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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 health-care. 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 NEGBENBOR, 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 policies 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?

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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 Professionalism⁵ 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 1996⁷ 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 "over-determined": 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 or 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 practice³³ and trauma-informed care³⁴ 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.

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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?

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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.

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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 telehealth,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 mortality¹⁰) 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 centers²⁵—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.

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

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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 “healthcare 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 148* 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., health-care 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 health-care 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, its 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-based²³ 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.

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