designated as skilled [most likely short-term rehabilitation residents] and non-skilled [typically long-term residents], certified nursing assistant [CNA] staffing levels [number who were full-time versus part-time or temporary], frequency of staff training on routine mouth care [at hire and/or annually], frequency of visits to facilities of different types of dental care providers [dentists, dental hygienists, dental hygiene students, prosthetists, and oral surgeons], regular availability of mouth care supplies [whether the items are kept in stock or can be delivered within 24 hours], insurance types accepted for dental care [Medicare [including fee-for-service and Advantage], Medicaid, private insurance, out-of-pocket, and other], and the number of residents enrolled in the nursing home’s dental care program. “Dental care program” was defined in the survey as the dental care services provided to residents by dental professionals or agencies with a formal or contractual arrangement with the nursing home. We also included the number of residents who had a preventive visit in the prior six months. “Preventive visit” was defined as a routine dental or denture assessment with a dentist or dental hygienist. Finally, we asked nursing home administrators to assess the significance of various potential barriers to oral health care for residents at their facility. Sample potential barriers queried in survey and found in the literature included transportation issues, availability of dental specialists, time constraints on facility staff, resident resistance to dental care, and resident financial concerns, among others. Administrators were asked to rate each potential barrier as “Very significant,” “Significant,” “Somewhat significant,” “Not significant,” or “Not applicable.”

Descriptive statistics and bivariate analyses were computed using SAS 9.3 [SAS Institute, Inc]. We defined “routine mouth care” as those services provided to residents by nursing home staff [i.e., not a dental professional], such as brushing teeth or cleaning dentures. “Episodic dental care” refers to services provided by a dental professional, which may be scheduled preventive care or unplanned care for an acute dental issue. We use “oral health” as an overarching term that includes both routine mouth care and episodic dental care.

**RESULTS**

Rhode Island nursing home administrators reported a mean of 19.2 [SD=18.8; range: 0-106] skilled beds and 83.1 [SD=42.8; range: 10-180] non-skilled beds. On average, facilities employed more full-time CNAs than part-time or temporary CNAs [mean of 33.4 versus 10.2, respectively]. Facilities reported that staff received training on routine mouth care at the time of hire in most facilities [71.8%]. More than three quarters of nursing homes indicated that Medicaid was accepted by their dental care providers [78.3%]; this was the most frequently accepted insurance type. Among the residents in participating nursing homes, about half [49.2%] had natural teeth only and 6.3% had dentures only. The remainder had a combination of natural teeth and dentures (Table 1).
Among the nursing homes (n=24) whose administrators responded to a question about the availability of different dental provider types, more than 90% reported that a dentist visited the facility at least once annually, and 100% reported at least an annual visit from a dental hygienist. Fewer facilities reported regular visits from dental hygiene students, prosthodontists, and oral surgeons.

Responding nursing home administrators reported that the following mouth care supplies were kept in stock or available within 24 hours: toothbrushes (95.7% of facilities), toothpaste (87.0%), denture tabs (95.7%), and mouthwash (97.8%). Two facility administrators reported having a space dedicated to dental care. All but one reported that their facility had a dental contract with an outside entity.

Nursing home administrators reported that, overall, 57.8% of their residents had a preventive visit in the six months prior to the survey. When we compared the 435 residents enrolled in a nursing home dental care program with the 297 residents not enrolled, we found that among those enrolled, 76.1% had a preventive visit in the prior six months, compared to 31.0% of residents among those not enrolled in a nursing home dental care program.

Responding administrators reported many oral health barriers for their residents. The barriers most commonly cited for both routine mouth care and episodic dental care were residents’ resistance to getting care (84.1% and 86.7% of nursing homes, respectively). Respondents also reported time constraints on facility staff as a barrier to routine care.

### Table 1. Characteristics of nursing homes responding to the 2018 Nursing Home Oral Health Survey (N=46)

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<thead>
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<th>FACILITY CHARACTERISTICS</th>
<th>mean (SD)</th>
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<tr>
<td>Skilled bed</td>
<td>19.2 (18.8)</td>
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<tr>
<td>Non-skilled beds</td>
<td>83.1 (42.8)</td>
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<tr>
<td>Staffing</td>
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<tr>
<td>Full-time CNAs</td>
<td>33.4 (21.0)</td>
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<tr>
<td>Part-time/per-diem CNAs</td>
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<tr>
<td>Frequency of staff training on mouth care, n (%)</td>
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<tr>
<td>At hire</td>
<td>33 (71.8)</td>
</tr>
<tr>
<td>Annually</td>
<td>25 (54.3)</td>
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<tr>
<td>Insurance types accepted for dental care, n (%)</td>
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<tr>
<td>Private</td>
<td>26 (56.5)</td>
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<tr>
<td>Medicaid</td>
<td>36 (78.3)</td>
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<tr>
<td>Medicare</td>
<td>18 (39.1)</td>
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<tr>
<td>Out-of-pocket</td>
<td>33 (71.7)</td>
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<tr>
<td>Other</td>
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### RESIDENT CHARACTERISTICS

<table>
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<th>Type of dentition*, n (%)</th>
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<tr>
<td>Natural teeth only</td>
<td>351 (49.2)</td>
</tr>
<tr>
<td>Natural teeth and dentures</td>
<td>317 (44.5)</td>
</tr>
<tr>
<td>Dentures only</td>
<td>45 (6.3)</td>
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</tbody>
</table>

SD: standard deviation; CNA: certified nursing assistant

*The denominator for this section is the total number of residents (N=713) at the facilities that responded to this specific question.
mouth care (60.9% of nursing homes) and financial concerns of both residents and their representatives as a barrier to episodic dental care (80.4% and 86.7% of nursing homes, respectively) [Figure 3].

All respondents reported that their nursing home leadership team and direct care staff were “committed” or “very committed” to resident oral health. Fewer than one in ten (9.1%) of nursing homes reported residents “often” mention oral health as a priority; one-third (34.8%) of nursing homes reported that their resident representatives “often” mention oral health as a priority.

Fewer than half of residents reported needing help with routine mouth care (43.4%), while 75.1% of resident representatives reported that their loved one needed assistance [Figure 4a]. Among the residents and resident representatives who reported that assistance was needed, more than half of residents (51.7%) and 41.8% of resident representatives reported “always” receiving that help from nursing home staff [Figure 4b]. Almost one in five residents who needed help with mouth care (17.8%) reported “never” receiving mouth care assistance from the nursing home.

**DISCUSSION**

Despite facility administrators reporting high levels of commitment to oral health, we found that not all Rhode Island nursing homes regularly provide preventive dental care to residents or train staff on how to perform routine mouth care. Increasing resident enrollment in nursing home dental care programs may improve uptake of preventive visits; this strategy would need to be tested prospectively. We identified multiple barriers to providing high-quality oral health in nursing homes, including residents’ resistance to care, staff time constraints, availability of dental providers, and financial concerns.

Nursing home administrators described care-resistant behavior as a leading barrier for both routine mouth care and episodic dental care. With 50% of residents likely to have some form of dementia,9 nursing homes can improve the capacity of CNAs to provide mouth care successfully by training them with evidence-based strategies used in other areas of dementia care,9 as well as with modules specifically designed to improve oral health in people with cognitive impairment, such as Mouth Care Without a Battle.33 Those providing professional dental services, including dentists and hygienists, would also benefit from learning how to reduce their being perceived as a threat by residents with dementia and from education on the level of dental care appropriate at different stages of cognitive loss. Facilities also indicated that staff time constraints were a barrier to routine mouth care. Designating a set of individuals who can perform mouth care more efficiently and have received extra training, particularly in care-resistant behavior, may also help in some nursing homes.34 Finally, prioritizing services provided based on an individualized care plan that incorporates risk assessment can maximize efficiency.

Nursing home administrators identified cost as an important factor in determining which residents received dental care. In Rhode Island, nursing home residents with Medicaid are able to receive dental services based on a negotiated encounter rate with participating providers servicing on-site; however, this option is not available for those whose insurance lacks dental coverage. Across the U.S., 30% of states’ Medicaid programs do not include a preventive dental benefit for adults. In Rhode Island, fewer than 50% of adults over 65 who are retired have any form of dental coverage.35

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**Figure 4.** Perception by nursing home residents and their representatives of assistance with routine mouth care in the nursing home, from the 2017 Rhode Island Nursing Home Satisfaction Survey

4a) Perception of residents’ need for assistance with routine mouth care

4b) Among those who reported needing assistance with routine mouth care, perception of how often that care is received from nursing home staff

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Despite the impact of oral health on overall health and quality of life, Medicare does not pay for dental care except in specific, hospital-based situations. Advocates have worked to include dental benefits in Medicare, and efforts are currently underway in the U.S. legislature. Even residents with insurance may experience barriers to care. These barriers may be due to limitations in coverage, especially with treatment needs beyond the preventive and diagnostic services provided by mobile dental services. Residents may also have difficulty finding dental specialists who are willing to take their insurance and who are comfortable treating frail older adults.

Higher proportions of residents who were enrolled in dental programs had preventive visits in the prior six months, compared to those who were not enrolled [Figure 2]. The strength of the dental program is therefore crucial and provides an opportunity to improve the quality of care provided. Hoben et al (2016) suggests that dental programs that overcome residents’ responsive behaviors to oral care or enable residents to perform their own oral care may be promising. Our results also support this suggestion given that resistance to care was reported as a barrier to care and that the majority of respondents reported being able to carry out routine mouth care [Figures 3 and 4a respectively]. Additionally, if more advanced services were adequately covered by insurance, dental care programs would be more likely to build up their capacity to provide those services; however, this would require appropriate space, equipment, supplies, and staff at nursing facilities.

Interestingly, our results demonstrated that residents and their representatives differ in their perceptions of how much assistance is needed for routine mouth care. While this difference may be due to respondent bias – resident respondents were cognitively intact, whereas resident representatives commented on all residents, including those with cognitive impairment – it is possible that residents or their representatives may have misjudged their abilities. This lack of certainty supports the call for nursing homes to systematically assess all residents annually, including an assessment of oral hygiene, followed by an oral health care plan which indicates the extent to which assistance with mouth care is needed. The degree of assistance should be tailored to the resident to maximize residents’ autonomy and best use CNAs’ time by allowing them to focus on specific challenge areas.

These results must be considered in the context of several limitations. Our findings may not extend to states with different Medicaid eligibility standards, benefits, and reimbursement. Additionally, states’ policies on the scope of practice of the dental workforce, particularly dental hygienists, vary substantially. Although our response rate was fairly high for administrators and resident representatives, the overall sample size was small, particularly for the question on the availability of dental providers. Respondents may have differed from non-respondents in ways that are not captured by the data; for example, administrators who did not respond may be more likely to work at facilities with limited dental care or may be unaware of dental services in their facilities. Finally, both surveys were administered by the state’s Department of Health, which may systematically affect the responses, particularly for the 2018 Nursing Home Oral Health Survey, because it was not anonymous. Future research would benefit from a national sample, anonymous survey design, direct observation of resident self-care abilities, and interventions that target the barriers identified by the authors and others.

In conclusion, our findings highlight several opportunities to better support nursing homes in providing their residents with high-quality oral health, with potential interventions targeted at both the nursing home and health policy levels. These include training nursing home staff and dental professionals on managing care-resistant behavior, routinely assessing residents’ ability to provide their own mouth care, tailoring care plans based on risk, expanding Medicare coverage to include dental care, increasing enrollment in nursing home dental programs, and engaging more with residents and their families around the importance of oral health. Given high levels of self-reported commitment to oral health by facility leadership and direct care staff, we anticipate that the long-term care community will be receptive to quality improvement initiatives related to oral health.

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The Use of Mobile Applications as Low-Vision Aids: A Pilot Study

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ABSTRACT

OBJECTIVE: To determine the most commonly used and highest-rated mobile applications (apps) for low-vision aids.

METHODS: This was a convenience sample survey. Patients known to use low-vision apps at a nonprofit low-vision center (INSIGHT, Warwick, RI) were contacted by phone between June and September 2019. Inclusion criteria: age 18+, Snellen visual acuity (VA) below 20/70, and the use of low-vision mobile apps for at least one month. A standardized script was used to record survey data and app ratings were evaluated by patients with a scale of one to five, one being the lowest and five being the highest.

RESULTS: Of the sample (n=11), nine patients (81.8%) stated they used an iPhone for low-vision mobile apps. A list of 14 mobile apps was identified: the two most commonly used apps were Seeing AI (81.8%) and Be My Eyes (63.6%); their average ratings were 4.43/5 and 4.75/5, respectively.

CONCLUSIONS: This survey suggests that Seeing AI and Be My Eyes are useful apps to help low-vision patients with activities of daily living.

KEYWORDS: low vision, mobile-health applications, activities of daily living

INTRODUCTION

Up to 35% of the world’s population is classified as being blind or having moderate to severe visual impairment. In Rhode Island, there is an estimated 22,000 people living with a visual disability as of 2016. Many have trouble performing activities of daily living and rely on the help of caretakers. With the rise of technology, they may utilize mobile apps as low-vision aids to help with daily living and becoming more independent. A literature review shows a lack of peer-reviewed studies on patient-centered mobile apps as low-vision aids. More information on these apps would be beneficial to physicians and vision rehabilitation facilities to disseminate to patients and their families, including obviating the need to sift through user reviews and find useful apps.

METHODS

Study approval was obtained from Massachusetts Eye and Ear Institutional Review Board and a data use agreement from INSIGHT (Warwick, RI, in-sight.org), a nonprofit vision rehabilitation organization that provides programs, children’s camps, and services to the blind and visually impaired. A 12-question phone survey was utilized in place of an online survey given that individuals with moderate visual impairment were the chosen population for this study and they could potentially have difficulties completing an online survey on their own. The survey script was developed by both authors and designed to utilize open-ended questions to capture all apps utilized by patients.

This study conducted a phone survey of patients seen at INSIGHT. Inclusion criteria included patients over the age of 18 who have been using low-vision mobile applications for at least one month with Snellen visual acuity (VA) below 20/70, defined as moderate visual impairment. With the assistance of the Executive Director of INSIGHT, 27 patients who used mobile low-vision apps and who met the study’s inclusion criteria were identified and invited to participate in the survey between June and September 2019. After verbal consent was obtained, a phone survey was conducted by one of the authors (DD) using a standardized script.

Subject age, gender and low-vision severity and onset were recorded. Severity of vision loss was determined by asking the participant their current vision for both eyes. They were then grouped into categories based on the International Classification of Diseases (ICD) utilized by the World Health Organization (WHO). Moderate visual impairment (category one) is defined as a Snellen VA of 20/70 to 20/200. Severe visual impairment (category two) is defined as a Snellen VA of 20/200 to 20/400. Blindness consists of three different categories ranging from Snellen VA of 20/400 to no light perception (Table 1).

<table>
<thead>
<tr>
<th>Category</th>
<th>Level of Visual Impairment</th>
<th>Snellen Visual Acuity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Moderate</td>
<td>20/70–20/200</td>
</tr>
<tr>
<td>2</td>
<td>Severe</td>
<td>20/200–20/400</td>
</tr>
<tr>
<td>3</td>
<td>Blindness</td>
<td>20/400–20/1200</td>
</tr>
<tr>
<td>4</td>
<td>Blindness</td>
<td>20/1200 to light perception</td>
</tr>
<tr>
<td>5</td>
<td>Blindness</td>
<td>No light perception</td>
</tr>
</tbody>
</table>
The type of cell phone (iPhone, Android, Google, or others), length of time since implementing apps and the apps used were recorded. All apps mentioned by patients were verified by research staff via the Internet and app stores. Patients were asked to name their favorite and second favorite app and give a subsequent rating. A scale of one to five, with five being the highest, was applied to determine the apps’ overall rating by the individual. They were then queried about their preferred component of all apps using an open-ended question. Answers were recorded using direct quotes and subsequent categorization. Patients were then asked the highest one-time cost they were willing to pay for an app. The data was analyzed using descriptive statistics.

RESULTS
The response rate was eleven subjects of the initial 27 patients who were identified in this study (Table 2). The mean age of the patients was 54 years (range 29–70); most were male (n=8, 72.7%). Participants’ education levels ranged from high school equivalent to a master’s degree; four patients had high school equivalents, four had associate degrees, two had bachelor’s degrees and one had his master’s degree. Based on the above ICD classifications, eight patients were categorized as being blind and the remaining three were categorized as having severe visual impairment. Three participants had low vision since birth and the remaining had a wide range of onset of low vision of three to 68 years.

The majority of patients used an iPhone for use of low-vision mobile apps (81.8%); the remaining two used an Android or state-issued phone by the Rhode Island Office of Rehabilitation Services. The mean length of use for mobile apps as low-vision aids was 38.2 months and the average participant utilized four apps regularly (range one to eight apps). Six subjects stated they had occasional help setting up, navigating or managing their low-vision apps from immediate or extended family or friends. The mean age of these family members or friends was 40.25 years, with a range from 15 to 69 years old.

Patient input yielded a list of 14 mobile apps: Seeing AI, Be My Eyes, KNFB Reader, AIRA, Money Reader, Soundscape, BARD, Seeing Eye GPS, Digit-Eyes, TapTap See, Document Scanner, Card Identifier, Podcasts, and Newsline NFB. The two most commonly used apps were Seeing AI (81.8%) and Be My Eyes (63.6%); their average patient ratings were 4.43 and 4.75 out of five, respectively. When asked what their favorite components of these apps were, participants most frequently stated navigation, person-to-person interaction, help with reading documents, and voice settings (n=2 for each). In particular, patients who utilized Be My Eyes stated that the app was “comprehensive and helps with daily activities on the go” and voiced that they “love that [they are]

Table 2. Survey questions and responses

<table>
<thead>
<tr>
<th>Question</th>
<th>Average Response or Counts</th>
</tr>
</thead>
<tbody>
<tr>
<td>How many years have you had low vision in both eyes?</td>
<td>Avg 22.5 years (range 3–68)</td>
</tr>
<tr>
<td></td>
<td>3 since birth</td>
</tr>
<tr>
<td>What is your visual acuity?</td>
<td>3 category two</td>
</tr>
<tr>
<td></td>
<td>4 category three</td>
</tr>
<tr>
<td></td>
<td>3 category four</td>
</tr>
<tr>
<td></td>
<td>1 category five</td>
</tr>
<tr>
<td>What type of cell phone do you currently use: iPhone, Android or another smartphone?</td>
<td>9 iPhone</td>
</tr>
<tr>
<td></td>
<td>1 Android</td>
</tr>
<tr>
<td></td>
<td>1 State phone</td>
</tr>
<tr>
<td>What current low-vision apps do you use?</td>
<td>See Table 3</td>
</tr>
<tr>
<td>How long have you been using low-vision apps for?</td>
<td>38.2 months</td>
</tr>
<tr>
<td>What is your favorite low-vision app and what would you rate it on a scale of 1 to 5 (5 being the best)?</td>
<td>See Table 3</td>
</tr>
<tr>
<td>What is your second favorite low-vision app and what would you rate it on a scale of 1 to 5 (5 being the best)?</td>
<td>See Table 3</td>
</tr>
<tr>
<td>What are your favorite components or features of all the apps you use which you find most helpful?</td>
<td>Navigation (2)</td>
</tr>
<tr>
<td></td>
<td>Personal interaction (2)</td>
</tr>
<tr>
<td></td>
<td>Help with documents (2)</td>
</tr>
<tr>
<td>What is the highest cost you would be willing to pay for an app?</td>
<td>Avg $49.50 (range 50-$150)</td>
</tr>
<tr>
<td>What is your age and gender?</td>
<td>Avg 54 years, 8 males</td>
</tr>
<tr>
<td>What is your highest level of education?</td>
<td>4 high school/GED</td>
</tr>
<tr>
<td></td>
<td>4 associates</td>
</tr>
<tr>
<td></td>
<td>2 bachelors’</td>
</tr>
<tr>
<td></td>
<td>1 master’s</td>
</tr>
<tr>
<td>Do you have other people in your household or family who help you navigate your mobile apps?</td>
<td>6 yes</td>
</tr>
<tr>
<td>If so, what are their approximate ages and their relationship to you?</td>
<td>67% from immediate family</td>
</tr>
<tr>
<td></td>
<td>Average age 40.25</td>
</tr>
</tbody>
</table>
CONTRIBUTION

talking to a live person and it is not expensive like AIRA.” Another patient stated they prefer to use Be My Eyes when he is alone or in an unfamiliar territory without his family or friends as the app makes it so “someone is right there to help if needed and [he] can do things on [his] own.” The mean maximum cost one was willing to spend on an initial, one-time app purchase was $49.50, with a range of $0.00 to $150.00, although many patients commonly listed free apps as their most-used [Table 3].

LIMITATIONS

The small response rate (11 of 27) is the major limitation of this study and may not provide representative data for the visually impaired population. As estimated by the INSIGHT Executive Director, the organization serves 950 adult patients per year, including one-time consults, and approximately 10% of these patients use cellular devices and low-vision apps. Of this population, not all patients were willing to participate or were able to be reached via phone after multiple attempts. In addition, many patients used apps that were not specifically designed for low-vision use, yielding the low sample size. Furthermore, this was a convenience sample, which results in selection bias, as all of the patients in this study were identified as frequent users of mobile apps by the INSIGHT Executive Director.

DISCUSSION

Our study can serve as a resource for physicians, low-vision specialists, or other providers consulting with the visually impaired. All patients spoke strongly about the apps they used with one participant stating apps had become “part of [their] complete toolbox to go back to normal functioning.” To help maintain autonomy and independence in daily life, it is important to connect patients with a new or existing visual impairment to low-vision apps.

The two most commonly used and highest-rated apps in this study are Seeing AI and Be My Eyes. These apps are free to users on both iPhone and Android app stores, which may contribute to their popularity given that competitors, like AIRA, require subscriptions. Seeing AI uses artificial intelligence and voice settings to help describe the user’s environment. Features of this app include reading short
text, reading documents, scanning barcodes to be informed of what a product is, recognizing people’s faces or scenes and identifying colors or lighting, among others. *Be My Eyes* functions as a video call between a person with low vision and a sighted volunteer. The volunteer is then able to help the requests of the visually impaired in almost any capacity with object identification, document reading, navigation, etc. These apps are two well-rated, free options that can be utilized in diverse ways, such as navigating an unknown space, reading the mail or going grocery shopping.

We recognize that many patients who are new to these apps may be apprehensive to use a cell phone with their visual diagnosis given the logistics of maneuvering a screen or camera. However, all of the participants had severe vision loss or blindness and roughly half navigated the apps on their own. Although some patients did emphasize there was “a steep learning curve, particularly with the camera function,” these apps can deeply impact the daily lives of patients living with a low-vision diagnosis.

**CONCLUSION**

This survey suggests that *Seeing AI* and *Be My Eyes* are particularly useful apps that can be utilized for help with activities of daily living for visually impaired individuals. These apps are free, comprehensive, and versatile, making them good options for patients beginning to incorporate low-vision tools.

**References**


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**Disclosures**

Magdalena Krzystolik, MD, serves on the Board of Directors at INSIGHT but has no related financial disclosures.

**Disclaimer**

The views expressed herein are those of the authors and do not necessarily reflect the views of Massachusetts Eye and Ear Infirmary or INSIGHT.
PCMH in a College Setting: A Brown Primary Care Transformation Initiative

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ABSTRACT
While the PCMH is the primary care model of choice for many healthcare systems, it is a relatively new area for college communities. The college health setting provides an important and challenging primary care platform because of developmental milestones that young adults face at this time of their lives. The Brown Primary Care Transformation Initiative (BPCTI) facilitated PCMH practice transformation efforts within a university center from 2013–2015. A mixed methods evaluative approach was used for baseline and follow-up periods as part of a broader transformation initiative that included interviews, surveys, focus groups, and observations. The college health practice was engaged in a number of other transformation activities concurrently. Results suggest that these multiple efforts, of which BPCTI’s facilitation was one, together had a positive effect in this college health setting. This intervention provides a unique window into strengths and challenges for a college health practice as it seeks to transform its provision of primary care.

KEYWORDS: PCMH, college, practice transformation, primary care

INTRODUCTION
College and its myriad academic and social opportunities can have both positive and negative effects on health-related behaviors, and many students lack a general awareness about how to navigate the health care system. Seeking care for illness when away from home for the first time, dealing with intricacies of health insurance, and sharing in medical decision-making are novel experiences for them. The Patient-Centered Medical Home model has represented a promising development in college health service systems – one that can assist students’ independence in managing their health care.

While no literature could be found describing a PCMH effort within a college health service as described in this paper, a number of practices of this type have sought and achieved PCMH accreditation. For instance, University of California Davis and University of South Carolina health services note on their websites that they are certified as PCMHs via the AAAHC (Accreditation Association for Ambulatory Health Care). The work of the Brown Primary Care Transformation Initiative (BPCTI) with this college health site began in 2013. This college health center had already implemented a number of innovations aligned with the PCMH model prior to the collaboration with the BPCTI, such as same day scheduling, expanded evening and weekend hours, medication reconciliation at every visit, enhanced modes of communication (e.g., secure messaging, texting), and a variety of quality improvement programs. The center’s work with BPCTI built upon these existing innovations and processes.

METHODS
Project Overview
The BPCTI, a 5-year Health Resources and Services Administration grant-funded program, was developed to promote and evaluate change, using the PCMH model, in eight RI primary care teaching practices, one of which was this college health service. The BPCTI approach involved pairing practices with staff from our team to provide PCMH coaching. This practice selected nine champions representing key roles to lead the transformation effort. A mixed-methods approach to data collection was used, with quantitative and qualitative data obtained from patients, staff and providers. Baseline data was compiled into a PCMH needs assessment provided to the practice. BPCTI facilitators met with practice champions to review this report, identify strengths and opportunities and guide changes, and then met regularly throughout the project.

The school health services director changed after our baseline data collection, while the BPCTI team worked with the practice. Several initiatives were launched at this time, including staff and provider programs to increase satisfaction, efforts to improve marketing and outreach to new freshmen, and outreach to students that had not utilized health services.

Data Collection Summary
The project obtained baseline data, and follow-up data approximately 1.5 years afterwards. Baseline quantitative measures included a practice demographic questionnaire, and provider and patient surveys. Baseline qualitative methods included
staff, provider, and patient interviews, pathways (described below), and observations. Patients were recruited from waiting rooms; staff and providers were recruited through phone, e-mail, and in-person verbal requests. Follow-up data collection included the same provider and patient surveys from the baseline data collection period, and champion interviews and/or focus groups.

Quantitative Measures
Three quantitative tools were used included the Maslach Burnout Inventory [MBI], for staff, a HRSA Patient Satisfaction survey, for patients, and the Insignia Health Patient Activation Measure [PAM], for patients. Patients and staff gave informed consent prior to completing surveys. Survey tools and descriptions can be found in Appendix A. Baseline response rate was 64%, while follow-up response rate was 17%. These were convenience samples and were not paired from baseline to follow-up.

Qualitative Methods
Qualitative methods for patients, clinic staff and providers included individual, semi-structured interviews; patient and staff pathways; and observations. Qualitative measures were designed to assess quality of services within a PCMH framework, burden on clinicians and other staff, work flow, satisfaction with work, ability to work with and communicate with team members, and feelings of support and investment in order to identify areas for improvement. Written consent was obtained prior to each interview or pathway.

Qualitative in-depth, semi-structured interviews of approximately 30 minutes duration were conducted with the PCMH champions, patients and staff. Sample size for clinical staff interviewed, including champions, was 30 at baseline and 9 at follow-up. Patients were purposively sampled from waiting rooms to include approximately equal numbers of young adult women and men. Patients were interviewed at baseline only (n=14). Table 1.

The interview questions were drawn from PCMH literature and findings from a PCMH Evaluation Think Tank hosted by our team at Brown University. For practice employees, interviews focused on initial plans for becoming a PCMH, attitudes and knowledge regarding PCMH transformation, job roles, work flow, communication, vision for practice and perceived barriers and facilitators to change. Patient interviews addressed patients’ perspectives on the nature and process of care they received. See Appendices for interview guides.

Pathways and Observations
A pathway involves accompanying a person in a particular role during their work or activity to better understand their point of view, experience, workflows, and activities. For staff pathways, researchers accompanied staff for 1–2 hours to observe the individual’s work. In patient pathways, researchers followed patients from check-in to check-out, including the time in the consultation room with the provider, other than stepping out for private exams. In addition, researchers conducted observations in the waiting rooms, pharmacy, laboratory, front desk, and nursing station.

Quantitative data analysis
Basic descriptive statistics (means and standard errors or percentages) were generated for patient and provider data. Data were analyzed for changes between baseline and follow-up assessments using generalized linear mixed models. Potential correlations in data collected within the practice were adjusted for within the analytic framework. All analyses were conducted using SPSS Statistics for Windows v23 (IBM Corp.).

Qualitative data analysis
Analysis of the qualitative data included a form of immersion/crystallization and aligned using the following protocol: 1) listening to the interview recordings, reading the summary notes and taking further analytic notes to extract data relevant to understanding the practice culture and factors that might impact the transformation process; 2) team group discussion of the data to arrive at interpretation of the findings; 3) creation of reports for each practice and presentation of findings for publication.

RESULTS
Quantitative Results
The demographics of the patient participants are described in Table 2. Patient characteristics were compared across the two assessment periods (baseline and follow-up), and no statistically significant differences were found among the two patient populations (results were not paired). For the patient surveys (Satisfaction and PAM), a total of 111 surveys were collected and analyzed at baseline and 115 surveys, at follow up.

Patient Satisfaction Survey
Results of the patient satisfaction survey are shown in Table 3. Overall, students rated the site highly, with the overall

<table>
<thead>
<tr>
<th>Data Type</th>
<th>Baseline n</th>
<th>Follow Up n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Surveys</td>
<td>111</td>
<td>115</td>
</tr>
<tr>
<td>Patient Interviews</td>
<td>14</td>
<td>0</td>
</tr>
<tr>
<td>Staff and Provider Surveys*</td>
<td>41</td>
<td>11</td>
</tr>
<tr>
<td>Staff and Provider Interviews</td>
<td>30</td>
<td>9</td>
</tr>
<tr>
<td>Pathways</td>
<td>12</td>
<td>0</td>
</tr>
</tbody>
</table>

*At baseline there are 9 (22.0%) providers and 32 (78.0%) nurse/staff. For the follow-up, there are 4 (36.4%) providers and 7 (63.6%) nurse/staff. These are not statistically different by time point (p=0.33).
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satisfaction score increasing slightly from baseline (29.0) to follow-up (30.3) (p=0.028). These scores represent a total of per-category scores. The average per category was 4.14 at baseline and 4.30 at follow-up, indicating a positive rating for most items surveyed. The lowest scored categories at baseline were waiting time (3.97) and payment (3.85) while the highest were satisfaction with nursing/medical assistants (4.57) and other staff (4.55). At follow-up, several questions on this survey increased significantly or increased with trend toward significance: “prompt return on calls” (p=0.089); “[waiting time] in exam rooms” (p=0.081) and “neat and clean building” (p=0.020).

A majority of students indicated in their survey responses that they considered the health service their regular source of care and this proportion increased from 79% at baseline to 85% of students surveyed at follow-up.

### Table 2. Patient Demographics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Baseline (n=111)</th>
<th>Follow-up (n=115)</th>
<th>Assessment p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years (mean, sd)</td>
<td>21.6 (3.5)</td>
<td>21.6 (4.1)</td>
<td>0.971</td>
</tr>
<tr>
<td></td>
<td>Median: 21</td>
<td>Median: 20</td>
<td></td>
</tr>
<tr>
<td>Gender, % Female</td>
<td>72.7%</td>
<td>67.5%</td>
<td>0.397</td>
</tr>
<tr>
<td>Race/Ethnicity (%)</td>
<td></td>
<td></td>
<td>0.633</td>
</tr>
<tr>
<td>Asian</td>
<td>14.8%</td>
<td>16.8%</td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>7.4%</td>
<td>9.7%</td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>18.5%</td>
<td>17.7%</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>53.7%</td>
<td>53.1%</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>5.6%</td>
<td>2.7%</td>
<td></td>
</tr>
</tbody>
</table>

* Baseline and follow up samples in Table 2 were not statistically different.

### Table 3. Patient Satisfaction Survey

<table>
<thead>
<tr>
<th>Domain</th>
<th>Baseline Average n=111 Mean (SD)</th>
<th>1.5 Year Average n=115 Mean (SD)</th>
<th>Assessment p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ease of getting care</td>
<td>4.26 (.64)</td>
<td>4.33 (.57)</td>
<td>0.33</td>
</tr>
<tr>
<td>Waiting time</td>
<td>3.97 (.78)</td>
<td>4.10 (.68)</td>
<td>0.18</td>
</tr>
<tr>
<td>Provider</td>
<td>4.41 (.69)</td>
<td>4.48 (.69)</td>
<td>0.40</td>
</tr>
<tr>
<td>Nurse and medical assistants</td>
<td>4.57 (.65)</td>
<td>4.61 (.61)</td>
<td>0.63</td>
</tr>
<tr>
<td>Staff-all others</td>
<td>4.55 (.61)</td>
<td>4.59 (.60)</td>
<td>0.62</td>
</tr>
<tr>
<td>Payment</td>
<td>3.85 (.92)</td>
<td>3.79 (1.0)</td>
<td>0.67</td>
</tr>
<tr>
<td>Facility</td>
<td>4.43 (.59)</td>
<td>4.55 (.52)</td>
<td>0.12</td>
</tr>
<tr>
<td>Overall satisfaction score</td>
<td>29.0 (4.9)</td>
<td>30.3 (3.5)</td>
<td>0.03</td>
</tr>
</tbody>
</table>

### Table 4. Patient Activation

<table>
<thead>
<tr>
<th>Assessment p-value*</th>
<th>Baseline</th>
<th>Follow-Up</th>
<th>National Average</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average Activation Score</td>
<td>62.28 (13.91)</td>
<td>59.19 (13.84)</td>
<td>36–100</td>
<td>0.094</td>
</tr>
<tr>
<td>Range: 35–100</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Activation Level (% (Stratified data)</td>
<td>11.9%</td>
<td>18.5%</td>
<td>19.3%</td>
<td>0.268</td>
</tr>
<tr>
<td>Level 1: score ≤ 45.2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level 2: score of 47.4 to 52.9</td>
<td>30.3%</td>
<td>31.1%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level 3: score of 56.4 to 66.0</td>
<td>38.5%</td>
<td>27.7%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level 4: score ≥ 68.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Baseline and follow up scores were not statistically different.

### Table 5. Provider and Staff Burnout

<table>
<thead>
<tr>
<th>MBI Scale</th>
<th>Baseline (n=41)</th>
<th>Follow-Up (n=11)</th>
<th>National Average</th>
<th>Assessment p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emotional Exhaustion</td>
<td>17.88 (13.67)</td>
<td>19.82 (15.47)</td>
<td>22.19</td>
<td>0.685</td>
</tr>
<tr>
<td>Depersonalization</td>
<td>3.46 (3.99)</td>
<td>4.00 (5.14)</td>
<td>7.12</td>
<td>0.711</td>
</tr>
<tr>
<td>Personal Accomplishment</td>
<td>40.48 (6.71)</td>
<td>41.18 (3.95)</td>
<td>36.53</td>
<td>0.661</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MBI by Clinical Role and Assessment</th>
<th>Baseline</th>
<th>Follow-Up</th>
<th>p-values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provider (n=9)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emotional Exhaustion</td>
<td>29.89 (14.18)</td>
<td>29.25 (14.43)</td>
<td>0.002</td>
</tr>
<tr>
<td>Depersonalization</td>
<td>4.88 (4.26)</td>
<td>8.25 (6.65)</td>
<td>0.005</td>
</tr>
<tr>
<td>Personal Accomplishment</td>
<td>38.44 (6.06)</td>
<td>41.25 (4.98)</td>
<td>0.588</td>
</tr>
</tbody>
</table>

### Patient Activation Measure

Results of the patient activation survey are shown in Table 4. At baseline, patients scored an average activation level of 3 on the scale of 1 to 4. At follow-up, scores decreased slightly, not a significant difference.

### Provider and Staff Burnout

At baseline and follow-up on the Maslach Burnout tool, providers and staff reported being less emotionally exhausted and more personally accomplished and connected to their patients than the national average. Still, within the study population, there were no significant changes from baseline to follow-up in aggregate. Separating out providers (MDs, NPs and PAs) vs. staff [nurses and medical assistants and other staff], revealed significant differences between providers [more emotional exhaustion and depersonalization] and staff [less emotional exhaustion and depersonalization] over time (p=.002 and .005, respectively). Table 5.
QUALITATIVE RESULTS

Patients
Baseline qualitative interviews, general observations and pathways indicated that patients felt providers and staff were dedicated to the students of the university. Patients appreciated the ease of scheduling; however, because of long wait times, appointments sometimes interfered with classes. Interviewees viewed positively the collaborations of the college health service with various other departments and services such as Psychological Services, academic deans, athletics and EMS. The health service also was noted for involving parents, primary care doctors, and other members of their patient population’s health care team into the care model. Patients, during pathways, praised their doctors and other clinical staff, such as the nurse, MA, pharmacist, and counselors. Most patients stated their care was inclusive, culturally appropriate, and that providers were open-minded.

Some challenges noted included poor signage and a confusing structural layout of the building as well as technology issues with EHR lags and interference with workflow. Another point of concern brought up in patient interviews was charges associated with visits. Patients reported feeling surprised by charges, and confused about insurance coverage and the health service fee, which most students are required to pay at the start of each semester.

Providers and Staff
In baseline interviews, providers and staff expressed that the practice was patient-oriented and providers were dedicated. Some staff viewed the practice as having good teamwork, while others viewed teamwork as a challenge. Most staff reported that the physical space constrained collaboration and operations. Change was viewed as an already-embedded value, though not all staff members found it easy or rewarding.

Follow-up interviews included discussions of how the school health services director had changed since baseline interviews, initiating efforts that occurred simultaneously with the PCMH facilitation. Some providers and staff felt overwhelmed with the number of projects undertaken.

DISCUSSION

This study represents a unique window into PCMH facilitation and data collection efforts in a college health setting. The transition in health care between adolescence and adulthood is a pivotal time, with national efforts focusing on improving such transitions. College health services stand at the crux of such transitions for many youth; efforts to enhance such clinics as medical homes could aid in transitions. Results show strengths of this health services and suggest that the multiple interventions undertaken during the study period, including BPCIT’s facilitation, may have had a positive impact. Patient satisfaction increased. Patients expressed appreciation for individualized and familiar clinical encounters, for their providers and care teams. Burnout scores were better than the national averages, while, at the same time, providers appeared more burnt out than other clinical staff. Perhaps much of the work needed to make PCMH changes is falling disproportionately on providers; perhaps expectations are different among different roles, or perhaps engagement in change differs. More research is needed.

A substantial minority did not consider the college health service their usual source of care. This presents a significant challenge to PCMH adoption. The fact that the university is run through academic sessions, combined with individuals’ primary identification with their PCP of origin, may have resulted in students’ unwillingness to adopt the college health center as medical home. Students’ perceived lack of knowledge of the basics of health insurance and fees and their lack of awareness of services at the clinic may have presented barriers to their accepting responsibility for their care. Education of students about PCMH may be warranted.

LIMITATIONS

This study had several limitations. One related to data collection. Patients were kept in the waiting room for only a limited length of time, and this was the primary location where students were asked to fill out surveys. Though they were encouraged to take surveys into exam rooms (where there might have been an additional wait), many declined to participate.

The samples of patients for surveys and interviews were convenience samples, which affects the generalizability of the study. Furthermore, these PCMH measures, methods and tools were designed for outpatient primary care practices that do not specifically serve a college student population, so the tools may not have suited these patients as well as they could have.

And, as noted above, this real-world study represented a PCMH intervention concurrent with other internally-driven practice transformation efforts. As such, it is difficult to tease out the effects of our team’s facilitation.

CONCLUSION

Applying PCMH in a college setting is an ambitious endeavor, as the age and transitional nature of the student/patient population pose unique challenges to the traditional construct and goals of a PCMH. Nevertheless, our team sought to tackle this challenge at a local college and was part of a group of interventions that contributed to important changes in patient satisfaction, as well as provider communication and teamwork. This intervention and study offer a unique view of patient, provider and staff experiences during practice transformation. Further exploration is warranted regarding the unique challenges posed by applying PCMH within the college setting.
References


Acknowledgments

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Enforcing the “4T”: An In-Line Calculator for HIT Antibody Ordering in the Electronic Medical Record

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ABSTRACT

Heparin-induced thrombocytopenia (HIT) remains a difficult clinical diagnosis, even with the under-utilized standardized scoring systems, like the ‘4T’ score, to aid in clinical decision-making. Our quality improvement study sought to assess the use of ‘4T’ score, improve the use of HIT antibody (HITA) testing and improvement management of possible HIT by implementing an in-line calculator with guidance within our electronic medical record (EMR) at our institution.

We retrospectively reviewed patient charts between October 2017 and October 2018, assessing practices before and after implementation of the ‘4T’ in-line calculator in April 2018. HITA were ordered inappropriately (for 4T <4) in 141 (67%) of 210 instances (75 before and 66 after). We found no statistically significant difference in positive predictive value (PPV) or 4T documentation in provider notes after its implementation.

We were able to identify problematic areas in HIT management, such as the ordering of non-heparin anticoagulants, and implement additional changes addressing these problems.

KEYWORDS: Heparin-Induced Thrombocytopenia, 4T score, Epic, Quality Improvement, EMR

INTRODUCTION

Immune-mediated (formerly Type II) heparin-induced thrombocytopenia (HIT) is one of the most concerning etiologies of thrombocytopenia in the hospitalized patient. Immune HIT occurs when an antibody is formed against the complex of heparin and platelet factor-4 (PF4), ultimately leading to platelet activation and potential arterial or venous thrombosis.1,2 Given its catchy acronym and paradoxical thrombosis formation despite falling platelet counts, it often vaults to the top of differential diagnoses of medical students and seasoned medical practitioners alike. However, it remains a rare entity compared to other etiologies of thrombocytopenia, namely infection, liver disease, bone marrow suppression, and other drug-mediated forms of thrombocytopenia. The incidence of thrombocytopenia in hospitalized patients is quite variable depending on the patient population, ranging from 1 to 9%, while rates in the critical care setting are even more variable, ranging from 8 to 68% upon ICU admission and 13–44% of patients during their ICU course.3,4 Although thrombocytopenia can occur frequently after heparin exposure [the frequency of non-immune HIT (formerly Type I) is estimated to be between 10-30%], the estimated frequency of clinically significant immune HIT for hospitalized patients is in the range of 1 in 2500 to 1 in 5000.5,6 The incidence rates of immune HIT vary greatly based on the patient population, duration and type of heparin exposure: estimated at 0.2% for low-molecular weight heparin [LMWH], 0.8% for subcutaneous heparin, and up to 2.6% overall for unfractionated heparin (UFH).7,8 HIT is ultimately a clinical diagnosis as many patients who develop antibodies do not have clinical HIT.6,9

In true cases of HIT, rates of thrombosis can reach 6% daily and have an overall risk of 20–50% without timely recognition and implementation of alternative anticoagulation.10,11 Fortunately, clinical scoring systems to assess the risk of HIT and guide management exist. The 4T score (4T) is based four clinical factors: degree of thrombocytopenia, timing of platelet count drop, other explanations for thrombocytopenia, and thrombotic events [new or worsening].12 Each of these factors are scored from 0–2 and a cumulative score is calculated, ranging from 0–8. A result of 3 or less is consistent with low risk, 4–5 with intermediate risk, and 6 or more with high risk of HIT.12,13 It has been well validated as a means to predict the likelihood of true HIT. A large meta-analysis has demonstrated the negative predictive value (NPV) of a low-probability 4T score (3 or less) to be 99.8%, while the PPV for high (6-8) and intermediate (4-5) scores were 14% and 64%, respectively.13 Traditionally, for high suspicion of HIT, our institutional practice has been to start alternative anticoagulation while confirmatory testing commences and to begin alternative anticoagulation with an intermediate score at clinicians’ discretion [Figure 1]. Alternative anticoagulation has traditionally consisted of argatroban, although fondaparinux, while not FDA-approved, appears safe and is approved in Canada, resulting in its increasing use.11,16 Finally, there is evidence to suggest that direct oral anticoagulants (DOACs), including rivaroxaban and apixaban, can be used as well, although their use remains off-label.17

With an intermediate or high score, guidelines suggest
CONTRIBUTION

The two primary classes of laboratory assays available to aid in making the diagnosis of HIT are: enzyme immunoassays (EIAs) that measure antibodies immunochemically and functional assays – such as serotonin release assay (SrA) – that measure antibody activation of platelets. Functional testing, namely SrA, remains the “gold standard” for HIT diagnosis in the US; however, its use is limited by cumbersome lab technique requiring a send-out to reference laboratories, leading to delayed results and yielding it ineffective in rapid clinical decision-making. As a result, many institutions rely on EIA testing to assist in bedside management of patients with suspected HIT. EIA testing measures either polyspecific antibodies (IgA, IgM, and/or IgG), or only the pathogenic IgG class alone. The limitation to EIA testing is that it cannot assess the functionality of the antibody (Ab) present. Both the polyspecific and IgG class EIA tests have robust sensitivity (98.1% and 95.8%, respectively), and negative predictive values (99.9% and 99.7%, respectively). However, the IgG-specific test has better specificity (93.5% vs. 89.4%) and PPV (49.6% vs. 38.7%), although a positive result via either method does little to confirm true HIT. The implementation of IgG-specific EIA has resulted in a decreased duration of exposure to parenteral direct-thrombin inhibitors (DTIs) without change in significant WHO Grade III and IV bleeding rates.

The introduction of electronic medical record (EMR) systems into healthcare systems has provided opportunities to embed clinical tools and critical information for decision-making, and alerts to assist providers in diagnosis and management of complicated and critical diagnoses. While studies across the United States have about the impact on healthcare outcomes had mixed results, these studies have been limited by small sample sizes. No studies have been published to date discussing the use of EMR tools in the diagnosis of HIT.

Figure 1. Initial Management Recommendations for Suspected HIT at our institution

While performing inpatient hematology consults, we found that the 4T score was seldom calculated, or even considered, prior to ordering of HIT antibody (HITA). Hence, there was the risk of false-positive results and either cessation of appropriate anticoagulation, or initiation of expensive and not indicated alternative anticoagulation. Our objectives were to use the electronic medical record to provide succinct education regarding the diagnosis of HIT, improve diagnostic stewardship through more appropriate ordering of HITA and improve the management of thrombocytopenia when HIT is considered.

METHODS

Our quality improvement study began with a retrospective chart review of patients in the Lifespan hospital network, a three-hospital, 1,095-bed system across Rhode Island between October 2017 and April 2018. Cases were identified in two ways. All HITA orders were retrieved through laboratory records and the reporting workbench function in the Epic® EMR. In addition, the SlicerDicer function of Epic was used to gather data including admission, orders and results. In April 2018, we implemented a 4T calculator directly into the order for HITA within the EMR requiring the following:

- Last five (5) platelet counts within hospital system’s EMR
- Heparin/Enoxaparin orders for the last 30 days
- Description of HIT testing and 4T score
- Reference link to online 4T score calculator
- Input for manually calculated 4T score result (Requires numerical input to place order)
- Table of 4T score interpretation and probability of HIT
- Recommendations on acute management based on patient’s pre-test probability

The ordering window required a numerical input into the field for 4T score result, but did not require the ordering provider to follow recommendations for ordering and management outlined within the window. At the time of ordering window creation, it was felt that mandating a specific number could result in appropriate orders not being placed. Since the 4T score is recommended to guide and not replace clinical decision-making, the calculator did not prevent providers from ordering HITA. This score was not required to order SrA which could be ordered separately. Our departmental recommendations for management of possible HIT were to discontinue all heparin products for intermediate and high scores, if not already done, and to start alternative anticoagulation only for high 4T scores. Immediate initiation of alternative anticoagulation for an intermediate score
was left to the treating physician’s discretion [Figure 1]. This recommendation strayed from the consensus guidelines based on our preliminary retrospective review that showed treating physician documented 4T scores were consistently higher than those calculated by reviewing hematologists, which raised concern for overuse of DTIs in patient’s potentially at higher risk for bleeding than clotting, given their low probability of HIT. The calculator included a note strongly suggesting hematology consultation at time of consideration of HIT, with further management based on results of polyclonal HITA [Figure 2]. After 3 and 6 months of the 4T calculator use, from April 2018 to October 2018, we again collected information about patients who underwent HITA testing by the same methods as our initial retrospective analysis. The review was approved by the Lifespan Internal Review Board (IRB), who determined the implementation of the calculator and subsequent review of cases to be exempt from IRB approval.

We retrospectively reviewed measures for management and test utilization, including discontinuation patterns of heparin products by managing service, initiation of alternative anticoagulation, and agent used. It also included review for potential confounding factors, rates of hematology consultation, and independently calculated 4T scores as well as provider-calculated 4T scores (hematology consultants and primary service). The independent reviewers were hematology fellows, consultants and residents with hematology oversight audited for concordance.

Although this quality improvement study was designed to test feasibility of incorporating a calculator into the EMR, we performed exploratory statistical analysis using STATA v15 software to examine rates of ordering, appropriate cessation of heparin and initiation of alternative anticoagulation as indicated. We evaluated for differences between the pre- and post-calculator groups using chi-squared test, and logistic regression with bootstrap standard error. We calculated the PPV and NPV for the HITA using standard 4x4 tables where the polyclonal HITA was the screening test. True positives were defined as a positive screening test with a positive confirmatory test, either IgG HITA (OD >2) or weakly positive IgG HITA (OD=0.5-1.99) with positive SRA, while false positives were defined as an elevated polyclonal with negative confirmatory tests [Figure 2].

RESULTS

Based upon our EMR database review, an abnormal platelet count while receiving heparin-based anticoagulants (UFH or LMWH) occurred in 7,562 of 23,119 admitted patients before and 7,397 of 23,288 admitted patients after the 4T calculator implementation. In the 6 months before the 4T calculator implementation, there were 109 HITA orders which reflexed to HIT IgG 21 times. The HIT IgG was then positive in 10 cases. An SRA was ordered 23 times, including 9 in the setting of an abnormal HITA. For the six months after the 4T calculator implementation, there were 101 HITA orders with 22 reflexes to IgG, of which 7 were positive. SRA was ordered a total of 20 times with 6 in the setting of an abnormal HITA.

By review of laboratory records and EPIC reports, we identified 210 patients on whom a HITA was ordered during the study period. Reviewed 4T scores were <4 in 141 (67%) of instances when HITA should not have been ordered. Before implementation of the in-line calculator and ordering window, 88 of the 109 patients with a HITA test ordered did not have a 4T score documented, while 3 patients had a low (<3) 4T score documented and 18 patients had an intermediate (4-5) or high (6-8) 4T score documented. After the implementation of the calculator, all patients tested had a documented 4T score within HITA order. Seventeen of 101 patients had a low score and the remaining 84 patients had either intermediate or high scores. Due to the lack of documentation before calculator implementation, risk scoring was determined by independent reviewer 4T score calculation. Based on these calculations, 75 patients before in-line calculator and 66 patients after in-line calculator who had HITA ordered were low risk by independent reviewer 4T score, and would not have required the test otherwise. No significant difference (p=0.249) was found between calculated 4T scores by independent reviewer and inpatient providers before the implementation of the ordering window, but a significant difference (p<0.001) was seen after it became operational with most independent reviewer scores falling into lower risk category than the documented scores by inpatient providers [Table 1]. No significant differences were seen between hematology consult provider and

![Figure 2. Further Management Recommendations for Suspected HIT based on polyclonal antibody results at our institution](image)
**DISCUSSION**

Our findings of only 5 cases before and 5 cases after the calculator is consistent with published incidence of HIT. There were fewer orders after the calculator despite an increased number of admissions in this time frame and a consistent number of confirmed cases of HIT, achieving our goal of improving diagnostic stewardship. It also offered potential cost savings as the billed cost of a HITA is about $200, the institutional cost to run the assay is approximately $60 and the cost of an SRA is $572.

We identified additional areas for quality improvement. We noted frequent orders for the SRA without knowing the result of screening HITA, often with low 4T scores. We are implementing methods to reduce this. Through consultation and chart review, we identified that treating providers had difficulties with ordering and administration parameters for argatroban, as well as bridging to vitamin K antagonists due to infrequent use. Through the pipeline developed for design and implementation of the 4T calculator, we were able to simplify and structure both ordering and monitoring of argatroban with a dedicated order set.

The in-line calculator and ordering window were intended to provide succinct education within our EMR and decrease inappropriate HITA orders. Our EMR lacks the ability to determine the number of times that the ordering window was opened and order was not placed, which we would expect to occur amongst those with a calculated ‘low probability’ score, thereby achieving the desired effect of the calculator and educational window. Unfortunately, we failed to meet our goal of improving management of suspected HIT and guide practitioners towards better management. The reasons for this are unclear. Given our initially positive results at three-month analysis, it is possible ‘click fatigue’ played a critical role in the lack of improvement in PPV at six-months since only inputting of a number is required, while accuracy or adherence to ordering recommendations (4T >3) is required to place order.21 Several institutions require hematology or similar specialist approval for these tests, which may be a more effective alternative. However, given the national shortage of non-malignant hematologists, developing an effective and reproducible system could help both the hematology workforce and improve patient care. Our decision to only recommend initiation of anticoagulation for a high-probability score at time of order likely played a role in the low number of alternative anticoagulants started at time of HITA order.

<table>
<thead>
<tr>
<th>Table 1. 4T Score Comparisons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-'4T Calculator' HITA (n=109)</td>
</tr>
<tr>
<td>Uncalculated/Uncollected 4T Score</td>
</tr>
<tr>
<td>Low 4T Score by primary provider (0-3)</td>
</tr>
<tr>
<td>Intermediate/High 4T Score by primary provider (4-8)</td>
</tr>
<tr>
<td>Low 4T Score by independent reviewer (0-3)</td>
</tr>
<tr>
<td>Intermediate/High 4T Score by independent reviewer (4-8)</td>
</tr>
<tr>
<td>No discrepancy between independent reviewer &amp; primary provider</td>
</tr>
<tr>
<td>Independent reviewer 4T score LOWER than primary provider</td>
</tr>
<tr>
<td>Independent reviewer 4T score HIGHER than primary provider</td>
</tr>
<tr>
<td>No discrepancy between independent reviewer &amp; hematology consult</td>
</tr>
<tr>
<td>Independent reviewer 4T score LOWER than hematology consult</td>
</tr>
<tr>
<td>Independent reviewer 4T score HIGHER than hematology consult</td>
</tr>
</tbody>
</table>

*Uncollected/Uncollected not included

<table>
<thead>
<tr>
<th>Table 2. Anticoagulation Management in Patients with Clinical Suspicion of HIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-'4T Calculator' HITA (n=109)</td>
</tr>
<tr>
<td>4T Score &lt;4 (% of HITA tests)</td>
</tr>
<tr>
<td>Heparin Discontinuation</td>
</tr>
<tr>
<td>‘Inappropriate’ Heparin Continuation</td>
</tr>
<tr>
<td>Heparin Already Held</td>
</tr>
<tr>
<td>Initiation of Alternative Anticoagulation for 4T &gt;3</td>
</tr>
</tbody>
</table>
Since our independent reviewer 4T scores were consistently lower than those entered by the treating providers even with the calculator in place the decision to leave initiation of alternative anticoagulation in patients with intermediate scores to the ordering provider still seems to be a reasonable choice. We believe that the lack of difference in 4T scores by reviewing and treating providers before the in-line calculator was due a small number of documented 4T scores which likely would only be achieved through a prospective study with enrollment and strict data collection. This would be outside the cost and scope of such a retrospective review and quality improvement project, but is certainly a limitation. Three main possibilities exist for differences in 4T scores after the calculator between our independent reviewers that are not mutually exclusive. Given initially positive findings, ‘click fatigue’ set in and ordering providers realized that any number entered would allow for ordering. The independent reviewer was more familiar with 4T review especially for categories such as ‘other causes of thrombocytopenia. Finally, reviewers were aware of HIT results at the time of review allowing for an element of bias.

Overall, we see that a screening HIT-A is still frequently ordered with a low 4T score, even if a 4T score needs to be entered. A possible intervention to improve this is to provide focused education to provider groups who most frequently order HIT-A testing. No outcome measures are worse and no harm seems to have come from this intervention. Furthermore, we also have no way to identify instances when a HIT-A may have been considered but was ultimately not ordered due to a low 4T. Hence, we may be underestimating the actual benefit.

Although some institutions have reported improvement in HIT-A test ordering with implementation of an integrated 4T score calculator, no such change was found at our institution.22-24 The negative results of our study provide an important balance against the small series saying that EMR-based interventions are a solution. Rather than target improvements by including a HIT calculator, other institutions have focused on educational improvements with success in reducing HIT-A orders. Ultimately, a quick click through screen may be insufficient to improve management and the education provided within the order window may be ignored amidst numerous other alerts in the EMR causing ‘alert fatigue’. The addition of education for in-hospital providers could have a more significant impact.

CONCLUSION

Immune-mediated HIT remains a rare entity with significant consequences if diagnosis is delayed or not obtained. While the methods for diagnosis, the importance of clinical suspicion, quantified by probability calculators, like the 4T score, remain paramount in assessing pre-test probability to guide further management decisions. While our study did not result in significant improvement in our system, in part because of the rarity of the condition, it highlights a continued area of needed research in this deadly disease. Additional quality improvement measures need to be made in the management of this potentially devastating clinical diagnosis. Continuing to combine systems-based improvement within the EMR, such as a refined order set, coupled with an increased focus on education to boost provider awareness could offer a long-term, sustainable solution.

References


IRB Approval
Our IRB approved the retrospective review and separately deemed the prospective intervention as quality improvement and therefore deemed this IRB exempt.

Disclaimer
The views expressed herein are those of the authors and do not necessarily reflect the views of Lifespan.

Disclosures
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Funding Source: None

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Serum Lactate is Not a Useful Predictor of Injury in Blunt Trauma Patients

TANEISHA WILSON, MD, ScM; GAGANDEEP SINGH, MD; REBECCA MENDELSOHN, MD; MICHAEL MELLO, MD, MPH; FRANCESCA L. BEAUDOIN, MD, PhD

Biomarkers can be used as adjuncts to clinical decision making in the Emergency Department (ED) (e.g., troponin or D-dimer levels). Serum lactate levels have been used in conjunction with clinical criteria to risk stratify and manage patients at risk of sepsis, and there has been an interest in establishing a similar role of acidosis (base deficit) and lactate levels in trauma care. Lactate predicts mortality in trauma and pre-hospital lactate may be beneficial in determining triage to trauma centers. However, it is unknown if lactate may be used as a surrogate marker for injury and whether it might be useful as a decision aid in determining which patients might benefit from whole body computed tomography (WBCT).

Injury detection in the trauma patient is of paramount importance as early detection and intervention decreases morbidity and mortality. Computed tomography (CT) imaging is one method used to identify the acute injury in blunt trauma patients. This modality is not without risk for the patient, and these risks include but are not limited to radiation exposure and increased costs. There have been multiple attempts to enhance this reduction in imaging with the development of clinical criteria. However, there remains some controversy surrounding both the development and execution of clinical criteria and determining who would benefit most from CT imaging based on these criteria.

Although some progress has been made in the decrease of radiation associated with CT, the risk of adverse effects from radiation is still present and is patently greater when using whole-body computed tomography (WBCT) than targeted imaging. We hypothesized that serum lactate elevation, a marker of anaerobic glycolysis and tissue hypo-perfusion, could be a marker for visceral or bony injury in ED trauma patients, and that lack of this elevation is correlated with negative WBCT.

We evaluated the sensitivity and specificity of elevated blood lactate in predicting patients who will have acute traumatic findings on WBCT. We conducted a retrospective electronic health record (EHR) review of ED visits and trauma team activations for blunt trauma during a one-year period from January 1, 2016–December 31, 2017. The study was conducted at a large, urban, academic Level-1 trauma center. Participants were adults who had both a serum lactate and WBCT imaging during their initial trauma evaluation (n=1035), WBCT and lactate are standard practice at the study institution for those with the highest level of trauma team activation, “Level A” (e.g., serious mechanism, unstable vital signs) and lower levels of trauma team activation with clinical suspicion for serious injury, “Level B or ‘C.”

Data were extracted electronically (e.g., demographics, laboratory values, WBCT). WBCT findings were categorized based on the presence of any acute intrathoracic, intrabdominal, intracranial injury or fracture based on the radiologist final interpretation. We calculated measures of association and receiver operating characteristic curve analysis between lactate levels and findings on CT.

Table 1 displays demographic and trauma characteristics for those with and without acute findings on WBCT. This population comprised 64.3% of those receiving WBCT compared to 35.7% of those with lower graded trauma, the majority of whom had positive findings on imaging 68.9%. Among those patients with a positive finding on WBCT mean lactate was 3.0 (SD ± 2.1) compared to a mean lactate of 2.5 (SD ± 2.2) among those a negative finding on WBCT (p=0.0047).

Although there was a significant difference between mean lactate levels in patients with and without positive WBCT findings (2.5 [SD ± 2.2] vs. 3.0 [SD ± 2.1]), we failed to identify a clinically useful cut-off that might indicate the need for advanced imaging. While levels >=2.5 were associated with the presence of acute injury, this value was neither sensitive nor specific in this population (46.3% and 66%, respectively) (Table 2). Figure 1 displays an ROC curve generated using the continuous values (0.4–17.1 mEq/L) for the lactate levels. The area under the curve (AUC) was 0.594 (95% CI: 0.55-0.63, Figure 1). Utilizing a higher cutoff (≥4 mEq/L) improved the specificity (87.6%), but also had poor utility as a screening with a sensitivity of 20.0% (+LR of 1.6, –LR of 0.91).

It should be noted that these findings may not generalize to other settings and populations. Additionally, we did not differentiate by severity of injury or injury scores (e.g., AIS, ISS). It is also notable that there was a high admission rate among patients with negative WBCT, likely indicated concomitant medical diagnoses. The presence of an acute medical conditions could confound the association between elevated lactates and injury findings on CT.
Though higher lactate levels are more specific for acute finding, the poor sensitivity makes this biomarker a weak-screening test for identifying ED trauma patients who may need imaging. There is still a need to identify other screening tests [e.g., biomarkers, clinical decision aids] to reduce unnecessary imaging. Unfortunately, these findings suggest that researchers and clinicians will need to look beyond lactate levels.

Table 1. Demographic characteristics of among those patients with negative and positive whole-body imaging.

<table>
<thead>
<tr>
<th></th>
<th>Negative WBCT</th>
<th>Positive WBCT</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age, m (± SD)</strong></td>
<td>53.4 (21.4)</td>
<td>53.5 (22.0)</td>
<td>0.9009</td>
</tr>
<tr>
<td><strong>Gender, n (%)</strong></td>
<td></td>
<td></td>
<td>0.086</td>
</tr>
<tr>
<td>Male</td>
<td>161 (63.6)</td>
<td>543 (69.4)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>92 (36.4)</td>
<td>239 (30.6)</td>
<td></td>
</tr>
<tr>
<td><strong>Race, n (%)</strong></td>
<td></td>
<td></td>
<td>0.806</td>
</tr>
<tr>
<td>White</td>
<td>200 (79.1)</td>
<td>607 (78.3)</td>
<td></td>
</tr>
<tr>
<td>Non-white</td>
<td>53 (21.0)</td>
<td>168 (21.9)</td>
<td></td>
</tr>
<tr>
<td><strong>Language, n (%)</strong></td>
<td></td>
<td></td>
<td>0.622</td>
</tr>
<tr>
<td>English</td>
<td>223 (88.1)</td>
<td>698 (89.3)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>30 (11.9)</td>
<td>84 (10.7)</td>
<td></td>
</tr>
<tr>
<td><strong>Trauma Level</strong></td>
<td></td>
<td></td>
<td>0.0001</td>
</tr>
<tr>
<td>Level A</td>
<td>129 (54.6)</td>
<td>487 (65.8)</td>
<td></td>
</tr>
<tr>
<td>Level B</td>
<td>26 (11.0)</td>
<td>98 (13.2)</td>
<td></td>
</tr>
<tr>
<td>Level C</td>
<td>81 (34.3)</td>
<td>155 (21.0)</td>
<td></td>
</tr>
<tr>
<td><strong>Trauma Type</strong></td>
<td></td>
<td></td>
<td>0.001</td>
</tr>
<tr>
<td>MVC</td>
<td>61 (24.2)</td>
<td>285 (36.5)</td>
<td></td>
</tr>
<tr>
<td>Fall</td>
<td>142 (56.4)</td>
<td>345 (44.1)</td>
<td></td>
</tr>
<tr>
<td>Assault</td>
<td>7 (2.8)</td>
<td>36 (4.6)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>42 (16.7)</td>
<td>116 (14.8)</td>
<td></td>
</tr>
<tr>
<td><strong>Disposition, n (%)</strong></td>
<td></td>
<td></td>
<td>0.0001</td>
</tr>
<tr>
<td>Admitted</td>
<td>88 (35.3)</td>
<td>54 (6.9)</td>
<td></td>
</tr>
<tr>
<td>Discharged</td>
<td>161 (64.7)</td>
<td>725 (93.1)</td>
<td></td>
</tr>
<tr>
<td><strong>Lactate (mEq/L, m (± SD)</strong></td>
<td>2.5 (2.2)</td>
<td>3.0 (2.1)</td>
<td>0.0047</td>
</tr>
</tbody>
</table>

WBCT = Whole Body Computed Tomography
SD = standard deviation
MVC = motor vehicle collision
Trauma level: A = most severe criteria of injury, B = moderate, C = least severe

Table 2. Whole-body computed tomography findings (WBCT) and versus dichotomous lactate levels with associated test performance characteristics.

<table>
<thead>
<tr>
<th></th>
<th>Lactate + (&lt;2.5mEq/L)</th>
<th>Lactate – (≥2.5mEq/L)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>WBCT+</td>
<td>362</td>
<td>420</td>
<td>782</td>
</tr>
<tr>
<td>WBCT–</td>
<td>86</td>
<td>167</td>
<td>253</td>
</tr>
<tr>
<td>Total</td>
<td>448</td>
<td>587</td>
<td>1035</td>
</tr>
</tbody>
</table>

Sensitivity=46.3 Specificity= 66

Figure 1. Receiver operating characteristic (ROC) curve of continuous values of lactate levels among patients with negative and positive whole-body computed tomography.

References


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

<table>
<thead>
<tr>
<th>VITAL EVENTS</th>
<th>REPORTING PERIOD</th>
<th>APRIL 2020</th>
<th>12 MONTHS ENDING WITH APRIL 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>Number</td>
<td>Rates</td>
</tr>
<tr>
<td>Live Births</td>
<td>913</td>
<td>11,217</td>
<td>10.6*</td>
</tr>
<tr>
<td>Deaths</td>
<td>1189</td>
<td>10,907</td>
<td>10.3*</td>
</tr>
<tr>
<td>Infant Deaths</td>
<td>3</td>
<td>58</td>
<td>5.2#</td>
</tr>
<tr>
<td>Neonatal Deaths</td>
<td>2</td>
<td>44</td>
<td>3.9#</td>
</tr>
<tr>
<td>Marriages</td>
<td>105</td>
<td>6,322</td>
<td>6.0*</td>
</tr>
<tr>
<td>Divorces</td>
<td>120</td>
<td>2,726</td>
<td>2.6*</td>
</tr>
</tbody>
</table>

* Rates per 1,000 estimated population
# Rates per 1,000 live births

<table>
<thead>
<tr>
<th>Underlying Cause of Death Category</th>
<th>REPORTING PERIOD</th>
<th>OCTOBER 2019</th>
<th>12 MONTHS ENDING WITH OCTOBER 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number (a)</td>
<td>Number (a)</td>
<td>Rates (b)</td>
</tr>
<tr>
<td>Diseases of the Heart</td>
<td>199</td>
<td>2,481</td>
<td>234.2</td>
</tr>
<tr>
<td>Malignant Neoplasms</td>
<td>190</td>
<td>2,252</td>
<td>212.6</td>
</tr>
<tr>
<td>Cerebrovascular Disease</td>
<td>36</td>
<td>469</td>
<td>44.3</td>
</tr>
<tr>
<td>Injuries (Accident/Suicide/Homicide)</td>
<td>77</td>
<td>906</td>
<td>85.5</td>
</tr>
<tr>
<td>COPD</td>
<td>28</td>
<td>491</td>
<td>46.3</td>
</tr>
</tbody>
</table>

(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 1,059,361 for 2019 (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.
It’s a new day.

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

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The biweekly e-newsletter exclusively for RIMS members.

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Informative.

Respectful of your time.

RIMS NOTES is published electronically on alternate Fridays.

Contact Dulce Cosme if you’ve missed an issue, dcosme@rimed.org.
Working for You: RIMS advocacy activities

September 1, Tuesday
RIMS Physician Health Committee: Herbert Rakatansky, MD, Chair (via teleconference)

September 8, Tuesday
Governor’s Overdose Taskforce, Harm Reduction Work Group (via teleconference)
AMA Advocacy Resource Center (ARC) monthly call regarding physician health programs

September 9, Wednesday
Board of Medical Licensure and Discipline Governor’s Overdose prevention and intervention Task Force: Sarah Fessler, MD, Past president

September 10, Thursday
Office of the Health Insurance Commissioner (OHIC) Telemedicine Advisory Group, Peter Hollmann, MD

September 14, Monday
Mental Health Association Parity Initiative via teleconference
RIMS Board of Directors Meeting, Peter Hollmann, MD, Chair

September 15, Tuesday
OHIC Health Insurance Advisory Committee

September 16, Wednesday
Department of Health (DOH) Primary Care Physician Advisory Committee (PCPAC), Elizabeth Lange, MD, RIMS President-elect

September 18, Friday
Diabetes Health Equity Challenge Leaning Collaborative

September 21, Monday
RIMS and Blue Cross BlueShield of Rhode Island (BCBSRI) Monthly Meeting, Catherine Cummings, MD, President (via teleconference)
Council of New England State Medical Societies/New England Delegation to the American Medical Association (CNESMS/NED) meeting, Peter Hollmann, MD, Senior Delegate; Alyn Adrain, MD, Delegate; Sarah Fessler, MD, Alternate Delegate; Catherine Cummings, MD, President

September 23, Wednesday
Diabetes Prevention Programs (DPP) Stakeholder Network meeting
Pfizer webinar on COVID-19 vaccine development (via teleconference)
DOH Health Professional Loan Repayment Board, Steve DeToy, Director of Government and Public Affairs, Member

September 24, Thursday
OHIC Telemedicine Advisory Group, Peter Hollmann, MD

September 28, Monday
Meeting with Alpert Medical School at Brown University regarding Continuing Medical Education (CME), Christine Brousseau, MD, Immediate past president; Patrick Sweeney, MD, CME Committee Chair
The Rhode Island Medical Society continues to drive forward into the future with the implementation of various new programs. As such, RIMS is expanded its Affinity Program to allow for more of our colleagues in healthcare and related business to work with our membership. RIMS thanks these participants for their support of our membership.

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

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.

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

In 2020 to date, more than 14,000 readers from more than 110 countries have read articles in the Rhode Island Medical Journal (RIMJ) or researched its archives. More than 7,500 others have accessed full-text pdfs via the PubMed Linkout feature.

Top 10 countries in September 2020:
1. US
2. Australia
3. Canada
4. UK
5. India
6. United Arab Emirates
7. Italy
8. Brazil
9. France
10. Japan

MARIN COUNTY, CALIFORNIA

[Left] Orthopedic surgeon Andrew Goldstein, MD, takes a break from playing the electronic saxophone outdoors with a physician friend socially distanced, to view the September Sports Medicine themed issue of the Rhode Island Medical Journal. Dr. Goldstein, shown here in Marin County, CA, is an East Coast native who graduated from the New Jersey Medical School, did an internship at Albert Einstein–Montefiore Medical Center and returned to New Jersey for his residency and orthopedic fellowship.

[Above] RIMJ Managing editor Mary Korr, accesses RIMJ articles on PubMed while socially distancing at the fitness center reopening.

Wherever you happen to be social distancing, visit the Journal on your mobile device, and send us a photo: mkorr@rimed.org.
URI Professor Gretchen Macht’s $700,000 grant project seeks to improve the in-person voting experience amid COVID-19

Project will enable researchers to examine voting process layouts to ensure public health safety and enhance efficiency

The project will explore the implications of designing voting processes, meant to mitigate COVID-19, at certain voting facilities across the country including Rhode Island, Michigan and Los Angeles County.

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Q & A with Christine Montross, MD, author of Waiting for an Echo: The Madness of Incarceration

MARY KORR
RIMJ MANAGING EDITOR

Author **CHRISTINE MONTROSS, MD**, an inpatient psychiatrist who also performs forensic psychiatric examinations, recently published her third book, Waiting for an Echo. It examines the fractured American incarceration system and the human suffering it generates, when individuals with mental illness – her patients – wind up in the nation’s jails rather than in therapeutic settings. In the book she describes harrowing visits to prisons, cauldrons of human suffering where mental illness deteriorates, despite the best intentions of often over-extended correctional staff and healthcare providers.

Dr. Montross asks the fundamental question: Why? And in the asking, the book seeks a path towards a greater humanitarian approach and the need for healthcare professionals to speak out. As the book states, “Our methods of incarceration take away not only freedom, but also selfhood and soundness of mind. In a nation where ninety-five percent of all inmates are released from prison and return to our communities, this is a practice that punishes us all.”

RIMJ reached out to Dr. Montross to discuss her literary/medical career trajectory and her journey into the prison system, the genesis of Waiting for an Echo.

**RIMJ:** What factors/experiences led you to your chosen field of psychiatry?
**DR. MONTROSS:** I have always been fascinated by the ways in which the mind can derail. I was a poet before I went to medical school, and for my MFA thesis in poetry I wrote a series of poems about madness. After graduate school I took a job in California teaching high school English. A large number of my students had been expelled from other public schools. Nearly all of them had profound psychosocial stressors, and many of them were prescribed psychiatric medications. It was working with those kids that led me to think about a career in mental health. I considered training as a social worker, or as a psychologist, but decided that if I wanted to be an educated voice that could speak to the complexities of the brain’s neurochemistry and make a cogent argument for or against medication when I believed a patient did or didn’t need it, I’d first need to learn anatomy and pharmacology. I’d have to go to medical school.

**RIMJ:** What did the research process in writing Waiting for an Echo entail?
**DR. MONTROSS:** This was a trajectory. I began by educating myself about prisons and about some of the seminal cases and issues at the intersection of psychiatry and the legal system. I read stacks and stacks of books and articles to that end. I also took an adjunct position in the wonderful department of Law and Psychiatry at Yale and took the train down to New Haven many Fridays to participate in their departmental seminars. Listening to expert clinician-scholars discussing big questions in forensic psychiatry turned out to be a foundational part of the book’s research process. And then my research turned experiential. I visited jails and prisons both in America and in Scandinavia to examine different approaches to corrections. I also began performing competency to stand trial evaluations in jails and prisons, and that firsthand experience of talking to incarcerated men and women was invaluable.
As a medical practitioner, how did you find the time to research and write this book?

**DR. MONTROSS:** I was a writer before I was a doctor. So from the first moment that I decided to go to medical school I’ve been clear about the fact that I wanted to be a doctor and a writer. To do that, I’ve had to purposefully structure my career in a way that prioritizes both aims. I’ve chosen clinical roles that I find deeply meaningful – but which also must be flexible enough to allow me to be as committed to writing as I am to my medical practice.

**RIMJ:** What was the most surprising revelation for you in writing the book, despite your years of working with people with mental health issues?

**DR. MONTROSS:** My clinical work is with hospitalized patients who have severe mental illness. Many of them come into contact with law enforcement, often due to their symptoms rather than any criminal intent. They yell at their hallucinations in the coffee shop, or they charge through the TSA checkpoint at the airport, or they believe they can walk down the center of the highway unharmed. In these moments the police are called. I was shocked to see how decisions in the moment of the police encounter can alter the trajectories of my patients’ lives. If police opt to take my patients to the hospital, there is a possibility they will be admitted and will receive treatment and care. But if mentally ill people in crisis are taken to jail, their symptoms are likely to make it difficult for them to comply with rules that must be obeyed. This sets them up to incur further punishment, and often additional legal charges. In addition, people with mental illness are sixteen times more likely to be killed by police than people who are mentally well. We do not send police to be the front lines of cardiovascular emergencies or vehicular traumas. We send EMTs, trained to appropriately intervene. We ought to treat psychiatric emergencies similarly. As physicians, we must speak out against this, and work to shift our patients out from under the auspices of law enforcement and back into the realm of health care.

**RIMJ:** Author talks have switched to Zoom and other online platforms for the moment. In these virtual sessions, the viewer gets a glimpse of the literary and family life of the writer. What is on your bookshelf?

**DR. MONTROSS:** My whole house is full of bookshelves! But I do have a shelf reserved for books that changed me or changed the way I think about the world. Some of what you’d see there: *Their Eyes Were Watching God* by Zora Neale Hurston, *The Argonauts* by Maggie Nelson, *Middlemarch* by George Eliot, *Atlantis* by Mark Doty, *Unless* by Carol Shields, *Anger and Forgiveness* by Martha Nussbaum, and *Pilgrim at Tinker Creek* by Annie Dillard.

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**Book Excerpts: Waiting for an Echo**


I once toured Manson Youth Institution, a high-security prison in Connecticut for fourteen- to twenty-year-old boys. On the tour I was led through one of the prison housing units, which, despite looking like typical cellblocks, are euphemistically referred to as “cottages.”

As we walked through the hallways, we passed one cell in which a boy was alone, standing on his toilet, neck craned, stretching his face toward the ceiling and talking out loud at full speed. I said nothing, assuming that the boy was mentally ill. After all, I frequently see actively hallucinating patients who are in conversation with visions that no one else can see or voices that no one else can hear. “Responding to internal stimuli” is the notation I make in the chart to record that my patient remains tethered to these perceptual abnormalities of psychosis.

Down the hallway we then passed another boy in another cell in the exact same position, doing the exact same thing, at which point I knew that the conclusion I had come to was wrong. Though I’ve seen an incalculable number of patients in the throes of psychosis, I have never seen the symptoms of mental illness manifest themselves identically in different people.

“Why are they standing on their toilets?” I asked the CO.
“It’s a big problem,” he said. “They figured out that they can talk to each other through the vents. It’s loud in here, and also they get in trouble if they’re shouting out their cell doors, so that’s the only way they’ve got to talk to each other. They climb on their toilets to get up near the vents, and then they have whole conversations that way.”

More than any other scenario that I’ve encountered in my career as a psychiatrist, this moment has stood out for me as incontrovertible evidence of the fundamental need for connection within us all. These boys on their toilets embodied the lengths of discomfort and risk and innovation that human beings will go to in order to reach out to another. To hear from another. To be heard by another. To wait for an echo. These are children in a critical period of neurodevelopment, in extraordinary circumstances, trying desperately not to go through it all alone.

It is disingenuous for us to imagine that the harsh environments in which we house imprisoned men, women, and children do not damage them. And it is unwise for us to ignore that damaging our imprisoned citizens undermines our communities more broadly.

...The aim of this book—its only aim—is to look closely at the psychiatric effects of American punishment and ask whether the results we yield align with the societal standards to which we hold ourselves and with the goals we set out to achieve. This is a question with enormous stakes for all of us—free and imprisoned alike.

We say that we incarcerate people in America because we want safer communities and justice, yet our current practices provide neither. Our practices are antithetical to these aims. My years of study of the human mind underscore this fact: when we condemn our citizens to the punitive conditions of our jails and prisons, we sentence those men and women and children not only to time but to a life in which they are less able to engage productively with society and less likely to demonstrate accountability for their actions. As a nation we say we want safety and justice, but our methods of punishment actively obstruct these very goals. And yet we double down on our current practices. Why?

The third part of this book, therefore, is about the choices that face us. If we look objectively at our prisoners and our prisons and determine that our current practices are failing us, then what are we to do about it?

...This book shares what I have come to know, as a psychiatrist, about our nation’s corrections system. “The degree of civilization in a society can be judged by entering its prisons,” Fyodor Dostoyevsky wrote more than a century ago. This book is about the choices we make in our society about safety and justice. It is about how we mistreat those who run afoul of our laws and how, in doing so, we violate our own standards of humanity. It is also about hope, and vision, and trust that once a problem is faced—truly faced—then perhaps it can be solved. ✤
October 1963: President Kennedy signs Community Mental Health Act into law; his last legislative signature

MARY KORR
RIMJ MANAGING EDITOR

The March 1963 issue of the Rhode Island Medical Journal published a summary from the American Medical Association on a multi-million dollar program President John F. Kennedy proposed to Congress to combat mental illness. It called for the establishment of hundreds of community health centers and services to research and address the needs of those with mental health issues and developmental disabilities, to be financed by federal and state or local governments. Congress was asked to appropriate $31.3 million in fiscal 1964 for the program.

According to the summary, President Kennedy listed three objectives:

1. Determining the causes of mental illness and finding effective treatments for them
2. Research and training of skilled personnel
3. Strengthening and improvement of programs and facilities for treating the mentally afflicted

“This approach is designed, in large measure, to use federal resources to stimulate state, local and private action,” President Kennedy said. “When carried out, reliance on the cold mercy of custodial isolation will be supplanted by the open warmth of community concern and capability. Emphasis on prevention, treatment and rehabilitation will be substituted for a desultory interest in confining patients in an institution to wither away.”

The President asked for prompt Congressional approval of legislation that would authorize grants to the states beginning in fiscal 1965 for establishment of comprehensive community mental health centers with the federal government providing from 45 to 75 percent of the project costs and short-term grants for initial staffing costs. The federal government would provide

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“Emphasis on prevention, treatment and rehabilitation will be substituted for a desultory interest in confining patients in an institution to wither away.”

— President Kennedy
up to 75 percent of operation costs in early months and phase out such support in about four years.

In addition, the summary reported, the Kennedy Administration’s budget for fiscal 1964 calls for increases for all activities of the National Institutes of Health with a boost of nearly 50 percent, to $166 million, for mental health work.

The estimated expenditures in the new budget for medical research through the NIH totaled $850 million.

On October 31, 1963, he would sign the legislation, known as the Community Mental Health Act, into law. The law was a start and much work needs to be done to fulfill President Kennedy’s vision 57 years ago.

It was the last piece of legislation he signed; three weeks later he was assassinated, on November 22, 1963 in Dallas, Texas. 
Lifespan and Care New England move forward with Letter of Intent to merge

Lifespan and Care New England have moved to the next step in their affiliation process.

LAWRENCE A. AUBIN, SR., board chair of Lifespan, and CHARLES R. REPPUCCI, board chair for Care New England, announced that both boards voted September 8th to move forward with a letter of intent to merge Lifespan and Care New England into a single entity.

The combined system would create a Rhode Island-based, nonprofit academic medical center with Brown University. The new system would include seven hospitals offering a full complement of specialty, women’s and children’s, and behavioral health, and visiting nurse services, research, and education. More than 23,500 employees would serve the people of Rhode Island and Southeastern New England, from prenatal care and delivery to elder care. The two organizations had collaborated on several initiatives related to the current pandemic. In early June, they announced their intent to study a more formal partnership.

“This affiliation will help build an even stronger future for our organizations while maintaining a strong commitment to Rhode Island and southeastern Massachusetts. We look forward to continuing this collaboration, sharing additional details about our vision for health care delivery as we begin the regulatory process,” said Charles R. Reppucci.

“By combining the talent, experience and resources of our two organizations, we can create a national model that fully leverages the integration and coordination of care. In doing so, we are better equipped to meet market challenges and mandates to improve outcomes while reducing health care costs,” said Lawrence A. Aubin, Sr.

“By working together, Lifespan, Care New England, and Brown University can create a fully integrated academic healthcare system for the people of Rhode Island,” said Lifespan president and CEO TIMOTHY J. BABINEAU, MD.

“Combining our investment in our physicians, clinical staff, researchers, technology and other health care staff will greatly help us continue to fulfill our mission of providing world-class health care to our patients, advancing medical discoveries and serving as a vital economic engine for our state.”

“A unified academic medical center with Brown University, Lifespan, and Care New England has always been the best solution for health care in Rhode Island,” said CHRISTINA H. PAXSON, president of Brown University. “I could not be more thrilled with this announcement. Capitalizing on the complementary strengths of our health care institutions with Brown University will make it possible to provide high-quality low-cost health care, attract and retain the best physicians, and grow our research enterprise while powering the Rhode Island economy.”

Lifespan/Brown form COVID-19 Biobank at RIH Clinical Research Center

Lifespan and Brown-based Advance Clinical and Translational Research [Advance-CTR] have established a COVID-19 Biobank, housed at Rhode Island Hospital’s Clinical Research Center, to facilitate research in Rhode Island. The Biobank, formed in May, includes the following samples:

- Plasma (0.5mLs)
- LI plasma (0.5mLs)
- Serum (0.5mLs)
- PBMCs (0.25mLs / ~2.5M cells)

Demographic data is available for each sample, as well as medical history and COVID-19 clinical actions.

A multi-institutional committee composed of representatives from Brown, the University of Rhode Island, Lifespan, Care New England, and the Providence VA Medical Center will review requests on a rolling basis.

All investigators at degree-granting institutions in Rhode Island are eligible to request access to COVID-19 specimens. For sample distribution, an IRB approval or exempt letter from an institution is required. If the researcher is not affiliated with Lifespan, data requests and sharing of specimens will require a Material Transfer Agreement (MTA) or Data Use Agreement (DUA), as applicable. Institutional Authorization Agreements (IAAs) must be established between non-Lifespan investigators’ home institutions and Lifespan. Investigators are required to cite Advance-CTR on any grants, publications, presentations and/or other products that result from access to the COVID-19 Biobank.

For more information, contact AdvanceRI@brown.edu. Website: https://www.brown.edu/initiatives/translational-research/covid-19-biobank
Rhode Island Hospital authors publish study on health disparities and influenza in Rhode Island

Study reveals differences in infection rates, hospitalization rates, based on measures of socioeconomic status

PROVIDENCE – Public Health Reports has published a study co-authored by Rhode Island Hospital Medical Director of Epidemiology and Infection Control and Brown University Professor of Medicine LEONARD A. MERMEL, DO, ScM, along with KORI OTERO, MPH, a recent graduate of The School of Public Health at Brown University.

The study, “Health Disparities Among People Infected with Influenza,” assessed Rhode Islanders with documented influenza during four respiratory virus seasons (Fall 2013 through Spring 2018) in Rhode Island to determine if health disparities were associated with risk of getting influenza, and if such disparities impacted the likelihood of severe disease manifested by a need for hospitalization. To address this issue, the authors measured median household income and educational level of influenza-infected patients.

Among the findings, there was a significantly greater number of confirmed influenza cases per 100,000 person-years in populations with low versus high median household income. Greater numbers were also documented in populations with low versus high educational attainment. Further, the risk of a severe influenza infection was significantly greater in the population with the lowest educational attainment. However, an unexpected finding was that the risk of severe influenza was also associated with a higher median household income.

Dr. Mermel notes that, “Our hypothesis was that we would find health disparities related to risk of influenza. This may be due to a lower access to primary care, less time available to receive influenza vaccination, and crowding living conditions.”

“This finding may help to focus public health interventions in Rhode Island and elsewhere,” said Otero.

Lifespan’s own Community Health Institute (LCHI) serves as a “community immunizer” in an effort to overcome possible issues of access to flu vaccine, targeting adults who are medically fragile, uninsured, without a medical home, isolated or without transportation. In the 2019–2020 flu season, its clinics provided immunizations to 844 adults, with numbers climbing each year since 2015. Clinics are currently being scheduled for Fall 2020, and community and faith-based organizations are invited to partner with the LCHI to host a flu clinic by calling 401-444-8063 or emailing mstepanian@lifespan.org.

The unexpected finding of increased hospitalization associated with higher household income may reflect a greater proportion of older adults in the higher socioeconomic groups, says Dr. Mermel, as well a possible intrinsic bias leading to a greater likelihood of hospitalization among people with higher socioeconomic status than among people with lower socioeconomic status.

“This study presaged some of the events occurring today with COVID-19, as health disparities remain a top-of-mind issue in addressing the needs of all Americans.”

URI Community First Responder Program offers free Narcan and training to rural Rhode Islanders to prevent overdose deaths

SOUTH KINGSTOWN – The Rhode Island Department of Health estimates that 308 Rhode Islanders died of an opioid-related overdose in 2019 and the first quarter of 2020 has seen a 22% increase in overdose deaths compared with the first quarter of 2019.

In an effort to combat this crisis, specifically in rural communities around the state, the University of Rhode Island launched the Community First Responder Program (CFRP), which offers free online learning modules on how to administer the life-saving medicine naloxone (Narcan). To see the free education and resources offered, visit uri.edu/cfrp/

CME credits
The program also offers separate resources specifically for healthcare professionals licensed in Rhode Island, including providers, pharmacists, nurses, social workers, and mental health counselors. These professionals can earn free continuing education credits through the interactive, educational modules on naloxone, telehealth, medications for opioid use disorder and laws related to opioid prescribing/dispensing.

In addition, the CFRP has begun reaching out to Rhode Island schools, community organizations and businesses that may benefit from knowing how to recognize and respond to an opioid-related breathing emergency. If an organization wants to train a group of people, the CFRP team is ready to conduct 45-minute live group seminars over video conferencing. Schools, community organizations, or workplaces that want to help combat the opioid crisis can schedule a Webex seminar for groups by submitting a request on URI CFRP’s website: uri.edu/cfrp/
Lifespan mounts public campaign to promote federal efforts to recruit volunteers for essential COVID-19 vaccine trials

*Immunology Center at The Miriam Hospital is encouraging volunteers to visit National Institutes of Health registry and is awaiting selection as a vaccine trial site*

**PROVIDENCE** – Lifespan has joined the COVID-19 Prevention Network – an initiative of the National Institute of Allergy and Infectious Diseases – and is actively supporting federal efforts to develop a vaccine for COVID-19 by helping to identify participants for vital clinical trials. This week Lifespan is kicking off a local campaign to promote the COVID-19 Prevention Network’s Volunteer Screening Registry statewide.

Lifespan is spearheading this public effort through The Immunology Center at The Miriam Hospital, which has a long and successful track record of participating in major clinical trials, including drugs for HIV and hepatitis C. More recently, it was among one of the most active sites in the world testing the use of remdesivir to treat COVID-19 patients.

Lifespan has created a website – www.lifespan.org/covidvax – that links to the COVID-19 Prevention Network (CoVPN)’s registry, where those interested in participating in clinical trials for a vaccine may sign up to volunteer in a local trial should one become available. Lifespan has also launched a digital campaign on social media platforms to raise awareness of the registry, which was launched by the National Institutes of Health.

The Immunology Center at The Miriam Hospital is awaiting selection as a COVID-19 vaccine trial site. Lifespan encourages those who are interested in being part of a future study to visit www.lifespan.org/covidvax and complete the CoVPN Volunteer Screening Registry survey using the code “LIFE.”

“Lifespan remains committed to making a healthcare impact that can be felt on a local, national and international level. This commitment is evidenced not only by the more than one-thousand COVID-19 patients we have cared for, but is also exhibited in our willingness to take the lead in the coordination of an effective statewide response to the spread of the virus. And while our efforts thus far have helped position Rhode Island to be among the nation’s best sites at limiting the spread of COVID-19, we will continue to leverage our clinical and scientific expertise to meet this moment. Lifespan’s involvement with the registry is one more way that we can make a national impact, said **Michael Henderson**, Vice President for Research for Lifespan. “We strongly encourage those who wish to join the fight against COVID-19 to please consider volunteering for a trial and signing up through the CoVPN registry.”

The CoVPN Volunteer Screening Registry was established by the National Institute of Allergy and Infectious Diseases, which is part of the National Institutes of Health (NIH). The registry is part of the federal government’s initiative, “Operation Warp Speed,” to undertake a public-private effort to accelerate the development, manufacturing and distribution of COVID-19 vaccines.

Funding for Lifespan’s public campaign comes from a $250,000 grant that The Miriam Hospital obtained from NIAID for COVID-19 emergency response efforts, including CoVPN support. It is being led by infectious diseases physician **Karen Tashima, MD**, director of clinical trials at The Immunology Center and clinical research site leader for The Miriam Hospital, a research site of the Harvard/Boston/Providence AIDS Clinical Trials Group.

Dr. Tashima helped oversee the enrollment at Lifespan of nearly 200 patients in the remdesivir study, which was conducted under the auspices of a Food and Drug Administration emergency use authorization and part of an international study sponsored by drug maker Gilead Sciences, Inc.

“Clinical trials are essential for identifying therapies that can prevent and treat disease and volunteers play a critical role when it comes to developing vaccines to rapidly respond to dangerous pandemics,” Dr. Tashima said. “We appreciate the selfless contribution of volunteers for these trials and encourage anyone who would like to participate to go to our website and volunteer at the registry. Don’t forget to enter “LIFE” when prompted for a code, that will flag you as a candidate for a clinical trial at Lifespan, which we hope will happen soon.”
Appointments

Shannon Sullivan, MSW, LICSW, CCM, named President and COO of Women & Infants Hospital

PROVIDENCE – Care New England has appointed SHANNON SULLIVAN, MSW, LICSW, CCM, as President and COO, Women & Infants Hospital. Sullivan had been serving as interim COO since June 1, 2020.

Sullivan has been employed with Care New England in various roles, since 2002. She began her career at Women & Infants Hospital as a clinical social worker, eventually working her way up to Director of Patient and Family Support Services, and later as System Director, Care Management. In 2018, Sullivan was appointed Executive Director of Care Coordination and Chief Access officer, and shortly thereafter, named Vice President of Operations at Kent Hospital. In 2019, Sullivan was named interim COO, Women & Infants Hospital.

In early 2020, Shannon oversaw the construction of field hospitals as the state battled the COVID-19 pandemic.

“It is my honor and privilege to accept this role and lead the region’s premier hospital for woman’s and infant health. Women & Infants Hospital has a pivotal role in improving the health outcomes of our diverse community and there is nothing I take more seriously than assuring that Women & Infants remains a national leader in exceptional clinical care, cutting edge research and Ivy League academics, while providing personalized patient- centered care. As a woman who had my own children here, this position is not only a professional privilege but a personal honor,” said Sullivan.

She has an Executive Master’s degree in Healthcare Leadership from Brown University [2021], and attended Boston College for Master’s degree in Social Work [2002]. Previously, she attended Providence College [1996–2000], where she earned her Bachelor’s degree in Social Work.

Rhode Island Hospital names senior vice president & chief nursing officer

PROVIDENCE – CYNTHIA DANNER, DNP, RN, NE-BC, has joined Lifespan as senior vice president and chief nursing officer at Rhode Island Hospital.

She comes to Providence from Northeast Georgia Medical Center [NGMC], a Level II trauma center and the 600-bed flagship hospital for the Northeast Georgia Health System. As associate chief nursing officer, she was responsible for acute care services, trauma, mother/ baby, pediatrics, intermediate care, and ambulatory care.

“We are thrilled to welcome Cynthia to Rhode Island Hospital and to Lifespan,” said hospital president John B. Murphy, MD. “A seasoned nursing executive like Cynthia will contribute greatly to our management team here at the state’s largest and busiest hospital.”

Cynthia was a senior member of NGMC’s system-wide COVID-19 contingency action team, tasked with expanding acute virus patient capacity, redefining medical-surgical nursing staff, creating and refining new protocols, and identifying and mitigating PPE shortages.

To respond to a doubling in ICU admissions, Cynthia helped operationalize a “Pandemic Partner” approach at Northeast Georgia Medical Center, pairing critical care and medical surgical nurses into teams to effectively manage the patient population.

Among her other accomplishments at NGMC, she championed an initiative to create an Endocrinology Center of Excellence to provide comprehensive diabetic care, served on a task force charged with developing a strategic plan for a comprehensive neurosciences program, and spearheaded a system-wide initiative to improve patient experience and nurse communication.

Cynthia’s more than 20 years of leadership experience in teaching and academic medical centers includes serving as interim chief nursing officer for Northeast Georgia Medical Center – Braselton, and a decade as nurse administrator for Mayo Clinic Florida, where she was one of five members of the steering committee that guided the effort to achieve Magnet designation in 2015, a prestigious nursing accolade.

Cynthia earned her bachelor of science degree in nursing at Old Dominion University, Norfolk, Virginia, followed by a master of science in nursing at University of Phoenix, Jacksonville, Florida. She received her doctor of nursing practice degree from University of North Florida, Jacksonville.

She is a member of the American Organization for Nursing Leadership, the American College of Healthcare Executives, and Sigma Theta Tau, and sits on the Medical Advisory Board of Sharps Technology Inc.

Peter Soden, MD, joins Brown Surgical Associates

PROVIDENCE – Brown Surgical Associates recently announced DR. PETER SODEN joined its Division of Vascular & Endovascular Surgery on September 1.

Dr. Soden’s clinical interests include carotid, aortic, and peripheral arterial disease, as well as venous disease.

He recently completed a two-year fellowship in vascular surgery at Beth Israel Deaconess Medical Center in Boston, where he also completed his surgical residency. He holds an undergraduate degree from Middlebury College in Vermont and an MD from Harvard Medical School.

Peter Soden, MD, joins Brown Surgical Associates
Appointments

Eilean Attwood, MD, MPH, appointed to ACOG leadership roles

EILEAN ATTWOOD, MD, MPH, an Assistant Professor of Obstetrics and Gynecology, Clinician Educator at the Alpert Medical School of Brown University, has been appointed to two national leadership roles, as Chair, American College of Obstetrics and Gynecology (ACOG) Private Payer Advocacy Presidential Workgroup, and advisor, ACOG Relative Value Scale Update Committee.

Dr. Attwood is a women’s health provider working in Women & Infants Hospital’s Emergency Department and other inpatient Ob/Gyn services.

She earned a master’s degree in public health from the University of Massachusetts in 2019 and her medical degree from The University of Texas Health Science Center in 2009.

She has a special interest in improving health care delivery and health economics and is actively involved with the American College of Obstetricians and Gynecologists to promote these goals for her patients and specialty.

Aaron M. Hattaway, MD, named CMO, VP of South County Medical Group

AARON M. HATTAWAY, MD, MBA, has joined South County Health’s Senior Leadership Team as Chief Medical Officer and Vice President of South County Medical Group. He is board-certified in diagnostic radiology with 15 years of clinical and progressive physician leadership.

Dr. Hattaway brings a proven track record to South County Health, with extensive healthcare administration experience as Medical Staff President, Chairman of Quality, and Medical Director of Radiology at Cape Canaveral Hospital, a 150-bed acute care hospital in Cape Canaveral, FL.

Dr. Hattaway served as a key officer of Brevard Physician Associates, a 100-physician, multi-specialty group in Brevard County, FL where he orchestrated the financial and business integration of six medical practices into one new multi-specialty practice, as well as unifying two separate radiology practices as a single, successful entity.

He received his medical degree from Emory University School of Medicine in Atlanta, GA. After completing an internship in Internal Medicine at Medical College of Virginia, he completed a residency in Diagnostic and Interventional Radiology at Indiana University School of Medicine.

He also received a Master’s of Business Administration in Business of Medicine from Indiana University, Kelley School of Business.

Melvin Philip, MD, joins Lifespan Physician Group Primary Care

NEWPORT — MELVIN PHILIP, MD, has joined Lifespan Physician Group Primary Care in Newport.

He is board-certified in internal medicine and has additional specialty training in palliative and hospice care. He is accepting all patients.

Dr. Philip received his medical degree from Ross University School of Medicine, Bridgetown, Barbados and completed his residency in internal medicine and primary care. He was named Resident of the Year at the Connecticut Institute for Communities, Danbury Hospital. He went on to complete his fellowship at Weill Cornell Medicine in palliative and hospice care, New York Presbyterian Hospital, Queens.

He is a member of the American College of Physicians and the American Academy of Hospice and Palliative Medicine.

Recognition

Betty Vohr, MD, receives 2020 Virginia Apgar Award

BETTY VOHR, MD, FAAP, Professor of Pediatrics at the Alpert Medical School and a neonatologist at Women & Infants Hospital, is the 2020 Virginia Apgar Award recipient.

The award represents the highest honor that the American Academy of Pediatrics Section on Neonatal-Perinatal Medicine bestows to an individual whose cumulative career accomplishments have had a profound and continuing influence on the well-being of neonates.

Dr. Vohr is a pioneer in efforts to aid infants and children with hearing loss, especially high-risk infants. Her work in Rhode Island helped pave the way for national newborn hearing screening. She is Director of the Neonatal Follow-up Clinic at Women & Infants and Medical Director of the Rhode Island Hearing Assessment Program.
**Obituaries**

**JAY ALAN SORGMAN, MD**, of Norton, MA, formerly of Brockton, MA, passed away peacefully with friends and family by his side on September 5, 2020.

Jay was born on March 30, 1961 as the second of three sons, to his parents Stanley and Elinor Sorgman. Growing up in Brockton, MA, Jay displayed a love of learning as a young boy and began reading before the age of 3. At six years old he wrote a book on dinosaurs, using a manual typewriter, which he was already proficient with. At seven years old, he confused his mother by explaining that he was reading the dictionary because he liked the etymology of words. At eight years old, he could often be found in his room, rain or shine, reading the Encyclopedia Britannica.

After graduating from Brockton High School in 1979, Jay enrolled at Brown University, graduating in 1983 with a Bachelor of Science in biology. He then attended The University of Massachusetts Medical School, where he began his journey to become a talented and compassionate doctor. His internship and residency were at The Medical Center of Central Massachusetts and he continued his post-graduate medical training with a Fellowship in gastroenterology at St. Elizabeth’s, Faulkner, and Lemuel Shattuck Hospitals in Boston, MA.

Helping people was a primary love of his and becoming a doctor provided the means to do so. Jay was a partner at Consultants in Gastroenterology and was on the staff of Rhode Island, Miriam, and Saint Joseph’s Hospitals. He was active on the Alumni Council at the University of Massachusetts Medical School and was passionate about teaching and enjoyed educating students, residents and fellows. He served as a Clinical Assistant Professor of Medicine at Brown University School of Medicine and a Tufts University Teaching Fellow.

Jay loved to travel and enjoyed learning about other cultures and immersing himself in their history, traveling to 44 countries, where he was often the self-appointed tour guide when friends and family accompanied him to foreign lands. One of Jay’s favorite trips was to Israel as a 15-year-old with the United Synagogue Youth, a Jewish youth group, where he learned about his heritage and participated in an archeological dig. Other favorite adventures included trips to Egypt, England, Italy, France, Greece, Morocco, Thailand, Iceland, South Africa and Australia, among many others. Driving across the USA in an old Ford Escort, camping or staying with distant friends and relatives along the way was a trip he often reminisced about. In 2016, Jay achieved his goal of traveling to all 50 states. During Jay’s travels he collected contemporary art from around the world, with each piece being linked to a story about a favorite trip.

One of Jay’s greatest characteristics was his ability to always make those around him feel special. Jay relished time spent with friends and relatives. He also compiled a detailed family tree and loved talking about past generations of his family. Jay was predeceased by his mother, Elinor Sorgman, and older brother Mark Sorgman.

Anthony Wilson of Norton, MA, his husband of 32 years, was the center of his life. He is survived by him along with his father, Stanley Sorgman, and Aunt Joan of Boynton Beach, FL; his brother David and sister-in-law Lisa of Canton, MA, and nephews and nieces Jeremy, Tyler, Katie, Bryana and Kierra as well as cousins.

To continue his legacy of giving back, Jay decided to donate his body to science at the University of Massachusetts Medical School so that in his own words, “somebody will learn something from me.”

Donations in Jay’s name may be made to the Center For Resilience at centerforresilience.org (Providence, RI), the Point Foundation – The National LGBTQ scholarship Fund, pointfoundation.org, or the Rhode Island Brain and Spine Tumor Foundation at ribstf.org

A private ceremony will be held to celebrate Jay’s life.

**RONALD M. WINTROB, MD**, of East Greenwich, Rhode Island died of complications related to chronic illness on August 17, 2020, at the age of 85.

He grew up in Toronto and graduated medical school at the University of Toronto in 1959 and completed his residency in psychiatry at McGill University in Montreal, Canada (1961–1965).

In 1961, Ron encountered Pauline Devine, a psychiatric nurse, who was also working at the Allan Memorial Institute/McGill University. Soon after they met and started dating, Ron and Pauline became engaged, and were married in June 1962. In June 1969, they moved to Connecticut, when Ron joined the faculty of the medical school at the University of Connecticut as a Professor of Psychiatry and Anthropology.

The family re-located to Rhode Island in 1982, and Ron took the position of Director of Education and Director of the Residency Training Program in the Department of Psychiatry and Human Behavior at Brown University (1982–1994). He became a Clinical Professor of Psychiatry at Tufts University’s School of Medicine (1997–1998). He then returned to Brown University as a Staff Psychiatrist where he worked part-time until he fully retired at the age of 80.
Professor Wintrob’s academic career spanned over 59 years. He was a major influence in the evolution of cultural psychiatry and development of the field internationally. After medical school at the University of Toronto, and his residency in psychiatry at McGill University, Dr. Wintrob was awarded a traveling fellowship in child psychiatry that led him to receive training in England, France, the Netherlands, and Switzerland. His interest in cultural medicine began in 1960 as medical director of a hospital in northern Laos. He also spent two years as the clinical and research director of Liberia’s psychiatric services and its only psychiatrist at the time. In 1966 upon returning to Montreal he had faculty appointments at McGill University in both psychiatry and anthropology.

Professor Wintrob was an internationally recognized leader in psychiatric education and in the field of cultural psychiatry. After leaving McGill University in 1969 he received academic appointments at the University of Connecticut School of Medicine in both the Department of Psychiatry and Anthropology. While on sabbatical at the University of Connecticut he began a twenty-year relationship as a visiting professor and lecturer with the University of Otago and later the Christchurch School of Medicine in New Zealand. In New Zealand he focused his research on the cultural change of the Maori. From 1982 to 1994 Dr. Wintrob was the Director of Education and Director of the Residency Training Program, Department of Psychiatry and Human Behavior at Brown University. Dr. Wintrob’s research focused on acculturative stress and adaptation among individuals and families, and on national immigration policy. While at McGill he researched change and coping ability among the Cree indigenous people of northern Québec. In 1969 he participated in drafting the American Psychiatric Association’s original position statement on transcultural psychiatry, delineating psychiatry’s role in transcultural studies, clarifying the terminology of the field, describing its interdisciplinary nature, and outlining its major objectives and areas of applications.

Dr. Wintrob was one of the founders of the Society for the Study of Psychiatry and Culture in 1971 and the first president of the leading cultural psychiatry professional organization in North America on Cultural Psychiatry. In 1983, he participated in the establishment of the Committee on Cultural Psychiatry of the Group for the Advancement of Psychiatry that produced a monograph on suicide, race, and ethnicity in the US population, another on alcohol use and alcoholism, and in 2002, a casebook on Cultural Assessment in Clinical Psychiatry.

He chaired the Committee on International Relations of the Group for the Advancement of Psychiatry which published a monograph on the Middle East. He subsequently became the co-chair of the World Psychiatric Association Transcultural Psychiatry Section and in 2005 the chair of the section for two terms. He organized numerous international cultural psychiatry conferences and promoted the field internationally. He authored and edited several books including Current Perspectives in Cultural Psychiatry and Psychiatrists and Traditional Healers: Unwitting Partners in Global Mental Health, and book chapters on cultural psychiatry in leading textbooks of psychiatry. Dr. Wintrob was highly generative having published widely in academic journals and in writing book chapters. As noted in his publications he consistently promoted his colleagues and mentees over himself insisting that they assume first authorships. Dr. Wintrob’s last publication was a book chapter in 2019 on Intracultural Psychotherapy.

In addition to his passion for medicine, he was an avid sailor and photographer, and a great admirer of architecture, in particular colonial-era houses. Many a time he would go for long walks on the East Side of Providence with family members, always intently listening as his children talked about what was going on in their lives, while he peppered the conversation with a keen analysis of the historic houses lining the streets they walked.

He is survived by his three children, Paul, Greg, and Jande, their spouses Margaret, Heather, and Jose Luis, and grandsons John, Jackson, and Brenton; Ron’s brother Ralph, wife Kitty, and their family in Toronto, Canada; his brother-in-law Phil Devine, wife Pat, and their family in London, Canada; and his extended relatives in Canada and the USA.

A celebration of his life will be held at the Brown University Faculty Club in Providence after COVID-19 has receded and it is safe to gather. Those interested in making a donation in his memory can help the World Psychiatric Association’s Transcultural Psychiatry Section continue to advance the field that he devoted his professional life to. Funds will be used to designate an annual award in his name to support the next generation of young psychiatrists from around the world. Donations made out to the “WPA – TPS” with “Wintrob” in the memo line of the check may be mailed to the following address:

World Psychiatric Association – TPS
Robert Kohn, Treasurer
42 General Street
Providence, RI 02904