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SPECIAL SECTION

PUBLIC HEALTH ETHICS

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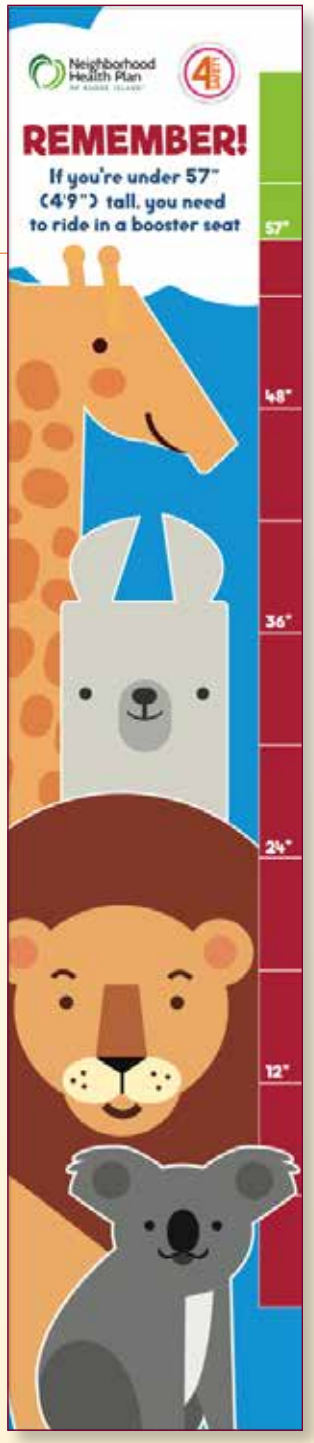

RHODE ISLAND MEDICAL JOURNAL

IN THE NEWS


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PEOPLE/PLACES

OBITUARIES

Introduction to the *Rhode Island Medical Journal* Special Issue: Public Health Ethics

JOSEPH H. WU, PhD, MD'23; ELI Y. ADASHI, MD, MS
GUEST EDITORS

Over two years into the COVID-19 pandemic, the importance of public health as a field has never been greater. Promoting and protecting the health of populations is often distinctly different from clinical practice wherein the focus is on the health of individual patients. Of particular significance, a population perspective on health raises distinct ethical issues that are often difficult to account for with standard bioethical principles that are otherwise appropriate in the clinical context. In the clinic, for example, a patient's decisions typically only affect his or her own interests, such that the principles of beneficence and non-maleficence can be balanced by evaluating the benefits and harms that affect that same individual. By contrast, a focus on population health often necessitates balancing benefits that accrue to some individuals against the harms that affect different individuals. In the case of COVID-19 lockdown policies, for example, it is far from clear how policymakers should trade off a diminished quality of education for school-aged children with the reduction of viral transmission intended to benefit the medically vulnerable.

Beyond the difficulties that arise in balancing diverse ethical goods, a population perspective on health is ethically complex because attention must be paid to distributional concerns. Apart and distinct from how benefits and burdens should be aggregated, there is the further question of whether such benefits and burdens are equitably distributed throughout the population. As several papers in this special issue highlight, the tensions between efficiency and equity can be difficult to reconcile. Moreover, the field of public health ethics must address the appropriate authority or limits of the government to implement measures that promote population health. The tension between individual liberty and the public good may well be familiar to many by now given recent controversies surrounding vaccine mandates. Needless to say, the real-world challenges facing public health today are animated by ethical, political, and legal complexities that warrant close examination.

In this special issue on Public Health Ethics for the *Rhode Island Medical Journal*, the contributions explore the complex moral issues that arise at the intersection of caring for individuals and populations. The papers below comprise excellent ethical analyses of several colleagues from Brown University, as well as from Dalhousie and Cambridge Universities. Taken together, these articles highlight several key practical and ethical challenges in the promotion of population health while seeking to develop answers to the fundamental moral questions facing medicine today: What do we owe to our patients? And what do we owe to society?

In his article, **"Non-Maleficence, Social Benefit and the Vaccination of Children,"** **STEPHEN JOHN, PhD**, examines a core tension in public health ethics: what can we do to the individual for the sake of the community? Such ethical tensions arise, for instance, when formulating COVID-19 vaccination policies. That is, vaccination may be in the interests of society, by way of decreasing COVID-19 transmission, but not in the medical interests of certain subpopulations, such as children, given the very low risk of serious COVID-19 disease in this age group. In the United Kingdom, the Joint Committee on Vaccination and Immunisation (JCVI) published a statement in September 2021 recommending against offering vaccines to otherwise healthy 12–15 year olds. Using the JCVI statement as a case study, Dr. John clarifies how the JCVI recommendation can be understood as an appeal to the principle of non-maleficence. Equally, however, he argues that the JCVI interpretation of the principle of non-maleficence in the context of vaccination policymaking was problematic. With vaccination policies, we are not merely trying to help people do something good *for them*; we are also helping them fulfill their ethical obligations *to others.* After all, in choosing not to get vaccinated, individuals are imposing a risk of harm on non-consenting third parties as well. Dr. John's ethical analysis serves to clarify the complex role that the principle of non-maleficence plays in public health.

In her article, **"Ethics of Advocacy,"** **LYNETTE REID, PhD,** examines the ethical dimensions of healthcare advocacy. In recent years, advocacy by physicians for health equity and for serving population health needs has gained prominence. Dr. Reid's paper clarifies the ethical basis of these trends: a physician's ethical obligation to advocacy can be understood both as a commitment to beneficence and as one to justice. Viewed in this light, the ethics of advocacy can quickly raise complex issues. Dr. Reid highlights four areas of ethical debate: 1) balancing the value of treating like patients alike and differentiating treatment to address barriers to access and to good outcomes, 2) the issue of how conceptions of justice should inform healthcare, 3) concerns about politicization of the medical profession, and 4) considerations of

non-maleficence in health advocacy. Concerning the notion of differing conceptions of justice, Dr. Reid asks whether, and to what extent, restorative justice has a role in healthcare. For example, when triaging critical care resources for COVID-19 patients, should one ensure that racialized minorities have the same access to critical care resources as others, or should one prioritize access for patients whose COVID-19 status is derived from their social determinants of health?

In their article, **"Melanoma Screening: The Ethics of Over- and Underdiagnosis,"** **JOSEPH WU, PhD, MD'23**, and **NICOLE NEGBENEBOR, MD**, examine ethical issues arising in debates about melanoma screening. Cutaneous melanoma is the fifth most diagnosed cancer in the United States and the incidence is increasing yearly. At present, population screening for melanoma is not recommended by national guidelines on account of insufficient evidence to assess the balance of benefits and harms. Indeed, there remains significant controversy over whether screening for melanoma via increasing the frequency of routine skin checks leads to tangible long-term health benefits for patients. The authors highlight how screening can impose harms such as overdiagnosis on otherwise healthy individuals and offer clarification on how the principle of non-maleficence relates to screening policies. The authors also explore the pressing issue of the underdiagnosis of melanoma in particular populations. In so doing, the authors underscore how the ethical duties of non-maleficence and justice must be balanced in dermatological practice.

In their article, **"Wandering Virtues, Moral Confusion,"** **MICHAEL FELDER, DO**, and **EZRA FELDER, BA, DO'26**, explore the relationship between our traditional understandings of bioethical obligations and the realities of medical practice during the COVID-19 pandemic. One way of approaching bioethics involves focusing on the virtues embodied by a "good" physician. By way of addressing what kind of person one wants to be, we can gain clarity on how to navigate moral conflicts. As this piece highlights, the psychological challenges of providing primary care amidst the pandemic can profoundly impact even one's mostly deeply held convictions about what virtues to embrace. The emotions experienced while caring for patients, including but not limited to frustration, resentment, and helplessness, may be infecting the moral virtues traditionally used to guide our bioethical thinking. In so doing, we would do well to pay close attention to how the moral distress being experienced by healthcare workers across the nation is perhaps precluding the possibility of being a "good" healthcare provider.

In their article, **"Toward an Improved Substance Use Disorder Treatment Landscape in Rhode Island: Barriers, Current Progress, and Next Steps,"** **HANNAN MOSES BRAUN, MD**; **JULIETTE A. HOLTZMAN, LICSW, LCDP**; **CAROLINE WUNSCH, MD**, and **SETH A. CLARK, MD, MPH**, highlight how the evidence-based treatment of substance use disorder (SUD) is a key issue for social and racial justice. Amongst the medical community, SUDs are still too often viewed as an acute condition as opposed to a chronic and treatable disease. While multiple efficacious interventions exist to reduce SUD-related morbidity and mortality, the authors point out that numerous barriers still prevent broader access for people in Rhode Island, such as the rigid scheduling for methadone dosing. For next steps, the authors underscore the imperative of eliminating polices that penalize ongoing substance use, such as employing punitive urine toxicology testing, and replacing them with harm-reduction practices. Additionally, they emphasize the imperative to diversify the addiction medicine workforce as another path to improving SUD care.

In their article, "**On the Ethics of Mandatory Reporting of Positive Drug Tests in Newborns and Pregnant Parents at the Time of Delivery,**" **JONATHAN SPIEGEL, MD'23**; **GREGORY COHAN, MD'23**; **E. CHRISTINE BROUSSEAU, MD**, and **ELIZABETH TOBIN-TYLER, JD, MA**, analyze the ethics of mandatory drug reporting for pregnant parents and newborns. The opioid epidemic has sparked debate about the optimal way to structure laws, agency policies, and hospital protocols for the mandatory reporting of illicit substances. In Rhode Island, the law mandates that positive drug tests in a pregnant parent or newborn must be reported to the Department of Children, Youth and Families. Given that state intervention is generally perceived by pregnant people as punitive, the authors examine the ethics of Rhode Island's approach to prenatal substance use from four perspectives: retribution, deterrence, rehabilitation, and incapacitation. Ultimately, the authors conclude that given the potential for the mandatory reporting policy to do more harm than good, resources would be better invested on clinical and community services that support substance using parents and their newborns.

As the articles in this special issue highlight, promoting the health of both individuals and populations can be an ethically complex endeavor. It is our hope that the articles in this issue of the *Rhode Island Medical Journal* will have stimulated the readers' interest in the moral dilemmas that can arise for physicians and policymakers working at the intersection of clinical medicine and public health.

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Non-Maleficence, Social Benefit and the Vaccination of Children

STEPHEN JOHN, PhD

ABSTRACT

Public health policy often involves a trade-off between promoting population health and protecting the interests of identifiable individuals. This paper analyses this trade-off as it arises in the context of decisions about the vaccination of children against Covid-19, where vaccination may be in the interests of society as a whole, as a means to stopping transmission, but not in the interests of individual children. The paper argues that the UK's Joint Committee on Vaccination and Immunisation resolved this tension by appeal to a version of a non-maleficence principle. It argues that, while this principle can be a useful guide to some public health policy decision-making, it is inappropriate in the case of vaccination.

KEYWORDS: public health ethics, vaccination ethics, Covid-19, public health policy

INTRODUCTION

The core aim of public health policy is to improve population health. However, we are sometimes faced with trade-offs, where we know that policies which will (almost certainly) improve population health will also (almost certainly) harm some people. Unfortunately, it may be impossible in advance to know who these people will be.[1] For example, we might know that a breast cancer screening programme will, overall, have a positive impact on population health, but, *via* overtreatment or overdiagnosis, will also have negative side effects for a very small, unidentifiable, number of people.[2] One key question in public health ethics concerns how to balance these trade-offs between harm to individuals and benefit to populations.[3]

In this paper, I explore the relationship between this challenge and a very general question: whether it is morally problematic to vaccinate children against Covid-19, even when this might not be in their own medical interests, as a way of preventing the transmission of disease. Some bioethicists have argued for such policies, on the grounds that stopping the spread of disease is of high importance.[4] Others, however, have argued that these policies risk treating children as "means to an end".[5]

For the sake of exposition, I focus on one high-profile example of this general problem, the United Kingdom's Joint Committee on Vaccination and Immunisation (JCVI) recommendation against Covid-19 vaccination of 12–15 year-olds. It is worth noting that this issue has now been resolved in the U.K. Ultimately, the U.K. decided to offer vaccinations to this age group on the basis of advice from the Chief Medical Officers. Moreover, at the time of writing, the Centers for Disease Control and Prevention in the U.S. recommends everyone ages 5 years and older to receive a Covid-19 vaccine. However, the JCVI example is still telling for two reasons. First, it is related to understanding ongoing debates about vaccinating even younger children, as exemplified in recent debates in the U.S. over whether to authorize Covid-19 vaccinations for children younger than 5. Second, as I explore, the JCVI's decisions can help us understand how ethical principles which might be proper in some contexts, such as cancer screening programmes, can be problematic in other contexts, such as pandemic control. By exploring the now-settled debate of whether to vaccinate adolescents against Covid-19, we can gain a broader understanding of the general question of when and why it might be permissible to burden some for the sake of population health.

Section 1 of this paper sets out the ethical problems around vaccinating teenagers as resolved by the JCVI. Section 2 argues that the JCVI's response was guided by a "non-maleficence" (or "first, do no harm") principle. Section 3 argues that this principle is inappropriate in the vaccination context.

1. THE JCVI CASE STUDY

From January 2021, in response to the global pandemic, the U.K. government adopted a plan to vaccinate the adult population against Covid-19.[6] Key decisions about this policy were guided by the JCVI, an arms-length expert body, whose recommendations on vaccination safety and schedules the U.K. Secretary of State of Health is statutorily obliged to consider.[7] In August 2021, the JCVI was asked for its opinion on proposals to extend the existing vaccination programme to offer vaccines to 12–15 year-olds, publishing a response in September 2021.[8] It is worth noting that, by this point, the U.S. Food and Drug Administration had already approved vaccination in this age-group, and soon after extended emergency use authorisation to everyone ages 5 years and older.

Despite this precedent, however, the JCVI seemed to adopt a more cautious approach.

To understand this approach, it is important to remember three key facts: first, that there are worries about the side effects of Covid-19 vaccination, and concerns that the chance of side effects is greater in younger age groups;[9] second, that the epidemiology of Covid-19 is such that the risk of severe illness sharply increases with age;[10] third, that, even if they are asymptomatic, children can transmit the virus to other, more vulnerable members of society.[11]

The JCVI's September 2021 response was slightly equivocal, but, nonetheless, against the policy:

> The health benefits from vaccination are marginally greater than the potential known harms. However, the margin of benefit is considered too small to support universal vaccination of healthy 12 to 15 year-olds at this time....Given the very low risk of serious COVID-19 disease in otherwise healthy 12 to 15 year-olds, considerations on the potential harms and benefits of vaccination are very finely balanced and a precautionary approach was agreed.[12]

Although the phrasing is complicated, we can understand the JCVI as making two claims. First, a claim about the balance-of-consequences: that, given the evidence, we have good ("precautionary") reasons to assume that the benefits to *12–15 year-olds* of getting vaccinated – i.e., reduction in the rate of severe or symptomatic disease – will be lower than the costs – i.e., in terms of side effects of vaccination. Second, a normative claim: that we should not vaccinate members of some group unless the (expected) benefits to members of that group outweigh the costs.

The next section gives a fuller account of the JCVI's reasoning. Before doing so, we can distinguish grounds for objecting to the JCVI's recommendation. First, we might reply that the benefits of vaccination for this age group *does* outweigh the costs, either because the JCVI has mis-estimated the epidemiological facts, or because vaccination reduces the risks of other, non-medical harms – for example, missing education through self-isolation.[13] Such responses dispute the balance-of-consequences claim but are consistent with the normative claim. Second, alongside prominent scientists such as Neil Ferguson, a key figure in building the epidemiological models which drove the U.K.'s pandemic response, we might respond that the JCVI erred by not considering the broader "social" benefits of vaccination, namely, reducing the likely transmission of Covid-19.[14] This response concedes the balance-of-consequences claim but disputes the normative claim. The second response was, apparently, what drove government policy, shifting U.K. vaccination policy away from a "high-risk" to a "transmission-reduction" strategy.

2. DO NO HARM AND VACCINATION PROGRAMMES

Precisely because the JCVI's conclusion was so equivocal, a decision was ultimately made in the U.K. to extend Covid-19 vaccination to the 12–15 age group. This decision was based on an assessment that, overall, the balance-of-consequences claim was false, i.e. that, overall, children are better served by receiving the vaccine than not. Still, this does not mean that the underlying normative issue is resolved. Particularly when we consider vaccination of younger and younger age groups – as in recent U.S. debates over vaccinating children under 5 – it becomes more and more plausible that the balance-of-consequences *for those cohorts* will be net negative. Nonetheless, we might still think that vaccinating these age groups would be an important tool for stopping Covid-19 community transmission. To understand these debates, then, we need to ask whether the normative claim noted above is justifiable. In this section, I argue that we can interpret that principle as reflecting a traditional, core concern of medical ethics: the principle of "non-maleficence".

Prima facie, even if we grant the "net negative" balance-of-consequences claim for the sake of argument, it might seem that the JCVI's response was misguided. It might seem that the JCVI was adopting a broadly "consequentialist" approach, arguing that we should adopt public health policies only when their expected net consequences are positive, and denying that the net consequences of vaccinating 12–15 year-olds are positive. Clearly, however, it is possible that the net consequences of some policy for a sub-population are negative, but the overall consequences for the entire population are positive. So, if we interpret the JCVI's opposition to vaccinating adolescents as based entirely on concerns about population health outcomes, they seem to have made a mistake in failing to consider broader effects of reducing transmission.

However, there is an alternative way of understanding the JCVI's decision. A core concern in traditional medical ethics is that physicians should be governed by a "non-maleficence" principle: "first, do no harm".[15] In the clinical context, we can interpret this principle as requiring that physicians do not harm some patients, even if the net consequences of their actions for other patients would be positive. For example, a physician should not deliberately harm her own patient, even if this would be an effective way of helping other patients.[16]

Despite the appeal of the non-maleficence principle, its status is disputed. First, it is not clear how we should use the principle in cases involving *risks* as opposed to *certainties* of harm: clearly, if "Do No Harm" (DNH) ruled out every intervention which ever posed even the slightest risk of harm, nearly every medical intervention would be ethically dubious. Second, and pertinent to this discussion, the principle seems inappropriate at the population health level, given that pretty much *any* public health intervention will have

"losers" as well as "winners". In the case of vaccination, for example, DNH seems to threaten to rule out any vaccination programme which leads to side effects, regardless of the size of potential benefit.

In recent work, however, John and Wu have argued for a revised "non-maleficence" principle which takes account of risk and can play a useful role in public health policy.[17] Their key move is to reformulate DNH in terms of individuals' *prospects*, i.e., individuals' *chances* of harming and benefitting, rather than in terms of a focus on *outcomes*. This concept can most easily be illustrated by means of two examples. First, consider an operation for a significant ailment which is successful 99.9% of the time, but leads to a very severe side effect 0.1% of the time. Plausibly, having this operation improves a patient's *prospects* – i.e., it increases her expected future well-being. Second, consider an operation for a significant ailment which leads to very severe side effects 99.9% of the time, but cures the ailment 0.1% of the time. Plausibly, having this operation worsens that patient's *prospects*. John and Wu interpret DNH as ruling out the second kind of operation, but allowing the first. A surgeon performing the first operation has not violated DNH, even if the patient *actually* suffers harm from the very rare side effect. By contrast, a surgeon performing the second operation has violated DNH even if, through some odd fluke, the patient recovers.

In formal terminology, the DNH principle reformulated in terms of prospects is termed the "*ex-ante* DNH" principle. John and Wu suggest that interpreting non-maleficence in terms of prospects can help us understand some puzzles in public health policy: for example, how we might justify instituting breast cancer screening programmes even when we know that some women will be harmed as a result of screening *via* overdiagnosis and overtreatment. On their analysis, such subsequent harm is permissible, as long as screening improves the *prospects* of each individual woman offered screening.[17] That some *actual* harm occurs does not show that non-maleficence is violated as long as each woman was expected to benefit more than she lost.

In many cases, whether or not some proposed public health policy violates *ex-ante* DNH can be assessed by looking at the overall expected balance of benefits and costs, as when health economists assess interventions in terms of whether they lead to a net gain in Quality-Adjusted-Life-Years (QALYs).[18] As long as the expected total benefits outweigh the total expected costs, then the intervention improves the prospects of the *average* person, and, as such, respects *ex-ante* DNH. That is, the two approaches coincide when we can assume that the prospects for the average person are a good guide to the prospects of each actual person.

With this background, we can better understand the JCVI's reticence toward vaccinating 12–15 year-olds in the U.K. When we focus solely on the costs and benefits of vaccination to members of the 12–15 year-olds population, it seems that vaccination has a net "cost". As such, getting vaccinated does *not* improve the prospects of the average 12–15 year-old and authorizing such a vaccination programme violates a plausible interpretation of non-maleficence, *ex-ante* DNH. Viewed in this light, the *ex-ante* DNH principle explains how the JCVI could rule against vaccination for the 12–15 years-old group, while favouring vaccination for adults. In both cases, vaccination will sometimes have harmful side effects, such as myocarditis. Therefore, if we thought that DNH was all about *outcomes*, all Covid-19 vaccination programmes would be impermissible because they impose harm on some individuals as a means to help others. However, this outcomes-focused interpretation of nonmaleficence would be implausible. By contrast, if we hold *ex-ante* DNH and focus on individual prospects, we can say that vaccinating adults would be permissible even if doing so will lead to harm, because getting vaccinated improves each affected individual's prospects by reducing the larger risk of severe Covid-19 illness. In the case of JCVI's reticence toward vaccinating children 12–15 years-old, non-maleficence rules actions as impermissible *even when they will benefit others*. As such, the fact that vaccinating children might well help adults, and boost overall population health was ethically irrelevant.

3. ASSESSING THE JCVI ARGUMENT

Should we follow the JCVI? If so, as noted above, this might have important implications not only for vaccinating 12–15 year-olds against Covid-19, but for vaccinating younger age cohorts. Even if the JCVI's calculations about the costs and benefits of Covid-19 vaccination are incorrect, the general principle has implications for other vaccination programmes; for example, consider debates over the policy of not vaccinating the young against chickenpox as a way of reducing the incidence of shingles in older populations.[19]

There are two routes to responding to the *ex-ante* DNH justification for the JCVI's proposals. One is to deny that non-maleficence concerns have any place in public health contexts; the second is to deny that they are relevant to the vaccination context specifically. The first option is a dead end. If considerations about "non-maleficence" have no role to play in public health, then, there would, in principle, be no problem with imposing massive costs on some for improving net population health.

Therefore, we should instead recognise that the vaccination context is importantly different from contexts such as screening. When someone goes to a screening test, they do something good *for them*; when they don't go, they do something bad *for them*. No one else is directly affected by their decisions. By contrast, when someone is vaccinated or not, this is not only good (or bad) *for them*, but has (direct) consequences *for others*. We have *ethical reasons* to get vaccinated. One way of understanding these ethical reasons is as grounded in a version of a "Do No Harm" principle:

in choosing not to get vaccinated, we are imposing risks of harm on non-consenting third parties.[20]

We pursue both screening and vaccination because we think such programmes will improve population health. However, in vaccination programmes, we are not merely trying to help people do something good *for them*, but we are also helping them fulfill their ethical obligations. We can have ethical obligations to perform actions even when those actions do not improve our prospects; for example, we have an obligation not to harm others, even if harming others would improve our chance of winning some money. Therefore, the normal injunction on the medical professional to "do no harm", which applies in the case of screening, is inapplicable in the case of vaccination.

CONCLUSION

This paper has interpreted the JCVI's decision in terms of *ex-ante* Do No Harm, and argued that their application of that principle is inappropriate here. This has important implications for thinking about the ethics of vaccination, as it implies that programmes of vaccinating younger children might be permissible. However, it has also argued that *ex-ante* DNH may still be an important consideration in other contexts, where we do not have similar ethical concerns, such as screening. These are steps towards one of the biggest problems in Public Health Ethics: what can we do to the individual for the sake of the community?

References

1. Cohen I, Daniels N, Eyal N (editors). Identified versus statistical lives: An interdisciplinary perspective. Oxford University Press, USA; 2015.
2. Plutynski A. Ethical issues in cancer screening and prevention. *J Med Philos.* 2012;37(3):310-23.
3. John SD. Risk, Contractualism, and Rose's" Prevention Paradox". *Soc Theory and Pract.* 2014;1:28-50.
4. Brusa M, Barilan YM. Voluntary COVID-19 vaccination of children: a social responsibility *Journal of Medical Ethics* 2021;**47:**543-546.
5. Giubilini A, Gupta S, Heneghan C. "A focused protection vaccination strategy: why we should not target children with COVID-19 vaccination policies" *J Med Ethics.* 2021;47**:**565-566.
6. Her Majesty's Stationery Office. Greenbook: Chapter 14a London, UK 2022. Online at: COVID-19 greenbook chapter 14a (publishing.service.gov.uk)
7. Joint Committee on Vaccination and Immunisation. Online at: Joint Committee on Vaccination and Immunisation – GOV.UK (www.gov.uk)
8. Public Health England. JCVI issues updated advice on COVID-19 vaccination of children aged 12 to 15. Sep 5th 2021. Online at: JCVI issues updated advice on COVID-19 vaccination of children aged 12 to 15 – GOV.UK (www.gov.uk)
9. Flynn H. Covid-19 vaccines for children: what are the side effects. *Medical News Today,* Nov.11th, 2021. Online at: COVID-19 vaccines for children: Are they safe? (medicalnewstoday.com)
10. Pijls B, Jolani S, Atherley A, Derckx R, Dijkstra J, Franssen G, Hendriks S, Richters A, Venemans-Jellema A, Zalpuri S, Zeegers M. Demographic risk factors for COVID-19 infection, severity, ICU admission and death: a meta-analysis of 59 studies. *BMJ.* 2021;11(1):e044640.
11. Coffin S, Rubin D. Yes, children can transmit COVID, but we need not fear. *JAMA Pediatr*. 2021;175(1):1110-1112.
12. Public Health England. JCVI issues updated advice on COVID-19 vaccination of children aged 12 to 15. Sep 5th 2021. Online at: JCVI issues updated advice on COVID-19 vaccination of children aged 12 to 15 - GOV.UK (www.gov.uk)
13. Brusa M, Barilan Y. Voluntary COVID-19 vaccination of children: a social responsibility. *J Med Ethics.* 2021;47**:**543-546.
14. Davis, N. UK vaccine advisers 'acted like medical regulators' over Covid jabs for children. *The Guardian* 5th Sep, 2021. Online at: UK vaccine advisers 'acted like medical regulators' over Covid jabs for children | Coronavirus | The Guardian
15. Beauchamp T, Childress J. Principles of biomedical ethics. Oxford University Press, USA; 2001.
16. Andrade G. Medical ethics and the trolley problem. *J Med Ethics Hist.* 2019;12:3
17. John SD, Wu JH. "First, Do No Harm"? Non-Maleficence, Population health and the Ethics of Risk. *Soc Theory and Pract.* Published online Feb 23, 2022. Available at: https://www.pdcnet.org/soctheorpract/content/soctheorpract_2022_0999_2_18_152.
18. Bognar G, Hirose I. The ethics of health care rationing: an introduction. Routledge, London; 2014.
19. Malm H, Navin MC. (2020). Pox Parties for Grannies? Chickenpox, Exogenous Boosting, and Harmful Injustices. *Am J Bioeth*. 2020;20(9): 45-57.
20. Flanigan J. A defense of compulsory vaccination. *HEC forum.* 2014;26(1)5-25.

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Ethics of Advocacy

LYNETTE REID, PhD

ABSTRACT

The physician duty to advocate for patients has evolved to address the need for high quality and sustainable care for all patients. As described in the CanMEDS Health Advocate role, health advocacy is about promoting health equity and engaging with partners across sectors to address the social determinants of health. Ethically, health advocacy is supported by beneficence (substantial medical benefit can be achieved by addressing the worst off) and justice (a commitment to sufficiency or equality in access to care and in health outcomes). Dilemmas or emerging challenges in health advocacy include distinguishing "special access" that is designed to address health inequities from preferential access for associates or "VIP"s, whether and when reciprocity or restorative justice should matter in healthcare, navigating the perception or reality of the politicization of medicine, and addressing responsibilities for non-maleficence ("do no harm") by examining privilege, promoting cultural safety, and engaging in affirming and inclusive practice.

DEFINITION: ADVOCACY AND THE HEALTH ADVOCATE ROLE

To advocate, by common dictionary definition, is to recommend or support a cause or policy publicly. In medical practice, advocacy has historically referred to advocating for a particular patient: to use influence to secure them the best possible medical care.[1–3]

The dictionary definition of advocacy has two key limitations. First, it describes a skill independent of ethical considerations about the content of the cause or policy for which one advocates. One could advocate for a harmful policy or a beneficial one, for personal interest or the public good. Second, it highlights a passive approach to advocacy – as though the responsibility to advocate could be fulfilled by clicking "like" or signing a petition. The traditional understanding of advocacy – for an individual patient – has its own key limitation: it is at odds with the ethical insight that the "best" care for one patient should not come at the cost of the best care for another.

Dodson et al. recommend separating the competency of promoting the individual patient's benefit (which they call agency) from advocacy as policy engagement, or "supraclinical" advocacy.[4] I argue that an ethical conception of health advocacy clarifies the relationship between advocacy at the clinical and the supraclinical levels.

ADVOCACY FOR WHAT?

Developments in medical education since the turn of the millennium have answered the question "advocacy for what?" Physician advocacy is advocacy for health equity and for serving population health needs. This is not to deny that key advocacy skills, for example change management or knowledge translation, are also applicable to quality improvement in clinical practice in general or to promoting advances in medical technologies (for example). However, the advocate role is specific to the obligations of physicians that are grounded in justice and beneficence: to address health inequities and to take a population perspective on health needs.

The ABIM Charter on Professionalism[5] focused on advancing equity through non-discrimination in practice and removing barriers to access to care, while indicating that health equity also requires "the promotion of public health and preventive medicine, as well as public advocacy on the part of each physician…". This ignited a debate about the scope of the physician responsibility to advocate for "improving aspects of communities that affect the health of individuals."[6]

The CanMEDS competency profile formalized the role of Health Advocate in 1996[7] and gave the role specific content:

> As Health Advocates, physicians contribute their expertise and influence as they work with communities or patient populations to improve health. They work with those they serve to determine and understand needs, speak on behalf of others when required, and support the mobilization of resources to effect change.[8]

The CanMEDS definition of health advocacy goes beyond passive support. It encompasses collaboration with communities and the active mobilization of resources, at both the clinical and the policy levels. Furthermore, it goes beyond achieving equity in *access*. It invokes the social accountability of the profession, which includes working in partnership across sectors (with community agencies, social services, education, and workplace health and safety, for example) to address the social determinants of health.[9]

The CanMEDS Health Advocate role does not distinguish working with individual patients and families and working with populations and communities. Helping patients and families navigate health care systems and connect with resources in the community is continuous with working with patients and communities to identify healthcare needs and secure the resources and policy changes necessary to meet those needs.[10–13] This should not be surprising: just as the practice of scientific medicine involves literacy in research, participation in research, and the application of the results of research in individual patient care, so health advocacy includes identifying and establishing resources in the community to help patients and families meet their healthcare needs, and connecting individual patients and families to those resources in clinical care.

WHY ADVOCACY?

Health advocacy has two ethical sources. Some physicians engage in health advocacy because greater health gains can be achieved by addressing unmet needs than by focusing on marginal benefits for those already well off. The good that health care providers can do individual patients is sometimes dwarfed by the effects of social structures and systems on their health opportunities and outcomes. Professional responsibilities extend to addressing structural factors that influence patient access to health care and broader factors that influence patients' health status and outcomes. That is, a commitment to beneficence may lead a physician to health advocacy work.

Others engage in health advocacy because of justice-inspired commitments, whether to health equity in particular or to social justice more broadly. Within the CanMEDS framework, health equity is defined as "individuals and populations reach[ing] their full health potential without being disadvantaged by, for example, race, ethnicity, religion, gender, sexual orientation, age, social class, economic status, or level of education."

The ethical obligation to advocacy is in this sense "overdetermined": it is supported by more than one core principle of health care ethics. This creates an ethically complex landscape: different grounding commitments can foster collaboration across political differences and can also raise ethical dilemmas when beneficence and justice would recommend different courses of action.

ETHICAL CHALLENGES IN HEALTH ADVOCACY

Health advocacy involves a number of ethical challenges.

Within health care, a focus on disparities in access and outcomes is relatively quantifiable and (relatively) politically neutral. But addressing the structural determinants of access and outcomes outside of health care takes the profession quickly into matters of public policy that are politicized.[14] In the political domain, the nature of a just society is contested: for example, protecting private property,[15] ensuring fair equality of opportunity,[16] and fostering relations of equals,[17] are different visions of social justice with their adherents. These differences will not be settled within health care. Ethical practice will involve being alert to the different considerations each conception of justice highlights.

In the following, I review four areas of ethical debate in health advocacy: balancing the value of treating like patients alike and differentiating treatment to address barriers to access and to good outcomes; questions about the range of conceptions of justice that should inform health care; concerns about politicization of the profession; and the considerations of non-maleficence in health advocacy.

Old and new expectations of patient advocacy

In a well-organized healthcare system that meets patient needs, advocating for additional resources for a particular patient could be equivalent to seeking preferential access. It could be unfair to other patients and, depending on how a service is funded and the relationship of the physician to the patient, a misuse of public resources for the benefit of one's own associates.[18] Advocating for individual patients experiencing health disparities carries some of the same ethical risks as advocating for special treatment. These risks are mitigated when patient need, and not personal relationships, drive the advocacy, and when the lessons learned from individual advocacy are directed towards changes in policies and procedures to meet the needs of other patients in the same situation.

For example, to ask a patient to return on another day or attend another clinic for follow-up, instead of providing it immediately on site, may be a minor inconvenience for a patient. But a friend, a colleague, or a patient accustomed to deferential treatment due to their social status,[19, 20] may pressure the physician of their staff for such a favour. For another patient, such a requirement may be a barrier to care, and providing follow-up immediately on site may enable access. Providing this "special treatment" is qualitatively different in its ethical goals. Similarly, flexibility in appointment time for all patients would be unsustainable, waste resources, and inconvenience other patients; flexibility for a small number of patients who lack access to transportation and face many competing practical priorities in their day may enable access to care they would forego without that flexibility. Establishing policies to clarify when patients do or do not qualify for pathways that facilitate access, and shaping clinical services to meet the needs of patients with insecure lives, ensures that patients who are relevantly similar can access equivalent services.

Should reciprocity or restorative justice play roles in health justice?

An open question in the ethics of health advocacy is whether compensation (in the form of reciprocity or restorative

justice) has a role in health care. Should we advocate to secure equitable access and/or outcomes, or should health care be an arena in which we compensate for inequities in other social dimensions that create or reinforce health inequities? An example is in triage of critical care resources in COVID: should we ensure that racialized minorities have the same access to critical care resources as others,[21] or should we prioritize access for patients whose COVID status is derived from their social determinants of health?[22] For example, consider that racialized minorities disproportionately work in the public-facing service economy, with precarious employment conditions and minimal provision for sick leave, while their families and communities take on their risk of exposure to COVID in turn due to high-occupancy housing and a lack of outdoor public spaces for safe recreation. In addition, they may serve a public that resists social distancing measures, placing them in unnecessary danger. Should they be prioritized alongside health care providers for reasons of reciprocity? Should they be prioritized for reasons of restitution, given the long-standing historical roots of oppression?

Politicization of the profession

It has been argued that an advocacy obligation is inconsistent with the profession's political neutrality and with scientific objectivity.[23] This critique assumes that policy engagement and commitments of solidarity with patients are driven by pre-existing political commitments. They may be informed by causal relations in the world and by medical need. To refuse to act on causes of health detriments because addressing the causes in question (for example, work conditions, gun laws, pandemic control policy) has been adopted as a political cause by one party or another would be to bow to political pressure.

Furthermore, when mainstream political parties fail to challenge or even offer the appearance of supporting the resurgence of ideologies detrimental to human rights and health, such as Naziism, the profession cannot take the threat of "politicization" as an argument for silence. In such an era, it is important to revisit the medical profession's history of complicity with fascism on the left (with Soviet medicine) and on the right (with Naziism), and affirm the profession's commitment to human rights.[24]

Nonetheless, physicians in their policy engagement must work with governments across the political spectrum, often raising dilemmas between ideal ethics and realism. The tension between ideal and realistic courses of action is a source of ethical dilemmas and moral distress.[25]

Non-maleficence in health advocacy

Many descriptions of the health advocate role highlight that physicians are uniquely situated to identify health inequities and to use their privilege to mobilize resources to address the social determinants of health.[3, 26] However, while physicians may observe some of the effects of the social determinants of health in their clinical practice, they may not be well-situated to identify causes or interventions. Assumptions and biases that arise from their own socioeconomic status may interfere with understanding others' lives and communities.[27] In health advocacy, the principle of non-maleficence, which encompasses avoiding harm and minimizing or mitigating unavoidable harms, deserves more attention. Although the Health Advocate role arose from an imperative to look beyond medicine to the social determinants of health, the profession must also address harms that occur within medical practice and within the medical profession.

First, to address blind spots, biases, and limitations in training in population health and relevant social and environmental sciences, it is essential to collaborate with health care and social service providers with experiences in these areas, as well as with researchers with relevant expertise.

Second, it would usually be inappropriate for physicians to prioritize which inequities to address. Community engagement, grounded in trust-building and guided by ethical principles, is crucial.[28] Community engagement is also a matter of epistemic justice, or taking seriously the "lived experience" of disparities.[29]

Third, a number of frameworks and models are available to guide clinical work and community engagement with specific communities to avoid harm in biases, assumptions, and language. Examples include cultural safety and humility or decolonization as frameworks for working with Indigenous patients and communities;[30] affirming practice for diverse sexual orientations and gender identities;[31] inclusive practice for different forms of disability.[32] Anti-racist practice[33] and trauma-informed care[34] can address the needs of multiple communities.

Fourth, physicians must take responsibility for barriers to social justice within the profession,[35] including (for example) policies and cultures that keep minorities out of medicine and women out of particular specialties, educational materials in which clinical conditions are presented solely in patients with white skin,[36] and the "minority tax" imposed on members of the profession who are expected to educate their colleagues and do the advocacy work within the profession.[37]

CONCLUSION

Health advocacy to advance health equity and serve the needs of the community has been defined and endorsed as a legitimate goal of medicine, grounded in beneficence and justice. We can distinguish old conceptions of advocacy for individual patients at the expense of the health care system from advocacy at the practice level for individual patients at risk of experiencing barriers in access to care or the detrimental effects of the social determinants of health.

Concepts of social justice are contested politically, but this need not prevent the profession from addressing structural influences on access and outcomes. As the health advocate role has largely been developed with the goal of encouraging physicians to engage in the public sphere on the social determinants of health, considerations of non-maleficence within the practice of medicine and within the profession have received relatively little attention within the literature on health advocacy, but are important areas for future development.

References

1. Schoolman H. The role of the physician as a patient advocate. *New Engl J Med*. 1977;296(2):103-105.
2. Hotchkiss W. Doctor as patient advocate. *JAMA*. 1987;258(7): 947-948.
3. Earnest M, Wong S, Federico S. Perspective: physician advocacy: what is it and how do we do it. *Acad Med*. 2010;85(1):63-67.
4. Dobson S, Voyer S, Regehr G. Perspective: agency and activism: rethinking health advocacy in the medical profession. *Acad Med*. 2012;87(9):1161-1164.
5. Brennan T, ABIM Foundation, ACP–ASIM Foundation, European Federation of Internal Medicine. Medical professionalism in the new millennium: A Physician Charter 15 months later. *Ann Int Med*. 2002;136(3):243-246.
6. Gruen R, Pearson S, Brennan T. Physician-citizens—public roles and professional obligations. *JAMA*. 2004;291(1):94-98.
7. Royal College of Physicians and Surgeons of Canada. *The CanMEDS 2005 Physician Competency Framework: Better standards, better physicians, better care.* Ottawa: Royal College of Physicians and Surgeons of Canada; 2005. http://rcpsc.medical.org/canmeds/CanMEDS2005/CanMEDS2005_e.pdf
8. RCPSC, Frank J, Snell L, Sherbino J. *CanMEDS 2015 Physician Competency Framework. 2015*. Available from: https://www.royalcollege.ca/rcsite/documents/canmeds/canmeds-full-framework-e.pdf
9. Boroumand S, Stein M, Jay M, Shen J, Hirsh M, Dharamsi S. Addressing the health advocate role in medical education. *BMC Med Educ*. 2020;20(1):28.
10. Goel R, Buchman S, Meili R, Woollard R. Social accountability at the micro level: One patient at a time. *Can Fam Physician*. 2016;62(4):287.
11. Meili R, Buchman S, Goel R, Woollard R. Social accountability at the macro level: Framing the big picture. *Can Fam Physician*. 2016;62(10):785-788.
12. Woollard R, Buchman S, Meili R, Strasser R, Alexander I, Goel R. Social accountability at the meso level: Into the community. *Can Fam Physician*. 2016;62(7):538-540.
13. Buchman S, Woollard R, Meili R, Goel R. Practising social accountability: From theory to action. Canadian Family Physician. 2016;62(1):15-18.
14. Smith M, Thompson A, Upshur R. Is 'health equity' bad for our health? A qualitative empirical ethics study of public health policy-makers' perspectives. *Can J Public Health*. 2018;109(5-6): 633-642.
15. Nozick R. *Anarchy, state, and utopia*. New York: Basic Books; 2013.
16. Daniels N. *Just Health*. Cambridge University Press; 2007.
17. Voigt K, Wester G. Relational equality and health. *Soc Phil Pol*. 2015;31(2):204-229.
18. Reid L. Introduction to the Special Issue: Precarious Solidarity—Preferential Access in Canadian Health Care. *Health Care Anal*. 2017;25(2):107-113.
19. Diekema D. The preferential treatment of VIPs in the emergency department. *Am J Emerg Med*. 1996;14(2):226-229.
20. Guzman J, Sasidhar M, Stoller J. Caring for VIPs: nine principles. *Cleve Clin J Med*. 2011;78(2):90-94.
21. Reid L. Triage of critical care resources in COVID-19: a stronger role for justice. *J Med Ethics*. 2020;46(8):526-530.
22. Bruce L, Tallman R. Promoting racial equity in COVID-19 resource allocation. *J Med Ethics*. 2021;47(4):208-212.
23. Huddle T. Perspective: Medical professionalism and medical education should not involve commitments to political advocacy. *Acad Med*. 2011;86(3):378-383.
24. Kolb S, Weindling P, Roelcke V, Seithe H. Apologising for Nazi medicine: a constructive starting point. *The Lancet*. 2012;380(9843):722-723.
25. Framing the issues: moral distress in health care [editorial]. *HEC Forum* 2012;24(1):1.
26. Hubinette M, Regehr G, Cristancho S. Lessons from Rocket Science: Reframing the Concept of the Physician Health Advocate. *Acad Med*. 2016;91(10):1344-1347.
27. Gallagher S, Little M. Doctors on Values and Advocacy: A Qualitative and Evaluative Study. *Health Care Anal*. 2017;25(4): 370-385.
28. Clinical and Translational Science Awards Consortium Community Engagement Key Function Committee Task Force, NIH, CDC, ATSDR of the DHHS. *Principles of Community Engagement.* Department of Health and Human Services NIH Publication; 2011. https://www.atsdr.cdc.gov/communityengagement/
29. Carel H, Kidd I. Epistemic injustice in medicine and healthcare. In: Kidd I, Medina J, Pohlhaus Jr. G, editors. *The Routledge handbook of epistemic injustice*. Routledge; 2017. p. 336-346.
30. Jones R, Crowshoe L, Reid P et al. Educating for Indigenous Health Equity: An International Consensus Statement. *Acad Med*. 2019;94(4):512-519.
31. Streed C, Lunn M, Siegel J, Obedin-Maliver J. Meeting the Patient Care, Education, and Research Missions: Academic Medical Centers Must Comprehensively Address Sexual and Gender Minority Health. *Acad Med.* 2021;96(6):822-827.
32. Ankam N, Bosques G, Sauter C et al. Competency-Based Curriculum Development to Meet the Needs of People with Disabilities: A Call to Action. *Acad Med*. 2019;94(6):781-788.
33. Argueza B, Saenz S, McBride D. From Diversity and Inclusion to Antiracism in Medical Training Institutions. *Acad Med*. 2021;96(6):798-801.
34. Brown T, Berman S, McDaniel K et al. Trauma-Informed Medical Education (TIME): Advancing Curricular Content and Educational Context. *Acad Med*. 2021;96(5):661-667.
35. Mateo C, Williams D. Addressing Bias and Reducing Discrimination: The Professional Responsibility of Health Care Providers. *Acad Med*. 2020;95(12S):S5-S10.
36. Singh N. Decolonising dermatology: why black and brown skin need better treatment. The *Guardian* 13 August 2020. https://www.theguardian.com/society/2020/aug/13/decolonising-dermatology-why-black-and-brown-skin-need-better-treatment
37. Campbell K, Rodríguez J. Addressing the Minority Tax: Perspectives from Two Diversity Leaders on Building Minority Faculty Success in Academic Medicine. *Acad Med*. 2019;94(12): 1854-1857.

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Melanoma Screening: The Ethics of Over- and Underdiagnosis

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ABSTRACT

Cutaneous melanoma is the fifth most diagnosed cancer in the United States and the incidence is increasing yearly. At present, population screening for melanoma is not recommended by national guidelines on account of insufficient evidence to assess the balance of benefits and harms. Indeed, there remains significant controversy over whether screening for melanoma via increasing the frequency of routine skin checks leads to tangible long-term health benefits for patients. In this paper, we highlight how skin cancer screening can impose harms such as overdiagnosis and suggest that the principle of non-maleficence should play a greater role in the formulation of screening policies. We also explore the pressing issue of the underdiagnosis of melanoma in particular populations. In so doing, this paper underscores how the ethical duties of non-maleficence and justice must be balanced in current dermatological practice.

KEYWORDS: cancer screening, public health ethics, non-maleficence, justice

INTRODUCTION

Cutaneous melanoma is the fifth most commonly diagnosed cancer in the United States and the incidence is increasing yearly. In 2021 alone, it is estimated that there will be 106,110 new melanoma cases with an associated 7,180 deaths.[1] In Rhode Island, there are approximately 230 new cases of malignant melanoma each year with an associated 30 deaths.[2] In addition, the healthcare costs associated with melanoma in Rhode Island is estimated to be $10 million annually.[2] More generally, the United States spends $3.3 billion annually on conditions related to the morbidity and mortality from melanoma.[3] Consequently, the accurate diagnosis and treatment of melanoma poses a notable health and financial burden for patients in our state.

Recent literature has underscored melanoma screening as a potentially important strategy to reduce melanoma-related morbidity and mortality.[4] The past several decades have seen several campaigns to increase public awareness of skin cancers, to incorporate novel diagnostic technologies, and to educate the public and health care professionals in efforts to promote the early detection of melanoma. Apart and distinct from the increased emphasis on early detection, therapies for melanomas have become ever more effective over the years. Contemporary treatments can now include wide local excision, Mohs, slow Mohs, immunotherapies, and topical treatments with imiquimod depending on the subtype of the tumor and discussion between the provider and patient.[5]

Nonetheless, there remains significant controversy over whether screening for melanoma via increasing the frequency of routine skin checks leads to tangible long-term health benefits for patients. At present, population screening for melanoma is not recommended by the United States Preventive Services Task Force (USPSTF) on account of insufficient evidence to assess the balance of benefits and harms.[6] In an ideal world, the impact of screening would be evaluated through a randomized controlled trial. This is because non-randomized studies examining the effect of screening on mortality are plagued by sources of bias including the healthy screenee effect, lead-time bias, and length-time bias.[7] However, not only has there never been a randomized controlled trial evaluating the impact of melanoma screening, but there is also no trial currently underway or planned.[8] Given the absence of randomized controlled trial data or planned future trials, decisions about whether to recommend melanoma screening must rely on indirect evidence, disease epidemiology, and the current understanding of pathophysiological mechanisms including the natural course of melanomas detected via screening.

In recent years, several non-randomized studies have deepened our understanding of the appropriateness of melanoma screening. For example, a recent cohort study of 2,452 patients diagnosed with melanoma from 2006–2007 in New South Wales reported a reduction in all-cause mortality, but not melanoma-specific mortality, for melanomas diagnosed through routine skin checks.[9] This may indicate that an individual's interaction with the healthcare system led to the detection of other issues that were impeding their healthcare status. In another study specific to Rhode Island, free public skin cancer screening events were held at beaches between 2015–2019, and data collected provided broad insights into the local epidemiology of disease amongst "presumptively-at-high-risk" individuals: of 2,354 people screened, 7 malignant melanomas were ultimately diagnosed.[2] Equally, however,

recent studies have also underscored the harms of increased diagnostic scrutiny for melanoma. Although cutaneous melanoma was once a rare neoplasm, the incidence has rapidly increased over the past 40 years, rising six-fold in that time frame.[10] A key question underlying these epidemiological trends is whether the significant rise in incidence constitutes a genuine increase in the occurrence of melanomas or, rather, an "epidemic of diagnosis" for some patient populations.

In this paper, we explore the question of what it means for melanoma screening to be ethically justifiable. Our focus is on population-wide screening for melanoma as formulated by guidelines issued from national institutions such as the USPSTF. Although it is tempting to assume that the controversy around population screening is solely an empirical matter, it is worth underscoring that conceptual and ethical clarity are prerequisites, too. After all, unless we can agree on what it means for melanoma screening to be ethically justifiable, the question of whether screening should be recommended has little prospect of empirical resolution, no matter how much data is collected.

CLARIFYING THE SCREENING DEBATE

Screening aims to reduce disease-related morbidity and mortality via the earlier detection of cancer. The premise is that early-stage cancer has better outcomes than later-stage disease. Therefore, it is theorized that the early detection of cancer should improve health outcomes. Though attractive in theory, the story has been very complicated in practice. For example, in several types of cancer including prostate, thyroid, lung, and breast cancers, there is evidence that screening increases the early detection of cancer *without* decreasing later-stage disease or improving health outcomes.[11] In other words, screening often leads to overdiagnosis, defined as cases in which individuals meet the diagnostic criteria for a particular disease but, in the absence of detection, the individual would not have suffered any reduction in length or quality of life.

Controversies around screening require distinguishing two different types of questions:

1) Does screening constitute a favorable benefit-harm ratio for a particular population?

2) Given the evidence, what are we licensed to conclude about the benefits and harms of screening?

The source of disagreement in screening debates is often ambiguous. We can see this by holding one issue fixed and varying the other.[12] To illustrate, consider the case of breast cancer screening. Although projections vary across studies, the USPSTF estimates that biennial mammography screening for women aged 50 to 74 years old saves one life from breast cancer for every 143 women screened over their lifetime. However, for every life saved, biennial mammography in this population leads to approximately 136 false-positive tests, 21 unnecessary breast biopsies, and 3 overdiagnosed breast tumors that may have been unnecessarily treated.[13]

Suppose we are absolutely certain that breast cancer screening saves one life for every 143 women screened but leads to all of the aforementioned harms. One way to disagree is if you think this is a favorable benefit-harm ratio, and if I do not. In this scenario, disagreement arises around how to aggregate the benefits and harms for those affected. Contrast this with the following. Suppose we both believe that screening should be recommended once we are 80% certain that an agreed upon benefit-harm ratio would be achieved for those affected. However, we disagree about whether the available evidence translates into 80% certainty that, were guidelines published to that effect, such a favorable benefit-harm ratio would be attained. This might occur if the population studied in trials is different in relevant ways from the intended population to be screened, or as in the case of melanoma screening, if there is an absence of randomized controlled trial data to rigorously assess the effectiveness of screening. In this scenario, disagreement arises not around what constitutes a favorable balance of benefits and harms, but rather, when the evidence is sufficient to act on recommending screening for a particular population.

THREE ETHICAL CONSIDERATIONS IN MELANOMA SCREENING

While there is a growing literature on the ethics of cancer screening in general,[14] the ethics of skin cancer screening in particular is less developed. One framework advanced by Stoff and Grant-Kels (2021) highlights the principles of utilitarianism, justice, and caring to guide our ethical thinking around skin cancer screening.[15] In their framework, they address three concerns: "Do skin cancer screening events reduce mortality from skin cancer?" (Utilitarianism), "Do skin cancer screening events provide access to care for underserved populations?" (Justice), and "Do skin cancer screening events cultivate relationships between the public and dermatologists?" (Caring). This section aims to further develop this ethical framework for skin cancer screening by highlighting three key ethical considerations.

DOES MELANOMA SCREENING IMPOSE HARM ON HEALTHY PEOPLE?

Discussions of the benefit-harm ratio for melanoma screening must acknowledge that screening may impose harm on otherwise asymptomatic people. As noted above, approximately 230 malignant melanomas are diagnosed annually in Rhode Island, which has a population of roughly 800,000 adults above the age of eighteen.[2] It is a truism of population screening that the lower the baseline incidence of disease, the higher the likelihood of false-positive results.[7] While it

may be tempting to dismiss false-positive results as trivial, this would be a mistake. In the context of mammography screening, false-positive results can lead to psychosocial consequences such as increased anxiety and sleep disturbance that persist even three years after the initial false-positive finding.[16]

A potentially more serious harm of melanoma screening is the overdiagnosis of pigmented lesions. Welch *et al.* (2021) recently argued that the six-fold increase in the incidence of melanoma over the past 40 years is largely the result of increased diagnostic scrutiny.[10] Several factors underpin this increased scrutiny: an increasing number of screening exams of the skin, decreasing thresholds for biopsy of pigmented lesions, decreasing pathological thresholds to diagnose morphological abnormalities as neoplasms, and an increasing amount of medical malpractice litigation. In further service of their argument, Welch and colleagues point to epidemiological signatures of cancer. While the incidence of melanoma has sharply risen in previous decades, there has been little reduction in melanoma mortality in that same timeframe. These population trends are highly suggestive of melanoma overdiagnosis. That is, increased diagnostic scrutiny may lead to more melanomas detected without much concomitant benefit.[17] Although it is true that melanoma mortality has declined slightly in recent years, Welch *et al.* (2021) point out that the timing of such mortality reductions coincides with advances in melanoma treatment such as checkpoint-blockade immunotherapies and targeted therapies for metastatic disease. It would thus appear that the better explanation for the decline in mortality is improved treatment for melanoma, rather than early detection.

Apart from the unnecessary treatment associated with the overdiagnosis of melanoma, we agree with Welch *et al.* (2021) that there are several additional screening-related harms to be considered. In the United States healthcare system, a cancer diagnosis can impose a crushing financial burden.[18] Of the total $8.1 billion for all direct skin cancer annual costs in the United States, melanoma comprises $3.3 billion of the costs.[3] Biopsies or excisions pose risks of harm as well. It is estimated that for every melanoma diagnosis, over 10 pigmented lesions are biopsied.[19] Excisions for overdiagnosed or benign pigmented lesions confer no benefit to the recipient, yet there remain the risks of scarring, bleeding, infection, and out-of-pocket costs.[10] Lastly, as Welch *et al.* (2021) point out, frequent, full skin exam surveillance is common in dermatology. Persons diagnosed with suspicious lesions are faced with potentially increased appointments, co-pays, and possible anxiety related to more frequent scrutiny of their skin moving forward. In light of there also being a paucity of dermatologic providers, an indirect harm can arise, namely, patients with more pressing dermatological issues may be impeded from receiving timely care because appointment slots are reserved for routine surveillance.[10]

NON-MALEFICENCE AND MELANOMA SCREENING

As discussed above, the ethical framework advanced by Stoff and Grant-Kels (2021) highlights the principles of utilitarianism, justice, and caring to guide our thinking around skin cancer screening. In their framework, a utilitarian perspective on skin cancer screening aims to "promote the most good for the most people using a relatively simple metric… reduction of death from skin cancer, specifically melanoma."[15] However, in light of the harms underscored in the previous section, the relationship between screening and the principle of non-maleficence should also be underscored.[20] Bracketing the issue of whether the "most good" should be understood solely in terms of melanoma-specific mortality, there is an additional ethical complexity here: improving aggregate population outcomes is consistent with violating the principle of non-maleficence.[21] By analogy, it is ethically impermissible to harvest one living patient's organs without consent for the sake of saving three others in need of organ transplantation, even if doing so would lead to better population outcomes.

Ethically speaking, there is an asymmetry between intrapersonal justification (justifying harms with benefits to the same person) and interpersonal justification (justifying harms to some people with benefits to different people). It has been argued that this ethical asymmetry is what the principle of non-maleficence is intended to capture.[21] Moreover, this asymmetry is one explanation for why it is ethically impermissible to harvest patients' organs for the sake of benefiting other people. From a population perspective, screening policies are ethically complex because screening-related harms such as false-positive results and overdiagnosis are inevitably imposed on some individuals in order to help others. To be ethically justifiable and avoid violating non-maleficence, we believe that population-screening should be recommended only when the expected benefits and harms of screening are favorable for *each individual* affected by the guidelines.[21]

Two implications of the preceding discussion are worth emphasizing. First, guidelines for screening typically include a criterion about the "balance of benefits and harms" for the intended population.[6] However, it is important not to conflate the interests of the "average individual" within a population with the interests of *each* individual.[21] Ignoring this distinction would be to assume that policies that lead to better aggregate outcomes are always in the interests of each individual. As the organ harvesting example illustrates, this can be problematic. Second, when debates around screening are only framed in terms of "cost-effectiveness" or "promoting the most good for the most people," we run the risk of obscuring the role of non-maleficence in population health policies. It is important to recognize that screening policies are not just a matter of deciding whom to help. Rather, screening can involve imposing real harm

on some as a means of helping others. These are precisely the circumstances that the principle of non-maleficence is intended to deem ethically objectionable.

JUSTICE AND MELANOMA SCREENING

While screening-related harms such as overdiagnosis are a pressing concern, the underdiagnosis of melanoma in particular populations must also be explored. With respect to the epidemiology of melanoma, it is reported that geriatric patients with lighter skin are at the highest risk.[22] Additionally, several studies have linked indoor tanning to a significant increase in the risk of melanoma. In particular, individuals who began tanning younger than 35 are at a high risk for melanoma.[23] However, studies suggest that individuals who reported engaging in indoor tanning were more likely to *avoid* skin cancer screening.[23] How might skin cancer screening be optimized by focusing on the subpopulations that would benefit the most from routine skin examinations?

Although skin cancer is more prevalent in White patients, studies have identified that when skin cancer does occur in patients of color, it presents at a more advanced stage with worse prognosis.[24] The morbidity and mortality is often higher for patients of color despite that in current data only about 2% of non-Hispanic Black and 5% of Hispanic patients are diagnosed with either a malignant melanoma or keratinocyte skin cancer.[25] For melanomas, there is a lower 5-year survival rate for both Hispanic and non-Hispanic Black populations as compared to White populations.[26] Previous studies have discovered that at the time of presentation, melanomas are likely to be greater in Breslow thickness and are more advanced in Hispanic and non-Hispanic Black patients.[27] One retrospective study examined demographics and trends for diagnoses of late-stage melanomas.[28] They found that advanced or late-stage melanomas were diagnosed in about 16% of White patients. However, late-stage melanomas were disproportionately diagnosed in 52% of non-Hispanic Black patients and 26% of Hispanic patients. From a justice-based perspective, it is imperative that if melanoma screening is to be recommended, then guidelines should be formulated to address the underdiagnosis of melanomas in underserved populations.

CONCLUSION

Population screening for melanoma and other skin conditions is an ethically complex intervention that rests at the intersection of clinical medicine and public health. To be ethically justifiable, melanoma screening must balance ethical duties including non-maleficence and justice. Focusing screening on high-risk individuals or limiting screening to solely an initial exam for patients who have had benign exams may reduce the risks of overdiagnosis while also reducing melanoma-related health inequities. However, high-quality studies are direly needed to provide evidence of an acceptable benefit-harm ratio prior to recommending population-wide melanoma screening. In Rhode Island, several community-wide interventions other than skin cancer screening have been implemented to increase sun protection behaviors, such as educational programming and behavioral counseling.[29] Such evidence-based interventions reflect the undeniable importance of reducing the burden of skin cancer in Rhode Island. Nonetheless, in the face of insufficient evidence to justify recommending population-wide skin cancer screening, thinking through the ethical dimensions of screening offers a different avenue to assessing a key question facing dermatology: when is melanoma screening ethically justifiable to both patients and populations?

References

1. National Cancer Institute. Cancer Stat Facts: Melanoma of the Skin. https://seer.cancer.gov/statfacts/html/melan.html
2. Lee KC, Fulton JP, Kazemi L, et al. Clinical Outcomes of Free, Public Skin Cancer Screening Events, Rhode Island, 2015-2019. *RIMJ.* 2021 Aug 2;104(6):22-27.
3. Guy Jr GP, Machlin SR, Ekwueme DU, et al. Prevalence and costs of skin cancer treatment in the U.S., 2002-2006 and 2007-2011. *Am J Prev Med.* 2015 Feb; 48(2):183-187.
4. Halpern AC, Marchetti MA. Melanoma Screening: Time for a Reset? *JAMA Dermatol.* 2021;157(12):1409-1411.
5. Davis LE, Shalin SC, Tackett AJ. Current state of melanoma diagnosis and treatment. *Cancer Biol Ther.* 2019;20(11): 1366-1379.
6. US Preventive Services Task Force. Screening for skin cancer: US Preventive Services Task Force recommendation statement. *JAMA*. 2016;316(4):429-435.
7. Raffle A, Gray M. 2007. *Screening: Evidence and Practice*. Oxford: Oxford University Press.
8. Halvorsen JA, Løberg PG, Roscher I, et al. Why a randomized melanoma screening trial is not a good idea. *Br J Dermatol.* 2018 Aug;179(2):532-533.
9. Watts CG, McLoughlin K, Goumas C, et al. Association Between Melanoma Detected During Routine Skin Checks and Mortality. *JAMA Dermatol.* 2021;157(12):1425-1436.
10. Welch HG, Mazer BL, Adamson AS. The Rapid Rise in Cutaneous Melanoma Diagnoses. *NEJM.* 2021;384:72-79.
11. Welch HG, Black WC. Overdiagnosis in Cancer. *JNCI.* 2010; 102(9):605-613.
12. Wu JH. The Limits of Screening. https://doi.org/10.17863/CAM.53085
13. Siu AL; U.S. Preventive Services Task Force. Screening for Breast Cancer: U.S. Preventive Services Task Force Recommendation Statement. *Ann Intern Med*. 2016;164(4):279-96.
14. Plutynski A. Ethical issues in cancer screening and prevention. *J Med Philos.* 2012; 37(3):310-323.
15. Stoff BK, Grant-Kels JM. The Ethics of Skin Cancer Screening. In: Bercovitch L, Perlis CS, Stoff BK, Grant-Kels JM. (eds) Dermatoethics. 2021. Springer, Cham.
16. Brodersen J, Siersma VD. Long-Term Psychosocial Consequences of False-Positive Screening Mammography. *Ann Fam Med*. 2013;11(2):106-115.
17. Welch HG, Kramer BS, Black WC. Epidemiologic Signatures in Cancer. *NEJM*. 2019;381:1378-1386.

18. Gilligan AM, Alberts DS, Roe DJ, et al. Death or Debt? National Estimates of Financial Toxicity in Persons with Newly-Diagnosed Cancer. *Am J Med.* 2018;131(10):1187-1199.
19. Lott JP, Boudreau DM, Barnhill RL, et al. Population-Based Analysis of Histologically Confirmed Melanocytic Proliferations Using Natural Language Processing. *JAMA Dermatol.* 2018;154(1):24-29.
20. Beauchamp TL, Childress JF. *Principles of Biomedical Ethics, 5th edn.* Oxford University Press, 2001.
21. John SD, Wu JH. "First, Do No Harm"? Non-Maleficence, Population health and the Ethics of Risk. *Soc Theory Pract.* Published online Feb 23, 2022. Available at: https://www.pdcnet.org/soctheorpract/content/soctheorpract_2022_0999_2_18_152.
22. Matthews NH, Li WQ, Qureshi AA, et al. Epidemiology of melanoma. *Exon Publications*. 2017;30:3-22.
23. Fischer AH, Wang TS, Yenokyan G, et al. Association of Indoor Tanning Frequency With Risky Sun Protection Practices and Skin Cancer Screening. *JAMA Dermatol.* 2017;153(2):168–174.
24. Gloster Jr. HM, Neal K. Skin cancer in skin of color. *J Am Acad Dermatol*. 2006;55:741-760.
25. Halder RM, Bridgeman-Shah S. Skin cancer in African Americans. *Cancer*. 1995;75:667-673
26. Byrd KM, Wilson DC, Hoyler SS, et al. Advanced presentation of melanoma in African Americans. *J Am Acad Dermatol*. 2004;50:21-24.
27. Cockburn MG, Zadnick J, Deapen D. Developing epidemic of melanoma in the Hispanic population of California. *Cancer*. 2006;106:1162-1168.
28. Hu S, Soza-Vento RM, Parker DF. Comparison of stage at diagnosis of melanoma among Hispanic, black, and white patients in Miami-Dade County, Florida. *Arch Dermatol*. 2006;142: 704- 708.
29. Tran MM, Smith CK, Andoscia G, et al. The Value of Partnerships in Multi-Component Skin Cancer Prevention Interventions. *RIMJ. 2022* Feb 1;105(1):42-45.

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Wandering Virtues, Moral Confusion

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INTRODUCTION

The COVID-19 pandemic has become an ego-dystonic period for physicians, posing competing moral needs and perceived obligations. This essay will review some of the traditional understandings of physicians' bioethical responsibilities and a description of the realities of the medical world that have challenged those understandings.

Within the many traditions of bioethics, there are commonly referenced principles, rules, and virtues that would animate the ethically refined physician.[1] Many physicians have taken the Hippocratic Oath, written in the 5th Century BCE.[2] Broadly speaking, the Hippocratic Oath obligates physicians to be grateful to those from whom they have learned, to apply their knowledge for the benefit of their patients, to avoid harming their patients, to maintain a certain moral purity, to avoid impropriety, and to maintain confidentiality. What this Oath suggests is that physicians must acknowledge and maintain a certain "art of medicine" and direct that art to the best interests of their patients. There are, however, many gaps in the "oath." It does not explicitly address the multiple ethical issues that occupy the beginning and end of life, ethical issues in managed care, the role of health insurance companies, nor the expanded role and prominence of Departments of Health. There is no implicit or explicit obligation to an overarching public health focused on improving population health.

To whom and to what are physicians obligated? The "good" of the patient? The "good" of the population? If so, which population?

DIRECTION OF OBLIGATIONS

It can be assumed that we, as physicians, perceive a primary obligation towards our personal patients. In the case of group practices, this obligation might extend to the well-being of our group's patients. Emotionally and ethically, however, we stratify these obligations. I (Dr. Felder) have a greater obligation to my own patients than to other patients cared for by my immediate colleagues. I have no particular obligation to patients cared for by other physicians with whom I have no professional relationship. Though, perhaps if a patient's actions directly, imminently, and significantly existentially threaten others, it provides the philosophical justification for overriding our obligation to the individual patient. What I am really touching on here is the limits of my ethical obligations, in direction and extent. Primarily, I am obligated to my patient. Only after that might I have obligations to others, in ever-expanding concentric circles. The primary care physician is not a public health physician with some broad obligation to society at large. This is neither mentioned in the Hippocratic Oath nor the Principles of Biomedical Ethics.[1,2] Rather, I have an obligation to the well-being of my patient.

During the COVID-19 pandemic, the direction of obligation has not been so clear. The presumed primacy of patient autonomy, as well as my obligation to my patients' best interests, are valued in the breach. We, as physicians, are often asked to donate personal protective equipment to other practices or institutions, instead of offering it to our patients. We are expected, at times, to pressure our patients to make medical decisions that will benefit others or that align with demands and rules of specific institutions, without considering the impact that those decisions may have on our own patients' health and autonomy. Specifically, when we require patients to be COVID-vaccinated in order to attend university or require a clinical professor to be COVID-vaccinated even when teaching "virtually", we are, essentially, saying that our patients' right to self-control and autonomy has been exhausted in favor of some other overriding principle or goal. When patients "agree" to the demands of others under threat of loss of employment or university enrollment, this "agreement" is hardly consistent with "informed consent", a fundamental expression of patient autonomy. This ought to trouble us. To the extent that physicians are party to this process, it reveals a lack of clarity regarding to whom our primary allegiance is owed. Am I obliged to respond to the needs of my patients, the Department of Health, the government, the requests of health insurance companies, or theoretical-future patients? If one ranks any of those "obligations" above the obligation to my patient, the burden of philosophical justification will be a heavy one.

Many other questions arise. Do physicians have an obligation to be vaccinated themselves or do they have the right to make decisions in accordance with their own personal values? Can physicians act upon views that differ from their parent medical organizations? Who will be authorized within an institution itself to make the very difficult moral

decisions and by what metric will those decisions be made? How do we understand the role of government and the rise of what appears to be a strong paternalism? Is strong paternalism justified? Has the COVID-19 pandemic reshaped our answers to these questions?

PSYCHOLOGY CHALLENGES VIRTUE

One of the greatest challenges to our ethical commitments comes from the psychological experience of caring for and about our patients. The inherent emotional strains of the COVID-19 pandemic have been dramatically different from any we have previously experienced. Virtually nothing was previously known about this infection. While we are accustomed to knowing much more about medical issues than our patients, this is no longer necessarily true. It can be threatening, humbling, and unsettling to our typical experience of relative expertise based on our sophisticated and academic fund of knowledge.

It can also be a lonely world as our interactions with colleagues now occur infrequently. I do not visit patients in the hospital or at home. Nor do I attend conferences. With COVID-19, cure is often impossible, and care can be elusive. How difficult it has been to counsel patients and families when their terribly ill relatives are hospitalized and the families are unable to visit. Patients are sad, hopeless, and helpless. Families want to hold their loved one's hand only to find that it is behind an impermeable synthetic barrier of infection control. Medicinal healing precludes a healing touch. We feel distant and disconnected, powerless, humbled, ineffective, unable to predict, lonely, burnt out, and frustrated. We are confused by our expanding real estate of medical uncertainty. We are, sadly, outraged by the widespread carnage that has resulted, in part, from our patients' personal and value-driven, yet unwise medical choices.

We have become all too familiar with our emotional experiences of negative judgment and frustration, anger, disappointment, and dislike. Many of these have been directed at the health insurance companies, the Departments of Health, the government, and, even, our patients. When the immunocompromised patient, who chose not to be immunized, calls demanding treatment, it can be challenging at the very least. When the insurance companies and public health officials believe that video "medicine" is as good as "in-person" health care, it can be hard to believe that we all have the same commitment to providing for the best interest of our patients. Depending on our moral development and social graces, we make the effort to retain our smile and provide help.

What we are observing is the contagious and insidious nature by which our psychological experiences invade our moral virtues. We experience a myriad of emotions including resentment, helplessness, loss of professional autonomy, loneliness, and confusion. These partly stem from our changing roles, a new (and perhaps manipulated) corpus and direction of ethical obligations, inadequate scientific knowledge, the narrowing knowledge gap between physicians and patients, and the experience of medical uncertainty. We experience our own transference, countertransference, and projection.

For many of us, these emotions and experiences chisel away at our aspirational virtues such as courage, self-effacement, empathy, non-judgmentalism, and care. It has become difficult, in some cases, to experience love and compassion when viewing our patients, as well as to experience solidarity when viewing (or thinking about/considering) our colleagues and leaders.

In the end, we will need to revisit some well-established metaethical questions. From where do our ethical principles come? How binding are they? What do we do when they conflict? How do we interact with others who possess a different "metaethical reality"? To whom do we look in times of moral uncertainty? What are the principles and methods of moral justification? How do we refine our character traits and moral virtues?

We will need to remind ourselves of the goals of medicine. We will want to continually remind ourselves of those moral beliefs and virtues which we hold most dear and simultaneously find a system for holding ourselves accountable. We are humans with foibles and challenges that can certainly be overcome by the enormous moral strengths that can be brought to bear.

References

1. Beauchamp, Tom L.; Childress, James F. *Principle of Biomedical Ethics*. 5th Edition. Oxford University Press; 2001;3-6:55-283.
2. Miles SH. *The Hippocratic Oath and the Ethics of Medicine*. Oxford University Press, USA; 2005.

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Towards an Improved Substance Use Disorder Treatment Landscape in Rhode Island – Barriers, Current Progress, and Next Steps

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ABSTRACT

Expanding addiction treatment services in Rhode Island has never been more urgent. Today, we face colliding syndemics of COVID-19, preventable drug overdoses, and HIV, with another year of record overdoses. While the treatment of substance use disorder (SUD) is an essential component of general medical care, numerous barriers prevent broader treatment access for patients in Rhode Island. Buprenorphine and methadone therapy have restrictions that are not applied to other areas in medicine, including for more dangerous medications. In this piece, we highlight existing barriers to care, applaud current progress being made in our state, and provide recommendations for next steps to turn the tide of this deadly epidemic. We hope that these proposed changes will help develop a robust treatment landscape for all patients with SUD in Rhode Island.

INTRODUCTION

With the colliding syndemics of COVID-19, opioid overdoses, HIV, and viral hepatitis,[1] as well as another year of record overdoses,[2] expanding addiction treatment services in Rhode Island has never been more urgent. Treatment of substance use disorder (SUD) is an essential component of general medical care, and any absence of its evidence-based prevention, screening, and treatment in healthcare is a matter of social and racial inequity. Too often, the medical and public health community treats substance use disorder as an acute condition, rather than a chronic and treatable disease with rates of successful management similar to that of hypertension and type II diabetes.[3] Fortunately, we have multiple efficacious interventions to reduce morbidity and mortality, improve wellbeing, and increase treatment retention for patients with SUDs; however, numerous barriers prevent broader access for patients in Rhode Island.

CURRENT BARRIERS

Buprenorphine and methadone therapy have restrictions that are not applied to other areas in medicine, including for more dangerous medications. Methadone treatment is tightly regulated by federal regulations and remains siloed from traditional clinical care, leading to disruptions in care and inaccessible treatment. For example, if a patient is newly initiated on methadone while hospitalized, this creates multiple barriers for continued care in post-acute care settings or inpatient addiction treatment after discharge. Rigid scheduling for daily methadone dosing frequently interferes with work scheduling, and certain occupations (i.e. truck driver) prohibit patients from methadone therapy. Buprenorphine clinics are often in inconvenient locations, have limited hours, and may require frequent visits or meetings with behavioral health as a prerequisite to medication initiation. Across the nation, neighborhood racial segregation predicts differences in access to both buprenorphine and methadone, with highly segregated Black and Hispanic/Latinx communities having more methadone facilities, while counties with segregated white communities having more buprenorphine facilities.[4]

Barriers are not limited to buprenorphine or methadone treatment. Spanish and other language services remain particularly limited in Rhode Island, especially among residential and intensive outpatient program (IOP) settings. Group counseling – which forms the crux of most IOP and partial hospital programs – can be especially difficult when interpreters are needed. Patients who lack insurance may only be able to seek SUD treatment at free clinics or mutual-aid meetings (Alcoholics Anonymous, etc.) and medications are often cost prohibitive. Patients on Medicaid are limited to certain residential treatment programs, Medicare does not cover inpatient addiction treatment, and insurance, rather than clinical stability, may dictate length of treatment for others. Residential facilities may legally reject patients who experience homelessness, or are not able to accept patients leaving the hospital with complex medical issues or who are not independent with activities of daily living. Group sober homes are largely unregulated, provide variable quality of living conditions, and may reject a patient for being prescribed opioid agonist treatment (OAT) or other prescribed controlled substances. Because of these systemic barriers, only a minority of patients receive evidence-based care,[5] such as OAT and interventions to address the social determinants of health. US immigration law dictates that a person is not eligible for a green card or a visa if they have a substance use disorder,[6] a policy routed in stigma, fear, and discrimination.

CURRENT PROGRESS

Our state has taken several important steps forward. For example, in 2016 the Rhode Island Department of Corrections became the first state correctional system to offer treatment with all FDA-approved medications (i.e., methadone, buprenorphine, and naltrexone) to incarcerated people with opioid use disorder; in the first year of this program's implementation, there was a 12% drop in statewide overdose deaths and a 61% drop in post-incarceration overdose deaths.[7] At the onset of the COVID-19 pandemic, after federal regulations changed to temporarily allow buprenorphine initiation via teleheath,[8] Rhode Island established a 24-hour buprenorphine hotline to serve as a "tele-bridge" clinic. Hotline providers evaluate callers in real time, initiate buprenorphine in appropriate patients, and then link them to longitudinal care in the community.[9] The Rhode Island Hospital Emergency Department has expanded their buprenorphine induction protocol after unintentional overdose (an intervention associated with a 37% reduction in all-cause mortality[10]) by post-ED visit outreach. Research initiatives are also being explored to address the overdose crisis by providing buprenorphine managed through the pharmacy (via a collaborative practice agreement)[11] and by increasing drug-checking services. Project Weber/RENEW, a peer-driven harm reduction organization, had provided over 900 HIV and hepatitis C tests, over 10,000 naloxone doses, over 48,000 condoms, and over 100,000 new needles in 2020 and 2021. To facilitate access to low-barrier treatment for opioid use disorder (OUD) and to increase screening and connection to care for HIV and viral hepatitis, Project Weber/RENEW has partnered with outreach physicians and the Miriam Immunology Clinic to create a clinic co-located in one of their drop-in centers. Project Weber/RENEW case managers and physicians are working together to provide wound care, rapid HIV and Hepatitis C screening, on-site STI screening, and streamlined treatment for hepatitis C and HIV pre-exposure prophylaxis initiation. In July 2021, Rhode Island became the first state in the nation to authorize an overdose prevention site (OPS)—a space for people to consume pre-obtained drugs with sterile supplies. Additionally, local legislation was recently changed to reclassify drug possession charges from a felony to a misdemeanor (for up to 10 grams of a substance) and decriminalize possession of nonprescribed buprenorphine.[12]

NEXT STEPS

A coordinated, compassionate, and evidence-based response can turn the tide of this deadly epidemic. Health service providers should examine and replace policies that penalize ongoing substance use (for example, employing punitive urine toxicology testing) in favor of harm- reduction practices, recognizing that ongoing use often indicates a need for more treatment rather than less. Establishing additional inpatient addiction consult services to more hospitals in the state is likely to benefit both patients and health systems.[13–15] Opening the newly sanctioned OPSs can be expected to reduce overdose mortality, drug use, and infectious disease risk, and facilitate access to health and social services.[16–19] In the first three weeks of their operation in November 2021 in New York City, the nation's first two sanctioned OPSs reversed 59 overdoses.[20] And in the setting of an increasingly toxic illicit drug supply, we need expanded access to opioid reversal agents (i.e. naloxone) and drug-checking technology (i.e. fentanyl or methamphetamine test strips). Drawing on the success of several injectable OAT programs in parts of Canada and Western Europe, it's time to have a serious conversation about safe supply, especially for treatment-refractory OUD.[21,22] Housing First is also an additional evidence-based practice to serve patients experiencing chronic homelessness with mental illness and SUD.[23]

Opioid Agonist Treatment

Changes are needed to increase the accessibility and flexibility of OAT. While the in-person daily dosing requirement for methadone is helpful for many, it is currently applied across the board and providers have limited ability to adjust or titrate as patients stabilize in recovery. During the COVID-19 pandemic when many clinics liberalized their take-home policy, many Opioid Treatment Program (OTP) patients did well with increased access to take home doses.[24] A change to consider is allowing for a limited or modified OTP license in academic health centers or community health centers[25] – settings in which patients with SUD already access care. We should consider allowing primary care providers to prescribe methadone for OUD with pharmacy-based administration, the current model for methadone delivery in several provinces in Canada, Australia, and the UK.[26] With appropriate clinical caution, primary care and outpatient addiction providers are well equipped to manage methadone maintenance therapy.

For buprenorphine, immediate steps to lower barriers to treatment include continuing the COVID-19 emergency exception authorizing audio-only tele-initiation and eliminating the prior authorization requirement for injectable buprenorphine. Additionally, discontinuing the X waiver requirement would allow more providers to prescribe buprenorphine.[27,28] At present, only higher-dose sublingual, buccal, subdermal, or subcutaneous buprenorphine formulation may be prescribed for OUD. Given the significant risk of precipitated withdrawal during buprenorphine initiation with increasingly pervasive fentanyl use,[29–31] expanded access to lower-dose transdermal and buccal buprenorphine formulations would support micro-induction in an outpatient setting. Currently, it remains illegal to prescribe these products for OUD, even for short courses to bridge patients to OUD-treatment dose buprenorphine. Anecdotally, some providers send their patients to the ED to obtain

these medications to facilitate induction, creating unnecessary strain for ED providers for care that otherwise could be delivered in the outpatient setting. Additionally, many buprenorphine formulations require prior authorization based on insurance preference and/or dispensing limits. The delay to treatment that these additional steps can cause can prove fatal given the current drug supply.

Primary care settings can take many harm reduction steps to better serve patients who use drugs,[32] such as providing naloxone, offering treatment on demand, approaching urine drug testing as just one tool in their overall assessment (and consider ordering only when the results will change management, such as confirming the presence of prescribed buprenorphine), and installing reverse motion detectors in high-risk areas to prevent overdose. To reduce and treat infections they could offer HIV, viral hepatitis, and bacterial STI testing, prescribe HIV pre- and post-exposure prophylaxis, vaccinate against hepatitis A and B, and co-locate hepatitis C and SUD care, in addition to providing harm reduction supplies such as syringes and fentanyl test strips to spark discussion on safer consumption technique.

Optimizing the Addiction Medicine Workforce

Diversification of the addiction treatment workforce provides a path to improve care. Steps include: promoting Black, Hispanic, and Native individuals to leadership, hiring individuals from affected communities, and formally including people with lived experience.[33] Since tailored care such as street outreach improve perceptions of treatment,[34] steps to combine street outreach and telemedicine offer promising opportunities to extend addiction providers' reach. More residential and inpatient medically managed withdrawal (i.e. detox) beds are needed in the state, especially for elderly patients and patients from the community rather than solely from hospitals. There is a particular need for inpatient addiction treatment programs that do both psychosocial support and treat medical complications of SUD.

LIMITATIONS AND CONCLUSION

These investments need to be developed while considering the impact that structural racism has on how patients with SUD are viewed and treated. Any efforts to improve addiction treatment must include support for justice-involved populations, and acknowledge the historic and systemic racism that has led to mass incarceration, particularly in communities of color.[35] We must continue to advocate for evidence-based criminal justice reform as existing laws often disrupt treatment and can prevent sustained recovery.

We recognize that many of the included points are most applicable to OUD. At the same time, opioids remain the main driver of overdose-related deaths. However, it is also vital to study and fund research into treatment for stimulant use disorders, and to promote access to safer stimulant consumption services. We also recognize that many of these changes described above require federal legislative and regulatory action. Still, we hope that these proposed changes will help develop a robust treatment landscape for all patients with SUD in Rhode Island.

References

1. Taylor JL, Ruiz-Mercado G, Sperring H, Bazzi AR. A collision of crises: Addressing an HIV outbreak among people who inject drugs in the midst of COVID-19. *J Subst Abuse Treat*. 2021;124:108280. doi:10.1016/j.jsat.2021.108280
2. Products – Vital Statistics Rapid Release – Provisional Drug Overdose Data. Published October 6, 2021. Accessed October 20, 2021. https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm
3. McLellan AT, Lewis DC, O'Brien CP, Kleber HD. Drug dependence, a chronic medical illness: implications for treatment, insurance, and outcomes evaluation. *JAMA*. 2000;284(13):1689-1695. doi:10.1001/jama.284.13.1689
4. Goedel WC, Shapiro A, Cerdá M, Tsai JW, Hadland SE, Marshall BDL. Association of Racial/Ethnic Segregation With Treatment Capacity for Opioid Use Disorder in Counties in the United States. *JAMA Network Open*. 2020;3(4):e203711. doi:10.1001/jamanetworkopen.2020.3711
5. Madras BK, Ahmad NJ, Wen J, et al. Improving Access to Evidence-Based Medical Treatment for Opioid Use Disorder: Strategies to Address Key Barriers Within the Treatment System. *NAM Perspectives*. Published online April 27, 2020. doi:10.31478/202004b
6. Section 212 of the Immigration and Nationality Act, 8 USC 1182: Inadmissible aliens. Accessed December 24, 2021. http://uscode.house.gov/view.xhtml?req=granuleid%3AUSC-prelim-title8-section1182&num=0&edition=prelim
7. Clarke JG, Martin RA, Gresko SA, Rich JD. The First Comprehensive Program for Opioid Use Disorder in a US Statewide Correctional System. *Am J Public Health*. 2018;108(10):1323-1325. doi:10.2105/AJPH.2018.304666
8. DEA. *DEA068 - SAMHSA Buprenorphine Telemedicine*. DEA; 2020. Accessed November 20, 2021. https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-022)(DEA068)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20%20(Final)%20+Esign.pdf
9. Samuels EA, Clark SA, Wunsch C, et al. Innovation During COVID-19: Improving Addiction Treatment Access. *J Addict Med*. Published online May 12, 2020:10.1097/ADM.0000000000000685. doi:10.1097/ADM.0000000000000685
10. Larochelle MR, Bernson D, Land T, et al. Medication for Opioid Use Disorder After Nonfatal Opioid Overdose and Association With Mortality. *Ann Intern Med*. 2018;169(3):137-145. doi:10.7326/M17-3107
11. Green T, Bratberg J. MATPharm: "A Collaborative Care Model for Addiction Treatment in Pharmacies" Submission: #3003369. Presented at: CPDD 83rd Annual Scientific Virtual Meeting; June 21, 2021.
12. Kneen O. R.I. changes drug possession charges from felonies to misdemeanors. The Brown Daily Herald. Published October 22, 2021. Accessed December 23, 2021. https://www.browndailyherald.com/article/2021/10/r-i-changes-drug-possession-charges-from-felonies-to-misdemeanors
13. Barocas JA, Savinkina A, Adams J, et al. Clinical impact, costs, and cost-effectiveness of hospital-based strategies for addressing the US opioid epidemic: a modelling study. *The Lancet Public Health*. 2021;0(0). doi:10.1016/S2468-2667(21)00248-6
14. Weinstein ZM, Wakeman SE, Nolan S. Inpatient Addiction Consult Service: Expertise for Hospitalized Patients with Complex

Addiction Problems. *Med Clin North Am*. 2018;102(4):587-601. doi:10.1016/j.mcna.2018.03.001

15. Trowbridge P, Weinstein ZM, Kerensky T, et al. Addiction consultation services – Linking hospitalized patients to outpatient addiction treatment. *J Subst Abuse Treat*. 2017;79:1-5. doi:10.1016/j.jsat.2017.05.007
16. Kral AH, Lambdin BH, Wenger LD, Davidson PJ. Evaluation of an Unsanctioned Safe Consumption Site in the United States. *N Engl J Med*. 2020;383(6):589-590. doi:10.1056/NEJMc2015435
17. Davidson PJ, Lambdin BH, Browne EN, Wenger LD, Kral AH. Impact of an unsanctioned safe consumption site on criminal activity, 2010–2019. *Drug and Alcohol Dependence*. 2021;220:108521. doi:10.1016/j.drugalcdep.2021.108521
18. Kral AH, Davidson PJ. Addressing the Nation's Opioid Epidemic: Lessons from an Unsanctioned Supervised Injection Site in the U.S. *Am J Prev Med*. 2017;53(6):919-922. doi:10.1016/j.amepre.2017.06.010
19. Wood E, Tyndall MW, Zhang R, Montaner JSG, Kerr T. Rate of detoxification service use and its impact among a cohort of supervised injecting facility users. *Addiction*. 2007;102(6):916-919. doi:10.1111/j.1360-0443.2007.01818.x
20. Overdose Prevention Centers Averted 59 Overdoses in First Three Weeks of Operation - NYC Health. Accessed December 22, 2021. https://www1.nyc.gov/site/doh/about/press/pr2021/overdose-prevention-centers-prevent-59-deaths.page
21. Kimmel S, Bach P, Walley AY. Comparison of Treatment Options for Refractory Opioid Use Disorder in the United States and Canada: a Narrative Review. *J Gen Intern Med*. 2020;35(8):2418-2426. doi:10.1007/s11606-020-05920-0
22. Harris MT, Seliga RK, Fairbairn N, et al. Outcomes of Ottawa, Canada's Managed Opioid Program (MOP) where supervised injectable hydromorphone was paired with assisted housing. *International Journal of Drug Policy*. 2021;98:103400. doi:10.1016/j.drugpo.2021.103400
23. Watson DP, Shuman V, Kowalsky J, Golembiewski E, Brown M. Housing First and harm reduction: a rapid review and document analysis of the US and Canadian open-access literature. *Harm Reduction Journal*. 2017;14(1):30. doi:10.1186/s12954-017-0158-x
24. Brothers S, Viera A, Heimer R. Changes in methadone program practices and fatal methadone overdose rates in Connecticut during COVID-19. *J Subst Abuse Treat*. 2021;131:108449. doi:10.1016/j.jsat.2021.108449
25. Taylor JL, Kimmel S, Walley AY. *Connecting Care Episode 7 – Strengthening Methadone Programs: Advancing Policy and Practice in the US*.
26. Joudrey PJ, Chadi N, Roy P, et al. Pharmacy-based methadone dispensing and drive time to methadone treatment in five states within the United States: A cross-sectional study. *Drug Alcohol Depend*. 2020;211:107968. doi:10.1016/j.drugalcdep.2020.107968
27. Fiscella K, Wakeman SE, Beletsky L. Buprenorphine Deregulation and Mainstreaming Treatment for Opioid Use Disorder: X the X Waiver. *JAMA Psychiatry*. 2019;76(3):229-230. doi:10.1001/jamapsychiatry.2018.3685
28. To Help Providers Fight The Opioid Epidemic, "X The X Waiver" | Health Affairs. Accessed December 11, 2021. https://www.healthaffairs.org/do/10.1377/hblog20190301.79453/full/
29. Martinez S, Jones JD, Brandt L, Campbell ANC, Abbott R, Comer SD. The Increasing Prevalence of Fentanyl: A Urinalysis-Based Study Among Individuals With Opioid Use Disorder in New York City. *Am J Addict*. 2021;30(1):65-71. doi:10.1111/ajad.13092
30. Ciccarone D. Editorial for "US Heroin in Transition: Supply Changes, Fentanyl Adulteration and Consequences" IJDP Special Section. *Int J Drug Policy*. 2017;46:107-111. doi:10.1016/j.drugpo.2017.06.010
31. Randhawa PA, Brar R, Nolan S. Buprenorphine-naloxone "microdosing": an alternative induction approach for the treatment of opioid use disorder in the wake of North America's increasingly potent illicit drug market. *CMAJ*. 2020;192(3):E73. doi:10.1503/cmaj.74018
32. Taylor JL, Johnson S, Cruz R, Gray JR, Schiff D, Bagley SM. Integrating Harm Reduction into Outpatient Opioid Use Disorder Treatment Settings : Harm Reduction in Outpatient Addiction Treatment. *J Gen Intern Med*. Published online June 22, 2021. doi:10.1007/s11606-021-06904-4
33. Jackson DS, Nguemeni Tiako MJ, Jordan A. Disparities in Addiction Treatment: Learning from the Past to Forge an Equitable Future. *Medical Clinics of North America*. 2022;106(1):29-41. doi:10.1016/j.mcna.2021.08.008
34. Kertesz SG, Holt CL, Steward JL, et al. Comparing homeless persons' care experiences in tailored versus nontailored primary care programs. *Am J Public Health*. 2013;103 Suppl 2:S331-339. doi:10.2105/AJPH.2013.301481
35. Gramlich J. Black imprisonment rate in the U.S. has fallen by a third since 2006. Pew Research Center. Accessed December 12, 2021. https://www.pewresearch.org/fact-tank/2020/05/06/share-of-black-white-hispanic-americans-in-prison-2018-vs-2006/

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On the Ethics of Mandatory Reporting of Positive Drug Tests in Newborns and Pregnant Parents at the Time of Delivery

JONATHAN SPIEGEL, ScB, AB, MD'23; GREGORY COHAN, AB, MD'23; E. CHRISTINE BROUSSEAU, MD; ELIZABETH TOBIN-TYLER, JD, MA

ABSTRACT

The opioid epidemic has renewed debate about how to structure laws, agency policies and hospital protocols for mandatory reporting of illicit substances during pregnancy. This paper analyzes the ethics of Rhode Island's approach to mandatory reporting – in particular, reporting of positive maternal and newborn drug tests at time of delivery. Given that state intervention is generally perceived by pregnant people as punitive and threatening to their family, we consider how four elements often used to justify punitive action by the state – retribution, deterrence, rehabilitation, and incapacitation (societal protection) – apply to Rhode Island's policy and approach to prenatal substance use. In addition, the paper considers the equity implications of Rhode Island's approach. It concludes that, given the potential for the policy to do more harm than good, investment of resources would be better spent on clinical and community services that support substance using parents and their newborns.

KEYWORDS: public health ethics, substance use, pregnancy, mandatory reporting law, hospital policies, child protective services

INTRODUCTION

A 22-year-old woman arrives at her obstetrician's office for her first prenatal visit. During the appointment, she is asked if she uses tobacco products, drinks alcohol, or uses illicit substances; she reports twice weekly cannabis use. This positive verbal drug screen triggers a urine drug test with a repeat test during the third trimester. The patient is informed that if the test in the third trimester is positive, she and her newborn will be tested at the time of birth. Rather than consent to this testing, the woman leaves the office and is lost to follow-up.

According to the Centers for Disease Control and Prevention (CDC), an estimated 48.2 million people used cannabis at least once in 2019, while the American College of Obstetricians and Gynecologists (ACOG) reports cannabis use during 2–5% of pregnancies.[1] This percentage increases to 15–28% of pregnancies among urban, young, and low-socioeconomic status populations.[2] In addition to cannabis use during pregnancy, there are an estimated 750,000 cocaine-exposed pregnancies each year, and maternal opioid use is found in 0.82% of deliveries.[3,4]

An intricate web of interacting federal laws, state laws,[5] government agency guidelines, and healthcare institution policies govern the response to substance use in pregnancy. An exploration of this complex landscape is beyond the scope of this paper; here we focus on how Rhode Island's state law, R.I. Gen. Law § 40-11-6, governing health care provider reporting of suspected abuse and neglect, is applied, implemented and enforced in cases involving substance use by pregnant patients.[6] While we focus on this specific law, the ethical and clinical questions raised by the case above apply to other state laws, agency policies and institutional practices surrounding mandatory reporting of positive drug tests in pregnant individuals and neonates.

This article assesses some ethical questions associated with the potential benefits and harms of Rhode Island's law and policy governing mandatory reporting of pregnant parents and newborns with positive drug tests to the Department of Children, Youth and Families (DCYF), the state's child protective services agency. We consider the potential ethical justifications and evidence for state intervention based on drug testing at birth. Given that DCYF involvement is generally perceived by pregnant people as punitive and threatening to their family, we consider how four elements often used to justify punitive action by the state – retribution, deterrence, rehabilitation, and incapacitation (societal protection)[7] – apply to Rhode Island's policy and approach to prenatal substance use. We also discuss the equity implications of the policy.

RHODE ISLAND LAW AND POLICY REGARDING PRENATAL DRUG EXPOSURE

RI Gen. Law § 40-11-6 mandates that whenever a "health-care provider is involved in the delivery or care of infants born with, or identified as being affected by, substance abuse or withdrawal symptoms resulting from prenatal drug exposure or a fetal alcohol spectrum disorder" they must report it to DCYF. DCYF guidance interprets the law to require that a provider must make a report when "a mother of a newborn tests positive for an illegal or non-prescribed controlled substance and/or misused prescribed controlled substance and the infant has not tested positive or when a neonate tests

positive."[8] At Women & Infants Hospital (WIH), RI's largest delivery hospital, neonatal drug tests are pursued for any newborn whose mother either tests positive for illegal substance use or refuses testing at the time of presentation to the hospital for delivery.[9]

Once a report is made to DCYF, it may open an investigation into whether the newborn is in danger of child abuse or neglect as defined by state law. In some cases, based on that investigation, a newborn may be temporarily removed from the care of parents. Although certainly removal is not the only outcome of an investigation, according to DCYF, 126 newborns less than 60 days old were removed from their parents' care in 2020.[10] The data does not indicate the reason for report or removal. Nonetheless, the possibility of removal resulting from a health care provider's report based on a positive drug screen induces fear among pregnant people. Thus, fear of removal may affect their decisions about their own health care, most importantly, obtaining regular prenatal care.[11] Given these potential consequences, it is important to assess the benefits and harms of the state's policy of mandating the reporting of all positive maternal and neonatal drug tests to DCYF at the time of delivery.

CURRENT POLICY MOTIVATIONS

To fairly assess the current policy, we first assess policymakers' motivations. In-utero exposure to many substances – both licit and illicit – can have significant health consequences for infants. Exposure to alcohol may cause fetal alcohol syndrome, characterized by cognitive deficits, changes in face structure, and impaired growth. Increasing evidence suggests that marijuana is associated with several adverse effects for fetuses.[12] Opioid exposure can cause neonatal abstinence, which involves symptoms of withdrawal, impaired growth, and seizures. And cigarette smoking is the largest known risk factor for low birth weight in developed countries.[13] Not only do these health conditions have severe and lasting impacts, but their burden falls on individuals who had no agency in bringing them about. It is understandable, then, that policy makers seek to protect infants from these outcomes. Well-intentioned though these policies may be, they must still be evaluated critically to understand if they are achieving their goals and promoting maternal and neonatal health and well-being.

Importantly, DCYF wears many hats after being contacted regarding a newborn with neonatal abstinence syndrome or a positive drug screening. DCYF's *Infant Plans of Safe Care Guidance Document 14*8 describes three goals: 1) identify infants at risk of child abuse and neglect as a result of prenatal substance exposure, 2) ensure that a Plan of Safe Care (POSC) is developed for these infants, and 3) ensure the referral of these infants and affected caregivers to appropriate services. Here, we focus on the first of these efforts by DCYF – identification of infants at risk of child abuse and neglect – for two reasons. First, identifying risk of abuse and neglect depends on discretionary decision-making by DCYF staff that may lead to the separation of parents and children as well as potentially inequitable outcomes based on socioeconomic status, race and ethnicity. Second, because DCYF involvement is perceived as punitive, requiring reporting in every case in which there is a positive maternal or neonatal drug test at birth undermines potentially more beneficial therapeutic options that could be undertaken in clinical settings. We describe these options later in this article.

JUSTIFICATIONS FOR DCYF INVOLVEMENT

Is DCYF intervention a Punishment for Drug Use?

While the consequences of the current policy (i.e., healthcare provider mandatory reporting of illicit substance use by pregnant people to DCYF) may not be intended as punitive, the policy constitutes a punishment by meeting the criteria set out by philosophers such as Bean:[15] it is a sanction handed out in response to an actual or alleged offense by an agency (in this case the clinician or hospital) and it is generally perceived as unpleasant by the victim (the patient). Indeed, subjective research supports the view that pregnant patients usually view DCYF involvement as unpleasant and as a punishment.[16] Given the evidence that pregnant people perceive intervention by child protective services agencies based on their use of substances as punitive, we analyze four ethical justifications for punishment – retribution, deterrence, rehabilitation, and incapacitation – to consider how these justifications function to address illicit substance use by pregnant people.

Retribution

Is illicit substance use during pregnancy something for which 'just desserts' must be served? More specifically, does use of substances potentially affecting the health of a fetus constitute abuse or another type of morally relevant harm? One of the problems with retribution based on potential harm to a fetus is that it opens up a slippery slope of government interventions based on a person's behavior during pregnancy. This is evident from proposed fetal protection laws that criminalize certain behaviors of pregnant people.[17] There are a panoply of other behaviors that state policymakers and state actors may deem less morally objectionable than illicit substance use that may still confer risk to fetal and neonatal well-being during pregnancy. For instance, should healthcare providers report and DCYF investigate every pregnant parent who smokes cigarettes, eats soft cheeses, drinks caffeine, works with pesticides, takes teratogenic medications they were prescribed, has unprotected sex with multiple partners, poorly controls their blood sugar or blood pressure, remains unvaccinated to infections, or goes without a mask or other COVID-19 precautions? Would choices made early in life among those who plan to have children, such as

working jobs that increase the risk of spermatogonia irradiation, be responded to with such investigations? Since none of these cases are deemed moral wrongdoings deserving of punishment, we therefore ask what justifications beyond social stigma earn illicit substance use during pregnancy its current unique status? Here we echo ACOG's committee opinion on this matter, in which they encouraged obstetrician-gynecologists to work to "retract legislation that punishes women for substance abuse during pregnancy."[18]

Deterrence

Another justification for punitive policies is deterrence. One might hypothesize that the threat of DCYF involvement reduces the likelihood of prenatal substance use. Most current literature, however, does not find evidence supporting a deterrence effect for substance use related punishments.[19,20] Further research suggests a possible explanation: while crime that involves conscious planning may be impacted by deterrence, substance use and addiction are rarely impacted by this sort of cost-benefit analysis.[21] Substance use disorder is now understood as a disease that requires proper therapeutic intervention, not a willful behavior that can be scared out of people.

Deterrence as a policy motivation is also potentially risky, as fear of losing one's newborn may deter help-seeking rather than deterring substance use. Some individuals, particularly those who are unable to abstain due to addiction, may be less likely to attend prenatal appointments or use the birthing hospital if they fear reporting to the state. Such potential loss of patients to prenatal care is particularly concerning given evidence that prenatal care reduces the impact of illicit drug use on perinatal outcomes.[22] Apprehension about reporting may prevent patients from speaking with their healthcare providers about their substance use during pregnancy, reducing the benefits conferred by prenatal care. Fear of state involvement might also drive those with addiction to go through withdrawal unaided, without critical supports and information about what to do in the event they relapse. Indeed, most people who use substances attempt to reduce their use or abstain when they discover they are pregnant, highlighting the opportunity for medical professionals to aid these individuals and raising the question of whether state involvement is the best means to promote deterrence.[23]

Rehabilitation

While the evidence does not support deterrence through punitive actions, and in fact suggests that there is the potential for more harm than benefit, other policies such as screening, brief intervention, and referral to treatment (SBIRT) protocols have been shown to effectively reduce substance use during pregnancy.[24] If the goal of requiring healthcare providers to report substance-using pregnant people to DCYF is to connect them to rehabilitative services and protect the health and safety of the newborn, then the question becomes: is a punitive policy (or at least one that is perceived as such) the best road to rehabilitation? Many pregnant persons are motivated to reduce or eliminate their substance use, often for the same reason that they fear DCYF involvement: a desire to be present in the life of and promote the well-being of their future child. This motivation can therefore likely be leveraged without the threat of family separation which looms over families when DCYF becomes involved. As discussed above, while DCYF currently does important work in trying to connect parents with rehabilitative programs and services, these same goals may be achieved through healthcare providers and their community partners (e.g., recovery programs, social service agencies, etc.), without families experiencing the strains that come with state involvement. Alternatively, if DCYF is to be involved, it's role should be to work collaboratively with clinicians, without the looming threat of removal, as early as possible in pregnancy. In situations in which healthcare providers – obstetric, pediatric, primary care – suspect that substance use is leading to abuse and neglect, they always have the option of reporting this to DCYF; indeed, they are mandated to do so.

Incapacitation

Perhaps it is incapacitation, then, that justifies reporting all positive screens for illicit drugs to DCYF at birth; allowing individuals to continue without intervention may increase the risk of substantial future harms. Notably however, there are no incapacitation benefits related to fetal development conferred by the current policy since DCYF involvement based on positive drug testing at birth only occurs after the end of the prenatal period. Apart from incarcerating a pregnant parent to restrict their use of illicit substances, incapacitation (preventing the unwanted behavior) can only occur after the delivery of the newborn. In order to satisfy incapacitation goals, therefore, illicit substance use during pregnancy would need to predict future (postnatal) mistreatment of a child, and DCYF involvement would seek to prevent this mistreatment.

Predicting future harm based on drug screening has not been well-studied; thus, there is not strong evidence for policy based on this justification for reporting. Further, if present substance use does indeed predict future child abuse and/or neglect, should any clinician caring for a parent who uses substances (e.g., in internal medicine and family medicine) assume such and report that parent to DCYF, even when they have no suspicion that the substance use endangers the patient's children? Policy governing mandatory reporting of parents to DCYF based on substance use is only justified if a strong nexus between use of illicit substances and potential for abuse and/or neglect is demonstrated.

EQUITY CONCERNS

The policy of mandatory reporting of all maternal or newborn positive drug screens at birth to DCYF is partly

justified as a way to remove discretion from healthcare providers whose decision-making may be driven by biases based on race, ethnicity and/or socioeconomic status. But as noted above, discretionary decision-making by DCYF officials still leaves room for inequitable outcomes (such as which parents have children removed from their care) based on bias. The reservation of mandatory reporting based solely on substance use of pregnant parents, but not that of other parents, also raises gender equity concerns. If the goal is to protect a child from the harms of parental drug use, then substance-using fathers and other partners would be just as relevant to potential future harm as a pregnant parent. Holding pregnant people, especially those from historically marginalized communities, uniquely accountable through a punitive approach for the societal problem of substance misuse is inequitable.

CONCLUSION

While we do not question that illicit substance use may, in certain circumstances, cause harm to a developing fetus, the current Rhode Island policy of mandatory reporting of all positive maternal and newborn drug tests at birth to DCYF does more harm than good. Because reporting to DCYF is generally understood by parents as punitive and because a positive drug test is not known to predict future child abuse and/or neglect, this response to substance use during pregnancy is counterproductive and lacks justification under any consideration of retribution, deterrence, rehabilitation, and/or incapacitation. Importantly, it tends to undermine, rather than support, treatment for maternal substance use disorders.

Instead, we support an equitable, evidence-based, and therapeutic approach which aims to prevent and reduce the harms caused by illicit substance use during pregnancy. This approach reinforces a trusting provider-patient relationship rather than penalizing patients for disclosing their substance use history. Limited resources now spent on testing, reporting and investigation would be better employed developing and implementing an evidence-based[23] rehabilitative and non-punitive approach that enables providers to develop and maintain therapeutic patient relationships and to connect patients to recovery and supportive social services. Most importantly, resources should be redeployed toward addiction treatment services tailored to pregnant people. These services are currently in short supply in Rhode Island.

References

1. Centers for Disease Control and Prevention. (2021, June 8). Marijuana and Public Health: Data and statistics. https://www.cdc.gov/marijuana/data-statistics.htm
2. Marijuana use during pregnancy and lactation. ACOG. https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2017/10/marijuana-use-during-pregnancy-and-lactation
3. Cain MA, Bornick P, Whiteman V. The maternal, fetal, and neonatal effects of cocaine exposure in pregnancy. *Clin Obstet Gynecol.* 2013;56(1):124-132. doi:10.1097/GRF.0b013e31827ae167
4. Hirai AH, Ko JY, Owens PL, et al. Neonatal Abstinence Syndrome and Maternal Opioid-Related Diagnoses in the US, 2010-2017. JAMA 2021; 325:146.
5. Substance use during pregnancy. Guttmacher Institute. (2022, January 5). https://www.guttmacher.org/state-policy/explore/substance-use-during-pregnancy
6. http://webserver.rilin.state.ri.us/Statutes/TITLE40/40-11/40-11-6.htm
7. Marson J. (2015). The History of Punishment: What Works for State Crime?. The Hilltop Review, 7(2), 4.
8. State of Rhode Island Department of Children, Youth and Families: Infant Plans of Safe Care Guidance. https://health.ri.gov/materialbyothers/guidelines/DCYFInfantPlansOfSafeCare.pdf
9. Women and Infants Hospital. Cannabis and Substance Use in Pregnancy Screening and Testing Policy. November 5, 2020.
10. Rhode Island Department of Children, Youth and Families. RPT 460R from 7/10/2020, count and percent of newborns less than 60 days old FY2018-FY2020.
11. Roberts SC, Nuru-Jeter A. (2010). Women's perspectives on screening for alcohol and drug use in prenatal care. *Women's Health Issues*, *20*(3), 193-200.
12. Martin GI. (2020). Marijuana: the effects on pregnancy, the fetus, and the newborn. *Journal of Perinatology*, *40*(10), 1470-1476.
13. Kramer MS. (1987). Determinants of low birth weight: methodological assessment and meta-analysis. *Bulletin of the world health organization*, *65*(5), 663.
14. Marson J. (2015). The History of Punishment: What Works for State Crime?. The Hilltop Review, 7(2), 4.
15. Roberts SC, Nuru-Jeter A. (2010). Women's perspectives on screening for alcohol and drug use in prenatal care. *Women's Health Issues*, *20*(3), 193-200.
16. What's wrong with fetal rights. American Civil Liberties Union. https://www.aclu.org/other/whats-wrong-fetal-rights
17. Substance abuse reporting and pregnancy: The role of the obstetrician–gynecologist. ACOG. https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2011/01/substance-abuse-reporting-and-pregnancy-the-role-of-the-obstetrician-gynecologist
18. Friedman SR, Pouget ER, Chatterjee S, et al. Drug arrests and injection drug deterrence. *Am J Public Health*. 2011;101(2):344-349. doi:10.2105/AJPH.2010.191759
19. The Pew Charitable Trusts. "More Imprisonment Does Not Reduce State Drug Problems: Data show no relationship between prison terms and drug misuse." March 2018.
20. Johnson B. (2019). Do Criminal Laws Deter Crime?: Deterrence Theory in Criminal Justice Policy: A Primer. MN House Research.
21. El-Mohandes A, Herman AA, El-Khorazaty MN, Katta PS, White D, Grylack L. (2003). Prenatal care reduces the impact of illicit drug use on perinatal outcomes. *Journal of Perinatology*, *23*(5), 354-360.
22. McHugh RK, Wigderson S, Greenfield SF. (2014). Epidemiology of substance use in reproductive-age women. *Obstetrics and Gynecology Clinics*, *41*(2), 177-189.
23. Martino S, Ondersma SJ, Forray A, Olmstead TA, Gilstad-Hayden K, Howell HB, Yonkers KA. (2018). A randomized controlled trial of screening and brief interventions for substance misuse in reproductive health. *American journal of obstetrics and gynecology*, *218*(3), 322-e1.

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Pembrolizumab-induced Toxic Epidermal Necrolysis in a Patient with Metastatic Esophageal Adenocarcinoma

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ABSTRACT

Adverse cutaneous reactions associated with the immune checkpoint inhibitor (ICI) pembrolizumab are well documented, yet life-threatening reactions such as Stevens-Johnson syndrome/toxic epidermal necrolysis (SJS/TEN) are infrequent.[1,2] We present a case of pembrolizumab-induced TEN in a patient with metastatic esophageal adenocarcinoma who was successfully treated with cyclosporine and systemic corticosteroids.

KEYWORDS: Stevens-Johnson syndrome, toxic epidermal necrolysis, pembrolizumab, cyclosporine

CASE REPORT

A 77-year-old white man with metastatic esophageal adenocarcinoma presented to his outpatient oncologist with an acute onset pruritic morbilliform eruption that began 24 hours after his fourth cycle of folinic acid, fluorouracil, and oxaliplatin (FOLFOX)/trastuzumab and second cycle of pembrolizumab (**Figure 1A**). He was treated with methylprednisolone 80 mg IV, diphenhydramine 25 mg IV, and sent home with an eight-day low dose oral prednisone taper (40 mg PO maximum dose). Seven days later, he returned given rash persistence for which he received an additional dose of methylprednisolone 80 mg IV and was initiated on an additional course of oral steroids (60 mg PO maximum dose). Two days later, he demonstrated bullae and presented to the Emergency Department. Physical examination revealed a hemodynamically stable, non-toxic appearing patient with a diffuse morbilliform eruption, scattered dusky foci, flaccid bullae on the abdomen and back, tense palmoplantar bullae, and sacral and medial buttocks with full-thickness desquamation. Orogenital and ocular mucosal surfaces were spared. Nikolsky and Absoe-Hansen signs were positive. Total body surface area (BSA) approached 90% (**Figure 1B**). He reported fevers and fatigue.

The patient was admitted to the trauma intensive care unit (TICU) and was started on prednisone PO 1 mg/kg/day. Skin biopsy revealed full-thickness epidermal necrosis with subjacent sparse superficial perivascular lymphocytic inflammation with few admixed eosinophils (**Figure 2**). Direct immunofluorescence (DIF) studies were negative for IgA, IgM, IgG, C3, and fibrinogen deposition.

Clinicopathologic correlation confirmed a grade IV immune-related cutaneous adverse event (ir-CAE) presenting

Figure 1. Clinical progression of pembrolizumab-induced TEN. (A) Diffuse pruritic morbilliform eruption noted in the setting of recent pembrolizumab infusion, prior to eruption of painful bullae. Photo taken 24 hours after pembrolizumab infusion. **(B)** Diffuse dusky morbilliform eruption with areas of frank desquamation. Photo taken 10 days after pembrolizumab, on day 1 of hospitalization. **(C)** Continued reepithelialization following combination therapy with cyclosporine and high dose oral prednisone. Photo taken on day 17 of hospitalization. **(D)** Near complete re-epithelialization after combination therapy with cyclosporine and high dose oral prednisone. Photo taken on day 24 of hospitalization.

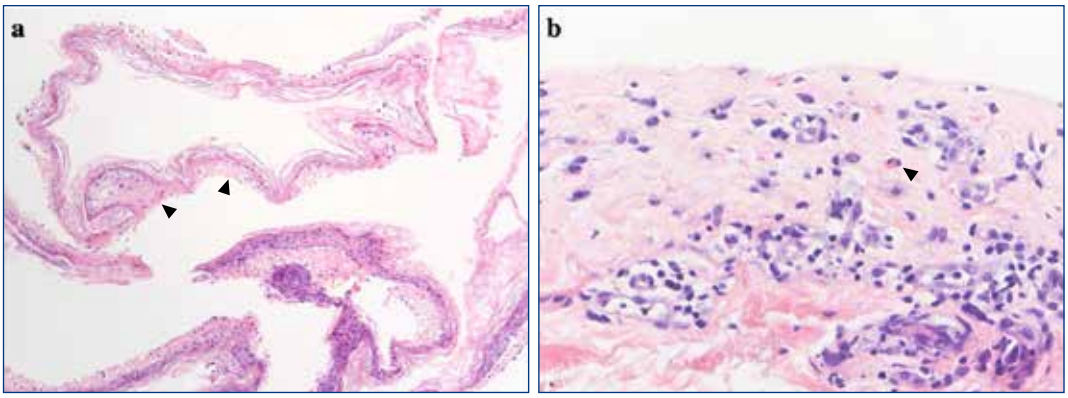

Figure 2. Histopathologic findings in pembrolizumab-induced TEN. **(A)** Full-thickness necrosis of detached epidermis (hematoxylin and eosin stain, original magnification x100). **(B)** Dermis with sparse superficial perivascular predominantly lymphocytic inflammation and rare eosinophils (hematoxylin and eosin stain, original magnification x400).

as TEN. SCORTEN was 3, indicating a mortality risk of >35.5%.[3] Review of medications revealed infusion with combination FOLFOX, trastuzumab, and pembrolizumab approximately 6 weeks prior to presentation without adverse cutaneous events. He underwent a subsequent infusion with FOLFOX and trastuzumab 4 weeks prior to presentation, again without adverse cutaneous events. Twenty-four hours prior to initial cutaneous eruption and 9 days prior to presentation for hospitalization, the patient was again administered an infusion with combination FOLFOX, trastuzumab, and pembrolizumab. Due to acute cutaneous eruption after the second exposure to pembrolizumab, and the known association of PD-1 inhibitors with ir-CAEs, pembrolizumab was favored as the culprit drug. A PubMed literature search and Litt's Drug Eruption and Database review failed to identify FOLFOX and trastuzumab as culprits of SJS/TEN. Thus, pembrolizumab was held indefinitely.

Due to progression of dusky cutaneous patches, prednisone PO was increased to 2 mg/kg/day and cyclosporine PO 4 mg/kg/day was initiated. The patient developed blood pressure lability and leukopenia; initiation of IV cefazolin effected improvement. Leukopenia was trended and favored to be multifactorial, attributed to TEN and cyclosporine. Reduced desquamation, decreased bullae formation, and early re-epithelialization were observed on day four of therapy, after which cyclosporine and prednisone were tapered.

On day seventeen of hospitalization, the patient was transferred to a step-down unit to continue down-titration of cyclosporine and prednisone as re-epithelialization progressed **(Figure 1C)**. The patient was discharged on day twenty-four with near total re-epithelialization **(Figure 1D)**.

Following discharge, the patient completed tapers of cyclosporine and prednisone totaling three and nine weeks of therapy, respectively. He demonstrated complete re-epithelialization with patches of residual lower extremity dyspigmentation, and intermittent dysesthesias of his right anterior thigh. During the final two weeks of his prednisone taper, he developed multiple vertebral compression fractures, and three months later, sustained traumatic fractures after a fall. He continued treatment for metastatic esophageal adenocarcinoma without pembrolizumab, and had three months of progression free survival. A small brain metastasis was successfully treated with gamma knife radiation. Continued follow-up is ongoing.

DISCUSSION

Ir-CAEs related to ICI therapy may involve cutaneous and extracutaneous systems. Pembrolizumab is an ICI initially approved for advanced melanoma in 2014 that was subsequently authorized for managing various malignancies including advanced small cell lung cancer, esophageal carcinoma, and classical Hodgkin Lymphoma.[4] Approximately 30-40% of patients receiving pembrolizumab may develop dermatologic complications, yet SJS/TEN has been reported infrequently.[5] Reports on the PD-1 inhibitor nivolumab suggest that dermatologic adverse events are the earliest to develop, with a median time to onset of five weeks.[6] However, ir-CAEs such as SJS/TEN may present at anytime during therapy.[1,2] Ir-CAEs are graded in severity according to morphology and BSA; morbilliform eruptions involving >30% BSA and skin sloughing <10% BSA both signify a grade III ir-CAE.[7] In relation to ICI therapy, TEN is defined as skin sloughing covering ≥ 30% BSA with associated erythema, purpura, or epidermal detachment and signifies a grade IV ir-CAE.[7] Differentiating ir-CAEs is paramount to management and impacts cancer therapy decisions; SJS/TEN dictates discontinuation of the implicated ICI.

In our patient, pembrolizumab-induced TEN demonstrated a prodromal morbilliform-like eruption that became dusky prior to bulla formation and desquamation. Mucosal involvement is a nearly universal feature of SJS/TEN and part of traditional diagnostic criteria. However, the relative lack of mucosal involvement in our and another reported patient suggests that this feature may represent a unique SJS/TEN phenotype.[1,2] Thus, clinicians should maintain high clinical suspicion for pembrolizumab-induced SJS/TEN even if mucosal involvement is absent; skin biopsy is essential in differentiating this entity from the spectrum of pembrolizumab-associated ir-CAEs, including bullous pemphigoid.[8]

Our patient improved after treatment with high-dose prednisone and cyclosporine, the latter of which reduces lymphocyte proliferation. Intravenous immune globulin (IVIG) was not part of our management strategy in accordance with published ir-CAE management recommendations in the *Journal of the American Academy of Dermatology*.[1] Cyclosporine's mechanism of action theoretically positions it as an ideal treatment for SJS/TEN, which is thought to represent a T-cell mediated delayed hypersensitivity reaction. The use of cyclosporine for SJS/TEN remains controversial with recent systematic reviews suggesting little to no benefit over supportive care.[9] However, our case adds to reports suggesting the efficacy of cyclosporine in managing pembrolizumab-induced SJS/TEN, which, given its unique phenotype, may respond differently to medical interventions than other forms of SJS/TEN.[1,2,9,10] In addition, our patient's adverse effects secondary to prolonged high dose systemic corticosteroid therapy for SJS/TEN emphasizes the need to closely monitor for extracutaneous complications of corticosteroids such as osteopenia.

With continued use of targeted cancer therapies, clinicians must maintain a high degree of suspicion for SJS/TEN in patients receiving pembrolizumab or other ICIs demonstrating blistering and/or skin sloughing even in the absence of mucosal symptoms. Cyclosporine may effect rapid cutaneous improvement in patients with pembrolizumab-induced SJS/TEN.

References

1. Geisler AN, Phillips GS, Barrios DM, et al. Immune checkpoint inhibitor-related dermatologic adverse events. *J Am Acad Dermatol*. 2020;83(5):1255-1268. doi:10.1016/j.jaad.2020.03.132
2. Cai ZR, Lecours J, Adam J-P, et al. Toxic epidermal necrolysis associated with pembrolizumab. *J Oncol Pharm Pract*. 2020;26(5):1259-1265. doi:10.1177/1078155219890659
3. Fouchard N, Bertocchi M, Roujeau J-C, Revuz J, Wolkenstein P, Bastuji-Garin S. SCORTEN: A Severity-of-Illness Score for Toxic Epidermal Necrolysis. *J Invest Dermatol*. 2000;115(2):149-153. doi:10.1046/j.1523-1747.2000.00061.x
4. Food and Drug Administration. KEYTRUDA® (pembrolizumab) injection, for intravenous use Initial U.S. Approval: 2014. Published 2021. Accessed September 6, 2021. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/125514s096lbl.pdf
5. Naidoo J, Page DB, Li BT, et al. Toxicities of the anti-PD-1 and anti-PD-L1 immune checkpoint antibodies. *Ann Oncol*. 2015;26(12):2375-2391. doi:10.1093/annonc/mdv383
6. Weber JS, Hodi FS, Wolchok JD, et al. Safety Profile of Nivolumab Monotherapy: A Pooled Analysis of Patients With Advanced Melanoma. *J Clin Oncol*. 2017;35(7):785-792. doi:10.1200/JCO.2015.66.1389
7. U.S. Department of Health and Human Services. Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0. Published November 27, 2021. Accessed September 6, 2021. https://ctep.cancer.gov/protocoldevelopment/electronic_applications/docs/ctcae_v5_quick_reference_5x7.pdf
8. Qiu C, Shevchenko A, Hsu S. Bullous pemphigoid secondary to pembrolizumab mimicking toxic epidermal necrolysis. *JAAD Case Rep*. 2020;6(5):400-402. doi:10.1016/j.jdcr.2020.03.003
9. Poizeau F, Gaudin O, Le Cleach L, et al. Cyclosporine for Epidermal Necrolysis: Absence of Beneficial Effect in a Retrospective Cohort of 174 Patients—Exposed/Unexposed and Propensity Score-Matched Analyses. *Journal of Investigative Dermatology*. 2018;138(6):1293-1300. doi:10.1016/j.jid.2017.12.034
10. Valeyrie-Allanore L, Wolkenstein P, Brochard L, et al. Open trial of ciclosporin treatment for Stevens-Johnson syndrome and toxic epidermal necrolysis. *Br J Dermatol*. 2010;163(4):847-853. doi:10.1111/j.1365-2133.2010.09863.x

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Disclosures

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Appendicitis Following Blunt Abdominal Trauma: An Illustrative Case

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ABSTRACT

Acute appendicitis is the most common abdominal surgical emergency, with an average of 7–9% of individuals developing the condition within their lifetime.[1] While cases of acute traumatic appendicitis are rare, medical literature supports their plausibility with the most famous case stretching back to the controversial 1926 death of stunt performer, Harry Houdini. Several mechanisms have been proposed by which blunt abdominal trauma results in acute appendicitis. In this review, we describe a young, otherwise healthy male, who developed epigastric abdominal pain after being struck in the abdomen while wrestling with his cousin of similar age. The patient was found to have peri-appendiceal inflammatory change, appendiceal mural thickening and edema consistent with acute uncomplicated appendicitis.

KEYWORDS: acute appendicitis, traumatic, appendiceal obstruction, pediatric

CASE PRESENTATION

An 11-year-old previously healthy male presented to the emergency department with several hours of epigastric abdominal pain. The patient had been in his usual state of health until earlier that day when he was wrestling with a cousin of similar age and was punched in the abdomen. He had no vomiting, nausea, fevers, headache, back pain, dysuria, hematuria, or testicular pain. He had a normal bowel movement after the incident. He maintained adequate intake throughout the day. The pain progressively worsened, prompting a visit to the emergency department.

On examination, the patient had no overt signs of trauma. He was uncomfortable appearing and vital signs were notable for tachycardia. The abdomen was non-distended and bowel sounds were present. There was tenderness maximally over the epigastrum without rebound, guarding, or hepatosplenomegaly. Genitourinary examination was unremarkable.

After the initial evaluation, the patient had an episode of non-bilious, non-bloody emesis and repeat vital signs revealed fever to 102F. Given the evolution of symptoms within the emergency department, as well as persistence of pain despite oral analgesia, an IV fluid bolus was given and labs were obtained.

Figure 1. Axial MRI

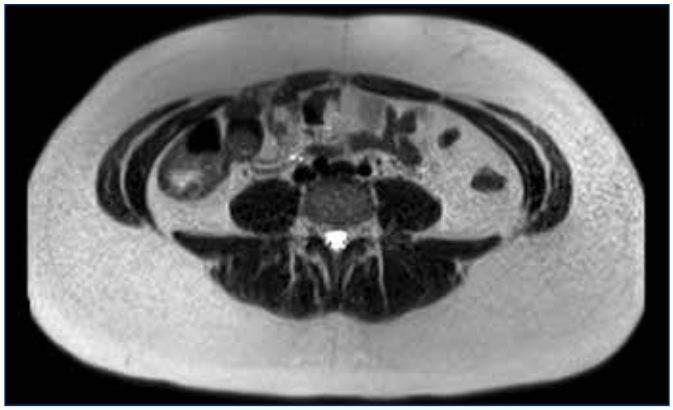
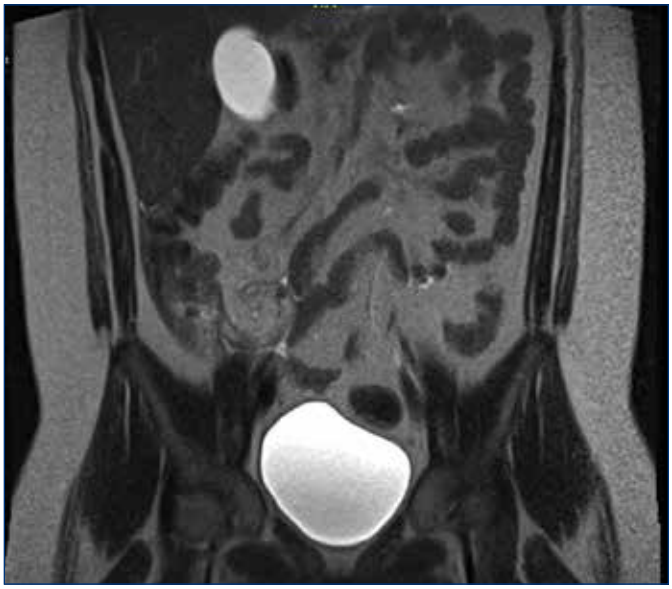


Figure 2. MRI Coronal



Laboratory workup was significant for leukocytosis of 22,000 without shift. Basic metabolic panel, hepatic panel, lipase, ESR and CRP were all within normal limits.

An MRI of the abdomen and pelvis was obtained (**Figures 1,2**) which demonstrated a diffusely dilated appendix measuring up to 10mm in maximal diameter with periappendiceal inflammatory change and appendiceal mural thickening and edema consistent with acute uncomplicated appendicitis.

The patient was treated with parenteral antibiotics before undergoing laparoscopic appendectomy. Operatively, the

patient's appendix was noted to be acutely inflamed. The postoperative course was uncomplicated, and the patient was discharged home the day after admission.

DISCUSSION

Acute appendicitis is the most common abdominal surgical emergency. Roughly 7–9% of individuals in Western countries will develop the condition during their lifetime.[1] Appendicitis is most common in the pediatric population, with peak incidence between 11 and 12 years of age.[2] Appendicitis is thought most commonly to develop as a result of appendiceal obstruction.[3] Obstruction can be caused by a number of conditions including fecalith, mass, lymphatic tissue, foreign body, or intestinal parasites. Obstruction of the appendiceal orifice increases luminal pressure resulting in mucosal edema, inflammation, and impaired venous and lymphatic drainage and ultimately, tissue ischemia. Ischemic appendiceal tissue may then necrose, leading to bacterial translocation and suppurative infection.[4]

While the development of appendicitis following blunt abdominal trauma is rare, it has been reported in medical literature as a plausible mechanism dating back to the turn of the 20th century.[5,6] Of historical interest, stunt performer, Harry Houdini, likely died of peritonitis as a result of a ruptured appendix after inviting a college student to punch him in the abdomen as part of an on-stage performance. Debate, however, persists regarding whether trauma is causative or coincidental in the development of acute appendicitis.[7,8] Several mechanisms have been proposed by which blunt abdominal trauma results in acute appendicitis. The first mechanism involves an indirect process in which a traumatic force causes a transient increase in intra-abdominal pressure which translates directly to increased intra-appendiceal pressure. Trauma may alternatively cause muscular irritation leading indirectly to adhesions or altered anatomic positioning of the appendix resulting in subsequent mucosal edema. Additionally, indirect abdominal trauma may result in visceral edema, limiting intra-abdominal space and therefore increasing intra-abdominal pressure. An alternative mechanism suggests a direct process in which focal trauma results in local edema, inflammation or lymphatic hyperplasia leading to appendiceal luminal obstruction. The presence of an appendiceal fecalith may contribute to increased luminal pressures after either direct or indirect trauma.[9] Case reports suggest that high energy trauma, particularly in the pediatric population, are at risk for developing delayed appendicitis.[10] In particular, it has been suggested that pediatric trauma patients requiring massive resuscitation are at risk for developing post-traumatic appendicitis possibly as a result of visceral edema.[11]

CONCLUSION

Blunt abdominal trauma is a rare, though plausible and well documented cause of acute appendicitis. It is important to consider the diagnosis of appendicitis in the workup of patients with abdominal pain following trauma. While the diagnosis of acute appendicitis following trauma may be coincidental, it is more likely attributable to the traumatic event if the presentation is temporally related to the trauma and the patient lacked antecedent symptoms. The diagnosis and management of acute appendicitis is similar regardless of relation to trauma.

References

1. Toumi et al. Systematic review of blunt abdominal trauma as a cause of acute appendicitis. *Ann R Coll Surg Engl*. 2010 Sep;92(6):477-482.
2. Addiss DG, et al. The epidemiology of appendicitis and appendectomy in the United States. *Am J Epidemiol.* 1990;132: 910-925.
3. Wangensteen OH, Bowers WF. Significance of the obstructive factor in the genesis of acute appendicitis. *Archives of Surgery*. 1937;34(3):496–526.
4. Schwartz's principles of surgery (9th ed.). New York: McGraw-Hill, Medical Pub. Division. 2010;Chapter 30.
5. Fowler R. The rare incidence of acute appendicitis resulting from external trauma. *Ann Surg*. 1938 Apr;107(4):529-39.
6. Behan RJ. Traumatic Appendicitis. Ann Surg. 1927;85:263-268.
7. Ciftci AO, et al. Appendicitis after blunt abdominal trauma: cause or coincidence? *Eur J Pediatr Surg.* 1996;6:350–3.
8. Hennington MH, et al. Acute appendicitis following blunt abdominal trauma. *Ann Surg.* 1991; 214:61–3.
9. Sharma AK, Vig S, Neades GT. Seat-belt compression appendicitis. *Br J Surg*. 1995;82:999
10. Etensel B, et al. The effect of blunt abdominal trauma on appendix vermiformis. *Emerg Med Journ*. 2005;22:874-877.
11. Ramsook C. Traumatic appendicitis: Fact or fiction? *Pediatr Emerg Care*. 2001;17:264–6.

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A Curious Case of Hypercalcemia

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ABSTRACT

Humoral hypercalcemia of malignancy is rarely seen in urothelial cancer. In this report, we present a case of an 81-year-old female patient who presented with a markedly elevated calcium level leading to severe altered mental status and was found to have urothelial cancer. To our knowledge, only three cases of urothelial carcinoma with squamous cell differentiation have been reported.

KEYWORDS: hypercalcemia of malignancy, urothelial cancer, oncology

INTRODUCTION

Hypercalcemia of malignancy can occur in up to 20–30% in all cancer patients.[1] In the US, it is most frequently diagnosed with breast, renal and lung cancer, and multiple myeloma.[2] We present here a rare case of urothelial cancer with squamous differentiation causing hypercalcemia.

CASE REPORT

The patient is an 81-year-old female with a past medical history of hypertension, hyperlipidemia, nephrolithiasis, recurrent urinary tract infections, and left-eye blindness from previous uveitis, who presented to the emergency department with worsening bilateral lower extremity weakness, altered mental status, and a general decline in her health in the past 2 weeks. Her daughter noticed hematuria on the morning of her presentation. The patient denied coughing, shortness of breath, chest pain, nausea, vomiting, diarrhea, and abdominal pain. She denied a history of substance abuse, including tobacco or alcohol. Physical examination demonstrated diminished air entry into the left lower lobe, chronic lymphedema with stasis dermatitis, and a slight tremor in the bilateral upper extremities.

Admission laboratory studies revealed elevated leukocytosis (16, 600/mm^3), calcium 14.4 mg/dL (corrected calcium 15.2 mg/dL), glucose 69 mg/dL, BUN 34, creatinine 1.81 mg/dL, lactic acid 2.6 mg/dL, total bilirubin 1.5 mg/dL (direct bilirubin 0.46 mg/dL, indirect bilirubin 1.04 mg/dL). PTH was low (7 pg/mL with normal range: 10–65 pg/mL), negative urine protein electrophoresis, and low 25-hydroxyvitamin D and 1,25-dihydroxyvitamin D levels (13.3 ng/ml and <8 pg/ml, respectively) (**Table 1**). Chest X-ray showed a left lower lobe opacification. She was treated concurrently for the acute kidney injury, pneumonia, and hypercalcemia with antibiotics, intravenous fluids, and Zoledronic acid. Her calcium down trended to 12.8 mg/dL (**Table 2**).

Table 1. Clinical laboratory data

	Admission	Reference range	Unit
Sodium	147	136–146	mmol/L
Potassium	3.9	3.5–5.0	mmol/L
Chloride	122	98–108	mmol/L
Bicarbonate	22	22–34	mmol/L
BUN	10	8–20	mg/dL
Creatinine	1.03	0.7–1.3	mg/dL
Glucose	72	73–110	mg/dL
Calcium	14.4	8.6–10.3	mg/dL
Phosphorous	1.8	2.7–4.6	mg/dL
Magnesium	1.4	1.5–2.4	mg/dL
Albumin	1.8	3.5–4.9	g/dL
WBC	16.6	4.0–10	x10^3/mm^3
Hemoglobin	10.2	13.0–17.3	g/dL
Platelet	145	150–450	x10^3/mm^3
Intact PTH	7	10–65	pg/mL
PTHrP	7.5	<2.0	pmol/mL
25-hydroxyvitamin D	13.3	25–80	ng/mL
1,25-dihydroxyvitamin D	<8	18–72	pg/mL
HbA1c	4.9%	3.8–6.4	%
TSH	4.34	0.30–5.50	mIU/L

Table 2. Uncorrected and corrected calcium from admission to stable state

	Uncorrected Calcium (mg/dL)	Corrected Calcium (mg/dL)
D0	14.4	15.5
D1	12.5	14.1
D2	12.6	14.3
D3	11.7	13.4
D4	11.2	12.8
D5	10.4	12
D6	9.8	11.7
D7	9	10.9

The patient's hospital course was complicated by fluid overload due to hypoalbuminemia related to her malnourished status, requiring diuresis with Lasix with close renal function monitoring (**Figure 1**). Renal-bladder ultrasound demonstrated a 7 cm large mass along the right bladder wall with right hydroureteronephrosis. PTHrP level was elevated (7.5 pmol/L), consistent with the diagnosis of hypercalcemia of malignancy. Bladder biopsy obtained from transurethral resection of the bladder tumor on hospital day seven demonstrated high-grade invasive urothelial carcinoma with extensive squamous differentiation and tumor necrosis (**Figure 2.**). Hematology-oncology evaluation identified that she was in chronic DIC with PT 15.1 seconds, INR 1.3, PTT 30.0 seconds, fibrinogen 148 mg/dL, D-dimer 12,026, thrombin time 20.2 seconds, likely due to the hypercoagulable state induced from cancer. She was recommended to undergo outpatient bone scan and PET-scan to investigate for potential metastasis, though she did not have evidence of lymphadenopathy on clinical exam and CT scans of the brain, thorax, abdomen, and pelvis did not reveal any masses.

Figure 1. Patient's trend of corrected and uncorrected serum calcium levels. Albumin fluctuated between 1.6 and 2.6 grams/dL during her hospital course

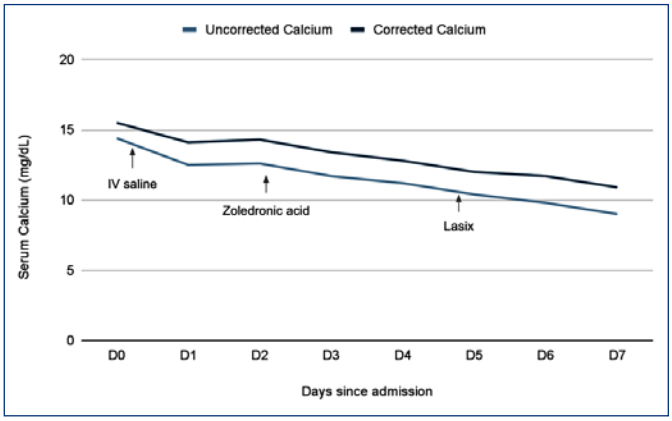
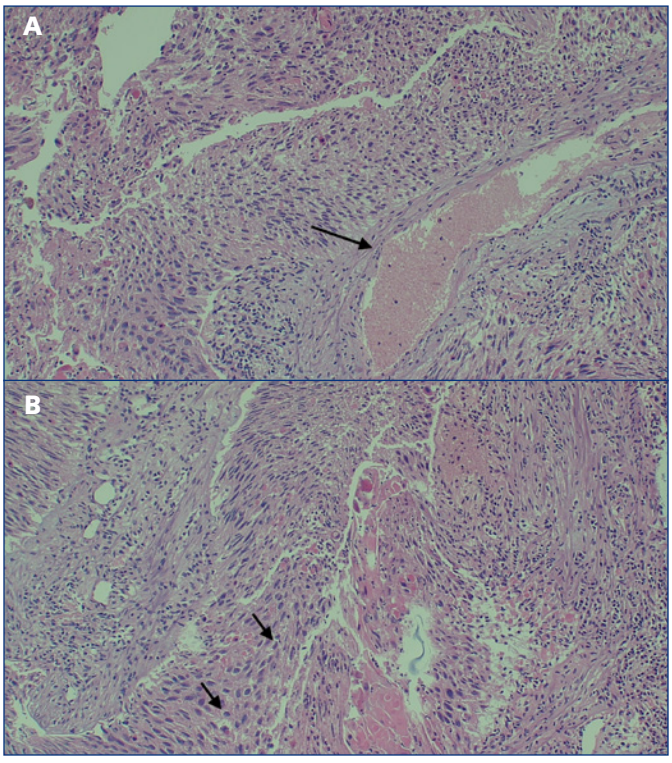


Figure 2. (**A**) Urothelial Carcinoma of the bladder with papillary cord (**B**) Focal area of squamous differentiation showing intercellular bridges



DISCUSSION

Malignancy can cause hypercalcemia through three different mechanisms: 1) lytic bone destruction through metastasis, 2) tumor production of PTHrP, or 3) tumor production of 1,25-dihydroxyvitamin D (calcitriol). Hypercalcemia is an uncommon phenomenon in bladder cancer, and it is rare for urothelial cancer to secrete PTHrP causing hypercalcemia. To our knowledge, there has only been three reports of urothelial carcinoma with squamous cell differentiation leading to an elevated PTHrP.[3,4,5] In these reported cases, cells in the squamous component showed higher immunoreactivity than those in urothelial component, suggesting squamous differentiation is the driving force of PTH-rP production subsequently elevated calcium.[6]

While a rare occurrence, humor hypercalcemia can happen in patients with urothelial cancer. Standard treatment for hypercalcemia typically shows good response and rapid clinical improvement for patients. Further workup for potential metastasis is warranted in these patients.

References

1. Stewart AF. Clinical practice. Hypercalcemia associated with cancer. N Engl J Med. 2005 Jan 27;352(4):373-9. doi: 10.1056/NEJMcp042806. PMID: 15673803.
2. Gastanaga VM, Schwartzberg LS, Jain RK, Pirolli M, Quach D, Quigley JM, Mu G, Scott Stryker W, Liede A. Prevalence of hypercalcemia among cancer patients in the United States. Cancer Med. 2016 Aug;5(8):2091-100. doi: 10.1002/cam4.749. Epub 2016 Jun 5. PMID: 27263488; PMCID: PMC4899051.
3. Kamai T, Toma T, Masuda H, Ishiwata D. Simultaneous production of parathyroid hormone-related protein and granulocyte colony-stimulating factor in renal pelvic cancer. J Natl Cancer Inst 1998; 90: 249–50.
4. Chaudhary UB, Milling DL, Bissada NK. Transitional cell carcinoma of the bladder producing parathyroid hormone-related protein (PTHrP). Can J Urol 2004; 11: 2136–38.
5. Matsuoka S, Miura Y, Kachi T, et al. Humoral hypercalcemia of malignancy associated with parathyroid hormone-related protein producing transitional cell carcinoma of the ureter. *Intern Med* 1994;33:107–9.
6. Tsuru T, Miyai K, Yoshitomi T, Hokari R, Matsukuma S. Humoral hypercalcemia of malignancy caused by renal pelvic urothelial carcinoma with broad squamous differentiation: An autopsy case. Pathol Int. 2020 Nov;70(11):909-911. doi: 10.1111/pin.13015. Epub 2020 Sep 8. PMID: 32896941.

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Trends and Risk Factors for Overlapping Stimulant and Opioid Prescriptions — Rhode Island, April 1, 2016–March 31, 2020

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ABSTRACT

OBJECTIVE: To investigate possible trends and risk factors for overlapping stimulant and opioid prescriptions in Rhode Island (RI).

METHODS: All RI residents with a stimulant prescription dispensed between April 1, 2016 and March 31, 2020 were obtained from the RI Prescription Drug Monitoring Program (PDMP). Individuals were stratified by overlapping stimulant/opioid exposure and compared by demographic and prescription characteristics.

RESULTS: While stimulant prescribing remained relatively constant, the percent of individuals with an overlapping opioid prescription declined. Individuals prescribed overlapping stimulant/opioid prescriptions differed significantly as a function of age, sex, payment method, type of stimulant prescribed, and prescriber type.

CONCLUSIONS: Among residents who were dispensed at least one stimulant prescription, individuals who were older, female, and on Medicare insurance were more likely to have an overlapping stimulant/opioid prescription. The RI PDMP can be used to identify trends and risk factors regarding prescribing patterns, which can inform future health policy and practice.

KEYWORDS: stimulant, opioid, prescription drugs, Rhode Island

INTRODUCTION

Although often overshadowed by the highly studied and publicized opioid overdose epidemic, the misuse of prescription and illicit stimulants remains a significant public health concern. Previous analyses of various drug databases and surveys have shown that prescription stimulant use doubled between 2006 and 2016,[1] with 6.8% of U.S. adults reporting prescription stimulant use in 2016.[2] Stimulants, as with other controlled substances, demonstrate a propensity for off-prescription misuse. This is particularly prevalent in school and college-age populations,[3] which in turn can be a risk factor for subsequent illicit drug use including stimulants and opioids.[4]

Recent studies have highlighted the prevalence and risk surrounding polysubstance use, particularly between opioids and stimulants, whether purposeful ("speedballing") or inadvertent (fentanyl-contaminated substances).[5-6] Hospitalization involving both opioid and amphetamine use increased by over 500% between 2003 and 2015.[7] National drug overdose death data from 2016 showed that approximately half of overdose deaths from psychostimulants with abuse potential also involved opioids[8] and about a quarter of synthetic opioid overdose deaths involved stimulant drugs including cocaine and other psychostimulants.[9]

Acknowledging the rise of polysubstance use and its associated risks, an analysis of the Rhode Island Prescription Drug Monitoring Program (PDMP) database was conducted to investigate possible trends and risk factors related to overlapping stimulant and opioid prescriptions.

METHODS

We conducted a retrospective cohort study utilizing data from the Rhode Island PDMP. All individuals who were Rhode Island residents with a stimulant prescription dispensed between April 1, 2016 and March 31, 2020 were included in our cohort.

We identified stimulant prescriptions using the American Hospital Formulary Service Pharmacologic–Therapeutic Classification Code (TCC) 28:20 associated with the National Drug Code of each medication in the IBM Micromedex RED BOOK. To identify opioid prescriptions, we included all opiate agonists (TCC 28:08.08), opiate partial agonists (TCC 28:08.12), and tramadol products (TCC 28:08.92.00.50). Buprenorphine products that were only FDA-approved for medication-assisted treatment for opioid use disorder as of July 30, 2020 were excluded from this analysis. An overlapping stimulant/opioid prescription was defined as any stimulant prescription that overlapped with an opioid prescription for at least 1 day. If an individual in either group had been dispensed multiple prescriptions, we randomly selected one for inclusion in the analysis to maintain independence of observations.

Individuals who received an overlapping stimulant/opioid prescription were compared to individuals who never received an overlapping prescription by demographic and prescription characteristics and compared with chi-square tests. Continuous variables (total number of stimulant

prescriptions dispensed during the study period and number of overlapping stimulant/opioid prescriptions dispensed) were compared using the Mann-Whitney U test.

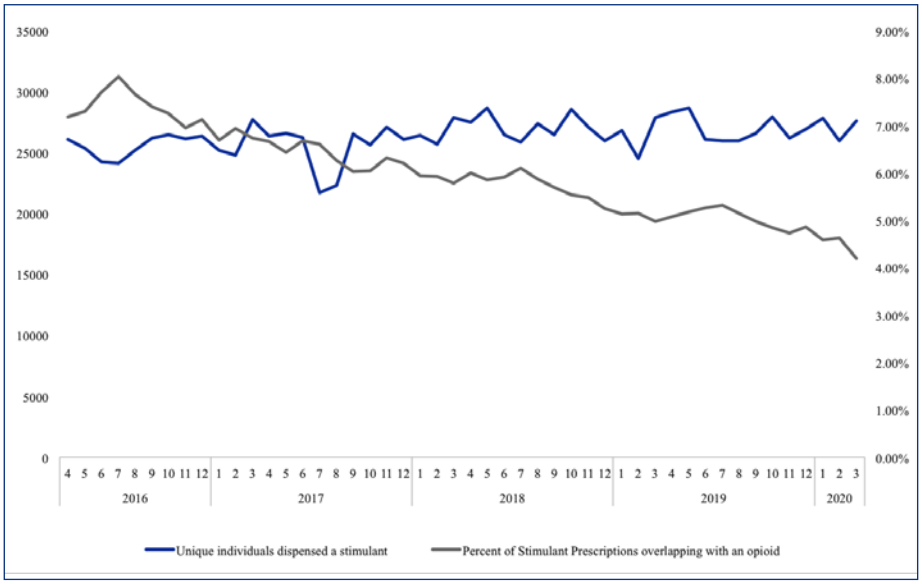
This study was part of RIDOH's response to the opioid overdose epidemic in Rhode Island and did not require institutional review board approval. All analyses were conducted in SAS 9.4 (Cary, North Carolina).

RESULTS

From April 1, 2016–March 31, 2020, 1,557,849 stimulant prescriptions were dispensed to 79,737 unique Rhode Island residents, with 15,073 individuals dispensed at least one overlapping stimulant and opioid prescription (18.9%). While the number of unique individuals dispensed stimulant prescriptions each per month remained relatively constant over the study period (April 2016: 26,064; March 2020: 27,596), the percent of individuals with an overlapping opioid prescription declined over the study period from 7.18% of stimulant prescriptions dispensed in April of 2016 to 4.19% of stimulant prescriptions dispensed in March of 2020 (**Figure 1**). As illustrated in **Table 1**, the prevalence of individuals ever prescribed stimulants who also ever received an overlapping stimulant/opioid prescription differed significantly as a function of multiple factors including age, sex, payment method, type of stimulant prescribed, and prescriber type (all $p < 0.0001$).

When looking at demographic factors, the proportion of stimulant-prescribed patients who received overlapping stimulant/opioid prescriptions increased significantly as age increased, ranging from approximately 4.1% amongst those in the age 0–18 year bracket to 39.1% in the age 65+ bracket. Furthermore, while the percent of individuals dispensed an overlapping opioid and stimulant prescription declined over time, this stratification pattern remained consistent across the entire study period. Females had a higher rate of overlapping prescriptions (22.5% compared to 14.6% in males), which also remained consistent from April 2016 through March 2020. The proportion of overlapping prescription varied by payment type, ranging from 16.5% (Medicaid payments) to 43% (Medicare payments). Additionally, while the median number of stimulant prescriptions dispensed was 12 (inter-quartile range (IQR): 4-30), this was substantially higher among individuals who received at least one overlapping stimulant/opioid prescription (median: 28; IQR: 13–44), when compared to individuals who never received an overlapping stimulant/opioid prescription (median: 9; IQR: 3–25).

Figure 1. The number of unique RI Residents dispensed an opioid, and the percent of stimulant prescriptions overlapping for at least 1 day with an opioid prescription, April 1, 2016–March 31, 2020.



DISCUSSION

While the number of stimulant prescriptions dispensed per month has remained relatively constant in Rhode Island during the study period, the percent of prescriptions dispensed with an overlapping opioid prescription has declined from 2016–2020. Overall, among Rhode Island residents who were dispensed at least one stimulant prescription, individuals who were older, female, and on Medicare insurance were more likely to have an overlapping stimulant/opioid prescription.

Although the proportion of stimulant prescriptions generally decreased as age increased, complimenting patterns found from nationwide data[2], the highest proportion of overlapping stimulant/opioid prescription were found in the oldest age group, with rates nearly 10 times that of the youngest age group. This is interesting when paired with the results showing Medicare as the payer group with the highest proportion of overlapping prescriptions, prompting future investigation into the prevalence of polysubstance prescriptions under Medicare.

Rhode Island is currently experiencing an increase in accidental fatal opioid overdoses that involve stimulants; however, the risk factors for a fatal overdose (younger, male) appear to differ from the risk factors for overlapping opioid/stimulant prescriptions (older, female) which is promising.[10] However, a sizable portion of younger/male individuals were prescribed overlapping stimulant/opioid prescriptions in this cohort, and future work will look to identify previous co-prescription exposure among individuals who died of an accidental stimulant/opioid overdose. Such analyses, in turn, could inform future public health policy and intervention efforts, including reducing exposure to potentially harmful drug combinations.

Table 1. Characteristics of Rhode Island Residents Dispensed Overlapping Stimulants compared to those dispensed overlapping Stimulants and Opioid Prescriptions, April 1, 2016–March 31, 2020*

	Ever Prescribed Stimulants	Ever Prescribed Overlapping Stimulants & Opioids		
		Yes	No	
Characteristic	**N=79,737 n (%)†**	**N=15,073 n (%)†**	**N=64,664 n (%)†**	**P-value†**
Patient				
Age				
0–18	20,915 (26.2)	853 (5.7)	20,062 (31.0)	<0.0001
18–24	10,406 (13.0)	1,317 (8.7)	9,089 (14.1)	
25–34	15,271 (19.2)	2,857 (19.0)	12,414 (19.2)	
35–44	12,365 (15.5)	3,202 (21.2)	9,163 (14.2)	
45–54	10,473 (13.1)	3,161 (21.0)	7,312 (11.3)	
55–64	6,918 (8.7)	2,358 (15.6)	4,560 (7.0)	
65+	3,389 (4.2)	1,325 (8.8)	2,064 (3.2)	
Sex				
Female	43,817 (55.0)	9,838 (65.3)	33,979 (55.6)	<0.0001
Male	35,913 (45.0)	5,234 (34.7)	30,679 (47.4)	
Unknown	7 (0.0)	<5	6 (0.0)	
Payment method				
Private insurance	53,118 (66.6)	9,689 (64.3)	43,429 (67.2)	<0.0001
Medicaid	13,787 (17.3)	2,272 (15.1)	11,515 (17.8)	
Medicare	3,205 (4.0)	1,379 (9.2)	1,826 (2.8)	
Cash	8,968 (11.2)	1,538 (10.2)	7,430 (11.5)	
Military	445 (0.6)	110 (0.7)	335 (0.5)	
Workers' compensation	12 (0.0)	5 (0.0)	7 (0.0)	
Unknown	202 (0.2)	80 (0.5)	122 (0.2)	
Prescription				
Stimulant type				
Amphetamine & Comb.	38,791 (46.6)	8,904 (59.1)	29,887 (46.2)	<0.0001
Armodafinil	472 (0.6)	153 (1.0)	319 (0.5)	
Benzphetamine	<5	<5	<5	
Dexmethylphenidate	2,494 (3.1)	181 (1.2)	2,313 (3.6)	
Dextroamphetamine	1,358 (1.7)	333 (2.2)	1,025 (1.6)	
Diethylpropion	49 (0.1)	10 (0.1)	39 (0.1)	
Lisdexamfetamine	6,390 (8.0)	1,125 (7.5)	5,265 (8.1)	
Methamphetamine	5 (0.1)	<5	<5	
Methylphenidate	16,511 (20.7)	2,050 (13.6)	14,461 (22.4)	
Modafinil	1,088 (1.4)	340 (2.3)	748 (1.2)	
Phendimetrazine	1,529 (1.9)	175 (1.2)	1,354 (2.1)	
Phentermine & Comb.	11,035 (13.8)	1,796 (11.9)	9,239 (14.3)	
Solriamfetol	13 (0.0)	<5	10 (0.0)	
Prescriber Type				
Physician	53,319 (66.9)	9,500 (63.0)	43,819 (67.8)	<0.0001
PA	2,355 (3.0)	546 (3.6)	1,809 (2.8)	
Adv Nurse	12,747 (16.0)	2,821 (18.7)	9,926 (15.4)	
Unknown	11,316 (14.2)	2,206 (14.6)	9,107 (14.1)	
Medication Info				
Total number of stimulant prescriptions‡	12 (4, 30)	28 (13,44)	9 (3,25)	<0.0001
Number of overlapping prescriptions‡	2 (1, 4)	2 (1, 4)	—	—
Quantity prescribed‡	30 (30, 60)	30 (30, 60)	30 (30, 56)	<0.0001
Stimulant supply(days)‡	30 (30, 30)	30 (30, 30)	30 (30, 30)	<0.0001

*For patients with >1 overlapping stimulant opioid prescription or >1 stimulant prescription, we randomly selected one for inclusion in this analysis. † Unless otherwise specified. ‡ Median (IQR). § This analysis excluded buprenorphine products only FDA-approved for medication assisted treatment of opioid use disorder.

Additionally, as of January of 2020, Rhode Island required International Classification of Disease (ICD-10) codes for every controlled substance prescription. Leveraging this diagnostic information will allow future investigation into why individuals may be co-prescribed specific drug combinations, and these insights could be translated into a safer and more gestalt prescribing framework.

References

1. Piper BJ, Ogden CL, Simoyan OM, et al. Trends in use of prescription stimulants in the United States and Territories, 2006 to 2016. *PloS ONE*. 2018;13(11):e0206100.
2. Compton WM, Han B, Blanco C, Johnson K, Jones CM. Prevalence and Correlates of Prescription Stimulant Use, Misuse, Use Disorders, and Motivations for Misuse Among Adults in the United States. *Am J Psychiatry*. 2019;175(8):741-755.
3. Varga MD. Adderall abuse on college campuses: A comprehensive literature review. *Journal of Evidence-Based Social Work*. 2012;9(3):293–313.
4. McCabe SE, Cranford JA, West BT. Trends in prescription drug abuse and dependence, co-occurrence with other substance use disorders, and treatment utilization: Results from two national surveys. *Addictive Behaviors*. 2008;33(10):1297-1305.
5. Mattson CL, Tanz LJ, Quinn K, Kariisa M, Patel P, Davis NL. Trends and Geographic Patterns in Drug and Synthetic Opioid Overdose Deaths—United States, 2013–2019. *Morbidity and Mortality Weekly Report*. 2021;70(6):202-207.
6. Goodwin RD, Moeller SJ, Zhu J, Yarden J, Ganzhorn S, Williams JM. (2021) The potential role of cocaine and heroin co-use in the opioid epidemic in the United States. *Addictive Behaviors*. 2021;113:https://doi.org/10.1016/j.addbeh.2020.106680.
7. Winkelman T, Admon LK, Jennings L, Shippee ND, Richardson CR, Bart G. Evaluation of Amphetamine-Related Hospitalizations and Associated Clinical Outcomes and Costs in the United States. *JAMA Network Open*. 2018;1(6):e183758.
8. Kariisa, M, Scholl L, Wilson N, Seth P, Hoots B. 2019. Drug overdose deaths involving cocaine and psychostimulants with abuse potential – United States, 2003-2017. *Morbidity and Mortality Weekly Report*. 2019;68(17):388-395.
9. Jones CM. Einstein EB, Compton WM. Changes in synthetic opioid involvement in drug overdose deaths in the United States, 2010-2016. *JAMA*. 2018;319(17):1819-1821.
10. Hallowell BD, Weidele HR, Scagos RP. Accidental Drug Overdose Deaths in Rhode Island: January 1, 2016–July 31, 2020. *Rhode Island Medical Journal*. 2020;103(10):62-65.

Ethics Statement

This study was part of RIDOH's response to the opioid overdose epidemic in Rhode Island and did not require institutional review board approval. This analysis is limited to prescriptions dispensed vs. prescribed, and overlap was assumed based on the dispensed date and day supply, which may inaccurately represent prescribing practices. All authors approve this work, and we have no conflicts of interest to disclose.

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Disclaimer

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Gambling: A Ubiquitous Behavior Among Rhode Island's Young Adults

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(***Editor's Note: Part 4 of a series***)

ABSTRACT

OBJECTIVES: Gambling is a prevalent behavior associated with numerous consequences. The purpose of the current study was to assess the prevalence of gambling and problem gambling in Rhode Island young adults and to identify sociodemographic correlates of gambling.

METHODS: Data from n=546 participants of the Rhode Island Young Adult Survey were used. Twelve types of gambling behaviors, and problem gambling, were assessed. Sociodemographic variables included age, race/ethnicity, gender, sexual orientation, social status, education, employment, and essential worker status.

RESULTS: The prevalence of any gambling was 62.3%, and odds of any gambling was 57% higher (95%CI = 1.08,2.27) among essential workers. The prevalence of problem gambling was 11.4%, and the odds were 3.6 times higher (95%CI = 1.32, 9.86) among persons who are transgender.

CONCLUSIONS: The prevalence of gambling and problem gambling are high among Rhode Island's young adults. Implementing programmatic and regulatory measures to prevent and treat problem gambling are vital.

KEYWORDS: gambling, problem gambling, sports, young adults, Rhode Island

INTRODUCTION

Gambling disorder entails continuous problem gambling behavior that leads to significant distress or impairment, according to the Diagnostic and Statistical Manual of Mental Disorders (DSM-5), although problem gambling itself is not defined.[1] Prior to this definition, in the DSM-IV, gambling disorder was categorized as an "Impulse-Control Disorders Not Classified Elsewhere,"[2] while it is now considered a "Substance-Related and Addictive Disorder," which places it in the same category as other substance use disorders, such as those concerning alcohol and opioids.[3] The move recognizes that gambling disorder and substance use disorders have similar etiologies, symptoms, and treatment procedures. The 11th revision of the International Classification of Diseases (IDC-11) combines gambling disorder with gaming disorder into the newly created category of "disorders due to addictive behaviors," which, similar to the DSM, recognizes that there are phenomenological and neurobiological similarities between gambling and substance use.[4]

Epidemiological data suggests that approximately four in five adults have gambled at least once in their lifetime.[5] Furthermore, 27.1% have gambled more than 100 times in their lifetime and 10.1% gambled more than 1,000 times. Using data from the National Comorbidity Survey, participants who were problem gamblers disclosed having first gambled, on average, at the age of 16.7, while non-problem gamblers began gambling at approximately 24 years old.[5] Those who were problem gamblers reported having gambling problems beginning in their mid-20s and symptoms continued for an average of 9.4 years. As accessibility to legalized gambling increases, a concurrent increase in prevalence of the development of gambling problems is expected,[6] and current literature recognized by the World Health Organization (WHO) has noted that greater availability of gambling will likely cause a subsequent increase in the prevalence of gambling disorder.[7]

Short-term consequences of problem gambling may include grave financial loss, emotional distress, and/or strained relationships.[8] Long-term, problem gambling may lead to sleep deprivation, cardiovascular issues, obesity, developing a substance use disorder, and the development of gambling disorder. Increased rates of suicide ideation and suicide attempts have also been associated with gambling behaviors, and almost 80% of problem gamblers have called a helpline reporting that they felt hopeless and suicidal at the time.[9] Gambling also has substantial effects on the economy, prevalence of crime, and homelessness.[9] Job-loss rates are notably higher in problem gamblers, and according to a survey of Gambler's Anonymous participants, approximately 57% of respondents reported stealing in order to finance their gambling urges. Previous research also identified gambling as a key determinant of homelessness.[10]

In Rhode Island, the minimum legal age to gamble is 18 years.[11] Types of legal gambling in the state include dog racing, horse racing, casino gaming, charitable gaming, and online sports wagering.[12] Since dog and horse racing are currently not running, casino gaming and online sports wagering is most popular. Casino gaming includes any casino style or table games played with the use of dice, cards, or other equipment for money. This includes, but is not limited to

games such as blackjack, roulette, poker, craps, big six, or any other banking game.[13] Rhode Island currently has two full-service casinos that offer these gambling opportunities.[14]

The aim of the current study was to examine the prevalence of gambling and problem gambling among Rhode Island's young adults. Previous research has typically used samples of all adults, which may hide specific risky behaviors that primarily occur in young adults. Additionally, the study sought to identify sociodemographic risk factors for participating in gambling and the presence of problem gambling symptoms. Given the significant costs due to problem gambling, a greater understanding of who is more affected by problem gambling can aid in creating targeted approaches to address the issue.

METHODS

Data

Data were obtained from the 2020 Rhode Island Young Adult Survey (RIYAS), which surveyed 18–25 year olds who were living in Rhode Island for part of 2020. Full details of RIYAS sampling, data collection methodology, and sociodemographic characteristics of the sample have been previously published.[15]

Measures

Twelve types of gambling were assessed (i.e., lottery tickets, scratch tickets, raffle tickets, betting on horse or dog races, sports betting, casino gaming tables, casino poker machines, pub or hotel poker machines, betting with family or friends, betting on games of skill [e.g., pool, darts], betting on video games, internet gambling) using previously validated items.[16] Participants originally indicated if they participated in each gambling activity *never, less than 6 times in the past 12 months,* or *more than 6 times in the last 12 months*. Due to highly skewed distributions, each item was dichotomized into past year or no past year gambling.

Problem gambling was assessed using three items with a sensitivity and specificity to detect gambling problems of 96% and 99%, respectively: *have you become restless, irritable or anxious when trying to stop/cut down on gambling?; have you tried to keep your family or friends from knowing how much you gambled?;* and *did you have such financial trouble that you had to get help with living expenses from family, friends, or welfare?*.[17] Possible responses to each item were *yes* and *no*. As suggested, responses were dichotomized across items where any *yes* response indicated current problem gambling and all *no* responses were required to indicate the absence of problem gambling.

Several sociodemographic covariates were measured, including age, race/ethnicity (White non-Hispanic, Black Indigenous People of Color [BIPOC]), gender (male, female, transgender), sexual orientation (heterosexual, LGB+), relative social status, education (enrolled, non-enrolled), employment (full-time, part-time, unemployed), and essential worker status (yes, no). Relative social status was measured using the MacArthur Scale of Subjective Social Status (MSSS), which requires participants to identify their social status relative to others in the community using a scale from 1 (worst off) to 10 (best off).[18] Essential worker status was self-reported and based on whether the participant's employer considered them an essential worker during the COVID-19 pandemic.

Statistical Analysis

The frequency and percent of each specific gambling behavior, any gambling behavior, multiple gambling behaviors, and any problem gambling in the sample were reported. Any problem gambling among only current gamblers was also reported. Two sets of univariate logistic regression models were specified to identify potential disparities in gambling behavior and problem gambling based on the measured covariates. In the models, White non-Hispanic, female, heterosexual, not enrolled in school, full-time employment, and not designated an essential worker were the reference categories. Statistical analysis was conducted using SPSS for Windows Version 26.0 (Armonk, NY: IBM Corp.), and statistical significance was determined using 95% confidence intervals ($\alpha = 0.05$).

RESULTS

Among the n = 546 RIYAS participants, 62.3% participated in any form of gambling in the past year, with buying scratch tickets (36.1%), buying raffle tickets (35.3%), and betting with family and friends (24.5%) the most common modes of gambling (**Figure 1**). Further, more than 10% of the sample gambled in casinos, participated in sports betting,

Figure 1. Frequency of gambling behaviors

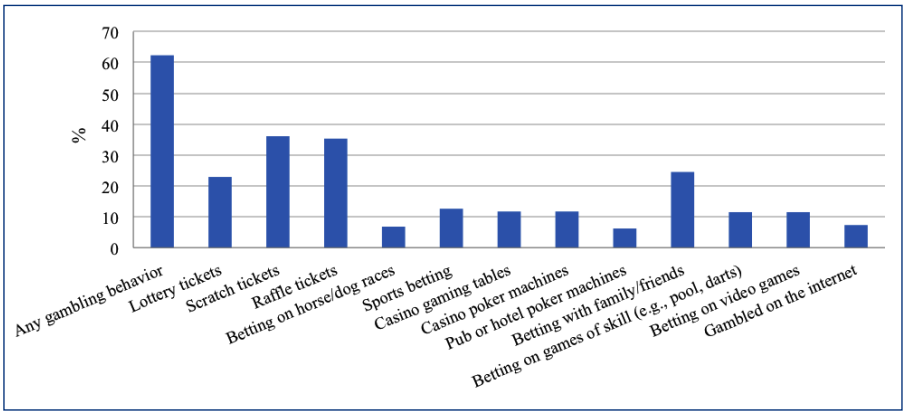


Figure 2. Sociodemographic risk factors of any gambling behaviors.

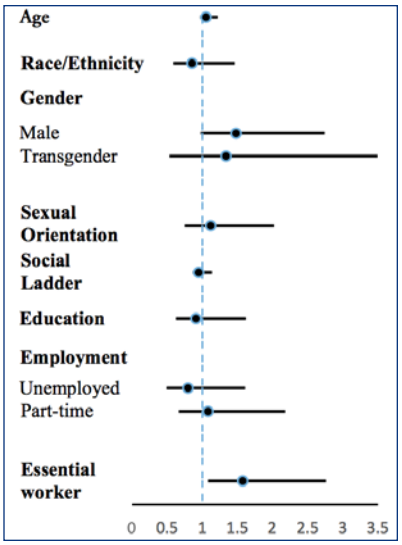
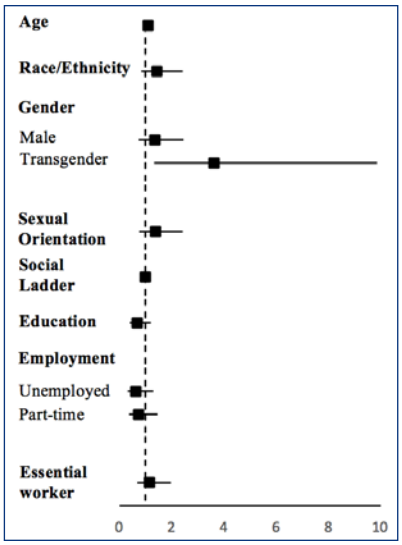


Figure 3. Sociodemographic risk factors of problem gambling symptoms.



Odds ratio and 95% confidence intervals calculated using univariate logistic regression models. Categorical groups were: Race = BIPOC v. White non-Hispanic (ref), Gender = male and transgender v. female (ref), Sexual Orientation = LGB+ v. heterosexual (ref), Education = enrolled in school v. not enrolled in school (ref), Employment = unemployed and part-time v. full time (ref), Essential worker = yes v. no (ref).

and bet on games of skill. 43.2% of participants participated in 2 or more gambling behaviors with 3.1% participating in all 12 behaviors assessed. There were few predictors of any gambling as no demographic variables were statistically significant predictors (**Figure 2**). The odds of gambling among essential workers were 57% higher (95% CI = 1.08, 2.27), although other economic predictors were non-significant.

Among all participants, the prevalence of problem gambling was 11.4%, and 3.5% participants had symptoms of problem gambling but did not gamble in the past year. Among current gamblers (n = 340), the prevalence was 12.6%. Similar to any gambling, there were few demographic or economic predictors of problem gambling (**Figure 3**), and only persons who were transgender had significantly higher odds of gambling problem symptoms (OR[95% CI] = 3.61 [1.32, 9.86]).

DISCUSSION

Gambling is a common and ubiquitous activity among Rhode Island young adults, and participants engaged in a variety of different gambling behaviors, which ranged from buying scratch tickets to casino gambling to sports betting. Of particular concern, a near majority of participants engaged in two or more forms of gambling, and some participants participated in all measured gambling behaviors. Problem gambling was also prevalent in nearly all identified sociodemographic groups. Essential workers gambled at a higher rate than non-essential workers, which may have occurred as a form of self-medication due to the substantial job strain of working during the COVID-19 pandemic, often in public-facing roles. Also, persons who were transgender had a higher odds of problem gambling, which is similar to other reports that problem gambling rates are higher among persons who are transgender despite similar levels of gambling behavior.[19] With multiple reports of consistent findings, the impact of gambling on the transgender community requires further research through a health equity lens.

Findings in Context

The prevalence of gambling in Rhode Island's young adults was comparable to those reported earlier for this population. For example, results from a national survey suggest that 68% of 14 to 21 year olds gambled in the past year.[20] Because the current data were collected during the early stages of the COVID-19 pandemic, it is likely that more recent gambling behaviors were suppressed and that prevalence rates decreased due to the pandemic.[21] Interestingly, the pandemic was also unlikely to cause a significant shift towards online gambling, as no pandemic attributable increases were noted by a recent scoping review.[21] Further, the problem gambling rate reported here was over five times greater than that reported from previous national surveys (11.4% v. 2.1%), and others have noted that problem gambling has been frequently associated with gambling during the pandemic.[20,21] Moreover, sports betting, but not other gambling behaviors, was associated with higher odds of problem gambling symptoms in young adults during the early stages of the pandemic.[22] Increased problem gambling may be due to the mental strain caused by the COVID-19 pandemic and the severe negative impact on financial and psychological well-being caused by long-term social isolation.[23]

Responding to the Problem

Given the unusually high rate of problem gambling in this age group, in response, Rhode Island could greatly benefit from enhanced and integrated programs designed to identify and assist those with problem gambling. The programs should largely target the entire young adult population, and this population may equally benefit from provider-based programs, community-based programs, and interventions designed to raise gambling awareness, although targeted programs for essential workers and persons who are transgender should be considered. Cognitive behavioral therapy has been considered the most effective treatment for problem gambling, although pharmacological treatments may also be effective in some cases.[24] Early prevention effects are also needed to minimize gambling uptake, protect against the consequences of gambling, and raise awareness on any gambling misconceptions.[25]

Policy Implications

The high prevalence of gambling and gambling problems in Rhode Island's young adults may be, at least partially, due to the state's lax gambling regulations (ex. 18 years minimum gambling age, allowing online sports betting),[11,12] and there are several remedial regulatory steps available. Raising the legal minimum gambling age to 21 can serve as an effective harm-reduction action step that can decrease the frequency of problem gambling in adolescent and young adult populations.[26,27] Higher taxes or fees should also be considered for wagers placed on sports or racing events. Higher taxation on unhealthy behaviors has been consistently associated with a decrease in that behavior due to the greater monetary expense involved.[28] Marketing of gambling activities should be highly restricted. Gambling marketing can increase gambling frequency as well as make it more strenuous for those who are already problem gamblers to attempt to gamble less.[29] Finally, decreasing the availability of gambling, particularly through online or digital platforms, may reduce problem gambling in young adults.

More information on gambling and problem gambling in Rhode Island is needed though, and state officials should consider adding relevant questions to the state components of well-established disease surveillance studies, such as the Youth Risk Behavior Surveillance System (YRBS), the Behavioral Risk Factor Surveillance System (BRFSS), and the Rhode Island Student Survey (RISS). More data will allow better tracking of trends in gambling and problem gambling over time and permit appropriate regulatory changes to be implemented.

Limitations

There are several limitations to acknowledge. Data were collected during the COVID-19 pandemic when many gambling locations and sporting events were closed, which suggests an underestimation of the true prevalence of gambling. Also, due to limited data, prevalence estimates herein cannot be compared to a pre-COVID-19 baseline. Data were collected via self-report, which may be subject to recall and social desirability bias, and at a single time point, which limits the ability to identify causal pathways. The self-report screen of problem gambling cannot be assumed synonymous with a diagnosis. The RIYAS may also not be representative of all young adults in Rhode Island since a convenience sample was used. Further, the sample was predominately female, which may also lead to underestimated prevalence rates, and had a higher than expected sexual minority population.

CONCLUSION

The prevalence of gambling and problem gambling are consistently high across sociodemographic groups among Rhode Island's young adults. Although the prevalence of gambling behaviors was comparable to previous studies, the prevalence of problem gambling was unusually high. Provider and community-based programs that prevent and treat problem gambling in young adults are needed. Gambling and problem gambling measures should be incorporated into existing disease surveillance systems, and regulatory changes should be considered.

References

1. American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders*. 5th ed. Washington, DC: American Psychiatric Association; 2013
2. Substance Abuse and Mental Health Services Administration. Impact of the DSM-IV to DSM-5 Changes on the National Survey on Drug Use and Health. Rockville (MD): Substance Abuse and Mental Health Services Administration (US); 2016 Jun. Table 3.38, DSM-IV to DSM-5 Gambling Disorder Comparison. Available from: https://www.ncbi.nlm.nih.gov/books/NBK519704/table/ch3.t39/
3. Weinstock J, Rash CJ. Clinical and Research Implications of Gambling Disorder in DSM-5. *Curr Addict Rep*. 2014;1(3):159-165. doi:10.1007/s40429-014-0026-7
4. Reed GM, First MB, Kogan CS, et al. Innovations and changes in the ICD-11 classification of mental, behavioural and neurodevelopmental disorders. *World Psychiatry*. 2019;18(1):3-19. doi:10.1002/wps.20611
5. Kessler RC, Hwang I, LaBrie R, et al. DSM-IV pathological gambling in the National Comorbidity Survey Replication. Psychol Med. 2008;38(9):1351-1360. doi:10.1017/S0033291708002900
6. Calado F, Alexandre J, Griffiths MD. Prevalence of Adolescent Problem Gambling: A Systematic Review of Recent Research. J Gambl Stud. 2017;33(2):397-424. doi:10.1007/s10899-016-9627-5
7. Brazeau BW, Hodgins DC. Gambling Disorder. Reference Module in Neuroscience and Biobehavioral Psychology. 2021, ISBN 9780128093245, https://doi:10.1007/s40429-014-0026-7
8. Fong TW. The biopsychosocial consequences of pathological gambling. *Psychiatry (Edgmont)*. 2005;2(3):22-30.
9. Maccallum F, Blaszczynski A. Pathological Gambling and Suicidality: An Analysis of Severity and Lethality. *Suicide and Life-Threatening Behavior*, Volume 33, Issue 1. https://doi.org/10.1521/suli.33.1.88.22781
10. National Gambling Impact Study Commission Final Report: Table of Contents. Unt.edu. Published 2019. https://govinfo.library.unt.edu/ngisc/reports/fullrpt.html
11. Gaming and Athletics. State of Rhode Island, Department of Business Regulation. https://dbr.ri.gov/divisions/gaming/. Published 2022.
12. Establishment and Extension of Gambling Activities and Other Facilities. Sports, Racing, and Athletics. Title 41, Chapter 9. R.I. Gen. Laws § 41-9-1
13. Video Lottery Games, Table Games and Sports Wagering. State Affairs and Government. Title 42, Chapter 61.2. R.I. Gen. Laws § 42-61.2-1
14. Player Restrictions Rhode Island Lottery, Rules and Regulations. *Rilotcom*. 2022.
15. Rosenthal SR, Sonido PL, Tobin AP, Sammartino CJ, Noel JK. Breaking Down Barriers: Young Adult Interest and Use of Telehealth for Behavioral Health Services. *R I Med J (2013)*. 2022;105(1):26-31. Published 2022 Feb 1.
16. Howe PDL, Vargas-Sáenz A, Hulbert CA, Boldero JM. Predictors of gambling and problem gambling in Victoria, Australia. PLoS One. 2019;14(1):e0209277. Published 2019 Jan 23. doi:10.1371/journal.pone.0209277
17. Gebauer L, LaBrie R, Shaffer HJ. Optimizing DSM-IV-TR classification accuracy: a brief biosocial screen for detecting current

gambling disorders among gamblers in the general household population. Can J Psychiatry. 2010;55(2):82-90

18. Adler NE, Epel ES, Castellazzo G, Ickovics JR. Relationship of subjective and objective social status with psychological and physiological functioning: preliminary data in healthy white women. Health Psychol. 2000;19(6):586-592.
19. Ruppert R, Kattari SK, Sussman S. Review: Prevalence of Addictions among Transgender and Gender Diverse Subgroups. Int J Environ Res Public Health. 2021;18(16):8843. Published 2021 Aug 22. doi:10.3390/ijerph18168843
20. Welte JW, Barnes GM, Tidwell MC, Hoffman JH. The prevalence of problem gambling among U.S. adolescents and young adults: results from a national survey. J Gambl Stud. 2008;24(2):119-133. doi:10.1007/s10899-007-9086-0
21. Brodeur M, Audette-Chapdelaine S, Savard AC, Kairouz S. Gambling and the COVID-19 pandemic: A scoping review. Prog Neuropsychopharmacol Biol Psychiatry. 2021;111:110389. doi:10.1016/j.pnpbp.2021.110389
22. Noel JK, Rosenthal SR, Sammartino CJ. Correlates of gambling and gambling problems among Rhode Island young adults: A cross-sectional study. J Public Health (Oxf). *In press*.
23. Håkansson A, Fernández-Aranda F, Menchón JM, Potenza MN, Jiménez-Murcia S. Gambling During the COVID-19 Crisis - A Cause for Concern. J Addict Med. 2020;14(4):e10-e12. doi:10.1097/ADM.0000000000000690
24. Menchon JM, Mestre-Bach G, Steward T, Fernández-Aranda F, Jiménez-Murcia S. An overview of gambling disorder: from treatment approaches to risk factors. F1000Res. 2018;7:434. Published 2018 Apr 9. doi:10.12688/f1000research.12784.1
25. Grande-Gosende A, López-Núñez C, García-Fernández G, Derevensky J, Fernández-Hermida JR. Systematic Review of Preventive Programs for Reducing Problem Gambling Behaviors Among Young Adults. J Gambl Stud. 2020;36(1):1-22. doi:10.1007/s10899-019-09866-9
26. Shi J, Colder Carras M, Potenza MN, Turner NE. A Perspective on Age Restrictions and Other Harm Reduction Approaches Targeting Youth Online Gambling, Considering Convergences of Gambling and Videogaming. Front Psychiatry. 2021;11:601712. Published 2021 Jan 25. doi:10.3389/fpsyt.2020.601712
27. Nordmyr J, Österman K. Raising the legal gambling age in Finland: problem gambling prevalence rates in different age groups among past-year gamblers pre- and post-implementation. Int Gambl Stud. 2016;16(3):347-356, DOI: 10.1080/14459795.2016.1207698
28. Kengganpanich M, Termsirikulchai L, Benjakul S. The impact of cigarette tax increase on smoking behavior of daily smokers. J Med Assoc Thai. 2009;92 Suppl 7:S46-S53.
29. Binde P. Exploring the Impact of Gambling Advertising: An Interview Study of Problem Gamblers. Int J Ment Health Addiction. 2009;7:54. https://doi.org/10.1007/s11469-008-9186-9

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Give Me A Boost: A Child Passenger Safety Educational Intervention

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ABSTRACT

BACKGROUND: Motor vehicle crashes (MVCs) are a leading cause of morbidity and mortality among children, yet belt-positioning booster seats remain underutilized. This study analyzed the impact of a provider-oriented child passenger safety (CPS) educational intervention on pediatric resident confidence, knowledge, and counseling behavior in the primary care setting.

METHODS: Pre- and post-educational intervention cross-sectional surveys were distributed to pediatric residents focusing on confidence, knowledge, barriers to, and frequency of CPS discussions.

RESULTS: Pre-intervention, only 16% (95% CI: 6.2–32%) of respondents reported confidence in their knowledge of the American Academy of Pediatrics' (AAP) booster seat recommendations. Post-intervention frequency of CPS discussion, confidence and knowledge in all measured aspects increased.

CONCLUSIONS: While pediatric residents are well positioned for CPS counseling, they lack adequate baseline knowledge of CPS recommendations, particularly for booster seats. Brief educational interventions can increase and maintain provider knowledge and confidence in counseling families on appropriate child car safety seats.

KEYWORDS: booster seats, child passenger safety, resident education, survey

BACKGROUND

Motor vehicle crashes (MVCs) are the leading cause of unintentional death and injury among children in the United States.[1] In 2017, there were 675 deaths and nearly 116,000 injuries due to MVCs in children ages 0–12.[1] Child safety seats (CSSs) aim to prevent serious injury and death while spreading the forces of the crash across the strongest parts of the child's body to help prevent serious injury.[2] Children should use a CSS with a harness until they exceed the maximum height or weight allowed for by the CSS manufacturer, both for rear-facing and then forward-facing seat positions.[2] When they outgrow their forward-facing CSS, children should then use a belt-positioning booster seat until the vehicle's lap-and-shoulder seat belt fits properly, which generally occurs when children are 4 feet 9 inches tall (approximately 145 centimeters) and are between 8 to 12 years old.[2] Belt-positioning booster seats have been shown to reduce the risk of injury to children by 45–59% when compared to seat belts alone.[3,4] Unfortunately, in children ages 4–7 years, booster seat use has been observed to be as low as <5%, even in states which require booster seats by law, and on average, 31.4% of children in this age range are not appropriately restrained.[5,6]

Parental education has been shown to significantly increase appropriate child safety seat usage.[7] Behavioral counseling interventions in the primary care setting are often effective at increasing short-term use of CSSs[8] and pediatricians are a primary source cited by parents for information on child passenger safety (CPS).[9] Pediatric primary care providers have variable knowledge and attitudes regarding CPS. A national survey of pediatricians practicing in the US found that only 81% were confident that they were counseling families on booster seats according to AAP guidelines.[10,11] Similarly, while pediatric residents are well positioned to provide CPS education and play a key role in providing healthcare (often to low-income, marginalized communities), their knowledge of and comfort with counseling on CPS recommendations varies.[10,12] Importantly, education provided during pediatric residency is associated with a greater likelihood that providers will continue to consistently counsel about CPS.[12] This is additionally supported by smoking cessation research that shows that brief educational interventions for providers are effective in increasing counseling behaviors in clinical practice, further emphasizing that residency is an optimal time for education on preventive topics.[13,14]

Besides focusing on education, some interventions utilize CSS distribution as a mechanism to increase parental usage of booster seats. For example, booster seat education by child care center staff paired with a free distribution program for booster seats has been shown to increase caregiver uptake of CPS information.[15] Indeed, research has shown that the largest effect on CSS usage occurs when interventions include a safety seat distribution program.[15,16] Brief educational interventions have been shown to be effective in increasing pediatric resident CPS knowledge and confidence, but have not examined the retention of this knowledge and changes

in attitude.[17,18] A single-point educational intervention on firearm injury prevention has been shown to increase medical student counseling self-efficacy significantly, with a reduction in retention at six months, indicating a need for continued education during residency on injury prevention topics.[19] So while it is apparent that educational interventions can be effective in increasing counseling behaviors in providers, and CSS distribution is an effective means of increasing CSS use, studies have not yet examined the effect of health care provider education paired with a booster seat distribution program.

OBJECTIVE

We aimed to assess the effect of an educational module paired with a clinic-based booster seat and car seat distribution program on pediatric residents' knowledge, attitudes, and self-efficacy around CPS recommendations.

METHODS

Study Design

This study was a pre- and post-educational intervention survey of pediatric residents at a large urban academic primary care practice in the northeastern United States from February 2020 to August 2020. A total of 48 pediatric residents train at this site and spend one half-day per week seeing primary care patients. An educational module on child passenger safety was delivered within the pre-existing educational conference structure as one of the weekly teaching conferences focused on a primary care topic. This module was delivered just before the initiation of a free booster seat distribution and car seat referral program in the primary care clinic, which continued throughout the six-month study period. The distribution program was funded by a local health maintenance organization, Neighborhood Health Plan, which supported booster seats and car seat vouchers for patients regardless of their insurance plan. The educational intervention was administered in person and via videoconferencing, and residents were surveyed pre-intervention, immediately post-intervention, and six-months post-intervention. Participants were excluded if they were not categorical pediatric residents or if they were study investigators. If participants did not complete the educational intervention, they were excluded from the immediate post-intervention survey.

Educational Intervention

The educational module was a 40-minute conference with participants either in person or via a live videoconference. The educational intervention utilized interactive components, including digital polling, multimedia content, and a short movement dance and sing-a-long to discuss CPS. Information covered included MVC injury prevention data and AAP recommendations for the use of and timing of transition for each type of CPS restraint, focusing on booster seats.

Survey Development

The surveys included items with multiple choice and Likert scale responses to gather participant confidence in and knowledge of CPS (including various restraint use and transitions), barriers to counseling patients on these topics, and self-report of counseling behaviors in the clinical setting. These items were rooted in the current AAP recommendations and integrated social-cognitive theories of behavior change which suggest self-efficacy and confidence are strong determinants of actual practices.[17-21] We also collected demographic data about the participants, including training level (post-graduate year), self-identified race/ethnicity, and number of children, and age of children.

Confidence & Knowledge & Barriers

A Likert scale from 1 "not confident at all" to 5 "very confident" was utilized to assess participant confidence in providing recommendations about each type of CPS restraint, including rear-facing CSS, forward-facing CSS, booster seats, and seat belts. We assessed resident knowledge of AAP booster seat recommendations using five multiple-choice items, which asked for the correct identification of: AAP recommendations on the transition out of a forward-facing car seat (to a booster seat) and out of a booster seat (to a seat belt), the average age based on height/weight recommendations to transition to these restraints, and the correct components of the seat belt fit test.[2] We assessed perceived barriers to booster seat counseling using a list of six barriers adapted from those identified previously in the literature.[10] Participants were asked to select the degree of each barrier using a Likert scale from 1 "not a barrier" to 5 "significant barrier." These three topics (confidence, knowledge, and barriers) were assessed at baseline, immediately post-educational module, and six-months post-intervention.

Counseling Behaviors

A Likert scale from 1 "never" to 5 "always" was used to assess the self-reported frequency of child passenger safety discussions with parents/guardians during primary care visits for the following patient age ranges: birth–2 years, 3–5 years, 6–10 years, and 11–18 years. These items were included in the baseline survey and the six-month post-educational module survey.

Data Collection

The electronic survey was generated and distributed using our institution's Research Electronic Data Capture (REDCap) system.[27] Pediatric residents were sent an email describing the survey, waiver of written consent, and a survey link. The surveys were distributed electronically before and after the educational module as well as at six months

post-intervention. Residents received a reminder email to complete the survey after the initial distribution of the surveys if they had not yet responded. All responses were anonymous, thus pre- and post-surveys were not linked. There was no incentive for participation. The study was approved by our Institutional Review Board.

Data Analysis

Likert scale data for confidence were dichotomized, grouping responses of 1–3 to indicate "not confident" and 4–5 to indicate "confident." Similarly, Likert scale data for frequency of counseling behaviors were dichotomized, categorizing responses of 4–5 as "frequent" counseling and 1–3 as "infrequent" counseling. Standard descriptive summaries were used for demographic variables. Categorical variables were compared using chi-square and Fisher exact tests, depending on the sample size.

RESULTS

Demographics

Thirty-seven pre-, 20 post-, and 25 six-months post-intervention responses were collected from respondents, giving a response rate of 77% pre-, 42% post-, and 46% six-months post-intervention. There was no significant difference in training year, age, or race of respondents across the survey time points. Less than 10% of all respondents across all time points had children. (**See Table 1**.)

Table 1. Demographics

	Pre-intervention	Immediate post-intervention	6-month post-intervention
	N = 37 (%)	N= 20 (%)	N = 25 (%)
Training Level			
PGY-1	12 (32)	6 (30)	1 (4)
PGY-2	12 (32)	9 (45)	9 (36)
PGY 3-6	13 (35)	5 (25)	15 (60)
Race/Ethnicity			
White	18 (49)	10 (50)	12 (48)
Black/African American	4 (11)	2 (10)	5 (20)
Other	10 (27)	4 (20)	4 (16)
No response	5 (14)	4 (20)	4 (16)
# of Children			
0	36 (97)	20 (100)	23 (92)
>1	1 (3)	0 (0)	2 (8)
Age of Children			
	N= 2 (%)	N = 0 (%)	N=2 (%)
Birth to 1 year	0 (0)	0 (0)	0 (0)
>1 year of age	2 (100)	0 (0)	2 (100)

*PGY: Post-graduate year

Confidence

At baseline, participants' confidence in providing counseling on car safety restraint types was lowest for booster seats. Only 27% (95% CI 14%–44%) of respondents felt confident in discussing booster seat use, with the most confidence reported for rear-facing car seat discussions (78%, 95% CI 60–91%). Immediately post-intervention and six-months post-intervention, the percentage of confident respondents about booster seat counseling increased significantly (p-value <0.0001), with 95% (95% CI 75-100%) feeling confident immediately post-intervention and 80% (95% CI 59%–93%) six-months post-intervention. Additionally, at baseline only 16% (95% CI 6%-32%) of respondents felt confident in their knowledge of AAP booster seat recommendations, whereas 75% (95% CI 51%-91%) felt confident immediately post-intervention, and confidence at the six-month post-intervention time period remained well above the initial confidence level at 68% (95% CI 47%-85%). In addition, participants' confidence in counseling about CSS and seat belts increased immediately post-intervention and remained higher than baseline at the six-month post-intervention survey as well. (**See Table 2**.)

Table 2. Resident Confidence in Providing Counseling About Child Passenger Safety (Pre/Immediate Post and Six-Months Post-Intervention)

	Pre-intervention	Immediate post-Intervention	6-months post-intervention	
	N= 37	N= 20	N=25	
Topics	**% Confident (95% CI)**	**% Confident (95% CI)**	**% Confident (95% CI)**	**P value**
Rear Facing Car Seats	78 (60–90)	95 (75–100)	100 (86–100)	**0.014**
Forward Facing	35 (20–53)	95 (75–99.9)	80 (59–93)	**<0.001**
Booster Seat	27 (14–44)	95 (75–99.9)	80 (59–93)	**<0.001**
Seat Belt Transition	41 (25–58)	95 (75–99.9)	84 (64–96)	**<0.001**
AAP Booster Seat Recommendations	16 (6–32)	75 (51–91)	68 (47–85)	**<0.001**

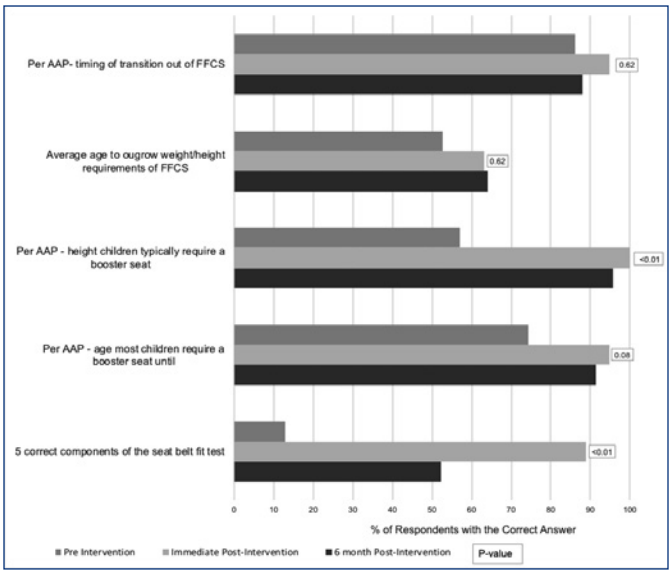
*AAP: American Academy of Pediatrics
Bolded values indicate p<0.05

Knowledge

At baseline, participants displayed the highest level of knowledge regarding rear-to-forward facing car seat transition (86% correct, 95% CI 71%-93%), and the least knowledge regarding key elements of booster seat use including: expected age for transitioning from a forward-facing car seat to a booster seat with 53% correct (95% CI 37%–68%), AAP recommended height for transitioning from a booster

seat to a seat belt (57% correct, 95% CI 41%–72%), and the five components of the seat belt fit test (13% correct, 95% CI 5%–29%). Statistically significant increases (p <0.01) in knowledge pre- and post-intervention were found only in the questions regarding the AAP recommended height for transitioning from a booster seat to a seat belt and correctly identifying the five components of the seat belt fit test, and was sustained at six-months post-intervention. (**See Figure 1**.)

Figure 1. Resident Knowledge of Car Seat Restraints Pre- and Post-Intervention



Self-reported Counseling Behaviors

Percent of "frequent" child passenger safety discussion increased after the educational intervention across all age ranges, though the only statistically significant increase was found for discussions with 11–18-year-olds. Fifty-seven percent (95% CI 40%–73%) of participants reported frequent child passenger safety discussions with 6–10-year-old patients at baseline, and 80% (95% CI 59%–93%) reported frequent discussions on the six-month survey. (**See Table 3**.)

Table 3. Resident Behaviors Regarding Child Passenger Safety (Pre/6-months Post-Intervention)

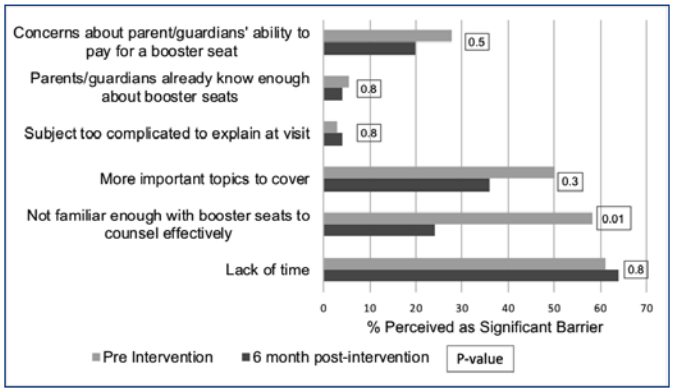
	Pre-Intervention	6-months Post-Intervention	
	N= 37	N=25	
Patient Age Group	**% Frequent (95% CI)**	**% Frequent (95% CI)**	**P value**
Birth–2 years	92 (78–98)	100 (86–100)	0.263
3–5 years	79 (62–90)	96 (71–99.9)	0.053
6–10 years	57 (40–73)	80 (59–93)	0.058
11–18 years	35 (20 –53)	76 (55–91)	**0.002**

* CPS: Child Passenger safety.
***Bolded values indicate p<0.01**

Barriers

Participants identified lack of time and lack of familiarity with booster seats as the most commonly identified barriers to counseling pre-intervention (**Figure 2**). The most common post-intervention barriers were lack of time and the large number of important topics to cover in a well-child visit. The only statistically significant change found in reported barriers from pre- to post-intervention was familiarity with booster seats. Lack of familiarity with booster seats dropped from 58% to 24% (p <0.01) of respondents as an identified barrier to counseling on this topic. Concern about parental ability to pay for a booster seat decreased slightly (from 28% to 20%, p = 0.5), despite the initiation of the free distribution program for booster seats.

Figure 2. Perceived Barriers to Booster Seat Counseling Pre- and 6-months Post- Intervention



* FFCS: forward-facing car seat, AAP: American Academy of Pediatrics

DISCUSSION

This study demonstrated the effect of a brief provider-focused CPS educational intervention paired with a booster seat distribution program on increasing provider knowledge and confidence in counseling families on appropriate child car restraint use, with retention of that knowledge and confidence six months later.

As shown in other studies, our results emphasize pediatric residents' limited knowledge and confidence regarding child passenger safety, especially for booster seats.[10,12] Because residents come from different institutional backgrounds, there is no standardized pre-residency curriculum regarding child passenger safety that trainees undergo before starting their training and role as primary care providers. Despite this limitation, pediatric residents are well positioned as practicing primary care providers and learners in the field, and education during training is especially important in building their practice patterns in family counseling.[26] If early comfort with and uptake of CPS counseling occurs in residency, a broader, more uniform practice among primary care providers will be lasting and impactful, leading to safer-riding children in the community. Indeed, literature has shown, counseling by pediatricians positively influences families' use of CSS.[8,9]

While lack of time is a barrier in nearly every patient interaction,[25] lack of familiarity with a topic can be readily addressed by increased exposure and education, as demonstrated in this study. By including child passenger safety education as part of a graduate medical education or residency-specific curriculum, providers can not only enhance their knowledge of evidence-based and practical child passenger safety recommendations but can pass that information along to patients and families. Notably, the largest knowledge gains were made regarding booster seat use and readiness for transition to a seat belt, directly related to the topics infrequently discussed at baseline and in need of improvement in real-world CPS practice by parents and caregivers.

The intervention did not show a significant reduction in residents' view of cost as a barrier to booster seat use for families, despite the inclusion of a free booster seat distribution program in the resident clinic. This may be due to the low cost of booster seats at baseline. Nevertheless, the availability of booster seats within the clinic removes one barrier for families' CSS use, and perhaps provided increased visibility of CPS as a key topic among residents, leading to some of the behavior changes. Though we could not discern the specific impact of the booster seat distribution in comparison to the education module, the sustained knowledge and confidence six- months post-intervention without additional educational sessions suggests this programming in the clinic may have been supportive.

Our booster seat and car seat voucher distribution program was supported by a local insurance agency that provides coverage for a large proportion of Medicaid patients. While this study does not examine changes in booster seat use by families, the evidence has shown repeatedly that education paired with incentive or distribution programs shows more consistent increases in booster seat usage than education programs alone.[28,29] Therefore, in addition to ensuring early education for pediatric trainees regarding booster seats and CPS, a new frontier for training programs may also be engaging with insurance companies to work with health care providers to improve child passenger safety.

Our study did have several limitations that must be considered. Firstly, the sample size was small, and while the response rate was fairly high, there may have been response and selection biases. However, the results clearly show a deficit in knowledge and confidence in pediatric residents regarding child passenger safety. Additionally, there were not any fully validated surveys to draw from about confidence and barriers regarding CSS, so the validity of the results may be unclear. This study was also conducted within a single residency program, which may limit the generalizability of the results. Finally, this study was conducted during the Coronavirus pandemic, which may have impacted the priorities during well-child visits of providers as well as patients and families.

CONCLUSIONS

While pediatric residents are well positioned for child car restraint counseling, they do not have adequate knowledge of or confidence in counseling about child passenger safety recommendations, especially in regards to booster seats. A brief, one-time educational intervention paired with a free booster seat distribution program can sustainably increase provider knowledge and confidence in counseling families on appropriate child car restraint use. Further investigation is warranted into the effect of increased provider education and ease of access to CPS products on the use of appropriate CSS use in the community.

References

1. Web-based Injury Statistics Query and Reporting System. National Center for Injury Prevention and Control, Centers for Disease Control. 2019 Aug 19.
2. Weaver, Nancy L., et al. Promoting Correct Car Seat Use in Parents of Young Children. Health Promotion Practice, 2012;14(2): 301-307. doi:10.1177/1524839912457567.
3. Durbin, Dennis R, et al. Child Passenger Safety. Council on Injury, Violence, and Poison Prevention, Pediatrics. 2018; 142(5). doi: 10.1542/peds.2018-2460
4. Arbogast, Kristy B., et al. Effectiveness of Belt Positioning Booster Seats: An Updated Assessment. Pediatrics. 2009; 124 (5) 1281-1286. doi: 10.1542/peds.2009-0908
5. Bruce, Beth S., et al. Promoting Booster Seat Use for Young Children: A School-Based Intervention Pilot Study. Paediatrics & Child Health. 2017; 22 (2): 89-91. doi:10.1093/pch/pxx025.
6. Li, H. R., & Pickrell, T. The 2017 National Survey of the Use of Booster Seats (Report No. DOT HS 812 617). Washington, DC: National Highway Traffic Safety Administration. 2018.
7. Durbin, Dennis R. Belt-Positioning Booster Seats and Reduction in Risk of Injury Among Children in Vehicle Crashes. JAMA, 2003; 389 (21): 2835. doi:10.1001/jama.289.21.2835.
8. Yellman, Merissa A., et al. Evaluation of Give Kids a Boost: A School-Based Program to Increase Booster Seat Use among Urban Children in Economically Disadvantaged Areas. Traffic Injury Prevention. 2018; 19 (4): 378–384, doi:10.1080/15389588.2018.1431833.
9. Morrongiello BA, Hillier L, et al. What I said' versus 'what you heard': a comparison of physicians' and parents' reporting of anticipatory guidance on child safety issues. Inj Prev. 1995;1(4):223-7. doi: 10.1136/ip.1.4.223.
10. Zonfrillo MR, Sauber-Schatz EK, Hoffman BD, Durbin DR. Pediatricians' self-reported knowledge, attitudes, and practices about child passenger safety. The Journal of pediatrics. 2014;165(5):1040-1045 e1041-1042.
11. Yingling F, Stombaugh HA, et al. Pediatricians' knowledge, perceptions, and behaviors regarding car booster seats. J Community Health. 2011;36(1):166-73. doi: 10.1007/s10900-010-9294-x.
12. Wright MS. Pediatric injury prevention: preparing residents for patient counseling. Arch. Pediatr. Adolesc. Med. 1997;151(10):1039-1043.
13. Anum A, Hannah D, et al. Enhancing hospitalists smoking cessation counseling and billing compliance by education intervention: a quality improvement project, Journal of Community Hospital Internal Medicine Perspectives, 2021; 11(5): 612-618. doi: 10.1080/20009666.2021.1961380
14. Ockene JK, Quirk ME, Goldberg RJ, et al. A Residents' Training Program for the Development of Smoking Intervention Skills. Arch Intern Med. 1988;148(5):1039–1045. doi:10.1001/archinte.1988.00380050045007

15. Thoreson S, et al. Effects of a Booster Seat Education and Distribution Program in Child Care Centers on Child Restraint Use Among Children Aged 4 to 8 Years. Arch Pediatr Adolesc Med. 2009;163(3):261–267. doi:10.1001/archpediatrics.2008.564
16. Williams, Selvi, et al. Primary Care Interventions to Prevent Motor Vehicle Occupant Injuries. Agency for Healthcare Research and Quality (US).
17. Ekundayo OJ, Jones G, et al. A Brief Educational Intervention to Improve Healthcare Providers' Awareness of Child Passenger Safety, International Journal of Pediatrics. 2013. doi: 10.1155/2013/821693
18. Morrissey D, Riese A, et al. Child Passenger Safety Training for Pediatric Interns: Does it Work? R I Med J. 2016;99(3):29-32. PMID: 26929969.
19. Kwong, J.Z., Gray, J.M., Rein, L., et al. An educational intervention for medical students to improve self-efficacy in firearm injury prevention counseling. Inj. Epidemiol. 2019;27(6) https://doi.org/10.1186/s40621-019-0201-3
20. Bandura A. Social foundations of thought and action: A social cognitive theory. Englewood Cliffs, NJ: Prentice-Hall; 1986
21. Ozer EM, Adams SH, et al. Provider self-efficacy and the screening of adolescents for risky health behaviors. The Journal of Adolescent Health. 2004;35(2):101–107.
22. Maiuro RD, Vitaliano PP, Sugg NK, et al. Development of a health care provider survey for domestic violence. American Journal of Preventive Medicine. 2000;19(4):245–252.
23. Cheng TL, DeWitt TG, Savageau JA, O'Connor KG. Determinants of counseling in primary care pediatric practice. Physician attitudes about time, money and health issues. Archives of Pediatric and Adolescent Medicine. 1999;153:629–635
24. Finch SA, Weiley V, Ip EH, Barkin S. Impact of pediatricians' perceived self-efficacy and confidence on violence prevention counseling: a national study. Matern Child Health J. 2008;12(1):75-82. doi:10.1007/s10995-007-0223-2
25. Cohen LR, Runyan CW. Barriers to pediatric injury prevention counseling. Inj Prev. 1999;5(1):36-40. doi:10.1136/ip.5.1.36
26. Hauer KE, Carney PA, Chang A, Satterfield J. Behavior change counseling curricula for medical trainees: a systematic review. Acad Med. 2012;87(7):956-68. doi: 10.1097/ACM.0b013e31825837be.
27. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)-A metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform. 2009;42(2):377-381. doi:10.1016/j.jbi.2008.08.010
28. Ehiri JE, Ejere HO, Hazen AE, Emusu D, King WD, Osberg SJ. Interventions to increase children's booster seat use: a review. Am J Prev Med. 2006;31(2):185-92. doi: 10.1016/j.amepre.2006.03.020.
29. Zaza S, Sleet DA, Thompson RS, et al. Reviews of evidence regarding interventions to increase use of child safety seats. Am J Prev Med 2001;21(4S): 31-47.

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An Evaluation of Contraceptive Methods After Implementation of a Novel LARC Program in a Residency Primary Care Clinic

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ABSTRACT

BACKGROUND AND OBJECTIVE: Internal medicine (IM) residency programs have inadequate education and training around contraception, creating and perpetuating a potential barrier for patients. Contraceptive access is a critical part of primary care, yet few IM residency programs offer long-acting reversible contraception (LARC) in their clinic. To address the LARC needs of our patients and education needs of our residents, one attending (MS) created a procedure clinic and provided LARC in our residency clinic in 2015. In this initial study, we sought to determine the use of contraceptive methods among reproductive age women at our residency clinic two years after offering LARC. This data will shape future care provision and resident education.

STUDY DESIGN AND METHODS: Data were extracted from 1,182 female patients ages 20–39 years attributed to the Rhode Island Hospital Center for Primary Care (CPC) between February 2017 to August 2018. Of the total, 260 patients were excluded because they had not been seen in the clinic within the preceding 12 months or had left the practice. Descriptive and bivariate methods were used to calculate the proportion of women using any contraception and long-acting reversible contraception (LARC) and to test for associations with demographic characteristics.

PRIMARY RESULTS: Fifty-five percent used any contraception and 19% used LARC. LARC use was higher among women ages 20–29 when compared to women 30–39. Demographic characteristics other than age were not associated with contraceptive use.

PRINCIPAL CONCLUSIONS: In this clinic, LARC usage exceeds the national average (19.0% v 10.3%). Residency training is ideal for learning skills around this aspect of medical care, providing the ability to ensure appropriate oversight and supervision. This initial study suggests almost one fifth (18%) of patients who utilize LARC find access at an IM residency primary care clinic acceptable. Internal medicine primary care clinics can address the nonsurgical contraceptive needs of their patients by providing access to LARC. To achieve this goal, internal medicine residents should receive training in and exposure to LARC provision.

KEYWORDS: internal medicine residency clinic, medical education, contraception, long-acting reversible contraception (LARC), women's health

INTRODUCTION

Contraceptive counseling and provision is uncommon in the internal medicine primary care setting, even when prescribing teratogenic medications.[1,2] Contraceptive access is a critical part of primary care yet many internal medicine residency programs have inadequate education and training opportunities around contraception in general and LARC in particular.[3] Literature is scarce regarding internal medicine training on and the provision of LARC by practicing internists. Most internal medicine program directors believe there is inadequate training around contraception.[3] This study shows the early impact of one faculty (MS) member's creation of a procedure clinic which includes LARC (IUD and implant). In this study, we sought to determine the use of contraceptive methods among reproductive age women at our clinic after 2 years of LARC implementation.

METHODS

Study design and setting

The Center for Primary Care (CPC) is the largest academic primary care practice affiliated with the Brown University Internal Medicine Residency Program in Providence, RI. Our patient population is socioeconomically, racially, ethnically and linguistically diverse. The CPC is the primary care practice for 7 faculty, 3 nurse practitioners, and 88 residents, supervised by a total of 28 attendings, many of whom have expertise in women's health. During the study period, two IM faculty supervised LARC procedures. Gynecologists do not practice on site. Our procedure clinic began with one faculty member doing one half day of procedure clinic a week. During the study period, our procedure clinic occurred one half day per week. Since September 2018, it has expanded to twice weekly sessions (four hour half-day blocks) plus an additional women's health clinical session weekly where LARC procedures can also be scheduled. Each session has an average of two residents seeing patients under attending supervision. Typically, five to six patients

per session are seen and there is a mix of gynecologic and musculoskeletal procedures done. In each session, the number of gynecological procedures ranges from zero to three. Additional resident education on contraception occurs for all residents in a 20-minute pre-clinic conference. Primary care track residents have an additional three hours of didactics dedicated to reproductive health (contraception, options counseling and medication abortion).

Patient selection

Data were abstracted from all female patients (n=1182), aged 20-39 years, attributed to the CPC between February 2017 to August 2018. Of the total, 260 patients were excluded because they had not been seen in the clinic within the preceding 12 months or left the practice, leaving 922 patients to be analyzed.

Defining prescription contraception

Prescription contraception is birth control that requires an interface with a healthcare provider and includes LARC, oral contraceptives pills, hormonal ring and patch.

Data collection, study procedures, and statistical analysis

A REDCap (Research Electronic Data Capture) database was created to identify the 922 eligible women, 20–39 years of age. Manual chart review was performed. Contraceptive method, location of contraceptive care and pregnancy desire were extracted.

The analysis was conducted in SAS© software, version 9.4 (SAS Institute Inc.). Chi-square and Fisher exact were performed for descriptive and bivariate analysis to report contraceptive use and any associations with demographic characteristics.

Ethical approval

This study was reviewed and approved by the institutional review board (IRB) at Rhode Island Hospital, Providence, Rhode Island.

Table 1. Baseline Characteristics of Analytical Study Sample

	Full sample size (n=922)
Age, mean (SD)	**29.6 (5.6)**
Age, no. (%)	
20–29 years old	459 (49.8)
30–39 years old	463 (50.2)
Preferred language, no. (%)	
English	621 (67.4)
Spanish	185 (20.1)
Other	116 (12.6)
Race	
Black or African American	233 (26.1)
White or Caucasian	284 (31.8)
Other/American Indian or Alaska Native/Asian/ Native Hawaiian or Other Pacific Islander	377 (42.2)
Hispanic	398 (44.5)
Using any contraceptive methods[b]	
Yes	500 (54.2)
No	218 (23.6)
Unknown	121 (13.1)
Seeking pregnancy/pregnant	83 (9.0)
Contraceptive method	
LARC	175 (19.0)
Non-LARC	325 (35.2)
Unknown/seeking pregnancy/pregnant	422 (45.8)
Location of contraceptive care, no. (%)	
Receiving prescription contraception through our clinic	118 (12.8)
Receiving prescription contraception through another site	184 (20.0)
Not receiving prescription contraception[a]	392 (42.5)
Unknown	228 (24.7)

Notes: a - contraception requiring an interface with healthcare provider;
b – excluding, Pregnant or Seeking pregnancy/Pregnant.
Abbreviations: LARC – long-acting reversible contraception; SD – standard deviation

RESULTS

Table 1 shows baseline characteristics and contraceptive use of our study sample. Overall, 54% of our sample used prescription contraceptive method, and of those using contraception 35% used LARC (n=175). Among those using LARC, 61.7% had an IUD, and the remaining had a contraceptive implant. Eighteen percent of LARC users obtained LARC in our clinic (n=33). Of the total, 20 received an IUD and 13 received a contraceptive implant. Among prescription contraception users, LARC was used by 65% of our sample ages 20 to 29 and 35% of our sample ages 30–39 (p-value <0.0001). Among LARC users, usage of IUD was higher (44, 72.1%) among women 30–39 years old using LARC compared to those aged 20-29 years old using LARC (64, 56.1%), p-value=0.0381. Demographic characteristics other than age were not associated with contraceptive use. LARC use was not associated with preferred language (English/Spanish) or race/ethnicity.

DISCUSSION

Comprehensive contraceptive access allows women agency over their reproductive health and can decrease rates of unintended pregnancy. In 2018, nearly 35% of pregnancies in Rhode Island amongst women aged 20–39 were unintended.[4] Our rates of LARC usage, 19%, exceed the national average in those aged 20 to 29 (13.7%) and those aged 30 to

39 (12.7%).[5] Given that 1 in 5 women who accessed LARC did so at our clinic, we believe that internal medicine residency clinics can be successful in making LARC available and onsite for a racially and ethnically diverse group of women. Offering LARC in IM residency clinics will allow patients increased access to insertion when contraception is needed and removal when pregnancy may be desired or contraception is now longer needed or desired. Internal medicine residents are capable of achieving competence in LARC procedures. Other IM training programs should be able to implement LARC with an initial single provider who is capable of performing and educating around these procedures.

LIMITATIONS

Because 13% of patients' contraceptive choice is not reported in our medical record, we identified an opportunity for improvement, such as ensuring follow-up visits and enhancing use of problem-list documentation for contraceptive choice. Our study population is a subset of our clinic population who are often relatively healthy and young and thus seen less often than other patients in an IM primary care clinic, making it more important to ask about contraception at every visit.

The data is from 2017–18 and we have not collected more recent data. We have since expanded access to LARC considerably at the clinic, therefore would expect these numbers to have increased. We will examine this in a future study.

Our single site study may not be generalizable. Chart review may overestimate prescription contraceptive use because documentation of any prescription during the study period was counted as use. Finally, we limited our study population to ages 20–39 years; the more traditional age limit of 18–45 includes women ages 40–45 who may be less likely to use a contraceptive method, thus overestimating contraceptive use as compared to the national data.

CONCLUSION

In an internal medicine residency clinic that increased education and training around contraception including LARC, a majority of female patients ages 20–39 used contraception, and 35% of those who used contraception used LARC. Our study demonstrates that internal medicine primary care clinics are well positioned to address the nonsurgical contraceptive needs of their patients, increasing access to these important services.

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References

1. Eisenberg, D. L., Stika, C., Desai, A., Baker, D. & Yost, K. J. Providing contraception for women taking potentially teratogenic medications: a survey of internal medicine physicians' knowledge, attitudes and barriers. *J. Gen. Intern. Med.* **25**, 291–297 (2010).
2. Dirksen, R. R., Shulman, B., Teal, S. B. & Huebschmann, A. G. Contraceptive counseling by general internal medicine faculty and residents. *J. Womens. Health* **23**, 707–713 (2014).
3. Spencer, A. L. & Kern, L. M. Primary care program directors' perceptions of women's health education: a gap in graduate medical education persists. *J. Womens. Health* **17**, 549–556 (2008).
4. Pregnancy risk assessment monitoring system (PRAMS): Department of health. https://health.ri.gov/data/pregnancyriskassessment/.
5. Daniels, K. & Abma, J. C. Current contraceptive status among women aged 15-49: United States, 2017-2019. *NCHS Data Brief* 1–8 (2020).

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Snapshot of Harm Reduction in Rhode Island (February 2021–January 2022)

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BACKGROUND/INTRODUCTION

In December 2021, the Substance Abuse Mental Health Services Administration (SAMHSA) announced $30 million in grant funding for Harm Reduction programs. This unprecedented opportunity signaled a shift in the national overdose prevention strategy, with harm reduction included as one of the four pillars of President Biden's strategy.[1] Harm reduction is a vital part of Rhode Island's approach to reducing overdose deaths and the transmission of HIV and hepatitis C virus (HCV). Due to the work of the harm reduction organizations, less than 4% of newly-diagnosed cases of HIV were identified in people who inject drugs from 2016–2020.[2] This shift in strategy at the national level comes at a critical time when overdose deaths across the nation are projected to be higher in 2021 than 2020.[3] Similarly, after declining from 2016–2019, in 2020 the number of lives lost to overdose in Rhode Island increased 25%, from 308 in 2019 to 384 in 2020. It is projected that 2021 data will result in even more lives lost to an overdose.[4]

According to the National Harm Reduction Coalition, "harm reduction is a set of practical strategies and ideas aimed at reducing negative consequences associated with drug use. Harm Reduction is also a movement for social justice built on a belief in, and respect for, the rights of people who use drugs."[5] One of the most recognized harm reduction strategies is syringe service programs (SSPs), which is an evidence-based intervention that saves lives, decreases the risk of infectious disease transmission, decreases injection drug use, and encourages proper disposal of used syringes.

Rhode Island has a long history of harm reduction that started in 1994 with a legislative bill enacting a pilot SSP at AIDS Care Ocean State (ACOS).[6,7] In 1997, it became law that the state was required to support a needle exchange program to prevent the spread of infectious diseases. In addition to syringe exchange, these programs are required to include education materials, HIV counseling and testing, and other infection and overdose prevention resources.[8]

For many years, ACOS was the primary provider of harm reduction services in Rhode Island, providing services in a variety of locations including walk-in services, mobile outreach, walking routes, home delivered services, and, most recently, harm reduction vending machines. This multifaceted approach allows for services to be provided in a way that is most comfortable to the client, decreasing stigma and respecting people who use drugs. As the need for harm reduction services has increased, due in part to the overdose epidemic, the Rhode Island Department of Health (RIDOH) has invested additional resources to increase capacity and expand harm reduction services in other organizations such as Project Weber/RENEW (PWR), which was founded to support sex workers of all genders, and the Hope Recovery C.O.R.E. (Community Outreach Response Efforts) Team at the Parent Support Network (PSN) of Rhode Island, which conducts mobile outreach across the state targeting suburban and rural communities. These harm reduction organizations provide critical services to people who use drugs by distributing safer drug use supplies (e.g., sterile injection, snorting, and smoking supplies, fentanyl test strips, and naloxone). They also provide direct peer support and case management particularly related to treatment and wrap-around services (e.g., housing, employment, and the provision of basic needs).

This article describes the population served by the outreach services of three harm reduction organizations in Rhode Island: ACOS, PSN, and PWR. These organizations, funded in part by the RIDOH, provide harm reduction services to prevent HIV and HCV infections and overdoses with dignity and compassion to persons who use drugs throughout Rhode Island. This analysis presents descriptive statistics related to the demographic characteristics of individuals who access harm reduction services from these organizations.

METHODS

The data used in this report were collected by outreach team members at ACOS, PWR, and PSN during each encounter with a client. The data collected includes demographic information about registered clients. Although each organization's data collection practices vary slightly, data are generally recorded on a shift sheet, entered in an organizational database, and submitted to RIDOH monthly, which is then aggregated and analyzed to identify data trends. RIDOH-funded harm reduction organizations have been working in the community for years, but reporting was not standardized across all organizations until February 2021. For this reason, one year of data between February 1, 2021, and January 31, 2022, is included in this report.

To receive harm reduction supplies and services, individuals are asked to register with each harm reduction organization. Individuals are provided with an anonymous client ID that they ask to be provided at any future encounters. In certain situations, harm reduction supplies and services are provided to individuals without requiring them to register, including instances where they are provided to a business or at community-based trainings/events. These encounters were excluded from our demographic summary of clients (**Table 1**).

Table 1. Demographic Characteristics of Clients Receiving Harm Reduction Services in Rhode Island by Frequency of Encounters (February 2021–January 2022)

	All Clients n (%)	1–3 Encounters n (%)	4–12 Encounters n (%)	>12 Encounters n (%)
Unique Clients	**5,922**	**5,166 (87.2%)**	**557 (9.4%)**	**199 (3.4%)**
Gender				
Male	3,598 (60.8%)	3,124 (60.5%)	352 (63.3%)	122 (61.3%)
Female	2,055 (34.7%)	1,816 (35.2%)	172 (30.8%)	67 (33.7%)
Non-Binary	13 (0.2%)	13 (0.3%)	0 (0.0%)	0 (0.0%)
Transgender	60 (1.0%)	51 (1.0%)	8 (1.4%)	1 (0.5%)
Race and Ethnicity				
Hispanic	1,156 (19.5%)	1,032 (20.0%)	99 (17.8%)	25 (12.6%)
Non-Hispanic, White	3,421 (57.8%)	2,959 (57.3%)	320 (57.5%)	142 (71.4%)
Non-Hispanic, Black	857 (14.5%)	754 (14.6%)	85 (15.3%)	18 (9.0%)
Non-Hispanic, Other	117 (6.3%)	97 (1.9%)	15 (2.7%)	5 (2.5%)
Unstably Housed During At Least One Encounter	3,577 (60.4%)	2,930 (56.7%)	463 (83.1%)	184 (92.5%)

The purpose of this analysis is to provide a comprehensive snapshot of individuals who are accessing the harm reduction programs and services that are provided through these organizations.

RESULTS

Between February 1, 2021, and January 31, 2022, harm reduction organizations in Rhode Island engaged 5,922 unique clients across 15,825 total encounters. The majority of clients are male (60.8%), and most clients self-identified as non-Hispanic white (57.8%), followed by Hispanic (19.5%), and non-Hispanic Black (14.5%). Housing instability is a significant problem among clients accessing harm reduction services; more than half (60.5%) of clients indicate they are unstably housed during at least one encounter. Finally, most clients had limited engagement, only one to three encounters (87.2%), with harm reduction services.

We conducted further analyses to determine if there were differences between clients based on how frequently they interacted with harm reduction organizations. The distribution of gender was generally the same across all three frequency groups. By contrast, the racial and ethnic distribution changes between frequency groups. Of clients with one to three encounters, 57.3% were non-Hispanic white, 14.6% were non-Hispanic Black, and 20.0% were Hispanic. Among clients with four to 12 encounters, and even more so among clients with more than 12 encounters, the proportion of non-Hispanic Black and Hispanic clients decreased while the proportion of non-Hispanic white clients increased. Housing instability is an issue for the majority of all clients accessing harm reduction services; however, it is even more prevalent among clients with more frequent encounters. A staggering 83.1% of clients with four to 12 encounters and 92.5% of clients with more than 12 encounters self-reported housing instability during at least one encounter.

DISCUSSION

Rhode Island has started to invest additional funds in harm reduction in recent years. This is demonstrated by the large number of people who are served by these harm reduction programs. During the 12 months of data collection, there were 5,922 unique individuals who accessed harm reduction services. Each individual is issued a unique code which is used for subsequent harm reduction encounters; this accounts for individuals who may have accessed services multiple times in a month. There are many individuals (87.2%) who accessed supplies one to three times during the time frame. This could be caused by a variety of factors, including the transient nature of this population, individuals providing a different unique code when accessing services, newly enrolled individuals who have not had the opportunity to access supplies multiple times, or outreach events in which individuals may engage with harm reduction staff once and they do not follow up.

Racial disparities continue to be experienced among people who use drugs. Specifically, fatal overdose rates for non-Hispanic Black and Hispanic are increasing faster when compared to rates of non-Hispanic white Rhode Island residents.9 Rhode Island's harm reduction organizations continue to raise up concerns around overdoses reported by people that use stimulants. In 2020, 74% of fatal overdoses among Black, non-Hispanic decedents involved cocaine, compared to 56% among Hispanic decedents or 47% among non-Hispanic white decedents in the same year.[9] As shown in the results above, harm reduction organizations saw a higher proportion of people who identify as non-Hispanic Black or Hispanic, compared to the distribution of these groups in the general Rhode Island population. Therefore,

harm reduction organizations are well-situated to continue to meet the needs and address the racial disparities.

One potential limitation to this analysis is that demographic data are collected at each encounter and is occasionally discrepant or missing. Therefore, for the purposes of this analysis, demographic data at first encounter during the time frame was used.

As these organizations continue to build their infrastructure around data and reporting, there is more opportunity for future analyses. It is evident from the increase in overdose deaths in recent years that there is still potential for further investment and scaling of these live-saving interventions. As data are better aligned across harm reduction organizations in Rhode Island, there is an opportunity to conduct further analyses of the types of services people are accessing, as well as examining the geographic distribution of harm reduction clients.

In conclusion, this recent increased investment in harm reduction in Rhode Island has been met with an unprecedented demand. The three highlighted Rhode Island organizations serve more than 5,000 people per year and provide them with lifesaving supplies and resources. Investment in harm reduction is an evidence-based practice that decreases infectious disease, keeps our communities safe, and utilizes an approach of respecting individuals who use drugs while decreasing unintended negative health consequences.

References

1. Haffajee, Sherry, Dubenitz, White, Schwartz, Stoller, Swenson-O'Brien, Manocchio, Creedon, and Bagalman. U.S. Department of Health and Human Services Overdose Prevention Strategy. Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. [Issue brief] 2021.
2. Rhode Island Department of Health. HIV, Sexually Transmitted Diseases, Viral Hepatitis, and Tuberculosis Surveillance Report. [Online] 2020. https://health.ri.gov/publications/surveillance/2020/HIVSTD.pdf
3. Ahmad FB, Rossen LM, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics. 2022.
4. Prevent Overdose RI. Overdose Death Data. [Online] https://preventoverdoseri.org/overdose-deaths/.
5. National Harm Reduction Coalition. Principles of Harm Reduction. [Online]. https://harmreduction.org/about-us/principles-of-harm-reduction/.
6. Rhode Island General Assembly. An Act Relating to Health and Safety – AIDS and HIV Transmission. [Online] 1994. http://webserver.rilin.state.ri.us/PublicLaws94/law94030.htm
7. Joseph, Kofman, Larney, and Fitzgerald. Hepatitis C Prevention and Needle Exchange Programs in Rhode Island: ENCORE, 2014, *Rhode Island Medical Journal*. [Online] http://www.rimed.org/rimedicaljournal/2014/07/2014-07-31-hepc-joseph.pdf.
8. Rhode Island General Assembly. An Act Relating to Sexually Transmitted Disease. [Online] 1997. http://webserver.rilegislature.gov/PublicLaws/law97/law97213.htm
9. Shin, Hallowell & Scagos. Racial and Ethnic Disparities in Accidental Drug Overdose Deaths – Rhode Island, 2016–2020, 2021, *Rhode Island Medical Journal*. [Online] http://www.rimed.org/rimedicaljournal/2021/10/2021-10-47-health-shin.pdf.

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Water: Proposed FDA revision

JOSEPH H. FRIEDMAN, MD

REQUEST FOR COMMENTS

Background: The number of adverse effects (AEs) listed in package inserts for drugs approved by the Food and Drug Administration (FDA) has increased dramatically. In a *New England Journal of Medicine* commentary published about five years ago, the mean number of listed AEs was 75. Under the new administration, the FDA is interested in overseeing more aspects of public health but is seeking to limit needless worry about possible AEs. With the intention of eliminating the listing of AEs that occurred during trials but which were most likely not related to the investigated drug, food, supplement or device, the following proposed handout was developed to meet a Congressionally-mandated directive to make Americans aware of public health hazards that they may not be adequately aware of. This document is not final and may be modified by your comments.

PROPOSED PACKAGE INSERT FOR WATER

Introduction: Water is a ubiquitous chemical that occurs naturally in the environment, often combined or contaminated with other chemicals as well as biological and non-organic substances too numerous to mention. In its pure form, it is a chemical composed of two parts of hydrogen to one of oxygen. Altered chemical forms of H_20 are not used for drinking and therefore do not come under the purview of the FDA. Currently, water composed of deuterated hydrogen atoms is the only available form of this drug, which is used primarily in nuclear reactors.

Water was approved in 2020 by an expert committee, which voted 9–3 with two abstentions, to approve FDA's approval of water for non-research uses.

Current status: There are numerous brand names of water available, all having between 80 and 120% of the stated pharmacological activity of the basic formulation of generic H_2O, approved by the FDA in 2020.

Pharmacology: The chemical activity of this drug is still undergoing testing. It is used primarily to satisfy electrolyte requirements in both individual cells as well as in various organs. It provides a substrate for the numerous chemical reactions within each cell, allowing them to travel from one structure to another. It suppresses the hypothalamic hormone vasopressin and is therefore the drug of choice for suppressing the discomforting sensation of thirst. It is important in temperature regulation through sweating, in digestion, and in numerous other physiological processes.

As widely used and as important as this drug is, its use, as is true of all drugs, may contain hidden dangers, whose importance is magnified greatly by its widespread use. For example, one recent study showed the average concentration of one liter of bottled water was 325 microplastic particles, and linked extended use to negative health outcomes – from cardiovascular disease to autoimmune conditions. Another study revealed that some products contained higher than FDA-recommended levels of arsenic (10 parts per billion (ppb)). Below are some common warnings PCPs might want to advise their patients, or use to prepare an office handout.

Water's potential side effects*:

1. If water is not swallowed very carefully, some may go down the trachea (aspiration) which can lead to coughing, bronchitis, pneumonia and death.

2. Coughing or laughing when drinking water may cause the fluid to go up the nose, leading to sinus infection, which may cause brain abscesses, sepsis and death.

3. Excessive water intake may cause hyponatremia, which can lead to confusion, seizures and death.

4. Excessive intake of water and other water-based liquids such as beer, increases the likelihood of hyponatremia, which may lead to confusion, seizures and death

5. Inadequate water intake may contribute to constipation. This may become severe, leading to complete blockage, causing "toxic megacolon" and possible death.

6. Excessive water intake leads to increased urination. This may lead to fainting in men (who urinate while standing), poor sleeping at night, leading to increased walking at night, leading to falls, and possible death.

7. Increased urination may lead to urinary urgency, causing older people to need to rush to get to the toilet, leading to increased risk of falling, which may cause hip fracture or brain trauma, leading to a need for major surgery, and death.

8. Excessive water drinking, especially at night, may cause incontinence, which may cause awakening and a need to get out of bed and change the sheets. This increases the risk of falls, which may lead to death.

9. Drinking water when driving increases the risk of motor vehicle accidents, leading to property damage, maiming and death.

10. Drinking water when driving leads to the increased need to urinate, which may lead to bladder urgency, leading to reckless driving and an increased risk of death.

11. Aspirating water in its frozen form can lead to blockage of the trachea, causing hypoxia and death.

12. Water increases the risk of worsened congestive heart failure which may lead to death.

13. Water increases the severity of fluid retention and swelling in the feet and legs. This increases the risk of falls due to increased heaviness of legs, as well as increased urination at night (see # 8) and may lead to death.

14. Other clear and colorless liquids such as bleach, vodka and cleaning solvents are often mistaken for water and swallowed without consideration of the consequences of such a mistake. Depending on the quantity imbibed, this may lead to death.

As is true for all medications, know your drugs and drink with care!

Please email your suggestions to the editor emeritus at: Joseph_Friedman@wedontcare.org.

*Potential side effects are based on adverse event reporting from several double-blind, placebo-controlled trials of water vs. water substitute for the treatment of diverse disorders including thirst,[1-7] diaphoresis,[8-11] hypernatremia,[12-33] oliguria.[34-39] (Reference citations available via the Freedom of Information Act.)

April Fools!

Author

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'Give Me a Boost!' Pediatric Car Safety Seat Program

A Hasbro Children's Hospital partnership with Neighborhood Health Plan of Rhode Island

JULIA R. DONNER, MD; VICTORIA QUINN, DO; ANDREA CHELI, CPSTI; CHRISTOPHER OTTIANO, MD; CAROL LEWIS, MD

INTRODUCTION

Considering the immense toll of motor vehicle crashes (MVCs) on children in the United States, initiatives that optimize the use of child safety seats are imperative. In children under the age of 12 who died in a crash, 38% were unrestrained.[1] Belt positioning booster seats have been shown to reduce the risk of injury to children by 61%, as well as reduce the risk of death.[2] Studies have shown that, unfortunately, around 46% of child restraint devices are used incorrectly which can minimize effectiveness and safety.[3] However, statewide data regarding booster seat laws is promising, illustrating that the number of children using booster seats increases when the age requirement increased, and therefore, the rate of children sustaining fatal injuries decreases in states with booster seat laws.[4]

Hasbro Children's Hospital (HCH) Pediatric Primary Care is a large academic primary center for urban and underserved families, among which many children are without adequate child safety seats. To meet the needs of children in Rhode Island, HCH Pediatric Primary Care and Neighborhood Health Plan of Rhode Island (Neighborhood), the largest Medicaid pediatric insurer in the state, partnered to develop the "Give Me a Boost" Program. Here, we introduce this program and share the impact this collaboration has had in providing car safety seats to children across the state.

DEVELOPMENT

HCH's Pediatric Primary Care and Neighborhood partnered in 2019 to develop a program to accomplish three specific aims: (1) to meet the car seat safety needs of children living in Rhode Island, (2) to train pediatric providers on how to counsel families on child restraints and safety, (3) to optimize the role of primary care physicians and the frequency of these discussions during well-child appointments.

To address the first aim of this initiative, Neighborhood granted funding to purchase and provide booster seats to families who were found to have need at their well-child appointments. In addition, through this funding, any child who requires a seat other than a booster is referred to the Injury Prevention Center to obtain a free car seat and

Figure 1. One example of educational materials available to help residents guide discussions on the proper use of child safety seats

Figure 2. Seat Belt Fit Test: One of the educational materials provided to families (English version pictured; also available in Arabic, French, Portuguese, Spanish and Swahili)

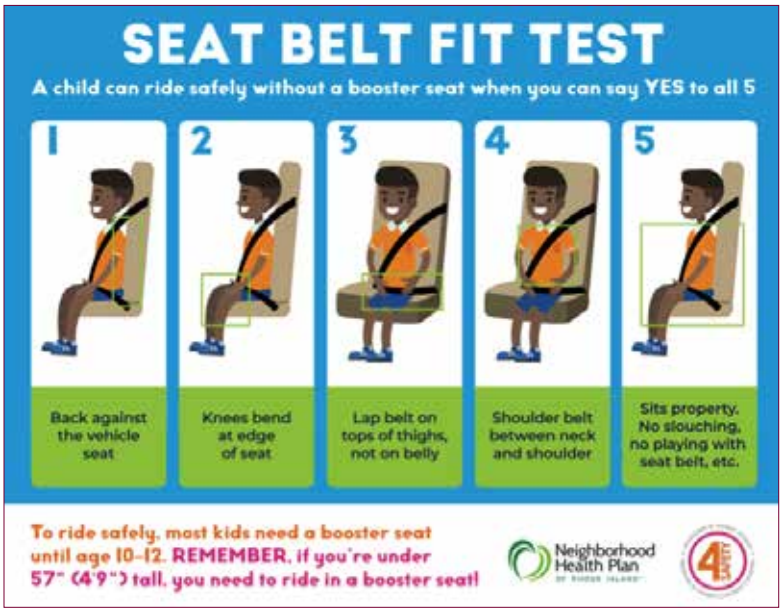
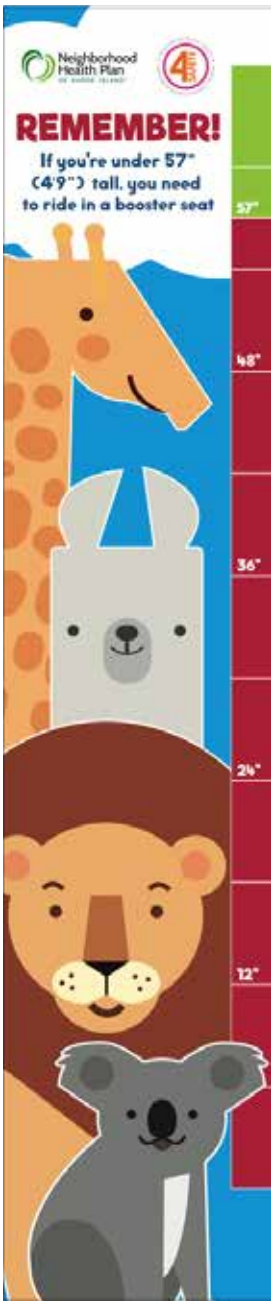


Figure 3: Booster seat height chart displayed in the Hasbro Children's Hospital Primary Care lobby for patients and families to reference



installation. In Rhode Island, all children under the age of 8 who are less than 57 inches and under 80 pounds are required to be restrained in a rear-facing car safety seat, forward-facing car seat, or booster.[5] In discussions with families, most children were previously inappropriately restrained with solely a seat belt (58.2%), a trend which has been seen in studies across the country.[6] Moreover, 20.5% of children who received a booster seat in clinic were previously not restrained at all; in fact, many caregivers (66.9%) reported not being aware that their child needed a booster seat. Parents may believe booster seats are designed to elevate children in the car and are unaware of the safety benefits of using a booster seat.[7] In addition, many parents believe their children are too large for a booster and are unaware of the height guidelines which delineate appropriate transition to a seat belt alone.[7] Other reasons for lack of appropriate booster usage included inability to afford a seat (5.7%) as well as having had a booster but requiring another (14.2%) due to lack of enough seats for the number of children requiring restraints, or age of existing seats. Lack of access to acquiring an appropriate booster seat is a likely reason as well, which this program bridges by making them available to all families at routine encounters.

The second aim of the program is to enhance pediatric resident education on the proper use of car restraints and safety seats, to increase confidence and ability in counseling families. In order to meet this objective, a series of resident-run lectures was held to review Rhode Island's car seat safety laws and specific parameters to guide proper child transition through various car safety seats. They also introduced residents to educational reference materials designed to provide to families (**Figure 1**) and strategies for leading these discussions with caregivers. The lectures were given at the beginning of each academic year to educate new residents and provide a review for the senior residents who had participated during the prior year. (See article 'Give Me A Boost: A Child Passenger Safety Educational Intervention' in this issue for a specific study on the impact of this program on pediatric resident education, page 51.)

To address the third aim of the initiative, increasing the frequency of car seat safety counseling in a primary care setting, a specific template was integrated into the electronic medical record to standardize the conversations on car seat safety during well-child checks. Considering that HCH Pediatric Primary Care serves nearly 5,000 patients between 5 and 8 years of age, it is essential that every well-child appointment is viewed as an opportunity to screen families in need of car safety seats, provide education on Rhode Island laws, and share resources for additional learning. Providing the family with the booster seat at the time of the visit fills a crucial need and provides safety tools at point of care. Educational materials for families were also provided by Neighborhood in multiple languages (**Figure 2**). Colorful booster seat height charts for parental guidance are displayed in the patient waiting area (**Figure 3**). Even if families already have the appropriate child safety seat at the time of the visit, by increasing the frequency of these conversations at each well-child check, providers are strengthening the patient-physician partnership and encouraging an open dialogue centered on their child's safety, and overall preventing childhood morbidity and mortality from car crashes.

CONCLUSION

HCH Pediatric Primary Care and its providers are uniquely positioned to serve as car seat safety champions for the children and families of Rhode Island. Not only is Hasbro the only pediatric hospital in the state, but it serves 10,000 children every year who are from socioeconomically disadvantaged families and require appropriate safety seats. Since the program's implementation two years ago, there has been success across all domains; the clinic has provided 415 free booster seats at well-child visits and referred 102 children to the Injury Prevention Center to pick up free car seats, three resident-run lectures were given to the pediatric residency program, and the electronic medical record for 5–8-year-old well-child appointments was updated to include a specific section on safety seat counseling. The success of the 'Give Me a Boost' program thus far indicates that this partnership between the largest pediatric primary care center and largest Medicaid insurance payor in Rhode Island has already made a significant, and measurable, impact. Our group looks forward to continuing this partnership and optimizing the safety of Rhode Island children and families.

References

1. National Highway Traffic Safety Administration (NHTSA). Traffic safety facts, 2019 data: children. Washington, DC: U.S. Department of Transportation, National Highway Traffic Safety Administration; 2021. Publication no. DOT-HS-813-122.
2. Bruce BS, et al. "Promoting Booster Seat Use for Young Children: A School-Based Intervention Pilot Study." *Paediatrics & Child Health*, vol. 22, no. 2, 2017, pp. 89–91., doi:10.1093/pch/pxx025.
3. Greenwall NK. Results of the national child restraint use special study. Washington, DC: U.S. Department of Transportation, National Highway Traffic Safety Administration; 2015. Publication no. DOT-HS-812-142.
4. Eichelberger AH, Chouinard AO, Jermakian JS. Effects of booster seat laws on injury risk among children in crashes. Traffic Injury Prevention 2012;13:631–9.
5. *State of Rhode Island. R.I.G.L. § 31-22-22(a)(1).* Rhode Island -Department of Public Safety. (n.d.). https://risp.ri.gov/safety/vehiclesafety/seatbelts.php
6. Yellman MA, et al. "Evaluation of Give Kids a Boost: A School-Based Program to Increase Booster Seat Use among Urban Children in Economically Disadvantaged Areas." *Traffic Injury Prevention*, vol. 19, no. 4, 2018, pp. 378–384., doi:10.1080/15389588.2018.1431833.
7. Williams S, et al. *Primary Care Interventions to Prevent Motor Vehicle Occupant Injuries*. Agency for Healthcare Research and Quality (US).

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Become a COVID-19 VACCINE PROVIDER!

Rhode Island State-supported vaccination sites will only be operating for a limited time, but COVID-19 vaccines and boosters are expected to become a part of annual care. To help ensure that COVID-19 vaccines continue to be widely available across the state, the Rhode Island Department of Health is asking primary care providers to enroll in the State-Supplied COVID-19 vaccine program.

Providers are best-suited to help patients make decisions about which COVID-19 vaccine to receive and when. Administration and storage have simplified since vaccines became available:

- Rhode Island is no longer supply-constrained.
- All COVID-19 vaccines can be stored in existing refrigeration units.
- Pfizer and Moderna vaccine vials can stay open for 12 hours (if refrigerated) after they have been punctured.
- COVID-19 vaccine can be co-administered in office with the flu vaccine as well as other routine vaccines.

Become a COVID-19 vaccine provider! To enroll in the State-supplied vaccine program visit **covid.ri.gov/vaxproviders**

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[**Managing Editor's Note:** The following article was written in 2007 by the late Stanley M. Aronson, MD, founding dean of Brown Medical School, and Editor-in-Chief of the *Rhode Island Medical Journal*.]

A Brief Chronicle of Appendicitis

STANLEY M. ARONSON, MD

EHRICH WEISS WAS BORN ON MARCH 24, 1874, in Budapest, Hungary, one of seven Weiss children. His father, a rabbi, was recruited by a congregation in Appleton, Wisconsin, and in 1889 the family left Europe and migrated to the American Midwest. Ehrich, called Harry by his family, was short, five feet and five inches, but otherwise physically active, with a love of sports and a fascination for traveling circuses. When the family moved to New York City, a youthful Ehrich worked briefly as a locksmith's apprentice and in his free time he sought employment as a trapeze-artist with one of the local circuses.

In 1892, at age 21, Ehrich Weiss declared himself to be a magician and, accordingly, changed his name to Harry Houdini after the renowned 19th-century French magician, Jean Robert-Houdin.

Houdini jumps from Harvard Bridge, Boston, 1908. John H. Thurston, photographer. [LIBRARY OF CONGRESS]

This advertisement appeared in the *Providence Journal* in 1925, advertising Houdini's appearance that year.

Houdini's career blossomed, particularly because of his inventive escape acts, freeing himself from jails, chains, handcuffs, straitjackets and even from locked, water-filled tanks.

By 1914, Houdini had reached the pinnacle of his career as an illusionist and escape artist, performing to enthusiastic audiences throughout Europe and North America. He now added two parallel vocations: he shared his prestidigitational secrets with both the British and American Secret Services during the first World War; and, by 1920, he invested his energies and resources in debunking so-called psychics and mentalists. This pursuit cost him the friendship of Arthur Conan Doyle, who was an implacable believer in spiritualism.

Houdini's final performance took place in Detroit's Garrick Theater on October 24, 1926. After a strenuous performance he retired to his dressing room couch. A student from McGill University, J. Gordon Whitehead, entered and asked Houdini if it was true that his abdominal muscles were strong enough to withstand blows of a human fist. Without waiting

Harry Houdini shown in chains in photos taken in 1899 and early 1900s.
[PHOTOS: LIBRARY OF CONGRESS]

for a reply, Whitehead struck Houdini's abdomen repeatedly with his fists until others restrained him. On the following day Houdini complained of nausea and abdominal pain. He sought admission to Grace Hospital. A diagnosis of appendicitis was made and surgery revealed an inflamed, ruptured appendix. Peritonitis developed and Houdini died on the afternoon of October 31 [Halloween], 1926. He was 52 years old. Most physicians declared that the blows to his abdomen played little if any role in his encounter with appendicitis.

Appendix in medical history

The human appendix, a vestigial structure with no known current function, is an inconspicuous worm-like extension of the ascending segment of the large intestine. It is rarely more than three inches in length. And while the appendix was clearly illustrated in the anatomical drawings of da Vinci [1492] and in the anatomy texts of Vesalius [published in 1543], the structure was not specifically named in any anatomy publication until the writings of the Italian anatomist, Berengario Da Carpi in 1521.

The first clinical recognition of disease of the appendix is assigned to an 1812 scientific paper written by a London physician, James Parkinson [1755–1824], who described a five-year-old boy suffering from acute abdominal pain associated with nausea. The child died within two days of the onset of the pains. An autopsy disclosed intense inflammation confined to the appendix and Parkinson coined the word appendicitis to give the disease an identity. This was the same physician who wrote extensively on the need for democratic reform in England [he was charged with high treason by King George III]. He also published extensively on geology, paleontology and authored, in 1817, "An Essay on the Shaking Palsy", now commonly known as Parkinson's disease.

A brief paper by Francois Melier added further autopsy-derived verification of appendiceal inflammation as a cause for pain in the right lower quadrant of the abdomen. But it wasn't until June, 1886, when Reginald Heber Fitz, MD, [1843–1913], Professor of Pathological Anatomy at Harvard, offered a scientific paper, "Perforating Inflammation of the Vermiform Appendix: With Special Reference to its Early Diagnosis and Treatment," that the disease became widely recognized. The recognition was not total, however. In 1897, Dr. Harvey Cushing, then in training in surgery at Johns Hopkins Hospital in Baltimore, made the diagnosis of acute appendicitis on himself. Few of his superiors believed it and Cushing, after 22 hours of searching, finally found a surgeon brave enough to operate. The diagnosis was confirmed and Cushing went on to become this nation's most prominent surgeon in the early decades of the 20th century. ❖

Working for You: RIMS advocacy activities

March 1, Tuesday

RIMS Physician Health Committee (PHC): **Herbert Rakatansky, MD**, Chair

American Medical Association (AMA) Advocacy Resource Center Scope of Practice webinar

AMA National Advocacy conference virtual Capitol Hill visits: Senator Whitehouse; **Thomas Bledsoe, MD,** President Elect; **Heather A. Smith, MD,** Vice President, AMA Council on Legislation, Vice Chair; **Stacy Paterno**, RIMS CEO

Legislative Committee hearings

March 2, Wednesday

Advancing a National Health Data Agenda: Realizing the Promise of All Payer Claims Databases webinar

Legislative Committee hearings

March 3, Thursday

Health System Capacity discussion: multiple state agencies; **Elizabeth Lange, MD**, President

Legislative Committee hearings

March 7, Monday

Joint RIMS Board of Directors and Council meeting with new Blue Cross & Blue Shield of Rhode Island (BCBSRI) president Martha Wofford: **Elizabeth Lange, MD**, President

March 8, Tuesday

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

Hospital Capacity Workgroup meeting: **Elizabeth Lange, MD**, President; **Catherine A. Cummings, MD**, Past President; **Thomas Bledsoe, MD,** President Elect; **Bradley Collins, MD**, RIMS Past President; and **Nadine Himelfarb, MD**, President RI-ACEP

Legislative Committee hearings

March 9, Wednesday

RI Department of Health (RIDOH) Board of Medical Licensure and Discipline (BMLD), **Herbert Rakantansky, MD,** Chairperson and **Kathleen Boyd, MSW**, LICSW, Director of the Physician Health Program presented to BMLD

March 10, Thursday

AMA Federal Update: **Heather A. Smith, MD,** Vice President, AMA Council on Legislation, Vice Chair

Legislative Committee hearings

March 15, Tuesday

Legislative Committee hearings

Political fundraiser House Majority Leader: Christopher Blazejewski

March 16, Wednesday

RIDOH Primary Care Physicians Advisory Committee (PCPAC): **Elizabeth Lange, MD**, President

White House equity forum: Broadband access and telehealth equity

NOURISH-RI Coalition meeting

Legislative Committee hearings

Political fundraiser Senator Majority Leader: Michael McCaffrey

RIMS NOTES: *News You Can Use*

Our biweekly e-newsletter is published on alternate Fridays exclusively for RIMS members. Contact Dulce Cosme if you've missed an issue, dcosme@rimed.org.

March 17, Thursday

Meeting with Senator Megan Kallman regarding RIMS legislation on Department of Correction

Executive Office of Health and Human Services (EOHHS) HIT Steering Committee

Legislative Committee hearings

March 18, Friday

Meeting with Pfizer representative Lorraine Santore, Vaccine Account Manager regarding vaccine adoption

March 21, Monday

Meeting with Office of the Health Insurance Commissioner (OHIC) physician credentialing: **Peter Hollmann, MD**

State House Update: **Michael Migliori, MD**, Public Laws Committee, Chair; **Peter Karczmar, MD**, RI Medical Political Action Committee (RIMPAC), Chair

March 22, Tuesday

Meeting with United Healthcare regarding logistics of upcoming meeting

March 23, Wednesday

Legislative Committee hearings

March 24, Thursday

Governor's Overdose Task Force: Racial Equity Work Group

Legislative Committee hearings

March 29, Tuesday

Legislative Committee hearings

March 30, Wednesday

Meeting with Senate President and Leadership regarding legislation

Legislative Committee hearings

RIMS CORPORATE AFFILIATES

The Rhode Island Medical Society continues to drive forward into the future with the implementation of various new programs. As such, RIMS is expanded its Affinity Program to allow for more of our colleagues in healthcare and related business to work with our membership. RIMS thanks these participants for their support of our membership.

Contact Ali Walz for more information: 401-331-3207 or awalz@rimed.org

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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.

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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

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VA Providence Healthcare System holds ribbon-cutting event for Harwood Research Center

Primary occupant: Center of Innovation in Long-Term Services and Support

MARY KORR
RIMJ MANAGING EDITOR

PROVIDENCE – The VA Providence Healthcare System (VAPHS) held a ribbon- cutting ceremony for the Capt. John H. Harwood Research Center on March 21st at the newly renovated site located at 385 Niagara Street.

VA officials, members of the state's Congressional delegation, and state and local officials attended the opening. U.S. Sen. **JACK REED**, an Army veteran, said the work in this new state-of-the-art facility will help identify better health solutions and improve outcomes for veterans and their families. "From better patient outcomes to systemic changes, we're continually pushing to improve VA access and services for our veterans, and this new facility is a vital part of that mission."

The VA said the research aims to improve care for veterans challenged by aging, disease or disability. **LAWRENCE CONNELL**, the VA director in Providence, said they are doing "groundbreaking medical research," in large part because of their partnership with Brown University.

Researchers in Providence are working on new interventions to reduce veteran suicide and substance abuse after hospitalization, and ways to reduce depression among elderly veterans living in community living centers. They're also identifying risk factors for food insecurity among veterans, assessing for Alzheimer's disease and dementia among homeless veterans, and looking at how veterans respond to COVID-19 vaccines and booster doses.

Above: Photographs of **Capt. Harwood** were placed on his grave during the D-Day remembrance service in Normandy in 2019. He is buried at the Normandy American Cemetery and Memorial overlooking Omaha Beach.
[PHOTO: WORLD WAR LL VETERANS HISTORY PROJECT; HTTPS://WW2VETERANSHISTORYPROJECT.COM/HOME]

Left to Right: **Kasim J. Yarn**, Rhode Island Director of Veterans Affairs; **Hon. Jorge Elorza**, Providence Mayor; **Hon. David N. Cicilline**, Congressman, Rhode Island 1; **Lawrence B. Connell**, Director, VA Providence Healthcare System; **Hon. Jack Reed**, US Senator; **Dr. James Rudolph**, Director, Long Term Services and Support (LTSS) Center for Innovation (COIN), VA Providence Research Service; **Hon. Seth Magaziner**, Rhode Island General Treasurer; **Dr. Gaurav Choudhary**, Associate Chief of Staff, Research, VA Providence Healthcare; **Matthiew Goulet**, Associate Director for Patient Care/Nurse Executive, VA Providence Healthcare System; **Dr. Annmarie Dunican**, Chief of Staff, VA Providence Healthcare System.
[PHOTO: VA PROVIDENCE PUBLIC AFFAIRS]

The facility

Total cost of the renovation for the nearly 30,000 square-foot research center, with a capacity for more than 100 researchers, totaled $12.8 million. The primary occupant, the Center of Innovation in Long-Term Services and Support, conducts research designed to improve the

understanding of veteran independence, supported community dwelling, and supervised living environments during the last phases of life.

The facility was originally built in 1950 as an Army Reserve Center and was closed during the base realignment and closure process in 2006. The property was officially transferred to the VAPHS in December 2012.

Capt. Harwood: RI Army hero died during D-Day invasion

The center is named for Capt. Jonathan H. Harwood, Jr., a native of East Greenwich, who died on June 7th, 1944, succumbing to wounds received on Omaha Beach during the allied D-Day invasion the prior day.

Born on Dec. 29, 1918, to Jonathan and Ruth (Fisher) Harwood, he attended the U.S. Military Academy at West Point, Class of 1941, and was a graduate of Cornell University. He then assumed a position in the U.S. Army as a fire control officer in the 293rd Signal Company.

According to the WW II Veterans History Project, which has compiled biographies of veterans, he was attached to the 2nd Ranger Battalion during the D-Day invasion and was among the first to land before the artillery barrage began. He and his fire control group were pinned down on the beach and cliffs, infested with nests of German machine-gunners. The battalion radioed the USS Texas for naval artillery support as they scaled the cliffs to try and disable the German gun batteries.

During the barrage, he was severely wounded, along with many in his group. According to the Veterans History Project, "What would prove to be the fatal round for Harwood was an armor-piercing shell that contained a yellow pigment known as "Explosive D", or Dunnite. According to a soldier who was there, 'The men were turned completely yellow. It was as though they had been stricken with jaundice. It wasn't only their faces and hands, but the skin beneath their clothes were yellow from that shell.' "

Capt. Walter Block, a hometown friend who served as battalion surgeon, tended his wounds, but Harwood died early the next morning. The valiant young officer from East Greenwich was but 25 years old. He was posthumously awarded the Purple Heart and Silver Star for valor in combat. The new research center named in his honor is an abiding legacy to Harwood and all veterans – past, present and future. ❖

Dr. Fauci to deliver keynote at RWU Commencement, receive honorary degree

BRISTOL – **ANTHONY S. FAUCI, MD**, Director of the National Institute of Allergy and Infectious Diseases and chief medical advisor to the president of the United States, will deliver the keynote speech and receive an honorary degree at the Roger Williams University Commencement ceremony on Friday, May 20.

"The ability to synthesize vast amounts of information and to make decisions that consider health, science, cultural, legal and political implications, is the type of education we strive to offer our students. Dr. Fauci's experience throughout his career, but especially over the last two years, has modeled how to do this exceptionally well and provides a real-world example to our students as they enter a complex world," said RWU President Ioannis N. Miaoulis. "We are thrilled to have Dr. Fauci join our distinguished group of honorary degree recipients and address our graduates and their families. We cannot imagine a more ideal leader to share insights on tackling monumental challenges and to inspire our graduates on how best to thrive in today's global society."

Dr. Fauci has served as director of the National Institute of Allergy and Infectious Diseases (NIAID) at the U.S. National Institutes of Health since 1984. As the long-time chief of the NIAID Laboratory of Immunoregulation, he has made many seminal contributions in basic and clinical research and is one of the world's most-cited biomedical scientists. He has advised seven presidents on HIV/AIDS and many other domestic and global health issues. He was one of the principal architects of the President's Emergency Plan for AIDS Relief (PEPFAR), a program that has saved millions of lives throughout the developing world.

Dr. Fauci has delivered lectures all over the world and received numerous prestigious awards, including the Presidential Medal of Freedom (the highest honor given to a civilian by the president of the United States) and the National Medal of Science.

The university ceremony will take place on the main athletic field. The processional steps off at 8:45 a.m. with the ceremony beginning at 9:30 a.m. ❖

AMA survey shows widespread enthusiasm for telehealth; urges Congress to take note of barriers to care

CHICAGO – An American Medical Association (AMA) survey released today shows physicians have enthusiastically embraced telehealth and expect to use it even more in the future.

Nearly 85% of physician respondents indicated they are currently using telehealth to care for patients, and nearly 70% report their organization is motivated to continue using telehealth in their practice. Many physicians foresee providing telehealth services for chronic disease management and ongoing medical management, care coordination, mental/behavioral health, and specialty care.

The survey comes as Congress recently extended the availability of telehealth for Medicare patients beyond the current COVID-19 public health emergency. Additional action by Congress will be needed to permanently provide access to Medicare telehealth services.

As physicians and practices plan to expand telehealth services, they say widespread adoption hinges on preventing a return to the previous lack of insurance coverage and little to no payer reimbursement. Payers, both public and private, should continue to evaluate and improve policies, coverage, and payment rates for services provided via telehealth.

"Physicians view telehealth as providing quality care to their patients, and policymakers and payers have come to the same conclusion. Patients will benefit immensely from this new era of improved access to care," said AMA President **GERALD E. HARMON, MD**. "This survey shows adoption of the technology is widespread as is the demand for continued access. It is critical that Congress takes action and makes permanent telehealth access for Medicare patients."

Physicians strongly support that telehealth via audio-only/telephone remains covered in the future to ensure equitable access. That coverage has been permitted during the public health emergency and extended for several months afterward.

According to the survey, 95% of physicians report patients are primarily located at their home at the time of the virtual visit. Allowing patients to be in their home is a key component of making telehealth more accessible. Before the pandemic, Medicare patients needed to be physically located in a rural area to access telehealth services, shutting out urban and suburban patients from receiving the same benefits of virtual care. Before the pandemic, rural patients needed to travel to an "originating site," essentially another health care facility, outside of their home to access telehealth services. The temporary extension in the omnibus will allow patients with Medicare to receive telehealth services anywhere they are located, including in their home. The AMA will continue to urge Congress to make permanent this and other policies that have offered coverage and convenience to patients.

Fewer than half of respondents report being able to access all of their telehealth platforms via their electronic health records, and more than 75% report that their support technology does not automatically collect and deliver patient-reported data. Improving interoperability between platforms and sup-port technology would improve and streamline telehealth services.

Physicians perceive technology, digital literacy, and broadband internet access to be the top three patient barriers to using telehealth. In addition, only 8% of physician respondents said they were using remote patient monitoring at this time. The AMA will advocate for patient populations and communities with limited access to telehealth service, including but not limited to, supporting increased funding and planning for telehealth infrastructure such as broadband and internet-connected devices. ❖

Providence announces next steps in creation of behavioral health crisis response program

City issues request for proposals to expand co-response model with Public Safety and Healthy Communities Office

PROVIDENCE – The City of Providence has released a Request for Proposals (RFP) to advance next steps regarding the City's implementation of a behavioral health crisis response program. The Behavioral Health Crisis Co-Response Team RFP is designed to implement the expansion of Providence's existing co-response efforts to include the fire department, and to increase the City's capacity to provide mental health guidance and intervention when residents dial 9-1-1.

"We're committed to challenging the way things have always been done and to find new solutions that better meet our needs," said Mayor **JORGE O. ELORZA**. "After designing this program with feedback from key stakeholders, this request for proposals will allow us to provide more and better treatment to people experiencing a mental or behavioral health crisis."

As Providence works to innovate and improve emergency responses to behavioral health crises, the City has invested in a multi-phased approach to creating a Behavioral Health and Social Service Crisis Response Program (BHSSCRP) within the Healthy Communities Office (HCO), in coordination with Providence Public Safety. As part of the program design phase, last year the City of Providence partnered with The Providence Center and Family Service of Rhode Island to provide analysis and planning services for public safety-related behavioral health and social service interventions. The partnership, guided by a multi-disciplinary Steering Committee, culminated with a final report titled, "Behavioral Health and Social Service Crisis Response Planning Services in Providence: Project Report and Recommendations." The RFP released by the City advances recommendations made within the report.

Expanding co-response efforts within the Providence Fire Department will allow the City to utilize existing infrastructure to rapidly respond to crises with appropriate interventions while also collecting necessary data and process improvements to scale up services. Responsibilities of the selected provider will include providing a clinician to respond to behavioral health and social services calls alongside the Providence Fire Department and emergency medical services crews, as well as providing a clinician to work with the Providence Public Safety dispatch team to answer and assist with behavioral health and social service emergency calls. The selected provider will also help the City to develop standard operating procedures and precedents for future behavioral health crisis response programs.

The Healthy Communities Office also announced the hiring of two full-time staff members dedicated to the programmatic management and evaluation of the City's behavioral health programming, including this effort. **SILAPHONE NHONGVONGSOUTHY** will serve as the Behavioral Health Program Manager and **RACHEL FERRARA** will serve as the Data and Evaluation Manager for the program.

"Our community and partner organizations have put in so much work already to design a robust program that meets the specific needs of Providence, and we're so excited to continue this work," said **LAURIE MOISE SEARS**, Director of the Healthy Communities Office. "I'm looking forward to working collaboratively to develop and implement this innovative co-response program."

Organizations interested in applying or learning more can read the RFP here and apply by the April 11, 2022 deadline.

The Healthy Communities Office (HCO) is the City's lead agency for health policy, health promotion and substance use disorder prevention. The HCO works to ensure that Providence residents have equitable access to the resources they need to lead healthy lives. ❖

HopeHealth Visiting Nurse earns home care and palliative care accreditation and recertification

LINCOLN – HopeHealth Visiting Nurse recently passed a rigorous federal review to maintain compliance with the terms of its home health care and community-based palliative care program accreditation and recertification.

The Joint Commission awarded HopeHealth its Gold Seal of Approval® for demonstrating continuous compliance with quality patient care performance standards after a five-day March 2021 review that took place virtually because of the COVID-19 pandemic. As part of that process, HopeHealth was required to pass a subsequent unannounced on-site inspection to achieve full compliance.

"We are pleased to have earned accreditation from the Joint Commission," HopeHealth Chief Operating Officer **MAUREEN BISCHOFF** says. "This approval confirms the deep commitment of our clinical care teams to providing quality care to our patients and their families."

The Joint Commission accreditation is valid for three years. ❖

Vivian Sung, MD, MPH, approved for $6.9M for study on nonsurgical treatment options for urinary incontinence

Funds awarded by the Patient-Centered Outcomes Research Institute

PROVIDENCE – A research team led by **VIVIAN SUNG, MD, MPH**, at Women & Infants Hospital has been approved for a $6.9 million funding award by the Patient-Centered Outcomes Research Institute (PCORI) to study nonsurgical treatment options for urinary incontinence.

This study will compare the next options of an oral drug beta agonist (mirabegron) or onabotulinumtoxinA injections (commonly referred to as Botox) among women who have unsuccessfully tried more conservative treatments. Both treatments have been shown to help UUI and are commonly used, but there are no studies directly comparing them, which makes decision making for patients more difficult and confusing.

This research led by Dr. Sung will enroll 432 adult women from five sites across the country, including Rhode Island, and will compare success and safety results that are most important to patients. The results from this study can be used by women and doctors to better decide their next best step for treating UUI. Patients have already worked closely with the study team to help design the study and choose the best ways to determine if a treatment is successful or not. The national research team also includes specialized community engagement teams, patient stakeholders, healthcare providers, representatives from social support organizations, insurer stakeholders, and community leaders from across the country.

Dr. Sung's study was selected for funding through a PCORI funding announcement specifically focused on comparing the effectiveness of nonsurgical treatment options for urinary incontinence for nonpregnant women.

"This study was selected for PCORI funding for its potential to fill an important gap in our understanding of how best to treat a health condition common among women," said PCORI Executive Director Nakela L. Cook, MD, MPH. "Although the efficacy of many nonsurgical interventions for urinary incontinence is soundly substantiated, evidence gaps remain, particularly related to direct comparisons of the options. We look forward to following the study's progress and working with Women & Infants Hospital to share the results."

Dr. Sung's award has been approved pending completion of a business and programmatic review by PCORI staff and issuance of a formal award contract.

PCORI is an independent, nonprofit organization authorized by Congress in 2010. Its mission is to fund research that will provide patients, their caregivers, and clinicians with the evidence-based information needed to make better-informed healthcare decisions. For more information about PCORI's funding, visit www.pcori.org. ❖

W&I announces plans for Labor & Delivery Center, Women's Health Research Institute

PROVIDENCE – Women & Infants Hospital will embark on an initiative to rebuild its Labor and Delivery Unit, by enhancing birthing options, enlarging delivery rooms, and providing an equitable, state-of-the-art environment in which women can deliver their babies.

In addition to the redesign of the labor, delivery, and recovery suite, the campaign will raise funds for the Women's Health Research Institute.

Plans for the new Labor & Delivery Center include larger rooms to accommodate a greater variety of birthing practices. And, the Women's Health Research Institute will tackle important projects including much-needed health equity research. Ultimately, the new unit will help meet Women & Infants Hospital's goal of eliminating disparities of care, as well as elevate every mother's birthing experience.

With the kickoff of the capital campaign to meet the financial obligations of the new building, Women & Infants seeks not only to raise capital but to include the entire community in its effort.

The Hospital will connect with the Rhode Island community through storytelling, multi-media communications and online channels, in-person events, and grateful patient testimonials.

The Campaign's two Honorary Co-chairs, **ALAN HASSENFELD** and **ANNE SZOSTAK**, are venerated business and philanthropic leaders who are committed to top-notch healthcare in the State. ❖

Dana-Farber Cancer Institute, Lifespan renew strategic alliance agreement

PROVIDENCE – Dana-Farber Cancer Institute and the Lifespan Cancer Institute have agreed to renew their strategic alliance to advance cancer treatment and research. The organizations signed an initial agreement in 2017.

This renewed agreement will continue to support the expansion of clinical trials, access for Lifespan physicians to cancer-specific disease expertise for complex cases, and the continuation of a highly successful program coordinating the treatment of cell therapy and transplant patients. Cellular therapies and transplants are provided in Boston at Dana-Farber and care surrounding these procedures is provided in Providence at the Lifespan Cancer Institute. The two organizations share patient information through their respective secure electronic health record systems and use the same clinical trials management platform, resulting in better care coordination.

A top priority of Dana-Farber and the Lifespan Cancer Institute's work together is the ability to offer the latest and most advanced clinical trials to patients in Rhode Island. While many of these trials are developed at and provided by Dana-Farber, opportunities exist for clinical trials to be developed at the Lifespan Cancer Institute and offered to Dana-Farber patients. Increasing access to diverse patient populations is a common goal to help accelerate the development of new therapies. Other areas to be explored include genomics and precision medicine, cancer disparities, innovation in the delivery of cancer care, and potential synergies in basic research. The two organizations have collaborated on a multi-site grant application for genomics with a health disparities component.

DAVID WAZER, MD, director of the Lifespan Cancer Institute, said, "The Lifespan Cancer institute offers a robust array of cancer services, convenient access to care, and a rapidly growing clinical trials program. Renewing our close working relationship with Dana-Farber will allow the Lifespan Cancer Institute to continue to elevate cancer care in Rhode Island and provide even more treatment options, all in a carefully coordinated manner that prioritizes the needs of patients and their families."

HOWARD SAFRAN, MD, chief of the Division of Hematology/Oncology at the Lifespan Cancer Institute said, "Together the Lifespan Cancer Institute and Dana-Farber are expanding access to the latest and most advanced clinical trials for patients locally, nationally, and worldwide. We are also collaborating to accelerate the development of new therapies and to reduce cancer disparities through outreach and innovation in the delivery of cancer care. The two organizations share patient information through their respective cancer-specific electronic health record systems and use the same clinical trials management platform, resulting in better care coordination." ❖

Dr. Lorna Breen Health Care Provider Protection Act signed into law

WASHINGTON, DC – A new law co-authored by U.S. Senator **JACK REED** (D-RI) and signed by President **JOE BIDEN**, will help prioritize mental health support, treatment, and care for doctors, nurses, and health workers while also reducing burnout and improving retention rates in the health care profession.

The newly enacted Dr. Lorna Breen Health Care Provider Protection Act will fund federal grants, in-depth studies, and public awareness campaigns to encourage health care workers to seek support, access treatment, and eliminate the stigma that deters health care professionals from seeking mental and behavioral health care.

The law is named in honor of Dr. Lorna Breen, an emergency physician in New York City who took her own life in April 2020 after working on the frontlines to care for patients during the first wave of the COVID-19 pandemic.

Specifically, the Dr. Lorna Breen Health Care Provider Protection Act will:

- Establish grants for health profession schools, academic health centers, or other institutions to help them train health workers in strategies to prevent suicide, burnout, mental health conditions, and substance use disorders. The grants would also help improve health care professionals' well-being and job satisfaction.
- Seek to identify and disseminate evidence-informed best practices for reducing and preventing suicide and burnout among health care professionals, training health care professionals in appropriate strategies, and promoting their mental and behavioral health and job satisfaction.
- Establish a national evidence-based education and awareness campaign targeting health care professionals to encourage them to seek support and treatment for mental and behavioral health concerns.
- Establish grants for health care providers and professional associations for employee education, peer-support programming, and mental and behavioral health treatment. Health care providers in current or former COVID-19 hotspots will be prioritized.
- Establish a comprehensive study on health care professionals' mental and behavioral health and burnout, including the impact of the COVID-19 pandemic on such professionals' health. ❖

Appointments

President Biden appoints Ashish Jha, MD, as the new White House COVID-19 Response Coordinator

WASHINGTON, DC – On March 17th, President Joe Biden appointed **ASHISH JHA, MD**, Dean of the Brown School of Public Health, as the new White House COVID-19 Response Coordinator. In announcing the appointment, he said, "Dr. Jha is one of the leading public health experts in America, and a well-known figure to many Americans from his wise and calming public presence. And as we enter a new moment in the pandemic – executing on my National COVID-19 Preparedness Plan and managing the ongoing risks from COVID – Dr. Jha is the perfect person for the job. I appreciate both Jeff Zients [outgoing coordinator] and Dr. Jha for working closely to ensure a smooth transition, and I look forward to continued progress in the months ahead."

Dr. Jha came to Brown in September 2020, after leading the Harvard Global Health Institute and teaching at the Harvard T.H. Chan School of Public Health and Harvard Medical School. He will take a temporary leave from his position at Brown beginning April 5th. ❖

Ronald Aubert, PhD, named Interim Dean at School of Public Health

PROVIDENCE – **RONALD AUBERT, PhD**, has been appointed the Interim Dean of the School of Public Health, effective April 4th. He is Visiting Professor of the Practice of Race and Ethnicity, CSREA and The School of Public Health. He is also a Faculty Director of the Presidential Scholars Program at Brown University.

Prior to joining Brown he has worked as Director of Research Strategy in the Data Generation and Observational Studies group at Bayer Healthcare, LLC; Chief Science Officer and lead scientist for Research and Evaluation Analytics, LLC; Vice President of Advanced Analytics in Medco Health Solutions' Department of Advanced Clinical Services and Research; Senior Health Care Analyst at the Aetna Center for Health Care Research; and a Commander for the U.S. Public Health Service, Chief of the Epidemiology Section, Division of Diabetes Translation at the Centers for Disease Control and Prevention (CDC).

He has held appointments at the Gillings School of Global Public Health, University of North Carolina; Rutgers School of Public Health and Emory University School of Medicine. He received a BA in Biology from Oberlin College, an MSPH and PhD from the University of North Carolina at Chapel Hill, and completed the Epidemic Intelligence Service fellowship at the CDC. ❖

Rhode Island Free Clinic Board appoints Dr. Forrest Daniels new CEO

PROVIDENCE – The Rhode Island Free Clinic Board of Directors recently announced the selection of **FORREST A. DANIELS, MPA, DSC, FACHE** as its new Chief Executive Officer. Dr. Daniels succeeds Dr. Marie Ghazal who retired on March 31st after twelve years of service and growth for the Clinic.

A former resident of Amherst, MA, and a graduate of Howard University and Indiana University, Dr. Daniels earned his Doctor of Science in Healthcare Leadership from The University of Alabama-Birmingham. He is board-certified in healthcare management, a Fellow of the American College of Healthcare Executives and a recipient of the ACHE Chairman's Service Award for his contribution to healthcare management excellence through his volunteer service to the profession and College.

Dr. Daniels returns to New England from the mid-Atlantic where he served with the Maryland Department of Health since 2019, most recently as CEO of the Eastern Shore Hospital Center. Dr. Daniels' career has focused on serving the nation's most vulnerable in senior management positions at hospitals, federally qualified health centers, and community organizations, including the District of Columbia Department of Health, and the D.C. Department of Corrections. "I look forward to moving to Rhode Island to work with Free Clinic volunteers, community partners, and supporters to advance the Clinic's mission to ensure vital health care for adults in need from throughout Rhode Island," said Dr. Daniels. ❖

Appointments

RIMJ welcomes new members to editorial advisory board: Drs. Charles Adams, Jr.; Philip A. Chan, Staci A. Fischer, Brett D. Owens

WILLIAM BINDER, MD, Editor-in-Chief of the *Rhode Island Medical Journal* (RIMJ), welcomed four new members to its editorial advisory board at its March meeting. In addition, he announced current board member **GEORGE P. BAYLISS, MD**, has been elevated to an associate editor position, joining **KENNETH S. KORR, MD**.

The new members of the board include:

CHARLES ADAMS, Jr., MD, FACS, FCCM, is a Professor of Surgery at the Alpert Medical School and Chief of the Division of Trauma and Surgical Critical Care at Rhode Island Hospital (RIH). Following an undergraduate education in pharmacy at St. John's University, he attended New Jersey Medical School and graduated with honors. During his residency he completed a basic science research fellowship studying the gut hypothesis of multi-system organ failure. His surgical residency in a high-volume penetrating trauma center sparked his interest in acute care surgery and led to advanced fellowship training in surgical critical care at Vanderbilt University in Nashville, Tenn.

His main focus is on trauma care, but he is also an active ICU physician, emergency and elective general surgeon, administrator, investigator, and teacher. Nationally, he is active in many societies and has leadership roles in the Society of Critical Care Medicine, the American Association for the Surgery of Trauma, and is the sitting treasurer of the Surgical Critical Care Program Directors Society, and is also a Region Chief for the American College of Surgeons Committee on Trauma.

PHILIP A. CHAN, MD, MS, is an Associate Professor in the Department of Medicine at the Alpert Medical School. He has a secondary appointment in the Department of Behavioral and Social Sciences at the Brown University School of Public Health.

Dr. Chan is medical director of the only publicly funded sexually transmitted diseases (STD) clinic in Rhode Island, as well as Rhode Island's only dedicated Pre-Exposure Prophylaxis (PrEP) Program. He is PI of multiple NIH grants to study HIV prevention and is also site PI of the local AIDS Education and Training Center (AETC) in Rhode Island. He serves as Consultant Medical Director for the Rhode Island Department of Health Center for HIV/AIDS, Viral Hepatitis, STDs, and TB, and is actively engaged in many clinical and community-based public health programs to respond to STD and HIV rates among sexual and gender minorities.

Dr. Chan has over 90 peer-reviewed publications.

STACI A. FISCHER, MD, FACP, FIDSA, is a graduate of the Louisiana State University School of Medicine in New Orleans and completed internal medicine residency and infectious disease fellowship training at Rush-Presbyterian-St. Luke's Medical Center in Chicago, Ill. She joined the faculty of the Alpert Medical School in 2000, providing infectious disease care to solid organ transplant recipients at Rhode Island Hospital and served in multiple roles in graduate medical education, including Designated Institutional Official overseeing the training of all residents and fellows at Lifespan.

She has received numerous awards in medical education and currently works for the Accreditation Council for Graduate Medical Education (ACGME), as part of the Clinical Learning Environment Review Team, assessing integration of residents and fellows in efforts to improve patient safety and health care quality in the institutions where they work and train.

BRETT D. OWENS, MD, is a Professor in the Department of Orthopaedic Surgery at the Alpert Medical School and practices in Providence. He attended the U.S. Military Academy and Georgetown University School of Medicine and completed his residency at the University of Massachusetts and the John A. Feagin, Jr. Sports Medicine Fellowship at West Point. He was an AOA North American Traveling Fellow as well as an AOSSM-ESSKA Traveling Fellow.

Dr. Owens has published more than 300 articles and four textbooks in orthopaedics and sports medicine. His research has garnered the O'Donoghue Research Award, Aircast Award, and NCAA Research Awards from the American Orthopaedic Society for Sports Medicine and the AAOS Kappa Delta Award. Dr. Owens has served as Associate Editor of the American Journal of Sports Medicine since 2012.

He is a retired colonel in the U.S. Army and previously served as Chief of Orthopaedics and Sports Medicine at Keller Army Hospital, West Point, NY. He is currently team physician for Brown University Athletics and the Providence Bruins (AHL). ❖

Appointments

East Bay Community Action Program appoints Lisa Denny, MD, associate medical director

EAST PROVIDENCE – East Bay Community Action Program (EBCAP) is pleased to announce the appointment of **LISA DENNY, MD**, of Barrington, RI, as EBCAP's new associate medical director. Dr. Denny has more than 20 years of experience in primary care medicine and will assist in providing medical leadership and supervision to EBCAP's medical staff as well as collaborate with the chief medical director to manage the daily operation of EBCAP's Health Centers.

Dr. Denny received her MD from Penn State College of Medicine in Hershey, PA, and earned her BA with honors in psychology from Trinity College in Hartford, CT. She completed her residency at Boston Medical Center and worked at Codman Square Community Health Center in Dorchester, MA, prior to moving to Rhode Island. ❖

Steven Katz, MD, joins Brown Surgical Associates' Surgical Oncology Division

PROVIDENCE – Brown Surgical Associates recently announced it is welcoming surgeon and researcher **STEVEN C. KATZ, MD, FAC**, to the practice's Division of Surgical Oncology.

Dr. Katz's clinical practice is focused on melanoma, sarcoma, and other complex, rare soft-tissue tumors. As the Chief Medical Officer of TriSalus Life Sciences – a Rhode Island and Colorado-based biotech company – his laboratory research endeavors focus on developing novel immunotherapy approaches for liver and pancreas tumors. Dr. Katz's overarching career goal is to develop novel immunotherapy treatments for presently incurable liver and pancreas tumors.

He attended the New York University School of Medicine, receiving the Alpha Omega Alpha Award for graduating with the top academic average in his class. He then completed his general surgery residency at the New York University Medical Center. Dr. Katz went on to complete fellowships in immunology and surgical oncology at Memorial Sloan-Kettering Cancer Center, where he served as the chief administrative fellow. As a researcher, he has served as the principal investigator for five solid tumor CAR-T trials, including four for liver metastases and one for peritoneal carcinomatosis. Dr. Katz has developed numerous cell therapy products and methods for solid tumor immunotherapy. He has received research grants from numerous societies, the National Institute of Health, and the Department of Defense, in addition to multiple industry partners. ❖

Blue Cross & Blue Shield of RI names Jon Fredrickson Vice President and Chief Risk Officer

PROVIDENCE – Blue Cross & Blue Shield of Rhode Island (BCBSRI) has named **JON FREDRICKSON** vice president and chief risk officer. In his new role, he will spearhead efforts to safeguard the organization's member, employee and proprietary information against ransomware and other digital threats.

Fredrickson, of Exeter, Rhode Island, is a seasoned IT security professional with a proven track record of creating mature cyber security programs using practical risk management techniques while meeting regulatory requirements and state privacy laws. He has been with BCBSRI since 2017, when he joined the company as information security officer. He has held various positions during his tenure at BCBSRI, most recently serving as the managing director of risk management, information security and privacy.

During his time at BCBSRI, Fredrickson has established a governance model and framework to successfully manage financial, operational, strategic and compliance risks. He also expanded the privacy office to ensure full compliance with HIPAA privacy regulations. In his new role, Fredrickson will continue to build exemplary security and risk programs that protect BCBSRI members and employees.

Beyond his role at BCBSRI, Fredrickson serves on the Rhode Island All-Payer Claims Database Data Release and K Logix Advisory Boards. He is also a member of several associations, including the Association for Executives in Healthcare Information Security; Evanta's CISO Governing Body; the Health Information Sharing and Analysis Center; and InfraGard's Rhode Island Member Alliance. Fredrickson earned his bachelor's degree in economics from the University of Rhode Island and completed Harvard's Managing Risk in the Information Age cybersecurity certification. ❖

Recognition

Dr. Abdul Saied Calvino of Roger Williams Cancer Center earns ACS award

Recognized for program to increase Hispanic community screenings for colorectal cancer

PROVIDENCE – **ABDUL SAIED CALVINO, MD, MPH, FACS**, a surgical oncologist at Roger Williams Cancer Center, has earned national recognition from the American Cancer Society (ACS) for his development of a comprehensive advocacy program that encourages members of the Hispanic community to receive screenings for colorectal cancer.

Dr. Calvino designed and coordinated a comprehensive, community-based education and outreach program, which, over a period of 18 months, dramatically increased colorectal screening participation by Hispanics in the metropolitan Providence area.

In recognition of this program and its results, the American Cancer Society has awarded its prestigious Lane Adams Quality of Life Award to Dr. Calvino. This national award is reserved for caregivers who lead by making a significant impact on cancer patients, their families, and their communities. In Dr. Calvino's case, the ACS cited his creative problem-solving skills to eliminate barriers to access cancer care.

Dr. Calvino, board-certified in general surgery and complex surgical oncology, has established an active community outreach and cancer navigation program to improve access to surgical care in underserved populations. He has received recognition and numerous awards at the local and national level including the CDC's Carol Friedman National Award for excellence in addressing cancer care disparities.

From left, **Lynn Basilio** and **Cori Chandler**, American Cancer Society; RI Gov. **Dan McKee**, **Dr. Joseph Espat**, **Dr. Abdul Calvino**, Lt. Governor **Sabina Matos**, and **Jeffrey Liebman**, CEO. [PHOTO: ROGER WILLIAMS CANCER CENTER, CHARTERCARE]

"We all know that the best cancer screenings are the ones that actually get done," commented Dr. N. Joseph Espat, Chairman of Surgery and Director of the Roger Williams Cancer Center. "I am especially proud today of our academic oncology team and their leadership in tailored culturally-sensitive patient navigation efforts to eliminate health access barriers to clinical outcomes in cancer treatment.

The award was presented to Dr. Calvino on March 14th at a ceremony attended by Gov. Dan McKee and Lt. Governor Sabina Matos and representatives from the American Cancer Society. ❖

Butler Hospital employees win first place – American Journal of Nursing Book of the Year awards

The American Journal of Nursing recently announced the winners of the annual American Journal of Nursing Book of the Year Awards, which honors exceptional print and digital texts for advancing healthcare quality. https://www.healthleadersmedia.com/nursing/annual-ajn-book-year-awards-recognizes-exceptional-print-and-digital-texts

Awards have been given across 18 categories, including adult primary care, advanced practice nursing, informatics, and nursing management and leadership.

First place winner – Psychiatric and Mental Health Nursing: Inpatient Psychiatric Nursing: Clinical Strategies, Medical Considerations, and Practical Interventions. Edited by Judy L. Sheehan, Joanne M. Matthew, Mary H. Hohenhaus, and Charles Alexandre. 2nd edition. ❖

Obituaries

ALBERT E. DAHLBERG, MD, 83, passed away peacefully on March 1, 2022, at HopeHealth Hulitar Hospice Center in Providence due to cerebrovascular disease. He is survived by his wife of 58 years, Pamela; three children, Albert (wife Hilary), Krista and Paul (wife Becky); six grandchildren and a brother (Jim) and sister (Cordelia). He was a researcher and professor of Molecular Genetics and Biochemistry at Brown University for 43 years. He published numerous research articles on the structure and function of the ribosome.

A 1960 graduate of Haverford College, he received his MD (1965) and PhD (Biochemistry 1968) from the University of Chicago. After completing a pediatric internship in 1967 at the University of Chicago hospitals, he served during the Vietnam War from 1967 to 1970 in the Public Health Service at the National Institutes of Health (NIH) in Bethesda, MD. While living in the Washington D.C. area, Al and Pam marched in the first ever White House vigil to protest the Vietnam War. They also joined the Society of Friends meeting and became lifelong Quakers. In 1970, they moved to Aarhus, Denmark for two years while Al continued his research in biochemistry.

In 1972, he received an appointment as an Assistant Professor of Medical Science at Brown University and the family returned to the US, settling in Providence. Al became a Full Professor of Medical Science in 1982. During his academic career he was a Visiting Professor at University of Wisconsin-Madison; University of Copenhagen, Denmark; and University of New South Wales, Sydney, Australia.

He received 43 years of uninterrupted funding from the NIH for his research, mostly focused on the structure and function of the prokaryotic ribosome. He co-authored two books and wrote chapters in fourteen books. He published over 120 academic journal articles on the topic of ribosomes. Forever committed to academic integrity and professional honesty, later in his career, Al published an article that refuted some of his previous findings on the mechanisms of ribosomal function. During his four decades at Brown University, Al taught, mentored, and advised countless undergraduate, graduate, medical and doctoral students, and post-doctoral researchers while running his research laboratory. In addition to this, Al served on numerous national and international scientific boards, the Faculty Executive Committee at Brown, as well as several local non-profits. Al was also the medical director of Beech Tree Laboratory, a founder of Milkhaus Laboratory and on the Board of Directors at The Monroe Institute in Virginia.

Above all, Al will be remembered for his gentle and kind spirit, ability to light up a room with his presence, his insatiable curiosity and wonder, love for his family and friends, and his desire to make this world a better place for all.

Memorial services will be announced at a later date. In lieu of flowers, the family requests a donation to the HopeHealth Hulitar Hospice Center or the Providence Friends Meeting, or to any charitable organization that promotes peace in the world. ❖

RICHARD P. IACOBUCCI, MD, 80, formerly of Lincoln, RI, died March 7, 2022 at Roger Williams Hospital. He was the husband of Nancy (Campanella) Iacobucci.

He graduated from the University of Bologna, School of Medicine in 1969 and practiced medicine in Rhode Island for 50 years. He was a highly respected cardiologist devoted to his patients.

In addition to his wife, he is survived by his three children, Cara, Ariana, and Paul; seven grandchildren, and a brother, Robert (Nancy) Iacobucci.

Donations may be made in his name to the Mother of Life Center, 400 Atwells Ave., Providence, RI 02909. ❖

ROBERT A. INDEGLIA, MD, PhD, 84, passed away on March 2, 2022. Born in Providence, he was the son of the late Marie Antoinette (Cianciarulo) and Pasquale V. Indeglia, MD. Bob – or Dr. Bob or Doc as he would be known throughout most of his life – lived a life of dedication and love.

He graduated from Classical High School in 1954 and entered the pre-medical program at Johns Hopkins University, where he graduated in 1958. He continued his medical education at Georgetown Medical School, and completed his medical residency and PhD at the University of Minneapolis at the Mayo Clinic.

Dr. Indeglia moved back to Rhode Island in 1970, and he became a lifetime resident of Narragansett. He established the Thoracic and Cardiovascular Surgery Center in New England. Practicing principally at St. Joseph's Hospital in Providence, Fatima Hospital in North Providence, and ultimately at Miriam Hospital, his medical career spanned almost 50 years with hospital privileges at virtually every hospital in Rhode Island.

In addition to being a passionate sports fan and an avid golfer, Dr. Indeglia was a prolific dog breeder and a distinguished dog show judge, having been selected to serve as the Best in Show Judge for the famed Westminster Dog Show in 2007. His love of people, his love of medicine, his love of dogs, his love of sports were all paled in comparison to his love and pride in his four boys and their families.

He is survived by his children, Vincent A. Indeglia and his wife Allegra, Robert A. Indeglia, Jr., and his wife Christine, Paul A. Indeglia and his wife Megan, and Marc A. Indeglia and his wife Karen. He was the beloved grandfather of Gabrielle, Lucas, Robert, Alexandra, Xavier, Benjamin, Kai, Nicholas, and Anthony and was the brother of the Honorable Supreme Court Justice Gilbert V. Indeglia and his wife Elizabeth.

For guest book and condolences, averystortifuneralhome.com. ❖