Supplement 1

American Journal of PUBLIC HEALTH

A PUBLICATION OF
AMERICAN PUBLIC HEALTH ASSOCIATION

Racial Disparities in Cancer Care | Access to Care for Transgender Veterans | Hepatitis C Among US Veterans | Battling Tobacco Use at Home | HEALTH EQUITY | How Might the Provision of Culturally Competent Services Be Enhanced for American Indian and Alaska Native Veterans? | Improving Trends in Gender Disparities | Suicidality Among Hispanic and African American Veterans Following Surgery

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COVER: Tse Cowan, 8, holds a hand written thank you note as he prepares to receive the coronavirus (COVID-19) vaccine at a vaccination pop-up site at P.S. 19 on November 8, 2021 in the Lower East Side in New York City. Chancellor Meisha Porter and Health Commissioner Dave A. Chokshi attended the first day of NYC's effort for children from 5 to 11 years old to receive the COVID-19 vaccine. Public schools across the city hosted vaccine pop-up sites after the FDA authorized an emergency use of the Pfizer-BioNTech vaccine for children. Cover concept and selection by Aleisha Kropf. Photo by Michael M. Santiago/Getty Images. Printed with permission.

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Promoting public health research, policy, practice, and education is the *AJPH* mission. As we widen our scope to embrace global issues, we also sharpen our focus to support the needs of public health practitioners. We invite contributions of original unpublished research, opinion and commentary, and letters to the editor.

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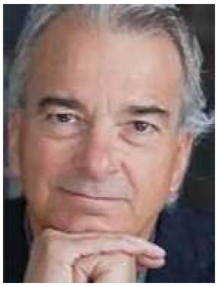
In Defense of Public Health



The COVID-19 vaccination campaign in the United States—as in many other countries—has been a success of historical dimensions. In about three months, 200 million Americans had been vaccinated at least once. As of January 6, 2022, 84% of Americans aged 12 years and older had at least one dose, and 71% were fully vaccinated. More than 95% of those aged 65 years and older got at least one dose, and 88% were fully vaccinated (https://am.ajph.link/NYT_VaccinesStats). If these were the results of a presidential election, their significance would be clear. Moreover, rates of death from COVID-19 dropped dramatically in the United States with the greatest prevalence of vaccination despite a highly contagious virus variant. These numbers are the result of a vigorous implementation process involving public health officers from the local to the federal level. Many hurdles had to be overcome to reach those who wanted to be vaccinated. This success will have long-term consequences. The experience accrued today of combining logistics and communication will strengthen processes to control the epidemics of, for instance, opioid use, obesity, smoking, diabetes, and HIV/AIDS (https://am.ajph.link/POD_June2021).

At the same time, the pandemic has sharpened the consciousness of structural injustice (https://am.ajph.link/Bowleg_July2020) with multiple dimensions (https://am.ajph.link/Krieger_Nov2020). Correcting these problems is now high on the agendas of many, and especially younger, public health researchers, practitioners, and activists.

Yet, a fifth or so of the adult population is still not vaccinated, slowing down the return to normal of schools and small businesses and stressing the health care resources of their states. The articles in this issue identify two types of vaccine resistance.

First, as the insurrectionist attack on the US Capitol on January 6, 2021 reminds us, proponents of far-right ideologies want to exclude immigrants and minorities from public health benefits, including vaccines. The chauvinist, racist, and xenophobic components of far-right ideologies focus on exclusion. They lead to discrimination against, and even exclusion and destruction of, subgroups of the population. Weindling (p. 248) reviews the laws of the Nazi regime, which sterilized hundreds of thousands of persons, including children, because they were persons with disabilities or because they were born to parents of mixed African and White or Asian and White ethnic origins. These ideologues are existential threats to democracy and public health (https://am.ajph.link/FascistThreat).

Second, some people oppose vaccines by asserting personal or medical freedom. Colgrove and Samuel (p. 234) show how the anti-vaccination movement, in its most genuine form, demonstrates a misunderstanding of the fundamental difference between medicine and public health: anti-vaccination supporters view public health recommendations, which are essential for the health of all, as if they were medical prescriptions that the individual patient may decide to follow or not.

These two types of vaccine refusal are different even though their adherents can be overlapping. They have in common, however, that they contradict all-inclusiveness, a long-standing principle of public health. Excluding some sectors of the population through chauvinism, racism, or xenophobia, as the far right does, or oneself because of personal preference, as vaccine refusers do, defeats the goals of public health. Public health identifies collective threats, devises safe, evidence-based collective responses, and enforces them because their success depends on everyone having access and complying. This is true for vaccines, as it is for environmental protection and occupational safety. Viruses, air pollution, and occupational risks are universal threats. The all-inclusiveness principle of public health may not be widely understood, even by the large majority of the population, which trusts public health. In defense of public health, it needs to be reaffirmed and explained. AJPH

Alfredo Morabia, MD, PhD
Editor-in-Chief AJPH

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3 Years Ago

Nazi Physicians as Leaders in Eugenics and "Euthanasia"

The involvement of health practitioners in conceptualizing, initiating, and implementing Nazi mass murder remains an unparalleled case of medicine and public health's participation in genocide. By January 1933, more than half of the German medical profession had joined the Nazi Party and many participated in the murder of Jews, Sinti, and Roma; the disabled; the mentally ill; and other "unfit" persons under the guise of improving public health. . . . The atrocities justified and performed by the health practitioners serving the Nazi eugenics and "euthanasia" programs exemplify how small steps along a slippery slope can lead to crimes against humanity. The Nazi doctors gradually progressed from eugenic sterilization to child and adult "euthanasia" and ultimately to murder and genocide. Framed in such medical terms as "healing work" and "death assistance," German health practitioners carried out the murder of thousands of the "unfit."

From AJPH, *January 2018, pp. 53–55, passim*

16 Years Ago

Eugenics in the Name of Public Health

In the late 19th century, eugenics . . . emerged in Britain and was soon incorporated into public health policy in numerous settings. . . . In the . . . applications of negative eugenic thinking . . . various interventions including sterilization were employed to "breed out" certain "defective" human characteristics, initially a variety of mental conditions and behaviors defined as criminal or immoral. . . . Although many accounts portray eugenics as a unitary movement informed by conservative ideas and supported by political counterparts, it was above all a technocratic development that could be and was appropriated and refashioned by utopians, social progressives, nativists, and Nazis. . . . In linking eugenics to right-wing political agendas, some scholars have inaccurately pointed to the end of World War II and the discrediting of "Nazi science" at the Nuremberg trials as the demise of eugenics. Yet . . . eugenics did not disappear then; support for eugenic sterilization [later] merged with growing concerns about overpopulation and family planning.

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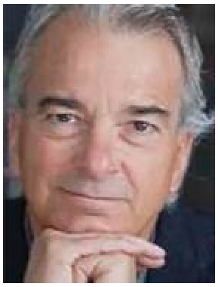
In Defense of Public Health



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Factors Associated With Vaccine Hesitancy in Brazil

Oliveira et al. explored the prevalence of and factors associated with COVID-19 vaccine hesitancy in Maranhão, a region in Brazil, given the increased polarization and wealth of disinformation. Of the 4630 participants surveyed between October 19 and October 30, 2020, 17.5% were hesitant. Hesitancy was greater in specific geographic regions and among females, older adults, evangelicals, and people with no reported COVID-19 symptoms. These sociodemographic and clinical characteristics should be considered when designing vaccine-related interventions and messaging with the goal of increasing COVID-19 vaccination.

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Prepared by Megan Marziali, Ahlam Abuawad, Luis Segura, and Vrinda Kalia, Columbia University, New York, NY. Correspondence should be sent to the AJPH *Global News team at vk2316@cumc.columbia.edu.*

DOI: https://doi.org/10.2105/AJPH.2021.306630

Factors Associated With Chinese Parents' Willingness to Vaccinate Their Children Against Influenza

Lau et al. conducted a telephone survey of 540 parents in Hong Kong to investigate factors associated with parental intention to have their ever-vaccinated (68.9% with intention to vaccinate) and never-vaccinated (19.8% with intention to vaccinate) children aged 24 to 59 months receive the influenza vaccine in the next 12 months. Perceived susceptibility (odds ratio [OR] = 3.20; 95% confidence interval [CI] = 1.07, 9.54), perceived benefit (OR = 4.77; 95% CI = 2.52, 9.05), perceived barriers (OR = 0.38; 95% CI = 0.17, 0.84), cue to action (OR = 3.57; 95% CI = 1.88, 6.78), subjective norms (OR = 11.23; 95% CI = 6.17, 20.46), and family members vaccinated (OR = 1.79; 95% CI = 1.09, 2.96) were associated with parental intention for ever-vaccinated children, whereas only perceived benefit (OR = 8.85; 95% CI = 3.36, 23.34) and subjective norm (OR = 21.66; 95% CI = 9.25, 50.71) were significant for never-vaccinated children. These results highlight the importance of segment health promotion strategies for different vaccination histories.

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Sociodemographic Factors Associated With Acceptance of COVID-19 Vaccine and Clinical Trials

Echoru et al. used online questionnaires to determine vaccine acceptance and intentions regarding participation in vaccine trials among people aged 18 to 70 years in western Uganda. Using a snowball sampling technique, they surveyed 1067 people between July and September 2020. Of the participants, 73.2% were male and most (32.6%) were between 31 to 40 years old. The overall vaccine acceptance rate was 53.6%, but only 44.6% were willing to participate in vaccine trials. When considering sociodemographic factors, the authors reported a higher likelihood of vaccine acceptance among men, those aged 18 to 20 years, those with tertiary-level education, and current students. Students and civil servants were more likely to accept participation in clinical trials than were people who were living in urban environments, unemployed, and retired. The authors suggest community-based methods to improve participation in vaccine trials.

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> *Prepared by Megan Marziali, Ahlam Abuawad, Luis Segura, and Vrinda Kalia, Columbia University, New York, NY. Correspondence should be sent to the* AJPH *Global News team at vk2316@cumc.columbia.edu.*

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Age and Trust in Government: Predictors of Vaccine Hesitancy

Trent et al. conducted a survey of adults residing in Sydney, Australia; Melbourne, Australia; London, United Kingdom; New York City; and Phoenix, Arizona to better understand reasons for vaccine hesitancy. Age and trust in government were key predictors. However, the direction of association between trust and willingness to be vaccinated depended on the country: in Australia the association was positive, with higher trust associated with higher willingness to become vaccinated, whereas in the United States, those with higher trust in their current government were less likely to be willing to receive the vaccine. Vaccine hesitancy is a complex issue that differs across political and cultural spheres, along with overall experiences with COVID-19.

Citation. Trent M, Seale H, Chughtai AA, Salmon D, MacIntyre CR. Trust in government, intention to vaccinate and COVID-19 vaccine hesitancy: a comparative survey of five large cities in the United States, United Kingdom, and Australia. *Vaccine*. 2021; Epub ahead of print. https://doi.org/10.1016/j.vaccine.2021.06.048

Factors Associated With Vaccine Hesitancy in Brazil

Oliveira et al. explored the prevalence of and factors associated with COVID-19 vaccine hesitancy in Maranhão, a region in Brazil, given the increased polarization and wealth of disinformation. Of the 4630 participants surveyed between October 19 and October 30, 2020, 17.5% were hesitant. Hesitancy was greater in specific geographic regions and among females, older adults, evangelicals, and people with no reported COVID-19 symptoms. These sociodemographic and clinical characteristics should be considered when designing vaccine-related interventions and messaging with the goal of increasing COVID-19 vaccination.

Citation. Oliveira BLCA, Campos MAG, Queiroz RCS, et al. Prevalence and factors associated with COVID-19 vaccine hesitancy in Maranhão, Brazil. *Rev Saude Publica*. 2021;55:12. https://doi.org/10.11606/s1518-8787.2021055003417

Factors Associated With Chinese Parents' Willingness to Vaccinate Their Children Against Influenza

Lau et al. conducted a telephone survey of 540 parents in Hong Kong to investigate factors associated with parental intention to have their ever-vaccinated (68.9% with intention to vaccinate) and never-vaccinated (19.8% with intention to vaccinate) children aged 24 to 59 months receive the influenza vaccine in the next 12 months. Perceived susceptibility (odds ratio [OR] = 3.20; 95% confidence interval [CI] = 1.07, 9.54), perceived benefit (OR = 4.77; 95% CI = 2.52, 9.05), perceived barriers (OR = 0.38; 95% CI = 0.17, 0.84), cue to action (OR = 3.57; 95% CI = 1.88, 6.78), subjective norms (OR = 11.23; 95% CI = 6.17, 20.46), and family members vaccinated (OR = 1.79; 95% CI = 1.09, 2.96) were associated with parental intention for ever-vaccinated children, whereas only perceived benefit (OR = 8.85; 95% CI = 3.36, 23.34) and subjective norm (OR = 21.66; 95% CI = 9.25, 50.71) were significant for never-vaccinated children. These results highlight the importance of segment health promotion strategies for different vaccination histories.

Citation. Lau JTF, Wu AMS, Ma YL, Lau MMC. Associated factors of behavioral intention regarding childhood influenza vaccination among parents of ever-vaccinated and never-vaccinated 24- to 59-month-old children in Hong Kong. *Asia Pac J Public Health*. 2021;33(2–3):262–272. https://doi.org/10.1177/1010539520973098

Sociodemographic Factors Associated With Acceptance of COVID-19 Vaccine and Clinical Trials

Echoru et al. used online questionnaires to determine vaccine acceptance and intentions regarding participation in vaccine trials among people aged 18 to 70 years in western Uganda. Using a snowball sampling technique, they surveyed 1067 people between July and September 2020. Of the participants, 73.2% were male and most (32.6%) were between 31 to 40 years old. The overall vaccine acceptance rate was 53.6%, but only 44.6% were willing to participate in vaccine trials. When considering sociodemographic factors, the authors reported a higher likelihood of vaccine acceptance among men, those aged 18 to 20 years, those with tertiary-level education, and current students. Students and civil servants were more likely to accept participation in clinical trials than were people who were living in urban environments, unemployed, and retired. The authors suggest community-based methods to improve participation in vaccine trials.

Citation. Echoru I, Ajambo PD, Keirania E, Bukenya EEM. Sociodemographic factors associated with acceptance of COVID-19 vaccine and clinical trials in Uganda: a cross-sectional study in western Uganda. *BMC Public Health*. 2021;21:1106. https://doi.org/10.1186/s12889-021-11197-7

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Better Late Than Never: The FDA's Sodium Reduction Targets

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See also Moran et al., p. 325.

The evidence, ranging from animal and epidemiological studies, to randomized controlled trials, to population-based intervention studies, has demonstrated beyond doubt that excess dietary sodium raises blood pressure, which in turn increases the risk of developing cardiovascular disease (CVD).[1] The most recent installment from the Global Burden of Disease Study found that, of the dietary risk factors linked to noncommunicable diseases, excess sodium intake is a leading risk factor, responsible for approximately 2 million deaths worldwide in 2019.[2] Almost all countries have an average population sodium intake above the World Health Organization's (WHO's) recommended maximum intake of 2000 milligrams per day; in the United States, average intake is 3400 milligrams per day.[3] The question now for governments worldwide isn't why should we act to reduce sodium intake, or even how should we act; it's why haven't we done more, with greater urgency?

Sodium reduction is one of the most cost-effective and impactful public health interventions available to us because, in most cases, it relies not on individual action but on government and food industry action. In many middle- and high-income countries, the majority of the sodium eaten by the population comes from the sodium added by manufacturers to processed, packaged foods. Therefore, governments can develop targets for key contributors of sodium to diets, such as bread, or across a range of processed foods with sodium added during processing. This provides a level playing field so that all food manufacturers work toward the same targets, gradually reducing levels of sodium in their products, which consumers can continue to buy as usual (Figure 1). More than 90 countries now have some form of sodium reduction strategy in place, and, of those, 48 have voluntary sodium reduction targets. It was the latter approach that was adopted by the National Salt Reduction Initiative (NSRI) in 2009, which helped to kick-start sodium reduction efforts in the United States.[4]

In the face of no action from the US federal government, it's admirable to see what the NSRI achieved. A coalition of more than 100 health organizations led by the New York City Department of Health and Mental Hygiene, the NSRI set sodium reduction targets across 62 categories of packaged foods and 25 categories of restaurant foods. A study by Moran et al. (p. 325) in this issue of *AJPH* analyzed changes in sales-weighted mean sodium density in 54 of the target product categories from 2009 to 2018. Their findings showed that mean sodium density decreased by 8.5%, from 591 milligrams per 100 grams in 2009 to 541 milligrams per 100 grams in 2018. Most progress was seen between 2009 and 2012 (5.1% decrease), with small changes seen between 2012 and 2018. Although food industry progress slowed in later years, Moran et al. highlight that the NSRI's model of sodium reduction was feasible. The NSRI was also able to unite many key stakeholders across the United States in support of the US Food and Drug Administration's (FDA's) intervention. Indeed, the NSRI's model of sodium reduction became the template for the FDA, leading to the publication of their draft 2-year and 10-year targets in 2016. After 5 long years of inaction, the FDA announced in October 2021 that they will implement short-term, voluntary sodium reduction targets.[5]

LESSONS FROM THE UNITED KINGDOM

The United Kingdom is frequently upheld as a leader in the field when it comes to voluntary sodium reduction. Targets were first set in 2006 for more than 85 food categories, with progressively lower targets set in 2009, 2011, 2014, and 2020.[6] Sodium levels initially fell by 20% to 40% in many products, which led to a significant reduction in population sodium intake.[7] Alongside parallel falls in average population

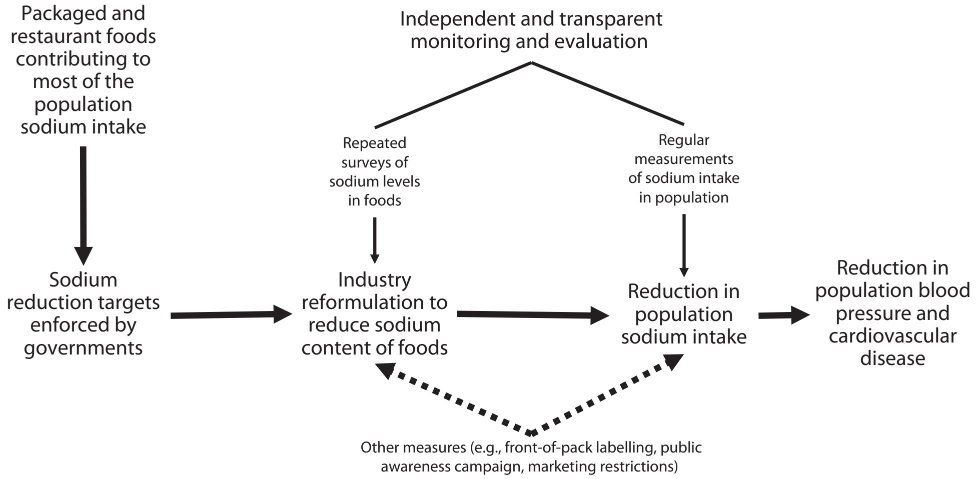

FIGURE 1— **Target-Based Approach to Reduce Population Sodium Intake**

blood pressure and CVD mortality, and crucially no loss in sales of products for the food industry, this intervention was a true win-win for industry and public health.

There are many things the United Kingdom did well, which the FDA should take on board. Any voluntary public health intervention can only be successful with strong and decisive leadership, and progress toward the targets must also be transparently monitored, with regular reports made available for wider scrutiny. In the United Kingdom, the independent Food Standards Agency fulfilled this function initially. A nongovernmental organization (NGO)—Consensus Action on Salt, Sugar and Health—also monitored food industry progress to reduce sodium in key categories of foods, recognizing and celebrating companies that had met targets while "naming and shaming" those that did not comply in media releases that gained attention from the public, the wider NGO community, and the government. The targets should be supported with other key measures, such as front-of-package labeling and public awareness campaigns; multicomponent interventions have proven to be the most effective.[8]

The reasons for failure will be just as important for the FDA to learn from. Responsibility for salt reduction in the United Kingdom has shifted many times over the past decade, and with this, there has been a move from independent monitoring to industry self-reporting progress.[9] Momentum and commitment for salt reduction faltered as a result and never fully recovered: A monitoring report of progress toward the targets set in 2014 that were to be met by the end of 2017 found that only approximately half (47%) of average targets had been met.[10] The most recent measurement of population sodium intake found that it has not fallen in the past 10 years, and the average intake was 3360 milligrams per day, much higher than the WHO's recommended limit.[11]

MAINTAINING SODIUM REDUCTION PROGRESS

The United Kingdom's—and indeed the NSRI's—experience shows what the FDA is up against, but there are opportunities for the FDA to maintain sodium reduction progress across the board. The WHO recently released its Global Sodium Benchmarks, which are based on the lowest maximum value for each category of food from existing national or regional targets. They are designed to be challenging yet achievable and should be viewed as a goal by the FDA and agencies in other countries in their sodium reduction journeys; the FDA's new targets are just the first step. The FDA must also be prepared to implement mandatory targets if progress across the board is poor. Argentina and South Africa have already led the way with mandatory targets. In Argentina, evidence shows that 90% of packaged products comply with the targets, and in South Africa, manufacturers began reducing sodium levels in their products when the targets were announced, with 67% of products compliant before the targets were even put in place. South Africa has also seen a 464 milligrams per day fall in average population sodium intake between 2015 and 2018–2019, demonstrating that their mandated sodium reduction program is having a large impact.[12]

In our globalized world, the fact that multinational food companies headquartered in the United States are now subject to a US-based sodium reduction strategy will have huge importance for both US and global health. Reducing global population sodium intake to the recommended level would prevent millions of deaths worldwide each year and result in huge cost savings to the health care services.

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F. J. He and M. K. Brown conceptualized the article. All authors contributed to drafting the manuscript and approved the final version.

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G. A. MacGregor is the chair of Blood Pressure UK and Consensus Action on Salt, Sugar and Health (CASSH). F. J. He is a member of CASSH. Blood Pressure UK and CASSH are nonprofit charitable organizations. G. A. MacGregor and F. J. He do not receive any financial support from them.

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Public Health Benefits of Paid Family Leave Policies Depend on Equitable Policy Design

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See also Hutcheon et al., p. 316.

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The critical public health importance of paid family leave (PFL) was convincingly reinforced by Hutcheon et al. in this issue of *AJPH* (p. 316). Using interrupted time series analysis of New York State population-based, all-payer hospital discharge records, they found that hospitalization rates for respiratory syncytial virus bronchiolitis and any acute lower respiratory tract infection among infants aged 8 weeks or younger decreased by 30% after the introduction of New York's paid family leave program in 2018. This research adds to a growing body of evidence that PFL programs have a positive impact on the health of birthing people and their families, including improved postpartum mental health, increased breastfeeding and infant immunization rates, and decreased infant mortality rates.[1,2]

At the time it was implemented in 2018, New York's PFL program was the most comprehensive in the country and provided 8 weeks of paid leave to care for a new baby, a seriously ill family member, or one's own serious illness. Hutcheon et al. focused on infants 8 weeks of age or younger. These children were the most likely to have had fewer respiratory infections had they benefitted from the program through delaying the start of out-of-home childcare. To rule out the possibility that the decreased rate of hospitalization for respiratory infection was caused by something other than the new PFL law, the authors conducted a negative control analysis with 1-year-old infants, a population that should not have been affected by the law because leave to care for a new baby must be used within 12 months of the child's birth. As expected, rates of respiratory syncytial virus bronchiolitis and any acute lower respiratory tract infection were unaffected by PFL in this older age group.

Like much of the literature linking PFL laws to health outcomes, Hutcheon et al. used an intent-to-treat analysis that estimates the impact of New York's state paid family leave policy as implemented in a real-world setting, which, as the authors point out, is particularly useful to policy-makers. This also avoids the selection bias that is common in observational studies of paid leave and other workplace benefits. Workers with access to paid leave differ in meaningful ways from workers without access to paid leave. Without any national PFL program in the United States, access to paid leave depends on individual and occupational characteristics. For example, 40% of US workers in the highest-wage occupations have access to PFL through their jobs, but just 7% of workers in the lowest-wage occupations do.[3] Similar disparities exist by industry, firm size, and full- versus part-time work hours. Workers of color are also less likely to have access to paid family leave through their jobs,[4–6] which could be attributable to institutional racism in workplace benefit policies and structural racism resulting in occupational segregation. Intent-to-treat analysis reduces statistical bias that derives from observed and unobserved differences in access to PFL and avoids overestimating the efficacy of PFL. However, this approach ignores the underlying inequities in the impact of state PFL policies in real life.

DESIGN AND IMPLEMENTATION CHALLENGES

While PFL laws strongly contribute to increasing access to paid leave, passing a law is not enough to ensure equitable access to the health benefits we know are possible. We continue to see inequitable access to paid leave even in states with PFL laws, such as New York. This is because of several policy design and implementation issues that have plagued PFL laws in the United States.

First, state PFL laws do not cover all workers. Many, like New York's, require minimum hours worked or program contributions or include only private-sector workers—restrictions that disproportionately exclude workers of color.[7]

Second, state PFL programs suffer from low public awareness. Appelbaum and Milkman found that just 49% of California workers who had recently experienced a qualifying event (e.g., becoming a parent or having a close family member become seriously ill) were aware of the state's PFL program five years after the policy went into effect, with even lower awareness among low-wage, immigrant, and Latina/x/o workers, and workers who had not finished high school.[8] More recent qualitative studies in California and elsewhere provide evidence of continued low awareness.[9]

Third, these policies are complex and many workers do not receive adequate support and information. Even those who have heard of state-level policies often misunderstand key policy elements, including eligibility.[10] Workers and their employers also confuse different laws and programs, potentially preventing workers from taking advantage of all available leave. For example, in their study of 75 lower-income mothers who had recently used California's PFL program for the birth of a child, Winston et al. reported that several participants realized during the focus groups that they had misunderstood the state benefits and, as a result, had requested or received substantially less paid leave than they were eligible for.[9] In our study of San Francisco, California's Paid Parental Leave Ordinance, lower-income parents were significantly less likely than their higher-income counterparts to report that their employer helped them learn about their parental leave benefits. In fact, the most common source of information about parental leave among lower-income parents was "nobody."[10]

Finally, most paid leave programs do not provide full pay or job protection,[11] which prevents some workers from taking full advantage of the laws.[12] The fact that most workers face separate eligibility for job protection and wage replacement, where available, contributes to the confusion described previously.

MOVING TOWARD POLICY SOLUTIONS

A growing body of literature suggests that PFL policies have the potential to have a positive impact on health, but without understanding and addressing these implementation barriers, positive health impacts may be limited to the most advantaged workers. Workers in the United States face huge inequities in access to PFL that are driven by structural forces. Now is the time to decide whether we in the public health community are going to focus on making sure workers have access to PFL. It is time we move from documenting the problem to identifying and enacting policy solutions.

As public health researchers focusing on the health impacts of PFL and other social policies, we need to explicitly examine the heterogeneous impacts of these policies across a population to determine whether they are reaching all of their intended beneficiaries. Furthermore, we need to interrogate the policy design elements that contribute to those differential impacts. Who is covered by a policy? Who is left out? Are benefits comprehensive enough to be truly accessible? What protections are in place for workers who face retaliation for using benefits defined in the law? Do people even know the policy exists?

PFL and other social policies of critical public health importance are being considered in the Build Back Better Act and in state and local governments across the country. By asking these questions, our research can inform these ongoing policy discussions to ensure the public health benefits are equitably distributed. AJPH

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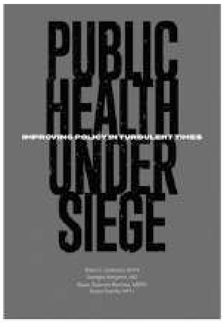

Bridging Science and Policy Toward a More Responsive Health Care System Beyond the COVID-19 Pandemic

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See also Maldonado et al., p. 308.

In an attempt to contain the transmission of the severe acute respiratory syndrome coronavirus 2, governments globally adopted policies early on to restrict population movement, aiming to reduce contacts and thus viral transmission. Data from the United States and more than 50 countries suggested large reductions in population movement during periods of strict mobility control measures, which correlated with changes in viral transmissibility.[1] After the lifting of many of these measures, which are mostly short-term remedies to deal with an unexpected pandemic, mobility increased substantially but still exhibited lower rates than in prepandemic periods, but viral transmission rates remained low.[1–3] These findings suggest that alternative control strategies, such as mask wearing and increased ventilation in indoor areas, coupled with enhanced and more complete contact tracing and evolving changes in human behavior, were associated with lower transmission rates.[2]

In this issue of *AJPH*, Maldonado et al. (p. 308) use mobility data in two large counties in California that implemented 20% capacity limits in different periods in December 2020 to explore changes in the number of visits, peak hour visits, and length of visits in grocery stores, pharmacies, and general merchandise stores. This specific capacity limit threshold was adopted by multiple counties and was based on a study which estimated that a 20% occupancy cap in the Chicago, Illinois, metropolitan area could result in a large reduction in infections of more than 80% while reducing visits by approximately 40%.[4]

The authors used a differences-in-differences framework with comparable time periods in 2019 as the baseline and the pre–post capacity limit implementation and a treatment group (county that implemented the capacity limit first) and a concurrent control group (county that did not implement the limit in that period) to assess changes in these outcomes. The authors conducted multiple analyses and found no significant policy-related changes in daily visits, peak hour visits, and median time of visits across all three sectors.

At first, these findings seem surprising, particularly because the authors used a mobility data set similar to that in the Chicago study.[4] Adaptive behaviors in response to previous mobility measures would suggest that the capacity limit would result in declines in the number of daily visits, peak hour visits, or the length of these visits. The authors unravel these findings by rigorously showing that the academic and authorities' policy definitions of capacity differed. For instance, business owners and authorities might use store square foot area to calculate occupancy, whereas researchers might use longitudinal secondary data to identify the average maximum number of visits. The authors estimate that the implemented policy limit was almost 200% higher than the maximum occupancy limit proposed by researchers because the underlying threshold estimation data deviated. Furthermore, Maldonado et al. show that the policy-enforced threshold did not practically impact activity during the enforced period, because stores were already operating below this threshold even before the pandemic.

The COVID-19 pandemic has highlighted the role of people, culture, infrastructure capacity, technology, and the environment in the public health setting.[5] The findings of the study by Maldonado et al. shed light on these roles and have multiple implications for evidence-based public health policy interventions in the current dynamically changing social and public health environment. First, scientific evidence, policy, and implementation are often distinct sites that need to be bridged through the translation of such evidence into practice.[6] The deviation of the same capacity limit threshold between academic research and government policy highlights the importance of bridging the gaps between the research and policymaker communities. Partnerships and coproduction of knowledge, as the authors propose particularly, during times of crisis among these communities are necessary to produce credible, understandable, timely, and useful evidence that can strategically inform and guide health policy decision-making processes.[7]

Moreover, the exponentially increasing amount of knowledge and information about COVID-19 requires reflexive and adaptive interventions that evolve dynamically and account for real-world changes.[6] In their study, Maldonado et al. present evidence of weak or no correlation between population mobility and COVID-19 case growth after May 2020 in Bay Area counties. As such, in a constantly changing environment amid the pandemic, the integration of timely information is critical to update and adjust metrics across stakeholders to attain societal goals.

However, as the COVID-19 pandemic has highlighted once more, health inequalities continue to prevail in the US healthcare system, with minorities and vulnerable populations being particularly hard hit by the virus itself but also by the unintentional consequences of strategies to slow the spread of COVID-19.[8] As such, collaborations across stakeholders to implement, review, and revise policy interventions based on real-world and real-time evidence must also take into account and incorporate provisions that address and fit the needs of diverse populations, aiming to enhance efficiency and equity. This will also require further investments in a multidisciplined, highly trained public health workforce and expanded infrastructure and surveillance systems for both infectious and chronic diseases beyond the pandemic.

In the current continuously evolving and changing landscape, scientists and policymakers must also build and maintain public trust by transparently disclosing health policy end goals to the public while acknowledging uncertainties not due to political interference.[3,9] These are critical to bolster compliance with coherent scientific and policy recommendations that aim to maximize societal welfare, particularly as vaccination rates increase but vary across heterogeneous population subgroups, and COVID-19 is eventually expected to become endemic.

The inconsistencies in policies and evidence during the COVID-19 pandemic as highlighted by the study of Maldonado et al. and the lessons learned provide a unique opportunity to reimagine the relationship and align science and policy to build a stronger and more responsive public health system beyond the pandemic.[10,11] Within this framework, systemically entrenched health inequities and disparities need to be addressed to improve the well-being of all populations and to empower all communities to move toward a better future.

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Caution Is Necessary When Estimating Treatment Need for Opioid Use Disorder Using National Surveys

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See also Saini et al., p. 284.

General population surveys are a leading source to estimate trends in drug use behaviors; however, caution should be used when the outcome of interest may be more prevalent among hard-to-reach or undersampled populations. Estimates of opioid use disorder (OUD) and treatment need using such national samples may not be accurate.

A new study by Saini et al. (p. 284) in this issue of *AJPH* attempts to disentangle two problems often conflated in studies of OUD treatment access: (1) the OUD treatment gap, defined in the National Survey on Drug Use and Health (NSDUH) as having a probable *Diagnostic and Statistical Manual of Mental Disorders*, 4th Edition (*DSM-IV*) diagnosis[1] of past-year OUD but not receiving treatment, and (2) perceived treatment need as self-reported by adults with OUD. With data from the 2015–2019 NSDUH, the authors estimated that only 10.5% of adults with OUD perceived needing treatment, but 71% actually needed treatment according to NSDUH measures of treatment need. Less than 30% of adults with a proxy diagnosis of past-year OUD according to *DSM-IV* criteria—the validated criteria used in NSDUH to assess OUD—received treatment in the past year. The most frequently reported barriers to treatment were affordability (49.3%) and access (42.1%).

METHODOLOGICAL LIMITATIONS OF POPULATION SURVEYS

We commend the authors for drawing attention to the widespread need for OUD treatment in the United States and the considerable barriers to accessing such treatment. However, we must point out several methodological limitations of the NSDUH that may bias estimates of the actual treatment gap. First, the way NSDUH measures OUD merits discussion. The NSDUH includes a module with 17 structured questions derived from *DSM-IV* criteria for abuse and dependence; combining these criteria allows proxy diagnosis of past-year substance use disorder (SUD) as per the *DSM-IV*.[1] OUD is defined as whether the respondent endorsed at least one of four abuse items or three of the dependence items. This indicator of *DSM-IV*–based criteria for OUD has good agreement with clinical judgment.[2] However, this clinical validation study was conducted on 288 adults and adolescents recruited from community and outpatient treatment programs prior to 2008.[2] Subsequent clinical validation studies, however, have shown somewhat better agreement for dependence than for abuse and for adults than for adolescents.[3,4]

The NSDUH measure of treatment need is a proxy measure for certain criteria that might signify needing treatment and does not represent a clinical diagnosis of OUD. *DSM-IV* abuse criteria[1,5] for OUD are hazardous use, social or interpersonal problems related to use, neglected major roles because of use, and legal problems related to use.[1,5] These classic abuse criteria lead to proxy diagnosis for OUD in the NSDUH, but not all individuals who "abuse" opioids need treatment. Using the 2015–2019 NSDUH data, we estimate that 5.7% (95% confidence interval [CI] = 3.8, 8.3) of adults with heroin use disorder met abuse criteria but not dependence criteria. Approximately one fifth (19.5%; 95% CI = 17.0, 22.3) of adults with prescription OUD did not meet criteria for dependence. This suggests that a substantial proportion of adults who only meet criteria for opioid abuse and not for dependence according to NSDUH criteria may not necessarily require treatment. At the same time, someone receiving medication for OUD might not meet NSDUH's past-year OUD criteria threshold and still need long-term treatment because of having started treatment in the past because of a previous OUD diagnosis.

BEHAVIORS AND UNMEASURED SUBSTANCES

Saini et al. correctly note that a limitation of NSDUH is that certain hard-to-reach populations and stigmatized behaviors may not be adequately represented in prevalence estimates. Heroin use in particular is thought to be severely underestimated by NSDUH largely because heroin use is a rare and particularly stigmatized behavior concentrated in hard-to-reach populations, whereas NSDUH aims to assess drug use trends in the general population.[6] NSDUH also does not include certain populations in its sampling frame that may be more likely to experience OUD, including unstably housed individuals not living in shelters and incarcerated individuals.[6,7]

In addition, as noted by Saini et al., NSDUH does not ask questions about illicitly manufactured fentanyl use—intentional use or unintentional use via exposure as an adulterant or contaminant in substances such as cocaine and methamphetamine.[8] The exclusion of fentanyl, its analogs, and other new synthetic opioids (e.g., U-47700) from NSDUH is particularly troubling given the shifting overdose epidemic, with rapidly increasing fentanyl-involved fatal overdoses and declining nonprescription opioid- and heroin-involved fatal overdoses.[8,9] The absence of measures of fentanyl and novel opioids might affect prevalence estimates of opioid use and OUD in the general population. Consequently, prevalence estimates of past-year opioid (mis)use may be underestimated in NSDUH, potentially biasing population estimates of OUD and associated treatment needs.

NSDUH also does not address the continuum of treatment care for people with OUD, such as frequency of visits to opioid treatment programs (OTPs) or adequacy of available treatment. As NSDUH queries any past-year SUD treatment, this broad measure may include adults who received treatment of substances other than opioids (e.g., alcohol), adults not retained in treatment, and adults who left treatment early and did not return.

TOWARD A BETTER UNDERSTANDING OF TREATMENT BARRIERS

Finally, understanding barriers to treatment access and retention are essential for coherent and impactful treatment policy recommendations. Saini et al. measured barriers to treatment by combining 14 NSDUH items into six broad categories, impeding nuanced investigation into the relative importance of their contributions to the treatment gap. For example, the authors measured "treatment access" by combining lack of transportation, no appropriate treatment program in their area, no open slots in the program, long distances, not knowing where to go, and not having time. This combines various barriers to treatment access (financial, structural) into one measure. Access to OUD treatment is regulated by federal and state agencies. At the time of the study (2015–2019), methadone could only be dispensed daily and in person at licensed OTPs, and some OTPs also supplied buprenorphine. Physicians in outpatient nonspecialty settings were authorized to prescribe buprenorphine after receipt of training and a waiver issued by the Substance Abuse and Mental Health Services Administration with limits on the types of providers eligible to prescribe buprenorphine and the number of patients at a time to whom a provider could prescribe buprenorphine.[10] Some of these strictures have been loosened to prevent coronavirus disease 2019 transmission (e.g., buprenorphine initiation via telehealth for new patients, 28-day medication supplies for established patients), but implementation of these policies across municipalities has been inconsistent.[11] Understanding the prevalence of individual structural barriers to treatment access could have important implications for policy planning and expanded delivery of OUD treatment services.

It is difficult to draw nuanced conclusions regarding unmet treatment need and perceived treatment need from national studies aimed at estimating the prevalence of certain behaviors in the general population. Although population studies such as NSDUH provide important insight into population-level trends, deeper investigation is necessary to adequately target treatment expansion for groups most in need of services. Nevertheless, expansion of policies to enable access to OUD treatment is essential, and implementation of these policies across all US states should be a priority. Ultimately, eliminating barriers to OUD care and expanding access to OUD treatment will help prevent morbidity and mortality from continued OUD. Although Saini et al. provide more evidence in support of the treatment gap, further nuanced investigation is needed to plan and implement effective policies that target populations most in need of treatment and reduce barriers to evidence-based, affordable, and compassionate care for adults with OUD who need treatment. AJPH

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CONFLICTS OF INTEREST

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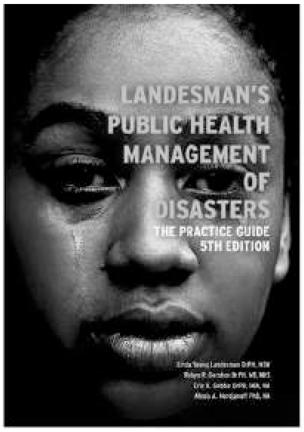

Vaccine Solidarity Requires Social Justice: A Public Health of Consequence, February 2022

Farzana Kapadia, PhD, MPH

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See also Colgrove and Samuel, p. 234, Yeh, p. 255, and Jain et al., p. 304.

In 1999, the Centers for Disease Control and Prevention published a list of the 10 greatest public health achievements that increased life expectancy during the 20th century. Included in this list were mass vaccinations to reduce infectious disease epidemics (https://bit.ly/3oEdSBr). The report was followed by two others in 2011, both of which reported declines in hospitalizations and deaths because of vaccine-preventable diseases domestically and globally (https://bit.ly/2Z4iwjs). Simply put, vaccination is the most cost-effective way to prevent death and disability from vaccine-preventable diseases. Despite this clear and incontrovertible fact, we have witnessed increased vaccine refusal, vaccine hesitancy, and vaccine mistrust over the past two decades.

Although the current rise in vaccine hesitancy and refusal to comply with vaccine mandates is fueled in part by rapid dissemination of misinformation and disinformation on social media, the vaccine refusal movement is not new. As Colgrove and Samuel (p. 234) describe, the history of vaccine refusal is rooted in antivaccination movements that took hold in the second half of the 19th century in the United Kingdom. Stemming from principles of individual liberty and personal freedom, the antivaccine movement and its proponents, in Great Britain and later in the United States, campaigned against state-mandated, compulsory vaccination laws. The politicization of the antivaccine movement as one framed around maintaining individual freedom and its melding with the medical liberty movement laid the foundation for the current antigovernment, antivaccination efforts. Lost in the antivaccine rhetoric was the notion of vaccination as emblematic of a social contract in public health that promotes vaccination mandates not only to protect the health of individuals but also to protect the health of populations.

Fast-forward to the present, and contentious debates about the political, ethical, and societal impacts versus individual liberties of vaccine mandates have resurfaced and intensified. Yeh's essay (p. 255) describing the concept of solidarity as grounds for enacting mandatory vaccination is predicated on the notion that citizens of a state should be willing to value, support, and take on the risks and costs of a vaccine because these interventions are for the greater good of the state. This notion of solidarity also draws on the concept of the social contract in public health—which requires the recognition of health as a public good and of vaccination as an act of civic responsibility in support of the health of the populace.

DRIVERS OF INADEQUATE VACCINE COVERAGE

An issue with grounding vaccine mandates in a solidarity framework is that concept rests on the assumption that all citizens in a state or community are held in the same value. Since its onset, the disproportionate burden of economic, social, political, and health consequences of the COVID-19 pandemic have been borne by communities of color and marginalized communities—communities that have historically not been afforded the same level of value in our society.

There is a large body of literature documenting the multitude of ways these layers of structural racism affect communities of color, and in an upcoming article in *AJPH*, Asabor et al.[1] add to it by presenting evidence on the lower availability of an essential public health service in communities of color during the COVID-19 pandemic. Their analysis of the spatial distribution of COVID-19 testing sites shows that cities with higher degrees of racially segregated neighborhoods (Los Angeles, CA; Chicago, IL; New York City, NY; and Houston, TX) had fewer COVID-19 testing sites in neighborhoods with higher concentrations of Black and Hispanic residents than other neighborhoods.

The lower number of COVID-19 testing sites in communities of color is not unique to this pandemic but a reflection of the chronic lack of public health services for vulnerable communities. And this historical underprovision of public health resources in communities of color continues to be a driver of lower vaccination availability and uptake among Black and Hispanic/Latino populations. In fact, state-level vaccination data compiled by the Kaiser Family Foundation show that racial/ethnic disparities in COVID-19 vaccination persist in the same states—California, Illinois, New York, and Texas—included in the Asabor et al. study (https://bit.ly/3HLHOED). As of November 15, 2021, Black and Hispanic/Latino residents in these states lagged White residents in receipt of a COVID-19 vaccine dose, with gaps ranging from −11% (Illinois) to −6% (New York) for Black residents and from −12% (California) to −9% (Illinois) for Hispanic/Latino residents. Compounding and exacerbating the impact of suboptimal public health infrastructure on vaccination uptake is the legacy of medical mistrust, which is another driver of vaccine hesitancy in communities of color.

Although not specifically about COVID-19 but relevant to disparities in vaccination uptake, Jain et al. (p. 304) report on the persistence of a rural–urban divide in self-reported influenza vaccination rates. Their findings show lower self-reported influenza vaccination among rural residents overall and a similar trend of lower vaccination among racial/ethnic minority rural groups compared with their urban counterparts. Again, we see in rural communities, and especially rural communities of color, which have been overlooked and ignored, that public health infrastructure is woefully inadequate and unable to meet the basic public health prevention needs of this vast and diverse population. The backlash against vaccination in many rural communities is yet another manifestation of antigovernment sentiment and often employs a corrupted version of "my body, my choice"—the hallmark slogan of the reproductive rights movement.

ACHIEVING VACCINE SOLIDARITY

Where does this leave us in trying to achieve adequate vaccination coverage? First, we must learn from historical lessons and not ignore the educational, economic, and social inequities that are not just persisting, but widening and fueling inadequate vaccine coverage. Second, we need political support to adequately fund state and local public health actions that protect the health of the most marginalized and historically disenfranchised people. Failure to do so will continue to erode the social contract in public health and trust in our government and its public health agencies. Third, consistent vaccination mandates for essential workers are required across all US states. Such policies will avoid further weakening confidence in our government response to the pandemic and protect our workforce and population (https://bit.ly/30ztTjF).

Without bold action, factors that are at the core of vaccine hesitancy, medical mistrust, and antivaccination movements will remain with us for generations to come no matter the weight of scientific evidence that supports vaccination programs. Although solidarity as a framework for vaccine mandates is meaningful and applicable in more egalitarian contexts, it will likely be successfully applied only if we dismantle the policies and systems of structural racism that sustain health disparities and health inequities by placing less value on the health and well-being of communities of color. This is not a surrender, but a call to action: for public health to positively impact vaccine solidarity, we must first and foremost redouble our commitment to social justice.

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Placing Racial Equity at the Center of Substance Use Research: Lessons From the HEALing Communities Study

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Structural racism, "the totality of ways in which societies foster racial discrimination through mutually reinforcing systems of housing, education, employment, earnings, benefits, credit, media, health care, and criminal justice," is pervasive in the United States, impacting all systems including addiction treatment.[1(p1453)] This article describes efforts to center racial equity in the Helping to End Addiction Long-Term (HEALing) Communities Study (HCS), a multisite implementation research study sponsored by the National Institute on Drug Abuse and the Substance Abuse and Mental Health Services Administration to reduce opioid overdose deaths in highly affected communities.[2] Guided by what Public Health Critical Race Praxis (a framework to help researchers understand and challenge the power hierarchies that buttress health inequities) terms "disciplinary self-critique,"[3] we share lessons and opportunities that we hope will resonate with researchers and funders in the addiction field and help us all better center racial equity in our work.

THE HEALing COMMUNITIES STUDY

The HCS aims to reduce opioid-related overdose fatalities by 40% over two years through the Communities That HEAL (Helping to End Addiction Long-Term) intervention (CTH).[2] CTH is a community-engaged, data-driven intervention designed to support the adoption of evidence-based practices for addressing opioid use disorder (OUD) in 67 highly affected communities (defined as counties or cities or towns in HCS) across Kentucky, Massachusetts, New York, and Ohio.

Community engagement (i.e., "the process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the well-being of those people")[4(p.xv)] is a core element of CTH, and communities consider how to reach high-risk and underserved populations. However, there is no explicit racial equity study aim. Given the pervasiveness of structural racism in the United States, addiction initiatives that lack an intentional focus on racial equity from the start risk perpetuating inequities.[5]

STRUCTURAL RACISM AND THE US OPIOID EPIDEMIC

Structural racism is evident in the US response to OUD. OUD among Black and Latinx people has long been addressed through punitive, rather than treatment-based, measures (e.g., the "War on Drugs").[6] Scholars note that federal methadone regulations, formed when OUD predominantly affected people of color,[7,8] including daily observed dosing and low thresholds for discharge, were racialized (i.e., created differently because of the race of individuals receiving treatment) and grounded in social control[8] (e.g., "liquid handcuffs.")[9]

The growth of prescription opioid use among suburban, middle-income White people ushered in a framing of OUD as a public health concern, rather than a moral or criminal issue.[10] The racialization of addiction treatment has contributed to a de facto segregated system.[11,12] Black patients have 77% lower odds of receiving buprenorphine—a treatment for OUD associated with decreased mortality[13]—than White patients.[12]

OUR JOURNEY AND LESSONS LEARNED

Because HCS began without an explicit approach for centering racial equity, efforts emerged organically at each site, which evolved into midcourse study-wide efforts, though not to its incorporation as a study aim. We are sharing selected real-world insights from our ongoing journey to help equip other researchers to center racial equity in similar work (Box 1).

Make Racial Equity a Required Component

In Massachusetts, calls to formally center racial equity in the study came early on. For example, staff raised concerns about lack of diversity among coalition and community advisory board membership. Some staff also questioned the prominent representation of law enforcement on coalitions and the tendency to focus on buprenorphine without addressing accessibility barriers for Black, Indigenous, and other people of color (BIPOC). Massachusetts established a Racial Equity and Social Justice (RESJ) committee to help formalize a focus on racial equity. The RESJ committee drafted a charter defining structures and strategies for integrating a racial equity lens in that site's work, which later helped to inform the adoption of a study-wide statement of commitment to racial equity.[15]

Expect Resistance to Antiracist Change

The development of the Massachusetts RESJ committee charter—an iterative process requiring several drafts back and forth between the committee and research site leadership—involved difficult conversations around racial equity concepts, such as "White supremacy culture" (i.e., the idea that the actions, thoughts, and beliefs of White people are superior to those of other races, especially the Black race),[16] that were unfamiliar or discomforting for some White team members. Such discomfort has been termed "White fragility."[17] To facilitate difficult but necessary conversations, the RESJ committee convened affinity groups—groups of individuals with similar backgrounds who teach each other about racial equity.[18] Conversations informed charter enhancements, including the addition of racial equity references. References to scientific literature added credibility to the

BOX 1— Insights on Centering Racial Equity in Addiction Research and Practical Examples

Insight	Practical Example
Formalize the integration of a racial equity lens early; make it an explicit and required component of the study.	Include an explicit aim related to assessing and achieving racial equity as part of the research study.
Expect resistance to antiracist change; difficult conversations are necessary to advance the work.	Establish affinity groups within study teams to provide a safe space for researchers and staff to discuss structural racism, health inequities, and racial equity principles.
Commit to assessing and advancing diversity and inclusion.	Disseminate job postings for study positions to historically Black colleges and universities and BIPOC-owned and professional organizations, engage BIPOC team members in recruitment activities and hiring decisions, and ensure a living wage for all study staff.[14]
Provide ongoing education on racial equity.	Provide trainings on racial equity topics, including the links between structural racism and health inequities, to researchers, staff, and community partners over the course of the study.
Meet communities where they are.	Tailor racial equity work to communities' starting points, learning from community experts when possible and promoting community-led equity work through study newsletters and learning collaboratives.
Dedicate resources to ensure communications materials—visual and written—resonate with BIPOC.	Dedicate resources early to translation and community engagement to support the timely development of culturally relevant materials.
Invest in data infrastructure.	Allocate resources for assessing relevant data infrastructure and building relationships and protocols necessary to fill data gaps so that racial and ethnic inequities can be identified and monitored and can inform interventions over the course of the study.

Note. BIPOC = Black, Indigenous, and other people of color.

charter and were resources that helped RESJ committee members understand and respond to senior study staff. Being able to contextualize the resistance to the charter and questions around equity work allowed RESJ committee members to persist when confronted with resistance.

Commit to Advancing Diversity and Inclusion

During the CTH planning phase, the New York team visited all 16 of their HCS communities and noticed few BIPOC coalition members. Majority-White research teams, community advisory boards, and coalitions can exclude or overshadow voices of "outsiders within" (e.g., BIPOC within majority-White organizations) who are in a unique position to point out the study's gaps in equity and help increase the team's understanding of the lived experiences of BIPOC, which leads to a more-thorough examination of the problems and to more culturally responsive solutions.[19]

Although diverse research teams alone do not ensure that racial equity is centered in research—as noted in Public Health Critical Race Praxis, power sharing and amplifying BIPOC voices is also needed—it is an essential step.[19] All four research sites are increasing the diversity of their teams and coalition partnerships. Key strategies include supporting research opportunities for underrepresented minority scholars and contracting with BIPOC-owned businesses. Some sites recruited existing coalitions for the study, so they had little influence over membership. In these cases, education was a key strategy for encouraging diversification. To date, methods of assessing study staff and coalition diversity have been informal; conversations on how best to formally assess staff and coalition make-up are ongoing.

Provide Ongoing Racial Equity Education

Addressing racial inequities in health requires raising awareness of inequities and building support to address them.[20] Thus, providing training and education on the link between structural racism and health inequities has been an important part of our efforts to center racial equity in the study. For example, Kentucky's community-facing staff are required, and lead researchers encouraged, to complete interactive trainings about unconscious bias and cross-cultural communication. The Kentucky team also recently partnered with Voices of Hope, a community-based recovery support nonprofit, to host a virtual town hall for researchers to connect with community members and learn firsthand about the barriers to care and recovery BIPOC face. Research sites continue to provide education as one component in a multipronged strategy for centering racial equity in HCS. Understanding the optimal types and topics of education is an ongoing process, guided by Public Health Critical Race Praxis and issues encountered by community-facing teams and other study staff.

Meet Communities Where They Are

Stark demographic contrasts across Ohio's HCS communities add to the complexity of racial equity work. In some of Ohio's urban communities, BIPOC comprise approximately 40% of the population, but they are less than 5% of the population in some rural communities. Some of Ohio's most-diverse HCS communities were already racial equity champions and innovators, which created an opportunity for the study team to learn from communities. HCS study staff in Ohio learned about existing community approaches to equity via coalition meetings, one-on-one meetings with key stakeholders, and conversations with existing racial equity groups. To meet all HCS communities where they are, the Ohio team drafted a health equity plan that acknowledges that structural barriers influence outcomes for marginalized populations (including not only BIPOC but also transitional-age youths and people in rural communities), that each Ohio HCS community has its own health equity priorities, and that each community is starting from a different place regarding understanding inequities. Meeting each community where they are has been an ongoing endeavor for the Ohio team, one that requires engagement to determine each community's understanding of OUD-related inequities. It also requires understanding the challenges communities face that can limit their racial equity work, such as data gaps and workforce shortages.

Ensure Communications Materials Resonate

Health communication campaigns were integrated into the CTH to help drive demand for evidence-based practices and reduce stigma.[21] To ramp up the campaign quickly, a workgroup reviewed stock photography for draft campaign materials. BIPOC are under- and misrepresented in the images available through the largest stock imagery companies.[22] The workgroup had always planned to provide a more diverse set of images for the campaigns and to support communities in using their own images, and those plans were fulfilled in time. However, when relying on stock images in initial message-testing materials, researchers must be mindful of how the lack of BIPOC representation can reinforce the marginalization of racial and ethnic minorities in our nation's response to OUD.

Beyond the development of culturally relevant resources, centering racial equity in HCS demands thoughtful distribution of materials, in languages appropriate for each community, so they are frequently seen and heard by BIPOC.[23] This is resource-intensive work, but dedicating the necessary time and funding to creating inclusive materials and distribution strategies is vital to advancing equity.

Invest in Data Infrastructure

Disaggregated data on treatment and overdoses can help raise awareness of inequities in treatment measures and outcomes and inform equitable evidence-based practice implementation. In response to communities' data needs, the HCS data team expedited estimates for 2018 and 2019 data on opioid overdose deaths in advance of state-level reports. Stratified data revealed disparate trends in overdose deaths among Blacks and Hispanics compared with Whites.[24] These data prompted action to better reach BIPOC; for example, a Massachusetts coalition hired a bilingual, bicultural outreach worker to dispense naloxone to individuals whom existing efforts were missing.

For other outcomes, the availability of stratified data is limited. For example, the state Prescription Drug Monitoring Program in Massachusetts does not contain stratified data, making analysis of initiation and retention on buprenorphine by race/ethnicity impossible. HCS is partnering with community organizations and state agencies to assess existing data sets and eliminate critical gaps.

CONCLUSIONS

HCS has vast potential to save lives and promote racial equity. Although HCS is focused on OUD, we believe these insights apply broadly to addiction research because of the way health care and society's response to addiction are shaped by racism. To realize this promise in HCS and similar studies to save lives but also promote racial equity (or at the very least, not worsen inequities), funders and researchers must intentionally and explicitly center racial equity from the start.[25] We also acknowledge that the pervasiveness of structural racism and inequities in social determinants of health demand far more than study-level improvements. As a research community, we need to critically examine and strengthen our methods of inquiry, intervention approaches, and funding practices to advance equity; this includes centering BIPOC voices in decision-making and investment in adapting evidence-based practices to ensure they reach, resonate with, and improve outcomes among BIPOC and other groups who have been excluded from the evidence-generating process.[26]

Based on the conversations this work has initiated, study leadership has expressed a commitment to examining and publishing on racial equity implications of HCS. Sharing lessons from our ongoing journey is one way to hold ourselves accountable; we hope that our insights will promote the centering of racial equity in addiction research.

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The authors have no conflicts of interest to disclose.

HUMAN PARTICIPANT PROTECTION

This study protocol (Pro00038088) was approved by Advarra Inc, the HEALing Communities Study Single institutional review board. The ClinicalTrials.gov identifier for the study is NCT04111939.

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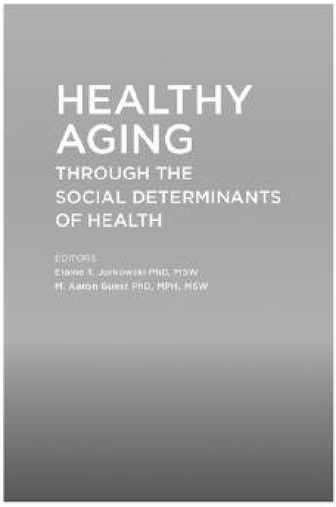

Lack of Arab or Middle Eastern and North African Health Data Undermines Assessment of Health Disparities

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Collection of race and ethnicity data has been controversial in the United States, and the identification of legally recognized race and ethnic categories has shifted over time as a result of changes in the sociopolitical climate. For example, the shift from using the Asian (Mongol) to the White classification for Arab or Middle Eastern and North African (MENA) populations came after contentious court battles at the beginning of the 20th century, when being White was a prerequisite for US citizenship.[1]

Furthermore, the accuracy of racial and ethnic categories has been questioned.[2–4] A case in point is that the Hispanic/Latino group did not emerge as a recognized ethnic group until the 1980 US census count,[5] and there was little consensus as to whether this category should be considered a race or an ethnicity.[6] The categories adopted in the US census tend to result from both research and political lobbying. The political motivations underlying the collection of race and ethnicity data range from remedying inequalities to advancing White supremacist values.[4,7,8] Accurate and robust collection of ethnicity and race data is the first critical step in identifying and addressing disparities in health.[9,10]

One ethnic minority group that is often omitted from medical and health-related data collection altogether is the Arab/MENA population in the United States. Race and ethnicity disparity statistics often exclude the Arab/MENA population because either data are not being collected on this population or the group is not being disaggregated from the White race category. A growing body of research shows that Arab/MENA Americans have both health and social patterns distinct from those of Whites. Findings suggest that, relative to non-Hispanic Whites, Arab/MENA Americans have a higher prevalence of metabolic disorders and cardiovascular disease,[11–13] as well as low birth weight[14,15] and depressive symptoms.[16,17] Furthermore, this group is bifurcated in terms of socioeconomic status, reporting both higher and lower educational levels than Whites.[18,19]

It appears that the experiences of Arab/MENA Americans place them at elevated risk of developing a myriad of health problems, perhaps owing to discrimination and social stress.[10,20] We argue that disaggregating the Arab/MENA population in race and ethnic group data collection by including an Arab/MENA ethnic category will advance the science of health disparities.

ADVANCING KNOWLEDGE ON HEALTH DISPARITIES

Data on the Arab/MENA population should be disaggregated from data on White samples to advance the science of health disparities. In particular, such data will address issues pertaining to external validity (the extent to which scientific findings are generalizable across people, settings, and times[21]). Sampling schemes that do not include Arab/MENA individuals compromise scientific inquiry by inaccurately attributing trends to Whites, making invisible the unique challenges faced by Arab/MENA populations and further obscuring disparities between White and minority individuals and groups. Such threats to external validity result in bad science. Because systematic comparisons cannot be made regarding the health outcomes of Arab/MENA Americans across contexts and communities, the strongest scientific statements are often generalizations that do not advance research on health disparities. The external validity of studies aiming to describe health disparities is thereby limited by incomplete and inaccurate descriptions of the racial and ethnic landscape in the United States.

We argue that studying Arab/MENA Americans is necessary to establish an accurate and comprehensive account of health disparities in the United States and offers unique opportunities for clarifying and revealing life course mechanisms that create and sustain these disparities. Accumulating research underscores the importance of distinguishing Arab/MENA Americans from Whites (often considered as a monolithic "control" group) to reveal hidden patterns of vulnerabilities among both Arab/MENA and other minority populations.[22] Because Arab/MENA Americans experience ethnic discrimination and "othering,"[10] placing them in the White category masks the disparities between Whites and other ethnic minorities (e.g., Blacks and Latinos).

For example, identification of Arab/MENA individuals separately from White individuals allows for an understanding of how patterns of social relations and health in the Arab/MENA population differ from those in the White population and, in so doing, makes the severity of disparities between Black and White groups more apparent.[16] Thus, a commitment to external validity in the scientific enterprise makes it imperative that the Arab/MENA population be disaggregated from the White category to adequately identify disparities between Whites and all racial and ethnic minority groups.

RECOGNIZING ARAB/MENA POPULATIONS

The Office of Management and Budget (OMB) determines the minimal reporting criteria for race and ethnicity data in the United States for federal agencies. Agencies such as the US Census Bureau apply these guidelines in their data collection and dissemination practices. As the largest purveyors of statistical insight into the condition of the US populace, federal agencies provide the de facto standards for how race and ethnicity data are collected on demographic forms across numerous sectors, including health care. Many organizations, including hospitals and health care organizations, use US census race and ethnicity questions to inform the demographic data they collect. These standard demographic forms do not include a separate category for Arab/MENA populations.

As evidence that the White racial category was an inadequate option for people of Arab/MENA descent, results from the 2010 decennial census indicated that more than 1 million individuals of Arab/MENA descent chose the "some other race" classification.[23] These same data showed that the number of Arab/MENA Americans was more than twice that of the recognized Pacific Islander racial group.[24] Evidence that the White racial category was an inadequate option for people of Arab/MENA descent prompted the Census Bureau to examine more appropriate options for categorizing Arab/MENA populations.

In its 2015 National Content Test, the US Census Bureau used updated forms including the MENA category as a standalone racial/ethnic category for respondents who traced their ancestry to Arabic-speaking countries and non-Arab countries in the Middle East and North Africa. The results from the test indicated that a separate MENA response category was optimal for collecting data from this population and that inclusion of a MENA category helps respondents more accurately report their identities.[9] When the Census Bureau recommendations regarding such a category were forwarded to the OMB, the office failed to make a decision by the decennial census operational deadline; no specific reason was given for failure to accept the recommendations.[25]

Population-representative health data for Arab/MENA individuals at the national level are limited to secondary data sets with inadequate specificity and generalizability. For example, the National Health Interview Survey allows for examination of the health of only first-generation immigrant Arab/MENA individuals. In addition, the US census allows for identification of Arab/MENA individuals through the ancestry question on the American Community Survey but includes only disability health measures. Similar to information for other ethnic minority groups, the data are usually pooled at the national level over multiple years to ensure that comparisons of health outcomes are well powered.

The majority of research on health outcomes relies on conveniently sampled surveys conducted in locations with large Arab/MENA populations.[26] One unique data set is the Behavioral Risk Factor Surveillance System, established in 1984 by the Centers for Disease Control and Prevention.[27] This ongoing state-based system of random-digit-dial, telephone-administered population-based health surveys collects information on health risk behaviors, preventive health practices, and health care access primarily related to chronic disease and injury among adults aged 18 years or older. In 2007, the state of Michigan added the question "Are you of Arab or Chaldean origin?" Although this question allows for initial examination of health issues at the state level,[28] it has yet to spur the inclusion of an Arab/MENA category in other health systems or large, nationally representative health studies despite evidence of disparities between Arab/MENA and White populations.

IDENTIFYING ARAB/MENA POPULATIONS

As a means of advancing good science toward the elimination of health disparities, we capitalize on the results of the Census Bureau's National Content Test to present three options for researchers, private organizations, or government institutions seeking to collect data on the Arab/MENA population.

Option 1: Streamlined/ Combined Question

This option is informed by the US census question combining race and ethnicity, assessed in the 2015 National Content Test and found to result in more accurate data.[9] This flexible option allows the responder to indicate both an ethnicity and a race (or either an ethnicity or a race). In addition, this approach allows researchers to compare outcomes across ethnicity and race categories. According to the US census, the six examples included in this tool were assessed in the 2015 National Content Test and were meant to show the broad geographic diversity of the Arab/MENA population. The census used the three largest Middle Eastern nationalities (Lebanese, Iranian, and Syrian) and the three largest North African nationalities (Moroccan, Egyptian, and Algerian) to test the MENA category.

Researchers should tailor examples included in the parentheses after the MENA option to their particular populations of interest. To determine which ancestry or ethnicity choices to include, researchers can consult the American Community Survey for top MENA ancestries selected in that survey by particular US region (2014 American Community Survey five-year estimates). Using the filters available in the US census's Web-based data tool, interested parties could also filter top Arab or MENA ancestry choices for a particular geographic location (Figure A, available as a supplement to the online version of this article at http://www.ajph.org, option 1).

Option 2: Separation of Ethnicity and Race

This option is adapted from the current US census question format, in which two separate questions are used to collect race and ethnicity data. For this option, an Arab/MENA ethnicity question is added that mirrors the Hispanic ethnicity question used in most major surveys. The standard OMB race categories remain the same. This option allows for independent examinations of ethnicity and race. This may be reasonable and necessary for certain research questions and for institutions interested in differences by race and ethnicity. MENA ethnicities should be removed from the White category examples to prevent confusion. It is assumed that Arab/MENA individuals who do not identify as White will choose another box as they see fit (Figure A, option 2).

Option 3: Adding a MENA Category

This option entails adding a MENA box to an existing data collection instrument (Figure A, option 3). The MENA box will be structured according to the format of the existing instrument. An example of an institution that uses option 3 is the Michigan Behavioral Risk Factor Surveillance System,[25] which in 2020 asked demographic questions largely according to OMB guidelines. In that survey, however, an additional question asking "Are you of Arab or Chaldean origin?" was included. Although not as broad as a MENA category, the intent was the same.

CONCLUSION

Omission of the Arab/MENA population from research on health disparities undermines rigorous scientific inquiry. The politics surrounding race and ethnic categories must be challenged directly to preserve and advance scientific inquiry. Not only are the experiences and health disparities of the Arab/MENA group being ignored,[29] but keeping this minority population in the White category masks disparities between Whites and other ethnic minority groups. Although institutions refer to the US census to determine how to adequately measure race and ethnicity, the OMB ignored $7.25 million in research by not implementing census recommendations for adding a separate Arab/MENA category.[9]

Given that the reason for the lack of an Arab/MENA category is likely associated with politics as opposed to science, it is imperative that researchers and practitioners take the initiative to include this group in data collection. If health professionals, scientists, policymakers, and program directors are to successfully identify inequities and develop interventions to remedy health disparities, data on the Arab/MENA population must be collected. AJPH

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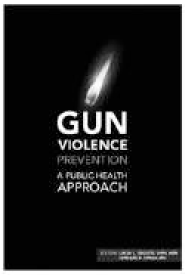

COVID-19 Vaccination: Health Care Organizations' Responsibility and Opportunity

Katie J. O'Conor, MD, Sherita H. Golden, MD, MHS, Mark T. Hughes, MD, MA, Stephen D. Sisson, MD, and Allen Kachalia, MD, JD

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With the authorization of effective vaccines to mitigate the COVID-19 pandemic, the United States saw an unprecedented public health effort to vaccinate the public as quickly as possible. The main approaches—mass vaccination sites, mobile pop-up clinics, and retail pharmacies—were high yield, likely in part because demand initially exceeded the supply, and interested individuals actively sought opportunities for vaccination. Vaccination rates have subsequently plateaued in the United States, with shots now available on a walk-in basis in many areas. However, less than 60% of the US population had completed a primary vaccination series as of November 2021,[1] well below estimates needed to achieve herd protection. The US population remains vulnerable to the proliferation of viral variants, and many hospitals are again becoming overwhelmed by surges in cases.[2,3]

Although some individuals are firmly opposed to undergoing vaccination, large segments of the public continue to experience a wide range of socioeconomic, geographic, and psychosocial barriers to vaccine access. National data suggest that, across all demographics, barriers to vaccine access may be more prevalent than hesitancy.[4] The current and subsequent phases of vaccine delivery—especially with the anticipated need for boosters and pediatric vaccination—must continue to address these barriers with a number of patient-centered location- and relationship-based strategies. Health care organizations are uniquely positioned to lead these efforts because they have the expertise as well as the ethical duty to serve the public health needs of their communities.

OPTIMIZING ACCESS

One intuitive approach has been vaccinating individuals in the primary care settings where they already seek health maintenance and preventive care and where they may already have a trusted relationship with a care provider. To facilitate vaccination, primary care settings may need to adjust clinic staffing, training, equipment, and accessibility infrastructure. Accessibility includes aspects as straightforward as expanded hours or as resource-intensive as mobile care for home-bound patients who are part of primary care practices. Making available single-dose vials of coronavirus vaccines may greatly expand the flexibility in COVID-19 vaccination for low-volume vaccination scenarios common to primary care.[5]

However, 25% of the US population does not have a primary care provider,[6] necessitating another approach via additional health care touchpoints. This includes emergency departments, urgent care, women's health clinics, specialty care, dialysis centers, pharmacies, and laboratory and radiology centers. Although offering vaccination in all of these areas would require significant training and workflow adjustments, these areas represent a prime opportunity to offer vaccination in a convenient setting with trusted providers.[7,8]

A third approach has been needed for those with the greatest socioeconomic, geographic, and psychosocial barriers to health care access—individuals who are also likely at highest risk for infection and adverse outcomes. For these individuals, it is imperative to meet them where they are, physically and behaviorally. Continuing to build innovative approaches to maximize access and safety is essential.

Population-centered approaches may include colocating with substance use and syringe exchange programs, housing shelters, safe houses, and prison clinics, as well as at schools, street fairs, barbershops, churches, food banks, and other locations where individuals receive support services outside of the traditional health care architecture.[9–11]

FOSTERING PATIENT-CENTERED VACCINATION

A relationship-based approach includes tailoring messaging to different groups and establishing rapport with each unique community. Some messaging needs may be general, such as vaccine safety and efficacy relative to COVID-19 infection risks and that vaccination is free, but other communication needs must be population-specific. For immigrant and non–English-speaking populations, the assurance of legal safety and the availability of language services support remain critical.[12] For complex populations including individuals with histories of substance use, mental health challenges, violence survival, or homelessness, vaccination initiatives should leverage clinicians trained in addressing the medical and psychosocial challenges of these groups and integrating with their essential wraparound services.[13,14] For individuals with disability and accessibility needs, communications may involve explicit description of physical and sensory accommodations and medical expertise available on-site. For many populations, including younger populations with lower vaccination rates, endorsement by trusted leaders, public role models, local peers and allies, and affinity groups may be more compelling.[15–17] For others, less is more when it comes to messaging—strong public pressure and behavioral incentives may have a paradoxical deterrent effect;[18,19] thus, any community event that brings people together is an opportunity to incorporate vaccination into an engaging and nonthreatening environment.

The relationship-based approach also includes reliability, predictability, and sustained commitment to the constituent populations until the need for vaccines has been exhausted. This includes offering walk-up clinic options on a widely publicized, routine schedule. This includes reliably showing up for communities with barriers to access. This includes returning regularly to mobility-limited individuals for all needed vaccine doses. Overall, this includes being present and continuing to be present in a community until everyone is ready and able to receive vaccination.[20,21]

Although vaccination rates have slowed, the early success in vaccinating hard-to-reach populations for their initial round of vaccination involved a coordinated multidisciplinary effort leveraging health care organizations, public health agencies, advocacy groups, community collaboration, and deliberate strategy. The heterogeneous population in the United States faces an array of barriers that necessitate a variety of patient- and population-centered interventions tailored to the barriers that have delayed or prevented them being vaccinated thus far. As we introduce new eligible populations, revisit prior populations for boosters, and continue to reach the remaining unvaccinated individuals, health care organizations should maintain a collaborative, committed, strategic effort to reach individuals with barriers to access. Furthermore, developing these uniquely tailored health care delivery strategies can serve as a model for improving other public health and preventive care engagement across all populations going forward.

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K. J. O'Conor was the primary author, conceptualized the manuscript, prepared the initial draft, and revised and finalized the manuscript for submission. A. Kachalia contributed to conceptualization and provided substantive comments, critical revisions, and edits to the manuscript drafts. S. H. Golden, M. T. Hughes, and S. D. Sisson provided substantive comments, critical revisions, and edits to the manuscript drafts. All authors gave final approval of the version to be published.

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The authors have no conflict of interest to report.

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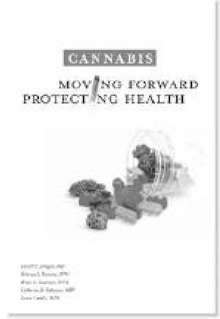

COVID-19 Outbreaks Associated With Youth Club Sports: Maricopa County, Arizona, September–November 2020

Ariella P. Dale, PhD, MPH, Sarah E. Scott, MD, and Rebecca Sunenshine, MD

The Maricopa County Department of Public Health in Arizona investigated three COVID-19 outbreaks associated with club sports, two in tournaments and one in a hockey league. During September through November 2020, 195 team-associated and 69 secondary household contact cases were identified among 2093 athletes, coaches, and staff members; the team attack rate ranged from 6% to 72%. Outbreaks occurred during high community transmission periods in Maricopa County. Identification of contacts and characterization of prevention strategies were challenging because of limited cooperation from athletes, families, and staff. (*Am J Public Health*. 2022;112(2):216–219. https://doi.org/10.2105/AJPH.2021.306579)

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In June 2020, approval for gatherings of more than 50 people in Arizona was delegated to local (municipal or county) authorities, including approval of club sports play as detailed in Executive Order 2020-43.[1] Tournaments occurred nearly every weekend in Maricopa County during September through December 2020. By November 2020, the Maricopa County Department of Public Health (MCDPH) was reporting high community transmission of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, with weekly case rates above 100 per 100 000 population and test positivity rates of 10% or higher.[2,3]

INTERVENTION

In November, MCDPH investigated three COVID-19 outbreaks associated with youth club sports. Two were associated with three-day tournaments: a 16-team baseball tournament and an 81-team basketball tournament. The third was associated with a 79-team regional youth club hockey league spanning multiple weeks. To investigate, we reviewed rosters of athletes, coaches, and staff involved in the tournament or league play to identify cases among these individuals in the statewide communicable disease database and developed a questionnaire to collect additional information to guide public health recommendations in this setting.

PLACE AND TIME

Our investigation focused on a 16-team youth baseball tournament occurring from October 22 to 25, 2020; an 81-team youth basketball tournament occurring from October 23 to 25; and regional hockey league play occurring from September 1 to November 30. All play occurred in Maricopa County.

PERSON

Council for State and Territorial Epidemiologists interim COVID-19 case definitions for confirmed and probable cases were used as a foundation for each of the definitions included here.[4] A team-associated case was defined as a confirmed or probable COVID-19 case in an athlete, coach, or staff member who engaged in tournament or league play during their 10-day infectious period or received a positive SARS-CoV-2 polymerase chain reaction or antigen test result within 14 days of play. An outbreak was defined as two or more team-associated cases among individuals who engaged in the same club sports activity (on the same team or in the same tournament) and participated during their 10-day infectious period or received a positive SARS-CoV-2 test result within 14 days of exposure to the index case patient. Secondary cases were laboratory-confirmed or probable COVID-19 cases among household contacts of patients with team-associated cases.

PURPOSE

We describe these outbreaks to understand SARS-CoV-2 transmission in sports. Outbreaks occurred during a period with a high rate of community transmission and a county mask requirement. Team-associated cases might have contributed to increased community transmission; previous investigations have revealed transmission in high-contact sports with infrequent masking and physical distancing.[5,6] Understanding what prevention strategies decrease transmission in club sports might inform future decision-making to allow routine practice and competition.

After identification of the outbreak, MCDPH provided isolation and quarantine guidance to affected athletes, coaches, staff, and contacts. Close contacts were advised to self-monitor for signs and symptoms of COVID-19 and where to seek testing. MCDPH also advised teams and tournament organizers of infection prevention strategies including masking, physical distancing, and the importance of testing, isolation, and quarantine to prevent further transmission.

IMPLEMENTATION

Rosters were obtained from the tournament organizer or publicly available Web sites and compared with the statewide communicable disease database for COVID-19 cases, to which data on all positive COVID-19 tests are submitted. Secondary cases were identified through reviews of available data by shared residential addresses. Team attack rates, including athletes and coaches, were calculated by team in each tournament and hockey league.

We developed a questionnaire to collect data on testing dates and results for athletes, coaches, and their household contacts; prevention strategies employed in and out of play; travel; and social behaviors outside of play (see the appendix, available as a supplement to the online version of this article at http://www.ajph.org). Response rates were calculated for individuals with accessible contact information. MCDPH partnered with the Arizona Department of Health Services to notify other Arizona counties and the out-of-state jurisdictions of non-Maricopa teams that participated in tournament play. Other Arizona and out-of-state jurisdictions were asked to report cases among athletes, coaches, staff, and attendees. No cases were reported; therefore, the scope of our investigation was limited to Maricopa County.

EVALUATION

MCDPH investigated outbreaks in youth sports including baseball, basketball, and hockey during November 2020.

Baseball Tournament Outbreak

A total of 109 individuals (101 athletes and eight coaches) from seven Maricopa County–based teams participated in the tournament (Table 1); among these individuals, seven (6.4%) team-associated cases (all among athletes) were identified. Eleven secondary cases were identified. Five of the seven (71%) teams reported one or more team-associated cases; the average attack rate among these teams was 9% (range: 6%–19%). Ten of 81 coaches and athletes contacted (12%) completed the questionnaire.

Basketball Tournament Outbreak

An examination of rosters from 31 of 35 (89%) Maricopa County–based teams revealed 421 individuals (390 athletes and 31 coaches) who participated in the tournament (Table 1); 16 (3.8%) team-associated cases (15 involving athletes and one involving a coach) were identified. No secondary cases were identified. Eight of the 31 (25.8%) teams reported one or more cases; the average attack rate among these teams was 14% (range: 7%–25%). Of the 421 athletes and coaches who participated in the tournament, six (less than 1%) completed the questionnaire.

Hockey Team Outbreak

Among the 1564 athletes, coaches, and staff associated with 79 Maricopa County–based teams (Table 1), 172 (11.0%) team-associated cases (133 among athletes, 32 among coaches, and seven among staff) and 58 secondary cases were identified. Forty-one percent of teams (32 teams) had an outbreak (two or more cases); 77.2% (61 teams) had more than one case. Among the 32 teams that had an outbreak, the average attack rate was 22.5% (range: 8%–72%).

ADVERSE EFFECTS

The outbreak investigations by MCDPH yielded no adverse effects.

SUSTAINABILITY

Implementation of traditional public health investigations to inform an

TABLE 1— Characteristics of Outbreaks in Two Youth Sports Tournament and a Hockey League: Maricopa County, Arizona, September–November 2020

Characteristic	Sport (No. of Teams)		
	Baseball[a] (16)	Basketball[b] (81)	Hockey (79)
Dates of tournament/league play	Oct 22–25	Oct 23–25	Sep 1–Nov 30
Maricopa County team rosters reviewed, no. (%)	7 (100)	31 (89)	79 (100)
Team-associated cases[c,d]			
Athletes, no. (%)	7 (6.9)	15 (3.8)	133
Coaches, no. (%)	0 (0)	1 (3.2)	32
Staff, no.	. . .	. . .	7
Average attack rate, % (range)[e]	9 (6–19)[f]	14 (7–25)[g]	23 (8–72)
Total, no. (%)	7 (6.4)	16 (3.8)	172 (11.0)
Test dates	Oct 13–Nov 11	Oct 21–Nov 8	Sep 28–Nov 27
Teams reporting ≥ 1 case, no. (%)	5 (71)[f]	8 (26)[g]	61 (77)
Individuals completing questionnaire, no. (%)	10 (12)	6 (1)	. . .
Secondary cases			
Household cases, no.[h]	11	. . .	58[i]
Test dates	Oct 24–Nov 13	. . .	Sept 28–Nov 27

[a] Nine additional teams participated in the tournament from outside of Maricopa County.
[b] Forty-six additional teams from nine states outside of Arizona participated in the tournament.
[c] Confirmed or probable cases associated with an outbreak of COVID-19 in the youth sport.
[d] A team-associated case is a confirmed or probable COVID-19 case in an athlete, coach, or staff member who engaged in the club sports activity and participated during their 10-day infectious period or tested positive for SARS-CoV-2 within 14 days of play.
[e] Average attack rate range represents only teams with outbreak cases, including athletes and coaches.
[f] Among seven Maricopa County teams.
[g] Among 31 Maricopa County teams.
[h] Secondary outbreak cases are confirmed or probable COVID-19 cases in household contacts of team-associated cases.
[i] Among 32 (41%) teams with two or more cases.

effective response in these settings was hampered by low questionnaire response rates, which was anecdotally due to perceived negative consequences such as the need to isolate or quarantine. At least two media articles documented COVID-19 testing hesitancy among athletes' parents or guardians, as reported on social media,[7,8] which could have led to underreporting of team-associated and secondary cases. Successful strategies to support safe sports play include regular testing of athletes and coaches, particularly in the case of unvaccinated participants.[9] Clear guidance and communication among tournament organizers, teams, and attendees about the importance of participating in a public health investigation could help enable a more effective public health response.

Several actions were taken during the MCDPH investigations to enhance efficiency on the basis of newly acquired data and experience. For example, after the tournament investigations, MCDPH concluded that traditional outbreak and case investigation strategies were inefficient and, when investigating the hockey league outbreaks, shifted to the use of publicly available information to perform case-finding activities, identify outbreaks, and deliver public health recommendations to coaches of outbreak-affected teams. During these investigations, MCDPH was alerted to an upcoming hockey tournament and, through active case finding, identified three teams on the tournament schedule with COVID-19 outbreaks whose tournament play would fall within the recommended quarantine period. MCDPH contacted team directors to recommend quarantine for affected teams, including not competing in the tournament. Two of the three teams complied with these public health recommendations.

PUBLIC HEALTH SIGNIFICANCE

MCDPH investigated three COVID-19 outbreaks associated with youth club sports play. During September through November 2020, 195 (9.3%) team-associated COVID-19 cases were identified among 2093 athletes, coaches, and staff members who participated in two club sports tournaments and a youth club hockey league; 88% of cases (172 cases) were associated with the club hockey league. An additional 69 secondary cases were identified among household contacts of patients with team-associated cases. These investigations highlight the need for public health officials and tournament organizers to collaborate on and communicate public health prevention strategies before and during club sports events, including communication of the importance of vaccination among participants 12 years or older, physical distancing and mask use among unvaccinated individuals, regular testing of unvaccinated individuals, and participation in contact tracing activities.[10]

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A. P. Dale was the lead author. A. P. Dale and S. E. Scott worked on data abstraction under the guidance of R. Sunenshine. A. P. Dale performed the analysis. S. E. Scott and R. Sunenshine provided editorial oversight. All of the authors contributed significantly to the article and the work described.

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CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

HUMAN PARTICIPANT PROTECTION

This research was reviewed by the Centers for Disease Control and Prevention (CDC) and was conducted in a manner consistent with applicable federal law and CDC policy.

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Targeting Equity in COVID-19 Vaccinations Using the “Evaluating Vulnerability and Equity” (EVE) Model

Benjamin W. Weston, MD, MPH, Zachary N. Swingen, BS, Shannon Gramann, BS, and Dan Pojar, BSEMS, FP-C, NRP

The COVID-19 pandemic has highlighted racial and ethnic disparities, most recently in vaccine administration. The EVE (Evaluating Vulnerability and Equity) Model combines a community’s vulnerability with vaccination rates to enhance the equity of vaccine distribution in an intentional, targeted manner. When applied to Milwaukee County, Wisconsin, two extreme categories of vaccination status were identified to aid in resource allocation and messaging: populations with high vulnerability and low vaccination levels, and, conversely, those with low vulnerability and high vaccinations levels. (*Am J Public Health*. 2022;112(2):220–222. https://doi.org/10.2105/AJPH.2021.306585)

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As the landscape of the COVID-19 pandemic response has shifted to vaccination, inequities have persisted in the provision of this critical resource.[1] In particular, higher-vulnerability communities—including those of color, of lower income, and with less technological, health care, and transportation connectedness—have experienced a decreased ability to become vaccinated.

INTERVENTION

Building on the fundamental structure of the previous SAFER Model, the EVE (Evaluating Vulnerability and Equity) Model has been developed and implemented to understand the interconnectedness of vulnerability and vaccination rates.[2]

PLACE AND TIME

The EVE Model output presented here was based on an 86-day period (December 15, 2020–March 10, 2021) in the 296 census tracts of Milwaukee County, the largest county in Wisconsin. In practice, the model can be updated regularly to show dynamics in vaccination rates.

PERSON

The EVE Model was applied to residents of Milwaukee County. The county has a population of approximately 946 000, with a racial and ethnic breakdown of 50.6% White, 27.2% African American, 15.6% Hispanic, 4.7% Asian, 1.0% American Indian or Alaska Native, and 2.8% two or more races.[3] During the period evaluated, EVE Model calculations were based on approximately 146 466 individuals having received first doses of the vaccine—about 20% of the eligible population (aged ≥ 16 years).

PURPOSE

The EVE Model aims to provide a geographic understanding of inequities in vaccination rates in vulnerable communities. By targeting vaccine supply, messaging, and resource mobilization to communities with high vulnerability paired with low vaccination rates, disparities in vaccination can be directly addressed to enhance the equity of vaccine distribution in an intentional, targeted manner.

IMPLEMENTATION

The EVE Model (Figure 1) incorporates a four-quadrant design to categorize geographic areas based on two variables: vaccination rate and social vulnerability. This results in four categories: Low Vaccination/Low Vulnerability (LVa/LVu), Low Vaccination/High Vulnerability (LVa/HVu), High Vaccination/Low Vulnerability (HVa/LVu), and High Vaccination/High Vulnerability (HVa/HVu).

On each of the gradients composing the four-quadrant model, a midpoint divides the lesser from the greater quadrants, creating the general color categorization. Then, each quadrant is subcategorized into four further quadrants to provide 16 subgroupings for

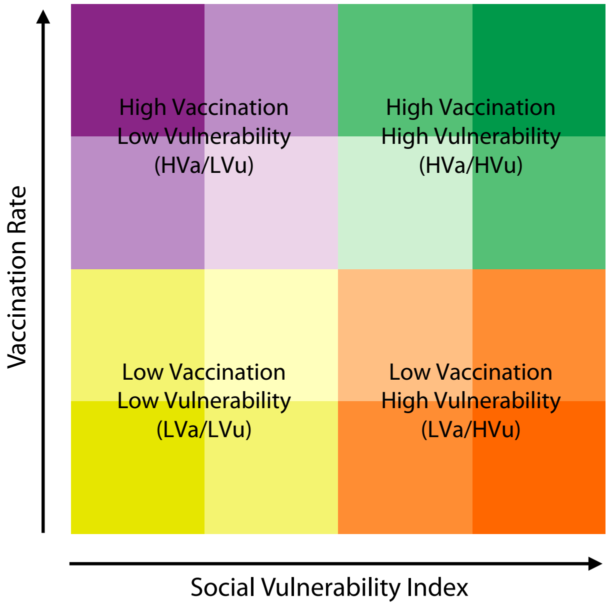

FIGURE 1— **The EVE (Evaluating Vulnerability and Equity) Model for Understanding the Interconnectedness of Vulnerability and Vaccination Rates**

the model overall to more clearly differentiate extremes in the variables.

Three classifications were developed for variable stratification. In all classifications, social vulnerability was stratified on the basis of the Centers for Disease Control and Prevention (CDC)-defined quartiles of the Social Vulnerability Index (SVI), with breakpoints at 0.25, 0.5, and 0.75.[4] This index is based on 15 census variables—such as poverty, housing, and transportation access—to assess the vulnerability of a community. The quartile breakpoint stratifications of the vaccination rate variable differed between classifications. The outlier classification ordered census tracts by vaccination rate, and the median value was used as a breakpoint to split the tracts into two groups (high or low). An outlier test (commonly called the "1.5 x IQR Rule") was then used to identify any tracts with particularly high or low vaccination rates, which were separated into the highest or lowest quartile categories. The quartile classification ordered tracts by vaccination rate and separated them into four groups containing an equal number of tracts (also known as quantiles). This classification forces half of the census tracts into the highest and lowest categories based on vaccination rate, which may make the values appear more extreme than they are relative to the rest of the county. The goal-oriented classification stratified tracts based on percentage of the population receiving at least one dose (0%–19%, 20%–49%, 50%–79%, and 80%–100% for each quartile).

EVALUATION

The maps and quartile (as well as subquartile) breakdowns of census tract distribution are shown in Figure A (available as a supplement to the online version of this article at https://www.ajph.org). The widest distribution of census tracts was found in the quartile classification, which had at least one census tract in each of the 16 subquartiles. The least distribution, in part due to the application of this model early in the vaccination effort, was with the goal-oriented classification. The outlier classification fell between these other two classifications, with few census tracts falling into the most extreme lowest and highest levels of vaccination stratification.

Overall, the outlier classification, used as our default view on the public facing dashboard, highlighted the disparities in the community, placing the majority of census tracts in either the HVa/LVu (purple, 110 tracts, 37.2%) or LVa/HVu (orange, 138 tracts, 46.6%) quadrants. This dichotomy in vaccine administration based on SVI demonstrated and geomapped the stark disparities in our community. Although the lowest vulnerability group had 91.7% (54/60) of census tracts above the median in vaccination rates, the highest vulnerability group had 90.2% (111/123) of census tracts below the median for vaccination rates.

ADVERSE EFFECTS

We are not aware of any adverse effects of this model. Rather than stigmatizing any communities, we hope that the EVE Model will bring further resources to vulnerable, underserved communities to enhance their overall health.

SUSTAINABILITY

The EVE Model may be fairly easily replicated by other communities of varying resources and sizes. As SVI is publicly available, provided a community has access to geographic-level vaccination rates, simple calculation may be performed to replicate this model in regions of any size, from county to state and beyond.

PUBLIC HEALTH SIGNIFICANCE

The EVE Model provides a simple view for both decision-makers and the general public to understand disparities in COVID-19 vaccine distribution. The dichotomy of high versus low SVI, compared with high versus low vaccination rates, allows for the clear highlighting of communities most at risk: those with LVa/HVu. High-SVI communities, often composed of populations of color, are inherently more likely to be left behind by health care initiatives, and the coupling of this metric with low vaccination rates can help to further pinpoint areas of greatest need.

The three views of the EVE Model may be used for different community aims and decisions. The outlier classification is better suited to understanding vaccination efforts across the county as a whole, as well as identifying any extreme disparities in vaccination rates. The quartile classification may be useful in identifying tracts of interest when few outliers are present in the data. Finally, the goal-oriented classification was designed to monitor progress toward the goal of full vaccination for 80% of the currently eligible population.

Although the EVE Model in this situation is used for determination of vaccine equity, the four-quadrant design of geomapping a health variable with the SVI may have applications in other equity-focused campaigns to guide resource allocation and messaging. Examples may include rates of bystander cardiopulmonary resuscitation in cardiac arrests, traumatic injuries in a population, food deserts in a community, or other disease burdens that may not initially be considered related to social vulnerability. Indeed, the SVI has been linked to many adverse health conditions, including pediatric trauma, heat-related health outcomes, and obesity rates.[5–7]

When applied to Milwaukee County, the model demonstrated substantial inequities in vaccine distribution between the low- and high-vulnerability groups. Specifically targeting disparities in transportation availability, health care access, and health literacy, the county expanded the availability of vaccination clinics in the LVa/HVu communities while simultaneously launching a door-to-door campaign to provide information and vaccine access, thereby increasing vaccine uptake.

The EVE Model provides a clear geomapped view of disparities in vaccination rates when considering a community's vulnerability. This model provides a roadmap for targeting vaccination resources, interventions, and messaging to communities most in need. AJPH

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All authors contributed to the model development and implementation, as well as manuscript development.

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CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

HUMAN PARTICIPANT PROTECTION

This study was reviewed by the Medical College of Wisconsin institutional review board and determined to not be human participant research.

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Developing a Case Investigation and Contact-Tracing System in Puerto Rico, 2020

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We present a record of events that led to the creation of the Puerto Rico Case Investigation and Contact-Tracing System (CICTS) to monitor and control the spread of severe acute respiratory syndrome coronavirus 2 in Puerto Rico. The development of the CICTS is a significant step toward establishing a comprehensive infectious disease surveillance system in Puerto Rico. Furthering the development of a CICTS infrastructure is critical in the response against future emerging infectious diseases in the region.

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To reduce the spread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in Puerto Rico, we developed a CICTS that we began using in April 2020. The creation of the technological infrastructure and protocols for this system was a collaborative effort involving the Puerto Rico Public Health Trust, municipality mayors, the Puerto Rico Department of Health, private organizations, and nongovernmental organizations.[1,2]

We developed a case investigation and contact-tracing system (CICTS) that identified and isolated patients who tested positive for SARS-CoV-2 across Puerto Rico to establish quarantine with contacts and reduce community transmission. We conducted interviews that we used to develop profiles of positive cases and their contacts. Also through the CICTS, we taught the community about prevention practices and generated daily publicly available transmission statistics. These digitally collected case profiles are the basis for the CICTS's real-time analysis and reporting system.

INTERVENTION

We developed a standard operating procedure to achieve the surveillance system's objectives (https://bit.ly/3Gs9axl), which included the following topics: team composition, case investigation, contact-tracing, data architecture, and reporting system.

PLACE AND TIME

An investigator with the CICTS contacted residents of 12 Puerto Rican municipalities from April to November 2020.

PERSON

The population covered by this system included participants aged 1 year and older (Table 1). For those younger than 21 years, we conducted interviews with the adult responsible for the minor.

PURPOSE

The purpose of the CICTS was to provide a case investigation and contact-tracing mechanism that could provide real-time, municipality-specific SARS-CoV-2 infection statistics to help reduce the chain of viral transmission in Puerto Rico.

IMPLEMENTATION

The contact-tracing team was composed of a supervisory epidemiologist, an administrative coordinator who handled referrals, a case investigator who conducted initial interviews, a contact tracer who conducted follow-up interviews, and a call center operator. All team members underwent standardized Health Insurance Portability and Accountability Act (HIPAA) compliance and COVID-19 case investigator and

TABLE 1— **Demographic Distribution of SARS-CoV-2 Cases Interviewed by the Case Investigation and Contact-Tracing System: Puerto Rico, June 1, 2020–November 2020**

Variable	No. Cases	Population	Proportion (95% CI)
Gender			
Female	1426	2660	53.61 (51.71, 55.50)
Male	1233	2660	46.35 (44.46, 48.25)
Age, y			
1–9	171	2691	6.35 (5.43, 7.28)
10–19	284	2691	10.55 (9.39, 11.71)
20–29	450	2691	16.72 (15.31, 18.13)
30–39	476	2691	17.69 (16.25, 19.13)
40–49	438	2691	16.28 (14.88, 17.67)
50–59	382	2691	14.20 (12.88, 15.51)
60–69	258	2691	9.59 (8.48, 10.70)
70–79	175	2691	6.50 (5.57, 7.43)
≥ 80	57	2691	2.12 (1.57, 2.66)

Note. CI = confidence interval; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

contact tracer training (https://bit.ly/3EESGly; https://bit.ly/3Iv7pBX).

In the CICTS, we investigated three types of cases: (1) a confirmed case, defined as a resident of a municipality under surveillance who was interviewed by a CICTS case investigator and received a positive molecular reverse transcription–polymerase chain reaction (RT–PCR) test result for SARS-CoV-2;[3] (2) a probable case, a person tested positive for SARS-CoV-2 antibodies but did not have a positive RT–PCR test; and (3) a suspect case, a person who was in contact with a confirmed case and was identified during the confirmed case's investigation. We reclassified suspect cases who were interviewed and later identified as receiving a positive RT–PCR test result as confirmed cases.

An investigation began when a positive SARS-CoV-2 RT–PCR result was obtained from either a collaborating laboratory or the Puerto Rico Department of Health, at which time the investigator conducted a telephone interview using a standardized questionnaire (Figure 1). In this interview, the investigator informed the individual of their test result, gave them advice regarding their current health status, and provided them with the appropriate public health quarantine and isolation guidelines and contact-tracing procedures (https://bit.ly/3GjMfog). The investigator also collected personal identifiers, demographics, geographical location, flu-like symptoms, chronic conditions, use of medical services, and need for assistance to maintain quarantine or isolation.

When identifying suspected cases, the investigator interviewed the individual and collected information on those with whom the individual lived or had close contact and locations the suspected patient recently visited. Suspected patients were instructed to observe a 14-day quarantine.

We gathered data using a Puerto Rico Public Health Trust Information Technology Department questionnaire guided by recommended standardized design features (https://bit.ly/3Gs9axl). The Puerto Rico Public Health Trust stored these data in a HIPAA-compliant SQL-Server database (Microsoft, Redmond, WA) containing three tables used to (1) record cross-sectional data, including demographic information; (2) create a person–period data structure in which each person had multiple records, one for each interview; and (3) collect patients' geographical information for cluster analyses.[4] The CICTS team used this table format to collect information from follow-up interviews, allowing the team to record changes in case status and evaluate compliance with quarantine and isolation recommendations.

The CICTS used a Web-based reporting system that helped teams coordinate case investigation, contact tracing, and quarantine establishment and compliance activities as well as produce updated transmission statistics. The reporting system provided daily access to various reports via a virtual private network and a Web-based link.[5]

EVALUATION

Several challenges warrant discussion. We implemented the CICTS quickly in response to COVID-19, and the questionnaire could neither be validated before use nor evaluated in the field, possibly introducing nondifferential misclassification. The quick questionnaire rollout also meant that some potentially valuable questions were excluded.

The CICTS should not be considered a representative sample of its underlying population because it includes only those willing to be tested for SARS-CoV-2 and interviewed. For this type of surveillance data to be generalizable, there must be support to test and trace the entire coverage population.

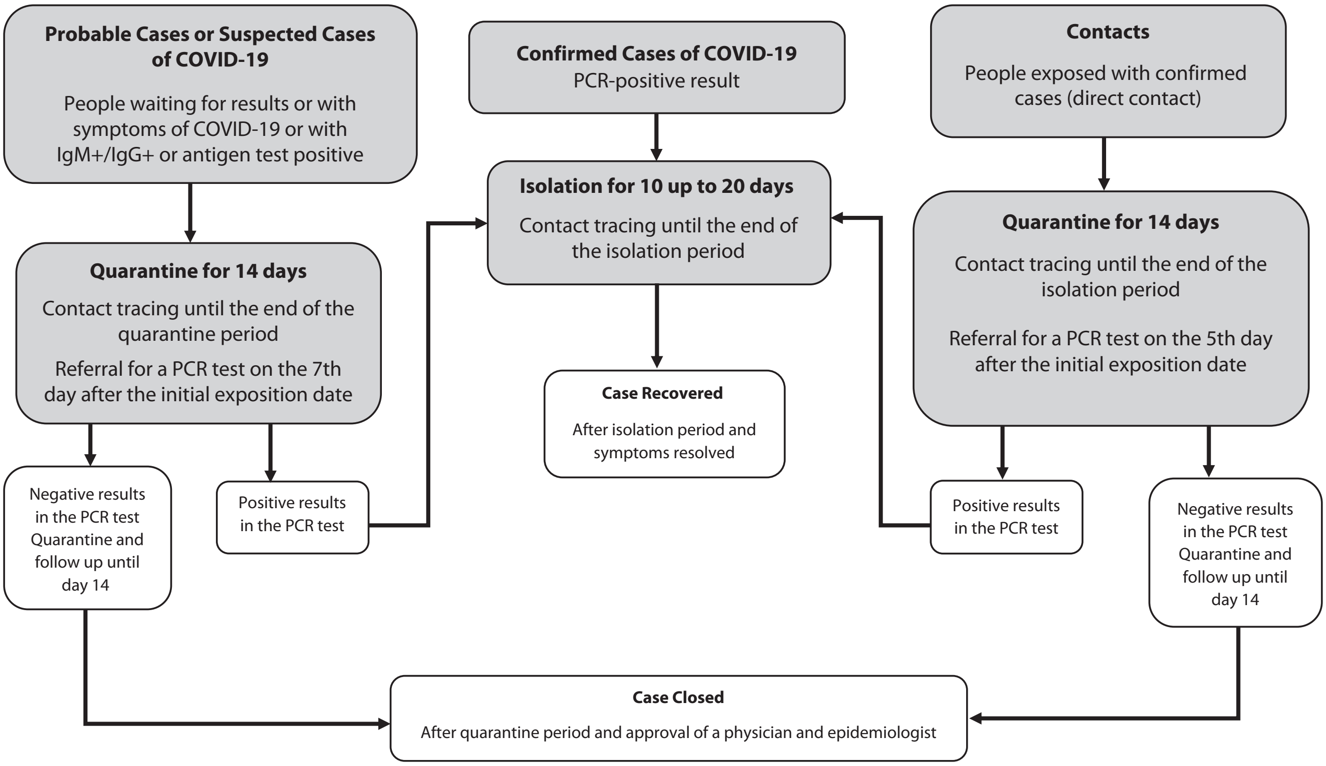

FIGURE 1— **Diagram of the Case Investigation and Contact-Tracing Process: Case Investigation and Contact-Tracing System, Puerto Rico, April–November 2020**

Note. PCR = polymerase chain reaction.

The availability of RT–PCR tests fluctuated during the pandemic, and it was not possible to test everyone contacted or who requested testing. When this occurred, CICTS members recommended a 14-day quarantine. Additionally, not all laboratories reported their results to the CICTS with continuity because of technological limitations, lack of infrastructure, third-party data bridge blockages between the laboratory and the CICTS, or Puerto Rico Department of Health technical regulations.

Of 26 897 interviews with 7388 unique individuals, we classified 2691 as confirmed cases. Although this represents a substantial surveillance and control effort, no formal evaluation of these efforts was possible. Resources limited the reach of CICTS's surveillance coverage, limiting its comparability to population-level incidence rates over this period.

The CICTS culminated efforts in November 2020. The government of Puerto Rico received funds to implement a new SARS-CoV-2 surveillance system, called SMICRC (Sistema Municipal de Investigación de Casos y Rastreo de Contactos); shortly after, the Puerto Rico Department of Health ordered CICTS activities to halt. On November 28, 2020, the SMICRC project coordinator requested that all municipalities use the SMICRC for future surveillance activities, forcing the cancellation of CICTS efforts.

ADVERSE EFFECTS

We found no adverse effects as a result of this intervention.

SUSTAINABILITY

An effective disease surveillance system is essential for an organized response to public health emergencies such as the COVID-19 pandemic. The successful reduction of viral transmission requires strict surveillance and prompt isolation of positive cases. The CICTS addressed this need and created a sustainable surveillance architecture via the standardized training of contact-tracing teams, a focus on collaboration, standardized data collection using standard operating procedures, and the creation of a Web-based, real-time reporting and analysis system.

PUBLIC HEALTH SIGNIFICANCE

The CICTS fulfilled an urgent need to establish a surveillance system in Puerto Rico at the height of the COVID-19 pandemic. The inclusion of more than 7000 individuals in the CICTS between April and November 2020 was a major public health undertaking. The CICTS was an efficient and replicable surveillance model; it was established quickly and collaboratively, used standardized training and data collection, and employed Web-based real-time analysis and reporting.

The CICTS successfully conducted surveillance and control efforts to reduce community transmission of COVID-19. Many features make this model efficient and replicable, including standardization of procedures and real-time analysis and reporting. The implementation of the CICTS was a significant step toward establishing a comprehensive infectious disease surveillance system in Puerto Rico, which is essential for future public health emergencies. AJPH

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CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

HUMAN PARTICIPANT PROTECTION

All collected data were stored in a SQL-Server database that was Health Insurance Portability and Accountability Act compliant, and the data were not linked to participants. This work did not directly use any data from human participants of the Puerto Rico case investigation and contact-tracing system.

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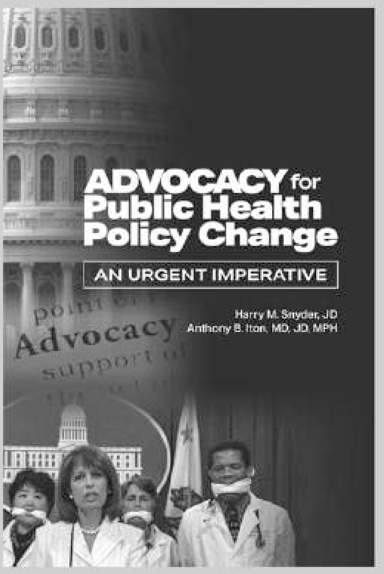

Vaccine Resistance and History in the Land of Liberty

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See also Colgrove and Samuel, p. 234.

James Colgrove is one of the nation's most important historians of vaccine politics, and his scholarship always speaks compellingly to issues related to vaccination policy and ethics.[1] He and Sara J. Samuel have produced an article that insightfully reveals how and why history truly matters as we seek to explain the wide scope, and the tenacity, of vaccine refusal throughout US history. Indeed, the COVID-19 pandemic arguably makes this history matter more in our current moment than at any other time in the past.

Simply put: we cannot explain the current widespread and deadly resistance in the United States to the Pfizer/BioNTech, Moderna, and Johnson and Johnson vaccines—and the various mandates associated with these vaccines—without understanding the long roots of outright opposition to vaccination mandates (along with vaccination itself) throughout American history. In this issue of *AJPH*, Colgrove and Samuel rightly point to the centrality of the period from the 1880s to the 1920s, when vaccination dissidence was at its height and when discourses of freedom and rights were central to opposition to modern public health policies.

Indeed, the origin of US controversies over immunization dates back even further, to exactly 300 years ago, when famed Puritan minister Cotton Mather and physician Zabdiel Boylston introduced inoculation against smallpox to Boston, Massachusetts, in 1721. The popular rebellion against the new medical procedure was intense, with vicious attacks emanating from both sides of the debate; the most explosive moment was an assassination attempt, by bomb, on Mather. The Puritan cleric blamed the resistance on Satan, but in fact issues of freedom—including arguments from Benjamin Franklin's brother, who was seeking to establish a free press—fueled the opposition to inoculation even in such a fervently religious environment so long ago.[2]

Colgrove and Samuel's focus on the power of ideas about freedom and rights is thus highly significant and should be of substantial interest to policymakers. The authors could, however, have strengthened their argument if they had compared their thesis with other possible explanations for vaccine resistance in American history. To be sure, there are various others worthy of consideration. The most prominent may involve an emphasis on ignorance, fraud, and deception; authors as prominent as Paul Offit rely on such themes in their historical narratives.[3,4] Or one could, I think much more productively, focus on the ways that specific historical moments and the political ideals and social movements that they generate in turn generate distinctive types of vaccine resistance. Conis's *Vaccine Nation* is, to me, the most outstanding example of this type of scholarship.[5]

Moreover, populism is a particularly rich—and especially in this moment quite resonant—concept to wrestle with in exploring and explaining vaccine resistance. Populism helps illuminate the frequent detestation, or at least substantial distrust, of experts within vaccine resistance movements; it also shines a spotlight on corporate power and citizen disempowerment. Above all, populism inspires us to recognize that conceptions and practices of democracy (even the seeming oxymoron of a democratic science) can be crucial in different varieties of vaccine dissidence, on both the right and the left sides of the political spectrum. After all, classic populist questions such as "how do The People rule?" and "who are the enemies of The People?" do not just matter when it comes to banking and financial disempowerment. They are, and always have been, intimately connected to the realms of the body, medicine, and public health as ordinary citizens have sought to keep or gain autonomy against (as the narrative goes) uncaring and dominating elites.[6,7]

By no means are any of these explanations contrary to, or at odds with, Colgrove and Samuel's mode of analysis emphasizing freedom and rights. Yet I would argue that we need more than one explanatory variable both to do good history and to point in a full and complex way toward the lessons of that history. To be sure, we always need to be careful about telescoping the present into the past. If we commit that crime of presentism, we come up only with our own reflections in the mirror instead of genuinely listening to what the people of the past might whisper to us if we were really listening. That said, there are patterns in the past, and a careful and disciplined set of historical perspectives that builds off Colgrove and Samuel's article would richly illuminate our most urgent concerns.[8]

I also wish that the authors had been more forceful in offering policy ideas, and even prescriptions, that might flow out of their historical analysis. In their conclusion, they correctly note that "[g]iven the grave public health threat posed by COVID-19 and the safety and efficacy of the available vaccines, compulsory measures are well justified from the standpoints of ethics, policy, and law" (p. 240). They are also right on the mark when they declare that "current efforts to protect public health will require confronting questions of freedom and rights, which remain as resonant—and as contentious—as they were during the birth of organized antivaccination activism more than a century ago" (p. 240).

Recognizing this paradox is quite valuable, especially at a moment when most elites—both inside and outside the public health world—are often more intent on simply condemning, rather than understanding (much less engaging), vaccine resisters.[9] Perhaps putting such paradoxes on the table is, ultimately, as much as historians are able to or should do. Indeed, I myself have no particular solutions to this difficult and perhaps insoluble problem.

Yet we arguably should want to use our explorations of history to tell us something deeper than the true (and crucially important) fact that the past points to the intractability of vaccine resistance. If this is all that history tells us, then the only real lesson we will learn is one that we likely already know: that we will, perhaps tragically, never be able to move toward a just and effective resolution of the fundamental paradox of a collectivist-oriented public health in a land of individual liberty.[10]

So what does "history" reveal here, or at least strongly predict? Foremost, COVID vaccine rates very well may—no, indeed are likely to—remain lower than necessary to expeditiously tame the pandemic. Colgrove and Samuel have implicitly, but compellingly, pushed us to reckon with this dismal picture. Yet another lesson might be that Americans have always been a bumptious, raucous, and contentious people, most (but, as we have recently painfully learned, not all) of whom are committed to robust democracy in all areas of their lives. Part of the resolution of the COVID crisis, then, may well involve public health practitioners more fully recognizing the strength of that democratic past as they formulate the most effective possible policies and practices in the polarized present. AJPH

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Understanding Vaccine Hesitancy and Refusal Through a Rights-Based Framework

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See also Colgrove and Samuel, p. 234.

Medical liberty can be thought of as the patient's "right to choose their preferred treatments without government interference" or "freedom of therapeutic choice."[1] As Colgrove and Samuel explore in their article "Freedom, Rights, and Vaccine Refusal: The History of an Idea" in this issue of *AJPH* (p. 234) medical liberty has shaped the American response to public health initiatives throughout the centuries, including diphtheria and smallpox vaccinations. Colgrove and Samuel are right to highlight the importance of medical liberty in American healthcare thinking, especially when it comes to vaccines. Medical liberty is a core tenet that ties the Anti-Vaccination League of America and the Anti-Vaccination Society of America of the late 19th century to current antivaccination groups on Facebook and state attempts to ban mask mandates.

Colgrove and Samuel focus on the period between the 1880s and 1920s as a formative period for American vaccine resistance. But their exploration of medical liberty, including rights and freedom-based arguments, can be applied to other significant vaccination conflicts, especially regarding childhood vaccines. Applying Colgrove and Samuel's analysis to the childhood vaccination debate can help us better understand the sources of vaccine resistance and how to better design public health responses.

Until the advent of coronavirus disease 2019 (COVID-19) vaccine mandates, opposition to school-based vaccination requirements was perhaps the foremost expression of vaccine resistance in modern life. Usually, the opposition to pediatric vaccines is presented as parental concerns regarding childhood development. In some regards, medical questions are a very present but ever-evolving concern for vaccine-hesitant parents.[2] The 1970s and 1980s saw a rise of antivaccination parental advocacy in the United States and the United Kingdom, spurred by a potential link between pertussis vaccination and neurologic disorders.[3] More recently, Andrew Wakefield's now debunked work suggested a link between the measles-mumps-rubella vaccine and autism.[4,5] In each case, however, concerns lingered long after it was made clear scientifically that these concerns were unfounded.[3,6]

The controversy over school-based vaccination requirements can also be analyzed using the rights-based framework articulated in Colgrove and Samuel's work, giving us better insight into the durability of vaccine hesitancy even after specific medical concerns are allayed. In 1922, the Supreme Court established, in *Zucht v. King*, that conditioning access to education on vaccine compliance did not violate the Fourteenth Amendment.[7] Rosalyn Zucht, the plaintiff, relied on a rights-based framing to justify her opposition to the vaccine mandate in question, arguing that it violated her liberty without affording her due process to contest the vaccination requirements. Justice Brandeis, writing for the Court, clearly did not find Rosalyn Zucht's rights-based argument compelling, noting that the constitutional question presented by Zucht was "not substantial in character" and was largely resolved by previous cases such as *Jacobson v. Massachusetts*.[8] This is in keeping with Colgrove and Samuel's analysis that *Jacobson* largely foreclosed legal remedies to compulsory vaccination.

The story of resistance to school-based vaccine mandates continued to follow Colgrove and Samuel's framework, with advocates turning away from courts to legislation and political advocacy, all while invoking medical liberty and a rights-based framework. The medical liberty arguments documented by Colgrove and Samuel appear time and time again in parental antivaccine advocacy. A 1969 survey of school-based vaccine mandates noted that one of the two major objections to these regulations was "based on a person's philosophy about governmental control and individual freedom."[9] Decades later, in a taxonomy of antivaccine advocates post-Wakefield, Anna

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Kirkland noted that a radical antivaccine underpinning comes from what she terms the “libertarian health freedom movement,” which includes a political theory of government illegitimacy in all healthcare matters.[6] Many of the advocacy groups she studied, such as the Citizens’ Council for Health Freedom (an advocacy group of nonphysicians) and the American College of Physicians and Surgeons (an ideologically right-wing group of private physicians that is now more commonly known as the Association of American Physicians and Surgeons), can be seen as the political and philosophical heirs to groups discussed by Colgrove and Samuel, such as the Anti-Vaccination League of America.

The medical liberty approach to vaccine requirements goes beyond advocacy meetings, finding its way into relevant public health legislation. Following *Zucht*, antivaccine advocates pushed for exemptions to school-based vaccine mandates based on religious and philosophical objections. The availability of these exemptions waxes and wanes.[10] In 2014, 20 states offered some sort of philosophical exemption and 48 offered some religious exemption.[11] In 2021, 15 states offered a philosophical exemption and 44 offered a religious exemption.[12]

Understanding the motivations behind these exemptions is important for promoting public health and vaccine adoption. Their availability can be problematic from a public health point of view, with communities falling below herd immunity when the number of exemptions granted grows too large.[11] These exemptions suggest that reducing parent vaccine resistance to concerns regarding neurologic development would be an oversimplification because these exceptions do little to address medical qualms. Instead, the exceptions to school-based vaccine requirements should be seen as the legislative expression of the pursuit of medical liberty.

The role that medical liberty plays in establishing exemptions to school-based vaccine requirements suggests that successful vaccine promotion must engage with libertarian health freedom arguments, not just debunk questionable scientific claims. That is to say, it is not sufficient to prove that vaccines do not cause autism. Vaccine proponents must also convince parents and policymakers “on the fence” that medical liberty does not justify undermining public health campaigns. It will not be easy to find arguments that can successfully counter medical liberty narratives, but it will be necessary for vaccine advocates to do so.

For example, to counter narratives of medical liberty, vaccine advocates may want to stress the risks posed to vulnerable individuals, such as infants and those who medically cannot receive vaccines, when communities overall fall below herd immunity. By presenting narratives and pictures of the “victims” of vaccine hesitancy—for example, a young baby with whooping cough or the story of a woman who miscarried because of measles—vaccine refusal and hesitancy could be reframed as a selfish choice instead of a “freedom-loving” choice. This approach would not reach those who are staunchly opposed to vaccines, but it may convince the vaccine hesitant to rebalance community public health goals in relation to medical liberty. More work should be done to find narratives and arguments that directly counter medical liberty–based objections to vaccines.

The lessons articulated by Colgrove and Samuel can help us better understand the opposition to school-based vaccine mandates, including explaining why religious and philosophical exemptions are so prevalent despite undermining public health goals. Colgrove and Samuel’s work reminds us that medical liberty is not a natural law as unavoidable as the pull of gravity but a choice, sometimes intentional, championed by previous antivaccine advocates after their court-focused appeals were unsuccessful. Looking forward, this framework could also be useful in addressing objections to COVID-19 vaccine requirements. As Colgrove and Samuel note, “[t]he conceptualization of vaccine refusal as a matter of rights and liberties may be consequential for efforts to control the COVID pandemic.” Pushing back on the rhetoric of medical liberty may ultimately be necessary to ensure high rates of COVID-19 vaccination, and Colgrove and Samuel’s work gives us the tools to do so.

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Beyond Vaccination Mandates: Solidarity and Freedom During COVID-19

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See also Yeh, p. 255.

In this issue of *AJPH*, Yeh (p. 255) argues that vaccinations against the severe acute respiratory syndrome coronavirus 2 virus should be compulsory for the general population. Yeh considers vaccination mandates grounded in the concept of solidarity as "ethically preferable" (p. 257) to previous justifications on the basis of (mostly) utilitarian arguments.

What is solidarity? Yeh refers to my and Buyx's conceptualization, which treats solidarity as a practice by which people accept some form of (financial, practical, emotional) cost to support others to whom they consider themselves connected in some relevant respect.[1,2] This connection could be a joint goal, a shared risk, or anything else that people feel they have in common with others. It is not important whether this commonality can be measured objectively or whether it is entirely "subjective." What matters is that amid all the differences that inevitably exist between people, those practicing solidarity see something that they share with others and make this commonality a ground for supporting them.

Solidarity can take place at several levels. At the level of individuals (i.e., when a person supports another person or persons), at the level of groups, or at the institutional level (Figure A, available as a supplement to the online version of this article at http://www.ajph.org). The last, "tier 3" type of solidarity, which is inscribed in the design of institutions, policies, or other norms,[1,2] is where Yeh's argument comes in. Publicly funded health care systems to which everyone contributes according to their level of income and everyone receives support based on need (independent of their ability to pay) are the paradigmatic examples of institutionalized solidarity. Another example is progressive income tax systems, or social transfers. For Yeh, COVID-19 vaccination mandates should also be seen as such a "solidaristic public institution" (p 257).

In Yeh's view, people's recognition of the need "to end the COVID-19 pandemic as soon as possible" (p. 257) is a commonality that binds them together. On the basis of this, people are willing to accept costs. Taken together, Yeh argues, this is a suitable basis for a solidarity-based vaccine mandate. Just as social health insurance systems require mandatory contributions and grant few (if any) opportunities for opting out, vaccination mandates should oblige everyone to participate. Those who refuse the vaccine without having a medical exemption would pay a fine and thus contribute to the solidaristic system in that way.

I do not agree with the author's conclusion that solidarity is a good justification for a general vaccine mandate. Even if everyone wants the pandemic to end as quickly as possible, unfortunately not everyone agrees that vaccination is a suitable way of doing so. In other words, it cannot be assumed that people in any given society are united in their willingness to accept the costs of vaccination to end the pandemic.

It could be objected here that institutionalized, tier 3, solidarity does not need public support as a justification. Institutionalized solidarity can be enforced without people's explicit consent; for example, by contributions to a publicly funded universal health care system. (What is enforceable in this case, strictly speaking, is not solidarity itself but the laws that give it shape.) Solidaristic institutions will be more stable, and have more legitimacy, if many agree with the values that it enshrines, but this is not a requirement for their existence. The yardstick for whether an institution is solidaristic is its outcomes—not the motivations of its designers or people participating or enrolled in these institutions. When the outcomes can best be described in terms of solidarity, and not merely in terms of justice, then the institution can be designated solidaristic. To stick with the example that Yeh also uses, in the case of European-style publicly funded universal health care, the outcome is that everyone's health care needs are addressed, independent of how much they have paid into the system—and those with higher incomes contribute more than the less wealthy.[3] The same cannot be said for vaccination mandates, where everyone is required to contribute the same—to get vaccinated or to pay a fine—with the latter posing much larger burdens on people with less wealth and income than on wealthy ones.

This does not mean that vaccination mandates cannot be justified. Of course they can, especially in light of the existing evidence on the safety and benefits of vaccination. But solidarity is not a suitable justification. I do not see how a vaccination mandate would meet the criteria for a solidaristic institution.

Having said this, the key contribution of Yeh's article goes beyond the question of vaccine mandates. It lies in framing the topic of vaccination without pitching individual rights and needs against public interests. Without using the word "freedom" explicitly, Yeh's argument highlights that freedom does not consist only of the negative freedom from undue state interference but also of the positive freedom of being able to move safely in public and other shared spaces.

The notion of solidarity does not, as is often wrongly claimed, posit that public interests should overrule individual autonomy and freedom. Instead, solidarity breaks up the dichotomy between the two. It understands people as relational beings whose interests and identities are shaped by their relationships to others.[4,5] People are autonomous because of, and not despite, their connections to their human, natural, and artificial environments.[6] Although this does not deny that some of these relationships and connections can be exploitative or harmful and that the interests of individuals can be in great tension with what is good for the collective in specific cases, it does not treat such tensions as the default state of human existence. In many instances, individual and public interests overlap in important ways. They are not a zero–sum game in which one must always give for the other one to gain. Consequently, the concept of solidarity captures an important feature of human nature, namely that our relations to others play an important role in forming our identities and interests. A greater acknowledgment of this fact in both public health and health care would help to address a number of issues.[7]

Most importantly, Yeh's focus on the level of institutionalized solidarity is immediately relevant to policymaking during and after the pandemic. In societies with strong public infrastructures, including those with well-funded and inclusive health care, people have been better insulated from some of the worst burdens of the pandemic. Social support systems have helped to avoid people losing their home and their livelihoods when they have lost their jobs or income. The importance of solidaristic institutions—such as policies that support people according to their need and require contributions according to economic ability—has been highlighted in the past 18 months. What we can take from this is a different way of thinking about pandemic preparedness—one that understands the creation and strengthening of solidaristic institutions as its core tasks, including the abolishment of poverty and the reduction of inequalities. Next to the immediate health effects of the virus, poverty and grave inequalities have been the root causes of human suffering during the pandemic.[8,9]

This will most likely also affect vaccination. People who trust political and societal institutions are more likely to participate in vaccination programs. But this trust needs to be deserved, and strengthening (the conditions for) solidarity will be necessary to get there.

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Freedom, Rights, and Vaccine Refusal: The History of an Idea

James Colgrove, PhD, MPH, and Sara J. Samuel, MPH

See also Morabia, p. 189, Kapadia, p. 202, Johnston, p. 227, and Shachar, p. 229.

We analyzed how activists opposed to vaccination have used arguments related to freedom, liberty, and individual rights in US history. We focused on the period from the 1880s through the 1920s, when the first wave of widespread and sustained antivaccination activism in this country occurred. During this era, activists used the language of liberty and freedom most prominently in opposition to compulsory vaccination laws, which the activists alleged violated their constitutionally protected rights. Critics attacked vaccination with liberty-based arguments even when it was not mandatory, and they used the language of freedom expansively to encompass individuals' freedom to choose their health and medical practices, freedom to raise their children as they saw fit, and freedom from the quasicoercive influence of scientific and medical experts and elite institutions. Evidence suggests that in recent years, vaccine refusal has increasingly been framed as a civil right. We argue that this framing has always lain at the heart of resistance to vaccination and that it may prove consequential for the rollout of COVID-19 vaccines. (*Am J Public Health*. 2022;112(2):234–241. https://doi.org/10.2105/AJPH.2021.306504)

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Organized opposition to vaccination has grown in strength and visibility in the United States over the past two decades because of a complex set of factors, especially the rise of the Internet as a medium for spreading misinformation and connecting like-minded activists. Historically and in the present day, vaccine-critical rhetoric has rested on two principal claims: (1) that vaccination is a dangerous procedure whose risks outweigh its benefits, and (2) that efforts to pressure or compel people to be vaccinated (or to vaccinate their children) violate individual rights.[1] A 2019 study of Facebook posts found that in recent years, arguments related to individual liberty have grown more prominent in antivaccination messaging, with vaccine refusers increasingly framing their choice as a civil right.[2]

In addition to the potential impact of this messaging on routine childhood immunization, the framing of vaccine refusal as an issue of individual liberty has potentially far-reaching implications for the use of vaccines to control the spread of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus. One of the most striking aspects of the COVID-19 pandemic in the United States has been the way that some members of the public have rejected public health measures as unacceptable intrusions on personal liberty. Measures designed to protect the common welfare and vulnerable members of the community, such as quarantine orders and recommendations or requirements for wearing face coverings, have repeatedly been met with opposition by small but vocal minorities who claim that public health interventions are a violation of rights by an overreaching and tyrannical government. Antimask protestors and antivaccination activists have presented their resistance to both measures as matters of personal liberty.[3]

"No idea is more fundamental to Americans' sense of themselves as individuals and as a nation than freedom," the historian Eric Foner writes.[4] Freedom is a protean concept, carrying different meanings across successive historical eras and encompassing political, legal, religious, and economic dimensions. Invocations of liberty in the context of vaccination have been similarly multifaceted. Most commonly, the language of liberty and freedom has been used in opposition to compulsory vaccination laws, for which alleged violations of constitutionally protected rights have been at issue. But critics have attacked vaccination with liberty-based arguments even when it was not mandatory. They have used the language of freedom expansively to encompass individuals' freedom to choose their health and medical practices, freedom to raise their children as they saw fit, and freedom from the quasicoercive influence of scientific and medical experts and elite institutions. In all of these cases, freedom-based arguments have been a reaction to the actual or perceived exercise of power, especially (but not only) by government.

We examine how claims related to liberties and rights have been used, substantively and rhetorically, in the arguments of antivaccination activists and organizations. Although there is evidence that this discourse has grown in salience in recent years, we argue that it has lain at the heart of resistance to vaccination since the 19th century. We focus on a five-decade period spanning the 1880s through the 1920s, which encompasses the first widespread and sustained wave of antivaccination activism in the United States. This period produced critical jurisprudence on the scope of liberty in the context of vaccination and other public health interventions, as well as numerous legislative and advocacy battles featuring lines of argument that continue to resonate in the present day.

THE RISE OF ORGANIZED RESISTANCE

From the first use of smallpox vaccination in this country at the beginning of the 19th century, critics of the practice raised concerns about its safety and efficacy, with claims that vaccination posed grave health risks, including transmission of syphilis and other sometimes fatal infections, and failed to prevent the occurrence of the disease. (The smallpox vaccine was crude by today's standards, and there is evidence that it did sometimes have the serious adverse effects attributed to it.[5]) Beginning in the 1880s, formal organizations were founded in response to the increasing use of legal compulsion to control smallpox. Although these organizations represented only a small part of the overall landscape of resistance to vaccination, they were influential in shaping the rhetoric used by vaccine opponents. Claims related to liberty and freedom—and their antagonist, tyranny—began to figure prominently. Use of vaccination was framed not just as unsafe and ineffective but as a violation of inalienable rights.

The movement in the United States was influenced by events in Britain. Organized resistance arose in Great Britain as a response to a series of public health laws passed by the British Parliament in the second half of the 19th century. In 1853, vaccination of infants was made mandatory, and refusers could face fines or jail. Numerous antivaccination organizations were founded in the United Kingdom in the second half of the century that lobbied Parliament and staged rallies, marches, and acts of civil disobedience.[6]

Their liberty-based arguments and their notions of the acceptable scope of government action with respect to constraining individual freedom embodied ideas that were captured in one of the most influential works of political philosophy of the 19th century: John Stuart Mill's 1849 treatise *On Liberty*. Mill's work articulated the harm principle, which held that the only justification for the use of coercive state power was to prevent imminent harm to others; a person's own good was insufficient reason. Although it was generally not named explicitly in antivaccination literature, Mill's harm principle permeated the debates on vaccination in the United Kingdom and eventually in the United States. In both countries, health officials claimed that people who refused vaccination for themselves or their children posed a danger to other members of the community, thereby justifying state intervention, whereas vaccine objectors argued that the laws were an impermissible violation of individual liberty.

In 1879, one of the most prominent British antivaccination activists, William Tebb, a businessman and social reformer, traveled to the United States to cofound the Anti-Vaccination League of America.[7] The American Anti-Vaccination Society, made up of several of the same members, was founded six years later. Other state and local organizations were founded at around the same time, sometimes making their stance toward compulsion explicit in their names, as in the Anti-Compulsory Vaccination League of Brooklyn, founded in 1894. Although the numerical strength and demographic composition of the original antivaccination societies are difficult to determine with precision, some generalizations can be made. Many of the leaders of these groups were physicians, often homeopaths or members of other alternative medical sects that flourished in this era. They were often active in other social causes, such as animal protection and antivivisection, and most were White and of middle- or upper-class backgrounds. The groups often shared officers and members. They were mostly located in the Northeast, with organizations emerging in other regions in response to local controversies.[8] Many individual activists not affiliated with any organization also contributed by expressing concerns about the infringement on freedom.

The discourse of freedom was a direct reaction to the growing use of vaccination laws in the late 19th century, when frustrated health officials sought to contain repeated resurgences of smallpox. In the 1880s, seven states adopted new compulsory vaccination laws.[9] The vigilance with which compulsory vaccination was enforced varied widely, however. In some jurisdictions, health departments sent squads of vaccinators with police accompaniment to secure mass vaccination, even when there was no law in effect.[10] Conversely, in some cities with laws on the books, enforcement was desultory, either because of limited budgets or because health officials preferred not to antagonize people opposed to the practice. With its decentralized and highly variable public health system and patchwork of often haphazardly enforced vaccination laws, the United States presented a different legal landscape from the United Kingdom, but the political force of the rhetoric of freedom was just as strong, resonating even with people in jurisdictions where vaccination remained voluntary.

VARIETIES OF FREEDOM

Activists in this era compared the enforcement of vaccination to other institutions of coercion, notably slavery. William Tebb, the British activist who cofounded the first US antivaccination society, had lived for a time in the United States before the Civil War and became active in the abolitionist cause. In subsequent decades, Tebb's publications, circulated on both sides of the Atlantic, frequently compared the loss of liberty in compulsory vaccination to slavery.[11] In a 1900 treatise, another prominent activist, James Martin Peebles, described his work decades earlier on the Underground Railroad and explicitly compared opposition to compulsory vaccination laws to resistance to the Fugitive Slave Act.[12]

However sincerely held the belief in this analogy, it was also strategic to associate the antivaccination cause with what many people regarded as the most morally righteous crusade of the century. Lora Little, an antivaccination activist and pamphleteer who was active in Minnesota and Oregon in the early 20th century, named her newsletter *The Liberator* after the newspaper published by the famed antislavery crusader William Lloyd Garrison.[13]

There was some irony in the comparison of vaccination to slavery. African Americans often looked with suspicion on vaccination and other practices of White doctors, and the country's most famous abolitionist, Frederick Douglass, expressed his opposition to compulsory vaccination.[14] In antebellum Northern states, however, some free Black people sought vaccination as an expression of their right to control their own medical care, and the Black press often expressed support for vaccination, praising its safety and efficacy and associating the occurrence of smallpox with the brutality and material deprivations of slavery. In these accounts, the ability to obtain vaccination—to take advantage of a preventive intervention that was sometimes denied to those in slavery—was a greater expression of liberty than the ability to escape vaccination.[15]

The depiction in words and images of physicians in league with police officers was common in the pamphlets, flyers, and posters in both the United States and the United Kingdom in this era (Figure 1). The figure of the policeman symbolized overreaching and tyrannical government, and activists implicitly or explicitly argued that compulsory vaccination was a violation of foundational political documents such as the Magna Carta, the Declaration of Independence, and the US Constitution. This claim was advanced by Henry Bergh, a prominent antivivisectionist and president of the American Society for the Prevention of Cruelty to Animals, writing in the *North American Review*, a monthly magazine of current events. Bergh observed with outrage that some US jurisdictions had imitated the much-hated 1853 British compulsory vaccination law, which, he argued, "tears to tatters the Great Charter of Englishmen's liberties." The law "has been imitated even in free America, in contravention of every citizen's inalienable right to 'life, liberty, and the pursuit of happiness.'"[16]

The proposition that freedom from vaccination was consistent with the country's founding principles diffused widely in this period, with phrases such as "life, liberty, and the pursuit of happiness" increasingly turning up in newspaper articles, letters to the editor, speeches, and addresses to state legislatures. A representative of the Anti-Compulsory Vaccination League of Brooklyn declared that the aggressive school vaccination programs run by the city's board of health were

> opposed to the principles of the American constitution. It is an undignified proceeding to go to the public schools and seize children, who are not guardians of their own persons, and vaccinate them without their own consent or the consent of their legal guardians.[17]

In their rebuttals to antivaccination arguments, vaccination proponents typically did not engage with the ethical and political objections, preferring instead to stick to matters of empirical fact. The *North American Review* published a response to Bergh's essay two

FIGURE 1— The Cover of Activist James Martin Peebles's 1900 Book *Vaccination: A Curse and a Menace to Personal Liberty*, Depicting the Vaccinating Doctor in League With a Police Officer

Note. Such depictions were a common rhetorical trope in the antivaccination literature of this era.
Source. James Martin Peebles, *Vaccination: A Curse and a Menace to Personal Liberty* (Battle Creek, MI: Temple of Health Publishing, 1900).

months later written by Henry Austin Martin, a prominent Boston physician who chaired the American Medical Association's Committee on Vaccination. Martin sidestepped the question of liberty entirely, instead rebutting only the empirical claims that Bergh had made about the safety and efficacy of vaccination.[18]

Although proponents of vaccination tended to foreground scientific arguments, they recognized the resonance that liberty-based rhetoric had with the public and the way such messages could threaten aggressive efforts to secure a vaccinated populace. One physician in 1897 wrote:

> The people of this country are too thoroughly imbued with a sense of personal independence to submit patiently to personal compulsion. The attempt would excite hostility to vaccination that does not exist at present, and would hinder rather than promote the cause of vaccination.[19]

LIBERTY, COURTS, AND LEGISLATURES

Paralleling the spread of compulsory vaccination and the rise of organized opposition were increasing numbers of court cases being brought against vaccination laws. Numerous lawsuits were filed in state courts in the 1880s. Conflicting decisions and continued litigation ultimately led to the 1905 Supreme Court case of *Jacobson v. Massachusetts*, which affirmed the constitutionality of compulsory vaccination. The constitutional questions at issue in *Jacobson v. Massachusetts* were whether Massachusetts's compulsory vaccination law violated the 14th Amendment, which prevents states from depriving any person of "life, liberty, or property" without due process. The *Jacobson v. Massachusetts* ruling included a statement about individual liberty that remains widely quoted today:

> The liberty secured by the Constitution of the United States to every person within its jurisdiction does not import an absolute right in each person to be, at all times and in all circumstances, wholly freed from restraint. There are manifold restraints to which every person is necessarily subject for the common good.[20]

With the *Jacobson v. Massachusetts* decision having foreclosed legal remedies to compulsory vaccination, activists looked for a political solution to their grievances: they turned to their legislatures, where arguments did not need to meet the exacting legal standards of the courts but could speak to laypersons' notions of rights. The two decades after *Jacobson v. Massachusetts* saw considerable legislative activity in states around the country, which produced varying outcomes. At least four states either repealed existing vaccination laws or disallowed future laws, and at least two other states made their laws less restrictive. By contrast, antivaccination measures went down to defeat in at least three states.[21]

One legislative battle, in Pennsylvania, sparked the formation of a new national organization. John Pitcairn, a wealthy Pittsburgh area businessman who was a devotee of homeopathy and whose son had experienced an adverse reaction to the smallpox vaccination, sought a bill to repeal the state's compulsory vaccination law. In an address he gave to the Committee on Public Health and Sanitation of the Pennsylvania General Assembly in 1907, Pitcairn's emphasis was apparent in the opening line: "We are here this evening in the cause of freedom."[22] The address made numerous claims about the dangers of vaccination, but its most prominent arguments centered on liberty. Quoting John Stuart Mill, Pitcairn compared opposition to vaccination with the great political struggles that have defined the nation's history. He also compared the right to refuse vaccination to constitutionally protected religious freedom.

The measure passed both houses of the Pennsylvania legislature but was ultimately vetoed by the governor.[23] The defeat prompted Pitcairn to found a new organization the following year, the Anti-Vaccination League of America. The league's cofounder and most active pamphleteer was Charles Higgins, a businessman in Brooklyn, New York. Both Pitcairn and Higgins were civic leaders in their communities and were active in politics and mainstream causes such as historic preservation, and both preached a gospel of individual liberty and freedom from government restraint. Higgins authored the League's 1912 pamphlet *Open Your Eyes Wide!*, which demanded that "parents, school officers, editors, judges, legislators, and doctors" rise up to oppose vaccination, and issued a warning "to all vaccinators . . . against forcing vaccination on any person against free will and consent"[24] (Figure 2).

"MEDICAL LIBERTY"

After the turn of the 20th century, antivaccination messages increasingly drew on and contributed to a discourse of "medical liberty." The United States had a long tradition of freedom in medical practice that had found expression in the repeal of medical licensing laws and the proliferation of alternative medical sects in the 19th century.[25] Several developments at the turn of the 20th century gave the issue new prominence. The American Medical Association established a Propaganda Department in 1905 and stepped up its efforts to expose quackery, medical fraud, and dubious patent medicines. The federal Pure Food and Drug Act of 1906 (Pub L No. 59-384) sought to clamp down on the sale of patent medicines that some antivaccinationists promoted. The publication in 1910 of the Flexner Report, commissioned by the Carnegie Foundation to raise standards of medical education, served to close the gates of medical practice to many nonallopathic practitioners.

All these developments threatened to marginalize medical dissidents who were among the most prominent antivaccinationists, and in some cases threatened their livelihoods. In his book *Vaccination: A Curse and a Menace to Personal Liberty*, the eclectic physician James Martin Peebles implicitly put mainstream medicine in league with the federal government and the police:

> And this is the free America, is it? This, a land of personal liberty, is it? This a country of inalienable rights, is it? No—it is rather an oligarchy manned by certain "professional" doctors, the repulsive Rules and unconstitutional laws of which, are to be enforced by the militia.[26]

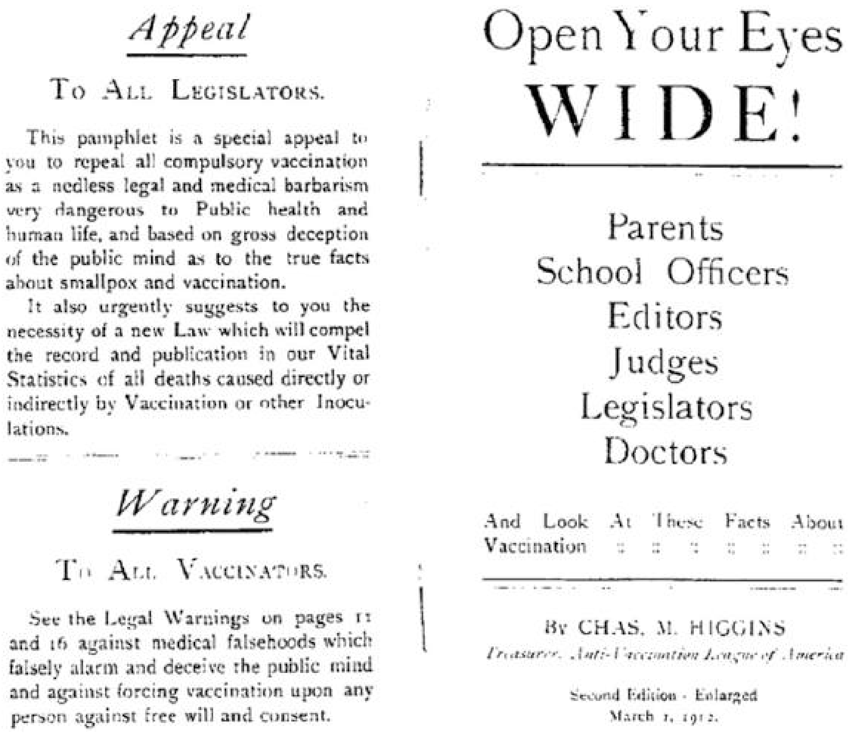
Among his other enterprises, Peebles marketed a cure for epilepsy that the American Medical Association analyzed and found to be fraudulent.

The discourse of medical liberty did not feature only in the context of these intraprofessional rivalries; it extended to arguments about how allopathic medicine might threaten the freedoms of ordinary Americans, especially when it was in league with government agencies. A particular area of concern was the expansion of health inspection for schoolchildren, which was seen as overreach to many ordinary Americans and generated antagonism toward entities such as local and state boards of health and education.[27] As historian Kim Tolley argues:

> The medical liberty leagues that arose during this period appropriated and expanded the constitutional arguments advanced by the nineteenth-century antivaccination societies, arguing that Americans had a constitutional right to choose their own medical treatment and a right to freedom from medical interference, not only in the form of compulsory vaccination, but in all areas of social life.[28]

The medical liberty movement brought together antivaccination activists in coalitions with other groups whose messages emphasized liberty interests. In 1910 they joined with Christian scientists, chiropractors, and antivivisectionists under the umbrella of the National League for Medical Freedom to campaign against a federal-level department of health.[29] Government health programs were also targeted by two organizations founded in 1919: the American Medical Liberty League, based in Chicago, Illinois, and the Citizen's Medical Reference Bureau, based in New York City.[30] In addition to their efforts to overturn state compulsory smallpox vaccination laws and impede the adoption of a newly developed immunizing procedure against diphtheria, both groups lobbied against measures that would strengthen the public health system more generally, such as the creation of health boards and appointments of health officers.[31] Their rhetoric capitalized on the anti-Bolshevist environment of the "Red Scare" in the aftermath of World War I.

Activists in this era also found common cause with other organizations and movements premised on notions of freedom, whether political or economic. The leaders of several antivaccination organizations campaigned against Prohibition; Charles Higgins wrote that "religious freedom, medical freedom, and alimentary freedom are equally unalienable rights of the American people and must be kept inviolate."[32] Directors of the Anti-Vaccination League of America and the Citizens Medical Reference Bureau were also financial backers of Sentinels of the Republic, an anticommunist organization founded in 1922 that was devoted to opposing the concentration of power in a centralized government and "checking the growth of Federal paternalism." The group



Appeal

To All Legislators.

This pamphlet is a special appeal to you to repeal all compulsory vaccination as a needless legal and medical barbarism very dangerous to Public health and human life, and based on gross deception of the public mind as to the true facts about smallpox and vaccination.

It also urgently suggests to you the necessity of a new Law which will compel the record and publication in our Vital Statistics of all deaths caused directly or indirectly by Vaccination or other Inoculations.

Warning

To All Vaccinators.

See the Legal Warnings on pages 11 and 16 against medical falsehoods which falsely alarm and deceive the public mind and against forcing vaccination upon any person against free will and consent.

Open Your Eyes
WIDE!

Parents
School Officers
Editors
Judges
Legislators
Doctors

And Look At These Facts About Vaccination :: :: :: :: :: :: ::

By CHAS. M. HIGGINS
Treasurer, Anti-Vaccination League of America

Second Edition - Enlarged
March 1, 1912.

FIGURE 2— A 1912 Pamphlet Published by the Anti-Vaccination League of America

Note. This pamphlet sought to persuade multiple audiences that vaccination was a dangerous procedure and that to compel it by law was a violation of fundamental freedoms.
Source. Charles M. Higgins, *Open Your Eyes Wide!* (New York, NY: Anti-Vaccination League of America, 1912).

fought against social reforms it viewed as communistic, including child labor laws and a proposed federal department of education.[33]

In addition to shaping public perceptions in ways that were pervasive, if difficult to quantify, the freedom-based arguments of antivaccination activists during these years left behind concrete legacies. In 1911, California added the first clause, modeled on a provision that had been adopted in the United Kingdom, allowing “conscientious objectors” to opt out of the state’s school vaccination law, a precursor to today’s “personal belief” exemptions.[34] More broadly, the constitutional arguments activists made in courts helped to define the legal scope of public health compulsion. Although the Supreme Court’s ruling in *Jacobson v. Massachusetts* affirmed states’ powers to compel vaccination, it also placed important limits on the extent of that power, setting forth principles such as harm avoidance, present danger, and equal protection.[35]

VACCINATION, RIGHTS, AND COVID-19

From the 1880s through the 1920s, the rhetorical battle over vaccination was waged on two fronts: that of scientific fact and that of legal and ethical principle. In a 1921 editorial in the *Boston Medical and Surgical Journal*, a prominent physician and former president of the Massachusetts Medical Society summed up the twin threads of antivaccination activism:

> The extreme individualist who objects to any compulsory measures whatever . . . is lined up with those persons who honestly believe that vaccination is a dangerous thing as well as a useless procedure.[36]

During this era, the meaning of “liberty” was mutable, with different connotations depending on who was using it. These claims were used in the context of constitutional challenges to compulsory vaccination laws, and more expansively in other spheres—legislative chambers, newspapers and mass circulation magazines, scholarly and professional journals—to argue against the accrual of power by elites and authorities, whether state governments, boards of health, or the medical and scientific communities, even when no direct infringement on a right or liberty was threatened. The language of liberty was a way for vaccination critics to align themselves—sometimes merely rhetorically, sometimes in practice—with other causes premised on notions of liberty, ranging from abolitionism to anticommunism.

Such a framing may have reflected the sincerely held beliefs of those who espoused it, but it also had a strategic advantage in shaping public opinion about vaccination policies and laws. It shifted the debate from the arena of empirical fact to the realm of principle, thus rendering arguments against vaccination impervious to falsification or disproval. This discourse is an example of what the political scientist Mary Ann Glendon labeled “rights talk.”[37] Framing demands for action in terms of an inviolable right has been an effective tool for inspiring justice and extending democracy, but, according to Glendon, it can also be polarizing, serving to foreclose debate and inhibit common ground, and it can overemphasize rights at the expense of communal responsibilities.

The conceptualization of vaccine refusal as a matter of rights and liberty may be consequential for efforts to control the COVID-19 pandemic. In March 2020, when the first vaccine trial in the United States began, the National Vaccine Information Center, a vaccine-critical organization, warned:

> The government has a National Vaccine Plan. It is a Plan designed to make sure you, your child and everyone in America gets every dose of every vaccine that government officials recommend now and in the future.[38]

The Center's Web site features prominent references to John Stuart Mill.

COVID-19 vaccines are being administered in a political climate characterized by the resurgence of often militant antigovernment sentiment directed at public health measures and an energized antivaccination movement. Polling by the Kaiser Family Foundation in early 2021 indicated that about 70% of Republicans believed that getting the vaccine was a matter of "personal choice," whereas 30% considered it a matter of "collective responsibility"; among Democrats, those percentages were reversed.[39] These beliefs appear to correlate with vaccination intentions. Among respondents who said they would "definitely not" get a COVID-19 vaccine, 67% were Republican, whereas only 12% were Democrat.[40]

Many experts in public health ethics and law have argued that compulsory vaccination against the SARS-CoV-2 virus would be justified should persuasive and educational measures prove insufficient to achieve optimal vaccine uptake. Such measures can be implemented either by state governments in the form of legislation or regulation or in the private sector as a condition of employment or college attendance, for example. Given the grave public health threat posed by COVID-19 and the safety and efficacy of the available vaccines, compulsory measures are well justified from the standpoints of ethics, policy, and law. Like any compulsory public health measure, a COVID-19 vaccine mandate—whether implemented through the public or the private sector—carries the risk of galvanizing backlash and resistance, which can have the unwanted and unintended effect of eroding, rather than boosting, vaccine uptake. This risk, well known to health officials of earlier generations, is heightened in the current political climate. As in past eras when contagious epidemics were more common, current efforts to protect public health will require confronting questions of freedom and rights, which remain as resonant—and as contentious—as they were during the birth of organized antivaccination activism more than a century ago. AJPH

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The authors report no potential or actual conflicts of interest.

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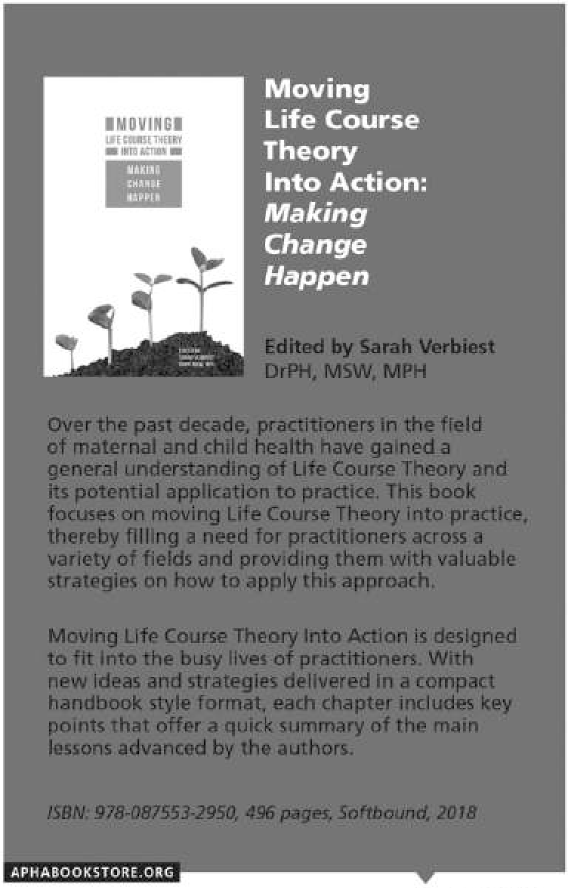

The 1918 Influenza Pandemic and the Rise of Italian Fascism: A Cross-City Quantitative and Historical Text Qualitative Analysis

Gregori Galofré-Vilà, PhD, Martin McKee, MD, DSc, María Gómez-León, PhD, and David Stuckler, PhD

Evidence linking past experiences of worsening health with support for radical political views has generated concerns about the consequences of the COVID-19 pandemic. The influenza pandemic that began in 1918 had a devastating health impact: 4.1 million Italians contracted influenza and about 500 000 died. We tested the hypothesis that deaths from the 1918 influenza pandemic contributed to the rise of Fascism in Italy. To provide a "thicker" interpretation of these patterns, we applied historical text mining to the newspaper *Il Popolo d'Italia* (Mussolini's newspaper). Our observations were consistent with evidence from other contexts that worsening mortality rates can fuel radical politics. Unequal impacts of pandemics may contribute to political polarization. (*Am J Public Health*. 2022;112(2):242–247. https://doi.org/10.2105/AJPH.2021.306574)

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Are those living in communities experiencing rising death rates more likely to turn to radical politicians? A growing body of evidence suggests that they are. In the United States, Bor et al. found that those counties where life expectancy stagnated or declined between 1980 and 2014 were more likely to swing toward support for Donald Trump in the 2016 presidential election.[1,2] Similarly, communities experiencing worsening health in the United Kingdom saw greater support for Brexit.[3] The same association also holds in different historical junctures. For instance, worsening mortality rates in German localities in the early 1930s were positively associated with the rise of the Nazi Party,[4,5] and influenza deaths in 1918 also correlated with the Nazi electoral boost.[6]

Given these examples, there are some concerns that the COVID-19 pandemic could further boost populist parties that have been attracting growing support in some countries since the global financial crisis. The risks are clear; in many countries, the pandemic has precipitated the biggest health, economic, and social crisis since World War II, and some researchers have suggested that democracies have fared worse that autocracies.[7] During epidemics, people are more likely to accept state-mandated collective action, supporting a rise in authoritarianism.[8]

Some populist politicians (like Jair Bolsonaro in Brazil) have exploited the pandemic by sowing divisions in society, creating cleavages between young and old, immigrants and established populations, and the rich and poor. Others, such as India's Narendra Modi, have used the crisis to consolidate their power and suppress opposing voices. The opposite also seems possible: a poor response to COVID-19 could bring calls for change, as shown by the November 2020 US presidential election.

We tested the relationship between the health consequences of a pandemic and support for Fascism by using a unique historical case: the rise of Fascism in Italy that occurred in the aftermath of the 1918 influenza pandemic (Appendix A, available as a supplement to the online version of this article at http://www.ajph.org). It was devastating, infecting 4.1 million Italians—among them Mussolini's wife, Rachele[9]—500 000 of whom died (Figure 1). For comparison, as of June 2021, in several waves, COVID-19 had infected 4.2 million Italians, of whom 127 000 died.

Since the beginning of the COVID-19 pandemic, there has been a renewed interest in the 1918 pandemic. Yet, while most articles have examined the economic aspects of, and governmental

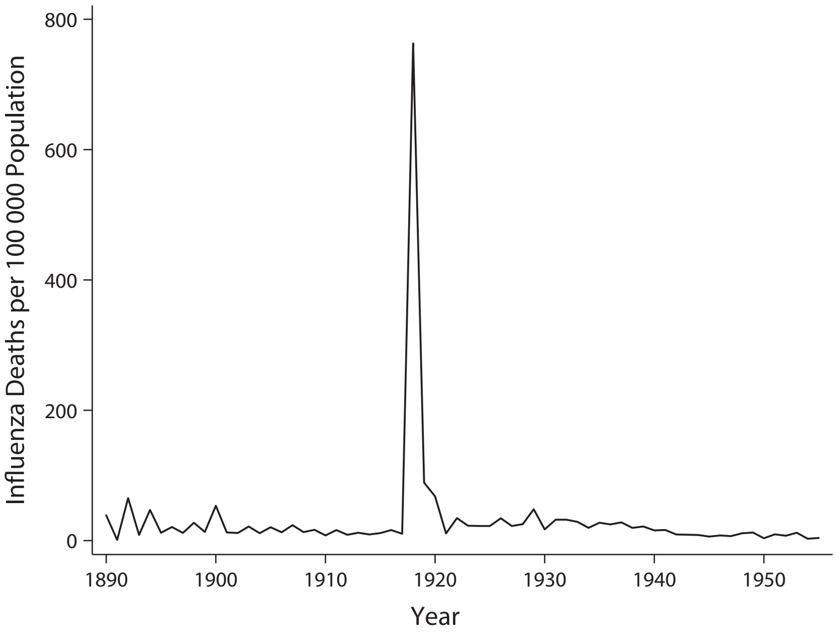

FIGURE 1— Deaths From Influenza per 100 000 Population: Italy, 1890-1959

Source: Mortality data are from Istituto Centrale di Statistica. *Cause di Morte: 1887–1955.* 1958. Available at: http://www.laveritasuivaccini.it/ftp/Causedimorte1887-1955.pdf. Yearly population data are from B. R. Mitchell. *European Historical Statistics, 1750–1975*. New York, NY: Columbia University Press; 1975.

responses to, the pandemic,[10] there has been relatively little written on the political consequences of high death rates at that time, even though the political aspects were recognized even then, with a contemporary cartoon in the magazine *Punch* showing Mussolini saying to influenza, “Go away—I am the big sneeze here” (Appendix B, available as a supplement to the online version of this article at http://www.ajph.org). The Italian case is particularly important, as Italy was the first European nation to turn to authoritarianism during the interwar period (with Spain, Greece, Germany, and others following later).

To test the hypothesis that communities experiencing influenza deaths saw greater support for the Fascists, we collected historical cause-specific mortality data and linked it to vote shares for the Fascist party in 73 Italian cities in the 1924 election.

BACKGROUND

We obtained official city-level data on voting patterns for the Fascist party and its main political competitors in the general election of April 1924 by using data from Corbetta and Piretti[11] and originally collected from official local state archives and historical newspapers (n = 73). Ideally, we would look at election outcomes over time, but we were restricted to just one election (1924) because, although the Fascist party was created in 1919, in the election of that year, the Fascists presented candidates in only a few electoral districts, and in 1921 they were part of the *Blocchi Nazionali* (a coalition of moderate and conservative parties). Hence, it was difficult to capture local Fascist support before 1924. We measured Fascist support as the ratio of the number of votes for the Fascist Party (*Partito Nazionale Fascista*) to the total number of votes cast in the 1924 election.

For the 73 cities included, we manually extracted cause-specific mortality data for each year from 1916 to 1924 from official sources (for details on data sources, see Appendix C, available as a supplement to the online version of this article at http://www.ajph.org). Specifically, we collected data on city-level deaths from influenza and other leading causes of death, including from accidents (that correlate with the economic conditions in each city), cancer (used as a placebo, as there is a long lag between carcinogenesis and death), tuberculosis (to assess whether results are explained specifically by influenza or simply as part of worsening deaths from infectious and communicable diseases), and all deaths (to measure the overall worsening health). Because age-specific mortality data are unavailable at city level in historical Italian records, we expressed the number of deaths from each specific cause as the unstandardized rate per 1000 population. Nonetheless, as we show in Appendix D (available as a supplement to the online version of this article at http://www.ajph.org), the pandemic had very little impact on older people, and most deaths occurred to persons between the ages of 20 and 39 years. However, our regional fixed effects would have accounted for any time-invariant characteristics of the local age distribution.

We added city-level controls to adjust for economic decline and the local characteristics of the cities. The variable population controls for the size of the city, and, to account for spatial autocorrelation, we added its latitude and longitude. We also controlled for the occupational and social structure of each city, with the share of workers in the primary sector, in industry, in liberal occupations, and that were owners in its total population. We also controlled for World War I military casualties (per 1000 population), and proxied for economic downturn and the effects of the *Biennio Rosso* (a period of intense social conflict between 1919 and 1920), with the city's fiscal deficit and levels of unemployment. Fiscal deficit is the difference between total revenue and spending (i.e., spending beyond the city's means).

We employed multivariate regression models to adjust for several socioeconomic and demographic factors in the following way:

$$Fascist_{c,1924} = Influenza_{c,t} + \Lambda' X_{c,1924} + \gamma_S + e_{c,t} \quad (1)$$

where *Fascist* is the ratio of the number of votes to the Fascist Party to the total number of votes cast in each city *c* in the 1924 election; *Influenza* measures the size of the pandemic as the change in the deaths from influenza between 1916 and 1918 (1916 being a prepandemic year) and per 1000 population. $\Lambda' X$ is a matrix of controls; γ_S denotes state-level fixed effects, absorbing much of the unobservable characteristics or the Italian states; and $e_{c,t}$ is the error term. Because we were using a range of controls measured in different units, we standardized data to have a mean of zero and a standard deviation of 1, so coefficients across models are directly comparable. In all models, we used heteroskedasticity-robust standard errors allowing for random variation at the city level. We explored clustering standard errors at the province or state level, but they displayed the same levels of statistical confidence. We also present R^2 values as a measure of goodness of fit.

MAIN FINDINGS

Figure 2 depicts the positive and statistically significant unadjusted association of influenza deaths and proportions voting for the Fascist party (Pearson's $r = 0.78$; $P < .001$). Each increase of one death from influenza per 1000 was associated with a 4.09-percentage-point increase in vote shares to the Fascist Party in 1924 (95% confidence interval [CI] = 3.24, 4.95).

Table 1 shows the results of multivariate regression models presented in equation 1. Here, each 1-standard-deviation increase in influenza death rates was associated with between one fifth to one quarter of 1 standard deviation of the dependent variable. Adjusting for the local characteristics of the cities (population size, occupation, and occupational structure) attenuated the association, but not significantly so. The effect of adding a control for World War I casualties was also limited. This variable might be colinear with influenza deaths as most soldiers who died in October and early November 1918 died from influenza rather than from military action.[12]

When we proxied for the lasting effects of the *Biennio Rosso*, both the fiscal deficit and unemployment increased standard errors, but results remained statistically significant ($P < .001$). Overall, despite the importance of these factors, when all covariates were included in the final model, it only attenuated the association between influenza death rates and radical voting, as results remained highly statistically significant at the 1% level of confidence (B = 0.26; 95% CI = 0.10, 0.42). Finally, we also show the isolated effect of influenza deaths on the rise of Fascism. The association was not driven by a general worsening of mortality; when we looked at all deaths or noninfluenza deaths, results were not statistically significant, reflecting the role of the 1918 influenza pandemic as an important correlate.

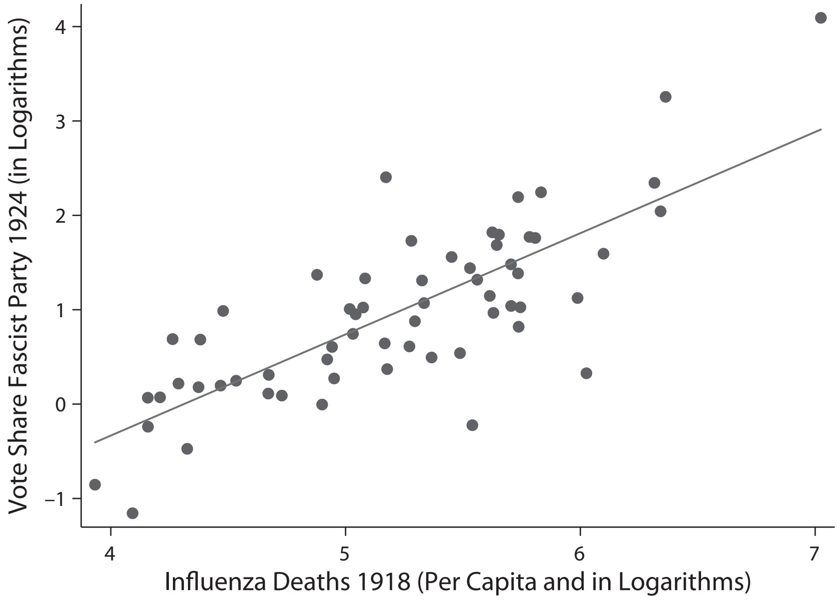

FIGURE 2— Percentage of Vote Share to the Fascist Party in the 1924 Election and Deaths From Influenza in 1918 (in Logs) in Different Italian Cities

TABLE 1— Association Between Changes in Influenza and Overall Death Rates Between 1916 and 1918, and Vote Share for the Fascist Party in 1924: Italy

	Deaths From Influenza (Δ1916–1918; n = 72)		All Causes of Death (Δ1916–1918; n = 72)		All Causes of Death Excluding Influenza (Δ1916–1918; n = 72)	
Covariates	**B (95% CI)**	R^2	**B (95% CI)**	R^2	**B (95% CI)**	R^2
Unadjusted	0.23 (0.07, 0.39)	0.52	0.02 (−0.21, 0.25)	0.44	0.12 (−0.32, 0.55)	0.45
Population[a]	0.24 (0.07, 0.40)	0.52	0.04 (−0.19, 0.27)	0.45	0.14 (−0.30, 0.59)	0.45
Location[b]	0.22 (0.09, 0.36)	0.53	0.03 (−0.20, 0.27)	0.46	0.10 (−0.30, 0.50)	0.46
Occupational structure[c]	0.21 (0.08, 0.34)	0.56	0.11 (−0.15, 0.36)	0.52	0.26 (−0.16, 0.68)	0.53
WW1 soldier casualties[d]	0.24 (0.08, 0.40)	0.52	0.10 (−0.30, 0.51)	0.44	0.11 (−0.34, 0.57)	0.45
Fiscal deficit[e]	0.24 (0.09, 0.40)	0.52	0.02 (−0.21, 0.25)	0.44	0.12 (−0.33, 0.57)	0.45
Unemployment[f]	0.24 (0.08, 0.41)	0.53	0.03 (−0.21, 0.26)	0.45	0.12 (−0.30, 0.54)	0.45
Fully adjusted	0.26 (0.10, 0.42)	0.60	0.37 (−0.17, 0.91)	0.56	0.23 (−0.31, 0.78)	0.54

Note. CI = confidence interval; WW1 = World War I. Parameter estimates are standardized regression coefficients to have a mean of zero and a standard deviation of 1, so coefficients across models are directly comparable, representing the vote share for the Fascist Party in the 1924 election associated with an increase of one death per 100 000 population between 1916 and 1918. All models include state-level fixed effects with robust standard errors clustered at that city level.

[a] Population size in December 1921.
[b] City's latitude and longitude in decimal degrees.
[c] Share of workers in the primary sector, in industry, in liberal occupations, and that are owners in its total population in 1921.
[d] WWI military casualties per 1000 population.
[e] Difference between total revenue and spending measured in thousand lire in 1924.
[f] Unemployment rates in industry and agriculture in 1924.

We performed a series of robustness and sensitivity tests. First, in Appendix E (available as a supplement to the online version of this article at http://www.ajph.org), we predicted the Fascist vote share in 1924 with deaths from influenza and other leading causes of death from 1916 to 1924 using yearly data in separate models. Only influenza mortality in the year 1918 predicted the vote share of the Fascist party (B = 0.62; 95% CI = 0.26, 0.97). In none of the other years are deaths from influenza associated with Fascism. Thus, the association we were exploring was not just capturing worsening economic or environmental conditions via communicable and infectious diseases in general but also the exogenous impact of influenza. The same appeared to be true when we looked at other important communicable causes of death like tuberculosis. As another placebo, we compared these patterns with causes of death that are less responsive to short-term social conditions, using deaths from cancer. Here, none of the models displayed statistically significant coefficients. Finally, we tested the association between Fascist vote shares and changes in overall mortality to provide reassurance that our findings are specific to deaths from influenza rather than simply reflecting broader mortality patterns.

Second, it is possible that some unobservables moderated this association. For instance, Autor et al.[13] found that many predominantly African American congressional districts exposed to trade with China and loss of manufacturing swung to the left, not the right. In Appendix F (available as a supplement to the online version of this article at http://www.ajph.org), we tested for other "effect modifiers" to show that deaths from influenza in 1918 were largely uncorrelated with the 1913 electoral conditions (the prepandemic election). Similar to our findings, Acemoglu et al. argued that "excess deaths from Spanish flu [*sic*] are broadly uncorrelated with the same pre-1919 economic, social and political variables."[14(p25)]

Third, in Appendix G (available as a supplement to the online version of this article at http://www.ajph.org), we also used equation 1 and measured t by the change between 1916 and 1919, between 1916 and 1920, and so on, to show that Fascism was only predicted by influenza deaths when we looked at the change between prepandemic year (i.e., 1916 or 1917) and 1918 (the pandemic year), as subsequent pairs (1916–1919, 1916–1920, 1916–1921, etc.) have low predictive power. In Appendix H (available as a supplement to the online version of this article at http://www.ajph.org), we also adjusted for the baseline controls in levels but allowed to measure economic circumstances (i.e., unemployment and fiscal deficit) as its change during the study period (i.e., the change between 1918 and 1924) showing no material change in our findings.

We also tested for nonlinearities by using a quadratic term, and, although the size of the coefficient was substantially reduced (B = 0.05; 95% CI = 0.01, 0.10), together with the visual aid of a locally weighted smoother, we concluded that the assumption of linearity was largely appropriate (Appendix I, available as a supplement to the online version of this article at http://www.ajph.org). From Table 1, we also weighted the fully adjusted regression by the level of population in 1919, to emphasize the data from the larger cities and eliminate undue influence of smaller towns, with no material change in our findings (B = 0.20; 95% CI = 0.01, 0.39). Our bottom line was that the association between influenza mortality and Fascism persisted even after we adjusted for a range of factors. Certainly, it was not reflecting a common trend in overall mortality or deaths from infectious and communicable diseases, nor influenza years outside the pandemic year. This implies that pandemic influenza was not simply a proxy or mediator for a relationship between income and Fascist support.

QUALITATIVE ARCHIVAL ANALYSIS

To provide a "thicker" interpretation of these quantitative findings, we used text mining in the newspaper *Il Popolo d'Italia* from June 1, 1918, until July 31, 1919.

Overall, we found that Mussolini's newspaper tended to blame "others" for the pandemic, such as Spaniards (*Il Popolo d'Italia*, June 13, 1918) and portrayed themselves as the voice of the common people against an out-of-touch "elite," exploiting the health crisis for political gain. On April 14, 1919, the Fascists said that "On the most important issues concerning the eight-hour day, we demanded an allowance for the flu epidemic" and denounced how "on the request of the special allowance requested for the flu epidemic . . . Minister Bonomi [from the Socialist party] has decided to replace it with an indemnity justified by the greater work in the last four years." Before, they also denounced that "the pandemic has affected many military wives leaving their poor children without assistance" (October 23, 1918).

When the pandemic stabilized, in mid-1919, the Fascists denounced its long-lasting consequences saying that "many people have suffered from the grippe, the Spanish [*sic*] grippe, the flu. Many did not succumb to this epidemic evil, but there are many who, although relatively favored, resent the terror of the evil and it is unknown if they will ever manage to get rid of it properly" (June 9, 1919). Beyond this qualitative evidence, a famous oddity of that time is that Mussolini replaced the handshake with the Roman salute, allowing for social distancing as he considered the handshake to be unhygienic and bourgeois. Modern scholars like Acemoglu et al.[14] are also of the opinion that "greater mortality from the Spanish flu [*sic*] pandemic . . . led to greater local Fascist Party activity."

CONCLUSION

Despite the renewed interest in the 1918 influenza pandemic as a frame of reference for anticipating potential effects of COVID-19, evidence of its impact has largely come from economic and social studies. Here we extended this work by looking at political outcomes, and we suggest a prima facie case for its contribution to the rise of populism: Italian Fascism. Our analysis shows a significant correlation between influenza deaths and vote share for the Fascist Party in 1924, even after accounting for other determinants of the rise of Fascism. Looking at Mussolini's newspaper *Il Popolo d'Italia*, we also found that the rhetoric of some of today's populist politicians concerning the COVID-19 pandemic mimicked that of earlier Fascist leaders.[15]

LIMITATIONS

As with all observational studies, our analysis had several important limitations. First, we were unable to adjust for the age distribution in cities, creating potential for error. However, our state fixed effects would have adjusted for any time-invariant characteristics of the age distribution. Second, our results rest on a balanced panel of 73 cities. While we lack complete national coverage, our data allowed us to control for observables. Indeed, in these 73 cities, we captured more than 65% of the total Italian population, and, still, in the 1920s, Italy was a poorly developed agricultural economy.

Third, it could be that the same settings that Acemoglu et al.[14] correlated with Socialist vote in 1919 to 1921 (such as casualty rates from World War I) do also correlate with the Fascist vote in 1924. However, in Appendix J (available as a supplement to the online version of this article at http://www.ajph.org) we show that the Fascist Party was the only party that managed to transform the pandemic experience into more votes. Neither parties on the left (the Socialists in the 1919 or 1921 elections) or far left (the Communists), nor parties at the center (such as the Italian People's Party), saw gains in support. The decline of the People's Party shows that Fascism drew votes not only from the Socialists but also from people of all political persuasions. As in Germany, the Communist Party, despite being the main party of protest for those workers disenchanted with the incumbent regime, was unable to transform suffering and misery into votes.[4,14] We interpret this as evidence that, at times when people are suffering, they may be more open to the siren calls of right-wing radical populist parties.

Finally, it is possible that previous local policy responses were associated with unobservable variables (such as the capability of local politicians) or that a third, underlying factor drove both influenza rises and Fascist vote shares. Recent research has shown that welfare generosity buffers the mortality–voting relationship.[1,5] The flu could have lingering political effects, and more work would be needed to understand the longer-term consequences of the epidemic for political changes. Our observational analysis can only demonstrate correlation, rather than causality. However, whether influenza in 1918 was one of the causes of Fascism, pandemics do appear to be early warnings of political polarization.

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CONTRIBUTORS

G. Galofré-Vilà created the study, collected the data, conducted the analysis, and wrote the first draft of the article. M. McKee, M. Gómez-León, and D. Stuckler oversaw the design of the study and facilitated interpretation of the findings. All authors edited the final draft of the article. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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CONFLICTS OF INTEREST

The authors have no conflicts to declare.

HUMAN PARTICIPANT PROTECTION

Institutional review board approval was not needed because we analyzed secondary public data.

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The Dangers of White Supremacy: Nazi Sterilization and Its Mixed-Race Adolescent Victims

Paul Weindling, PhD

Mixed-race African German and Vietnamese German children were born around 1921, when troops drawn from the French colonial empire occupied the Rhineland. These children were forcibly sterilized in 1937. Racial anthropologists had denounced them as "Rhineland Bastards," collected details on them, and persuaded the Nazi public health authorities to sterilize 385 of them. One of the adolescents later gave public interviews about his experiences. Apart from Hans Hauck, very few are known by name, and little is known about how their sterilization affected their lives. None of the 385 received compensation from the German state, either as victims of coerced sterilization or as victims of Nazi medical research. The concerned human geneticists went unprosecuted. (*Am J Public Health*. 2022;112(2):248–254. https://doi.org/10.2105/AJPH.2021.306593)

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Hitler's 1925 racial–political manifesto, *Mein Kampf* ("My Struggle"), called for compulsory sterilization to remedy what he regarded as damage to the German nation's hereditary stock. He attacked risks of racial pollution through intermarriage and sexually transmitted disease. He warned most famously how "German blood" was corrupted by mixing with Jewish blood, believing that Jewish blood contained racially polluting particles and that these particles hereditarily transmitted inferior psychological characteristics.[1] But Nazi race theory similarly viewed Asian and African (Black) blood as genetically polluting. Exploring this aspect of Nazi "racial hygiene" will help illuminate the pernicious consequences of Aryan-supremacist racial theory and its translation into negative eugenic practices more broadly considered.

Behind Hitler's prejudices lay the work of the anatomist and anthropologist Eugen Fischer, who, after a southwest African research expedition in 1908, had applied Mendelian genetics to studies of racial intermarriage in the then-German colony of what today is Namibia.[2] Fischer did this work at the time when Germans were imposing policies of containment on the Herero people, who were vindictively repressed after a rebellion in 1904 that resulted in many thousands of deaths. It was in this context that Fischer studied what he called the "*Basters*," who were descendants of German or Boer men who had fathered children by the native women (Hottentots) in that area. Fischer applied Mendelian genetic laws to understanding patterns of variation in the next generation of a people whom he referred to as a "*Bastardvolk*."[3]

Fischer's research became the foundation of "scientifically" based racial prejudice. While in Landsberg Prison in 1924, Hitler acquired a copy of Fischer's book coauthored with the geneticists Fritz Lenz and Erwin Baur on the genetics of heredity.[4] After his release from prison, Hitler and the Nazi Party reached out to the professional middle classes, whose support was facilitated by the founding in 1929 of the National Socialist Physicians' League. The aim was to make Nazi racism seem respectable to the German public. Doctors then lobbied for the sterilization of "racial degenerates."[5]

The expectation that Hitler's rise to power as Reich Chancellor in January 1933 would result in coercive eugenic measures was rapidly confirmed: in July 1933, the Nazis passed a law for compulsory sterilization. State-imposed sterilization represented a major stepping-stone to a fully racialized system of Nazi medicine, which included Nazi Party affiliations of the directing members of the hereditary courts and racial clinics, coercion, and racial stigmatization of victims. The psychiatric geneticist Ernst Rüdin drew up the "scientific" basis for the law and worked with the public health supremo Arthur Gütt and the judicial official Falk Ruttke.[6] The law was targeted at a range of allegedly inheritable clinical conditions, notably schizophrenia, muscular dystrophy, Huntington's chorea, epilepsy, severe mental defect, inherited deafness, and chronic alcoholism. Any citizen who had any of these conditions could be forcibly sterilized. Sexual and mental abnormalities attracted special interest.

The Nazi sterilization law drew on an earlier 1932 voluntary sterilization proposal in the Weimar Republic, a Danish law, US state sterilization laws, and US antiracial miscegenation laws as precedents. Sterilization legislation was proposed in Britain but defeated in Parliament in 1931. By contrast, US eugenic notables Henry Laughlin and Lothrop Stoddard praised the German sterilization courts as late as 1940.[7]

RACIALIZING PUBLIC HEALTH

Despite the widespread international take-up of sterilization, German sterilization measures were intertwined with the rise of Nazism. Race and welfare were fused in 1933 with the rapid Nazification of welfare provision. German public health was centralized, and this allowed Nazi officials to issue orders for sterilizations, thereby overriding the role of municipalities and community-based and democratically accountable public health. Social welfare was similarly racialized under the Nazis as Jews were excluded from the social security system and dismissed from public employment while losing entitlement to pensions, which caused widespread destitution and pauperization.[8]

Under the Nazi regime, sterilization was authorized by tribunals of two doctors and a lawyer. These roles were filled by Nazi Party members or at least sympathizers. At least 375 000 individuals were sterilized by the German authorities. In annexed Austria, the German law was imposed November 14, 1939. Although the law was generally approved of, by 1940, there was the alternative of patient killing, which was extensive in the former Austria. There was also an estimated number of 5000 to 20 000 deaths as the fatal complications (overwhelmingly among females) of sterilization.[9]

In September 1935, the Reich Citizenship Law limited citizenship to those of "German and related blood." The Blood Protection measures forbade marriages and sexual relations between Germans, Jews, and non-Whites alike. These were the so-called Nuremberg Laws.[10] They were based on the misconception that blood was vested with physical and psychological properties and could be infected by sexual relations with someone of another "race."

The Marriage Law of 1935 required hereditary health examinations before marriage. Nazi health propaganda encouraged Germans of "good" eugenic breeding stock to have at least three children. Health officers registered the birth of the disabled and "unfit." Marriage certificates involved tests to make sure that no one married with a sexually transmitted disease or if carrying a genetic disease.[11] Nazi racial experts set out to identify and research male homosexuals, many of whom were held in concentration camps, as well as Jews.

The Nazified Kaiser Wilhelm Institute of Anthropology (KWIA) under Fischer trained 20 *Schutzstaffel* (SS) doctors in genetics in 1934 for the new racial health offices and another 18 SS doctors in 1936.[12] A medical lobby around Hitler pressed for the introduction of killing of the malformed and incurable in 1935, although the practice was not introduced until September 1939 in German-occupied Poland, and from October 1939 in Germany. Hitler saw the sick as an economic burden on the healthy and wished to rid the German race of their "polluting" effects on the nation's "genetic treasury."

In June 1936, a Central Office to "Combat the Gypsy Nuisance" opened in Munich, Germany. This office became the headquarters of a national data bank on so-called "Gypsies" (correctly referred to as Sinti and Roma). Robert Ritter, a medical anthropologist at the Reich Health Office, concluded that 90% of the "Gypsies" were "of mixed blood." He described them as the products of matings with the German criminal asocial sub-proletariat and as "primitive" people who were incapable of social adaptation.[13]

CHILDREN FATHERED BY OCCUPYING TROOPS

Within this context, Nazi public health authorities also identified mixed-race children in the Rhineland as eugenic targets. These were African German and Asiatic German children derogatively referred to as the "*Rheinlandbastarde*." These children had been fathered by French colonial soldiers in the post–World War I occupation of the German Rhineland, an occupation that lasted in phases from December 1, 1918, until June 30, 1930.[14] One child, Gregor Bartz, born in 1921, is known to have been fathered by a US infantryman of a Filipino background.[15] In 1919, France had stationed between 25 000 and 40 000 colonial soldiers in the Rhineland. The German racist response in newspapers and propaganda aimed at the "Black Shame." German newspapers exaggerated the numbers of children fathered by French colonial troops, associated the children with idiocy and congenital syphilis, and created a mythology of the exterminatory threat these children posed to the "white race." The colonial French soldiers were accused of spreading influenza, skin diseases, tuberculosis, and parasites, as well as racial "pollution" because of children born by German women. German state officials had considered compulsory sterilization of the mixed-race children as early as 1927.[16]

ANTHROPOLOGISTS AS PERPETRATORS

Labeling the children as "Rhineland Bastards" was stigmatizing in the way it used the generic term for a crossbreed with the derogatory term for illegitimacy. The nationalist right popularized the term "bastard" as part of a racist campaign against the children. In July 1933, the KWIA anthropologist and Fischer's assistant Wolfgang Abel, an Austrian Nazi, examined 39 children in the district of Wiesbaden.[17] The group included 27 part-Moroccan and six part-"Annamite" (Vietnamese) children. Abel took photographs and measured physique and mental capacity. He claimed to have found all sorts of degenerative traits, notably tooth decay and recessive gums, and traces of rickets. He condemned their mental and emotional defects, concluding that nearly all of the children were subnormal. Abel's findings were publicized by the Racial Political Office in 1934, and its head, Walter Gross, a physician and fanatic for racial purity, pressed the case for sterilization at the expert committee for population and race policy. Abel was, by August 1935, an SS member, and remained dedicated to racial research, rising ultimately to be Fischer's successor to the chair of anthropology at the University of Berlin.

Beginning on March 11, 1935, Nazi race hygienists and civil servants planned the sterilization of the mixed-race children.[18] Walter Gross of the Racial Political Office hoped their mothers would give written permission, as the 1933 sterilization law did not allow for mandatory measures. In all, 385 "mixed race" children aged 13 to 16 years were sterilized in 1937. They were subjected to psychological, anthropological, and genetic evaluations. A hereditary health commission from the KWIA, composed of Abel, Fischer, Heinrich Schade, and Engelhard Bühler, evaluated the children. The sterilizations established a pattern—first, using administrative machinery to identify a group of racial undesirables, then academic study and evaluation, and then, finally, their sterilization.[19] This process happened time and time again under National Socialism with research on a "pathological" group preceding destructive intervention, whether forced sterilization or (for the Sinti and Roma) their deportation to Auschwitz, where most were killed.

Although the sterilization of the Rhineland adolescents represented one of the first instances of coerced research by the KWIA and also one of the first Nazi measures used to further medical research, this combination of racial sterilization and medical research has remained shadowy and underdocumented. There has been historical neglect of the fanatical perpetrator Abel in terms of his career as racial researcher and then postwar immunity from prosecution. Abel acted alongside the better-documented but similarly unprosecuted Fischer.

Abel was an Austrian Nazi. His father, the paleontologist Othenio Abel, was the ringleader of a powerful group of 18 anti-Semitic academics who joined together to block the appointment of Jewish academics at the University of Vienna.[20] Abel moved to Berlin, Germany, where he joined the KWIA in 1931. He used his position to instigate the documenting and rounding up of the mixed-race children.[21] Abel had a highly successful career, boosted by joining the Nazi Party in 1933 and SS in 1935. He served in the *SS-Rasse-und-Siedlungshauptamt* (Race and Settlement Office), and was a higher judge in the *Reichssippenant* (Reich Hereditary Office), adjudicating cases deciding whether a person was Jewish, an issue on which lives depended. In 1940, he ran a department for racial studies in the KWIA; in 1941, he became associate professor; and his crowning achievement was that, in 1943, he became the successor of Fischer with a professorial chair at the University of Berlin. At this time, he was working on a vast plan of imposing racial selections in German-occupied Russia to separate Nordic from "inferior" Slavic individuals.

EXCEPTIONALLY IDENTIFIED

While the figure of 385 sterilized adolescents is cited as the total number of these coerced sterilizations, only 11 of the victims are known by their full names. One victim has reflected on his experiences, remembering in three public interviews the terror of the procedures and the impact of his sterilization. Hans Hauck was born in Frankfurt am Main on August 10, 1920, as the son of an Algerian soldier and a German mother. He joined the Hitler Youth in 1933. But he was summoned for sterilization. When Gestapo officers collected the children, he recollected, "We all were too scared to object. I suspected something would happen, but did not know about sterilisation and castration." He had to sign a declaration that he would not marry or have sexual relations. He was held for 14 days with a group of mixed-race adolescents, who were all very scared, while research was conducted on the detained group. Later, Hauck fulfilled his patriotic ambition by joining the German army.[22] He felt well treated while he was a Soviet prisoner of war until 1949, and later spent time in Canada, but then returned to the German village of Dudweiler bei Saarbrücken in the westerly region of the Saarland where he had been born and grew up.[23]

The question arises over whether it is permissible to name the 10 additional victims alongside Hans Hauck. They were all healthy adolescents (as Hauck clearly was) who were the victims of criminal Nazi violence. After the war, German justice did not prosecute the perpetrators. German historians and archivists black out names of victims of medical research and medical killings. The questions arise over why this is done and whether the practice restigmatizes victims. Naming can be seen as restoring their dignity as persons. Genocide victims are named, in the first instance by families seeking to commemorate, and also by historians. To suppress names can be understood as pathologizing victims as sick or defective, which was not the case for the Rhineland mixed-race adolescents.[24] Historian Tina Campt has been pioneering in her sensitive analysis of Hauck.[25] Hauck had courageously placed himself in the public domain. He is iconic of a victim group, yet each individual life history should be constructed.

THE NEED TO NAME

One can consider that 11 abused adolescents (at the very least) should be named, and that anonymization of the adolescents abused at the threshold of vast Nazi genocidal schemes is unethical. German practices on anonymization of Nazi victims have changed in recent years with historical consensus that victims of racial medicine should be named.[26] A legal basis is provided by the International Holocaust Research Alliance (with both Germany and the United States as members) having obtained exemption of Holocaust victims, interpreted as all victims of Nazi racial oppression, from European privacy regulations.[27] This opens the way to the naming of multiple types of victims of Nazi medicine. Where there is some discussion is only to what extent detailed medical diagnoses might be cited, but describing victims in generic terms of an ethnic racial group or as psychiatric or other sorts of patients or victims is fully accepted.[28] This renders obsolete earlier practices of blacking out names, something long overdue. What is important is that doctors and scientists legitimated their intrusive violence through scientific rationales that in reality were a form of extending Nazi racial oppression. To argue that Nazi racial violence should be covered by medical confidentiality is to legitimate that violence. Medical confidentiality should not be used to justify hiding crimes that physicians perpetrated on individuals without consent. This was assault, and in most cases, we do not hide the names of assault victims. German localities have now begun to name their "forgotten victims," reconstructing their life histories, alongside those of Jews and Jehovah's Witnesses.[29]

Box 1 shows the seven names known from files from the *Reichsministerium des Inneren* (Reich Ministry of the Interior; R 18). Naming the victims here is intended to open the window to a full life history with individual experiences within the wider community as well as how victims were hunted down by racially minded public health experts. The original files are held in Warsaw, Poland, by the *Główna Komisja Badania Zbrodni Hitlerowskich w Polsce* (*Główna* Commission for the Study of Hitler's Crimes in Poland), and copies were transferred to Berlin.[30] A full listing by name is not available or, at least, no historical reconstruction has been attempted for commemorative

BOX 1— Seven Mixed-Race Adolescent Victims of Sterilization by the Nazis, From "*Reichsministerium des Inneren*" (Reich Ministry of the Interior) Files

Family Name	First Name	Place of Birth	Date of Birth
Paulus	Erna	. . .	Aug 12, 1922
Feck	Josef	Mainz	Sep 26, 1920
Borinski	Cäcilie	Koblenz	Apr 7, 1922
Hauck	Hans	Frankfurt am Main	Aug 10, 1920
Braun	Marianne	Wiesbaden	May 16, 1925
Knubben	Irma	Giessen	Feb 28, 1925
Angst	Adolf Alfred Kandel	. . .	Mar 14, 1920

BOX 2— Four Other Mixed-Race Adolescents Who Were Victims of Nazi Sterilization in World War II

Family Name	First Name	Place of Birth	Date of Birth	Date of Death	Notes on Death and Background
Barth	Willi	Euskirchen	Jul 29, 1923	Sep 26, 1944	German soldier in Northern Italy[31]
Schneider	Josef	Röhl bei Bitburg	Jun 26, 1924	Mar 3, 1942	Died in a children's ward[32]
Kaiser	Josef	. . .	. . .	. . .	Deceased[33]
Bartz	Gregor	. . .	1921	. . .	Son of a US infantryman[34]

purposes. Some local studies now provide commemorative biographies, providing details of four other lives cut short in the war (Box 2).

Local and regional studies also illuminate how public health and medical personnel and institutions became involved in identifying and sterilizing. These efforts could have taken the numbers of victims to more than 400. Sporadic attempts to prosecute the doctors involved after World War II, notably in the Saarland under French occupation, failed.[35]

Robbie Aitken and Eve Rosenhaft, in their 2013 book, follow earlier estimates of around 800 mixed-race German children in all.[36] The Nuremberg Laws made the marriage of these children illegal, and they were excluded from education. Certainly, the remainder were in fear of sterilization. That only Hauck reflected in later life on his sterilization speaks of the stigma of these sterilization victims.

POSTWAR MARGINALIZATION AND STIGMA

Some sterilization victims demanded refertilization as an operation, but most did not know that this was a possibility. This was the least that should have been offered to the victims, and not doing so shows that public health authorities in the Federal Republic after the war implicitly accepted the legitimacy of the Nazi measures.[37] The sterilization laws were suspended variously in the postwar occupation zones. The occupying powers had difficulty in bringing sterilization to trial as the victims were German citizens.[38]

An apology by representatives of the German state or Bundestag was never made as it should have been to this group. Austria remained unconcerned about Abel's criminal past as he quietly withdrew to the Mondsee near Salzburg, Austria. Overall, the situation regarding coerced sterilization victims in Germany remains shameful. The Rhineland mixed-race adolescents should have been compensated. They were victims of medical research and of sterilization as a racial measure. The Max Planck Society did not make a public apology to the mixed-race children, as it did for the Mengele twins in 2001.[39] It is doubtful whether any compensation was ever awarded to any of these sterilized victims.

Certainly there were sterilization victims who were claimants under other German schemes. At first, x-ray and chemical sterilization victims at Auschwitz and the concentration camps of Ravensbrück received pitifully low rates of compensation of between 1000 and 3000 Deutsche mark. The x-ray sterilization victims were mainly Polish Jews and Greeks. Many of the victims remained in excruciating physical pain. Roma were excluded from compensation as German officials regarded them as "criminal" by definition. Poles were generally excluded as Germany disputed the frontiers. Later, around 1968, when Hungary and Poland insisted on the International Committee of the Red Cross making awards, the sterilized were awarded sums at 30 000 Deutsche mark.[40]

As the Cologne Museum Exhibition on *Schwarze im NS-State* (Blacks in the Nazi State) commented in 2002, "*Niemand von ihnen hat bis heute eine Entschädigung erhalten. Eine Anerkennung als Opfer des Nationalsozialismus blieb diesen Menschen versagt* [None of them have received compensation. They have been denied recognition as victims of National Socialism]."[41] Overall, the situation is disgraceful and reflects on how the mixed-race victims had no lobby whether within or outside Germany. The database Victims of Biomedical Research Under NS, Collaborative Database of Medical Victims, which is maintained at the German National Academy of Sciences Leopoldina, in which all victims of Nazi coerced research (to date 28 551 persons) are as far as possible named and their life histories summarized, is a unique aid to assessing the full victim group. It provides commemoration for individual victims while providing an evidence-based analysis for the full spectrum of all victims of this iconic yet undeservedly marginalized group.[42]

Yet the Rhineland adolescent victims of Fischer and Abel of the KWIA remain shrouded in obscurity. During their lifetimes, the victims of sterilization were subjected to hostile propaganda. Although much photographed by racist anthropologists, few are known in terms of names and their biographies. The continued availability of these anonymized photos remains stigmatizing and only naming can offset this. As they were born around a century ago, the rationales for withholding their names disappears, and arguably never existed. They have received no compensation, no apology, and limited recognition as named persons. Only Hauck courageously reflected on his life experiences, and recently others with memories of the children and localities have begun to accord recognition. But being able to name only 11 out of approximately 400 victims is far too few. In the current circumstances, other German mixed-race lives appear, if not to matter at all, then not to matter enough for full recognition of the extent of the atrocity, their experiences of a forced violation of their body, and, then, living with its implications, wider public and medical racism, and, for those who survived the war, the post–World War II nonrecognition of the medical atrocity.

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CONFLICTS OF INTEREST

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Solidarity in Pandemics, Mandatory Vaccination, and Public Health Ethics

Ming-Jui Yeh, PhD

See also Kapadia, p. 202, and Prainsack, p. 232.

Mandatory vaccination has been a highly disputed policy for tackling infectious diseases. Here I argue that a universal mandatory vaccination policy for the general public against the COVID-19 pandemic is ethically preferable when grounded in the concept of solidarity, which is defined by Barbara Prainsack and Alena Buyx as an enacted commitment to a relevant respect recognized by a group of individuals with equal moral status. This approach is complementary to utilitarian accounts and could better address other reasonable oppositions to mandatory vaccination.

From a solidaristic account, the recognized relevant respect is to end the COVID-19 pandemic as soon as possible. This group of individuals would be willing to carry costs to assist each other in this respect, and a mandatory vaccination policy could be their institutionalized mutual assistance. The costs to be carried include both the financial costs of vaccination and the health costs stemming from potential adverse events and scientific uncertainties.

The proposed social health insurance similarity test suggests the degree of coercion the mandatory vaccination policy could undertake within each state's specific legal and judicial context. (*Am J Public Health*. 2022;112(2):255–261. https://doi.org/10.2105/AJPH.2021.306578)

Vaccination is one of the most prevalent and effective policies adopted by modern public health authorities against infectious diseases. In cases in which the pathogens are highly contagious, vaccination is a necessary policy to end disease transmission. Throughout recent history, however, hesitation, mistrust, and fear toward vaccination are also common social phenomena that have been observed across various societal and cultural contexts. A major ethical issue arises as to whether and to what extent the state could adopt a coercive vaccination policy requiring all citizens and other residents under its jurisdiction to be vaccinated, even if the policy is against the people's will. (Note that in this article, the term state refers to sovereign state, the political entity owning the sovereign power and related rights to govern, rather than any other governing entities at the subnational level.)

On one hand, mandatory vaccination is an effective disease control strategy that has been widely practiced for tackling infectious diseases among different subpopulations such as children, people of specific age groups, health care workers, and employees in other sectors with higher risks of infection.[1–3] From a utilitarian perspective aiming to maximize population health benefits, this mandate could be defended given that vaccines do work. On the other hand, it is also a highly disputed strategy, as individuals' autonomy and moral integrity are at stake.[4] Reasons ranging from conscientious objection to right to body and personal unwillingness have their merits in ethical debates. The benefits of effective control and the burdens of potential infringements are to be balanced under different circumstances.

Proponents have argued for mandatory vaccination policies for different infectious diseases among different populations. In the case of health care workers, some scholars have argued for mandatory vaccination based on utilitarian considerations and health professionals' preexisting moral obligations or professional codes of ethics.[4–7] For children, Pierik has argued for mandatory vaccination from the perspective that the parents do not have the right to stop their children from being vaccinated and avoiding the spread of preventable diseases; in addition, it is the government's duty to pursue the common good in the form of preventing vulnerable populations from being infected.[8] For the general public, Brennan has made the case that even from a libertarian perspective, mandatory vaccination is ethically warranted by the clean hands principle he proposed.[9]

Giubilini and Savulescu focused on the liberty to make autonomous decisions about taking risks and, using the analogy of the mandatory seat belt law, posited that some limits on the liberty to refuse taking the risk of adverse events from vaccination could be justified.[10] Douglas et al. made a case for mandatory vaccination with a comparative approach to other disease control constraints that are acceptable for the public.[11] Savulescu, likewise, argued for mandatory vaccination from a utilitarian account.[12]

Although these arguments for mandatory vaccination are compelling in their respects, they have different limitations regarding the situations that people are facing in this COVID-19 era. First, ordinary citizens are not held to the same moral obligations and professional codes of ethics as are health care workers; hence, the justifications for health care workers might not be applicable to ordinary citizens. However, ordinary citizens might still have some degree of obligation toward their fellow citizens.

Second, others who are defending mandatory vaccination ground their arguments largely in utilitarian accounts, which confirm that the vaccines for diseases such as measles are mature and their safety and effectiveness are largely scientifically verified. However, this is not the case for an emerging pathogen such as the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). This virus is not only new but also rapidly mutating. Although vaccines against this strand of virus have been developed (with adequate safety and effectiveness established to an extent), distributed, and implemented around the globe, their overall effectiveness against mutations is still under evaluation. Significant scientific uncertainties remain and indeed underpin the debate on whether to put a mandatory vaccination policy in place.[13,14]

The highly contagious, virulent, and uncertain (in terms of possible vaccine-resistant variants in the future) nature of the coronavirus further intensifies this debate, particularly in those more developed regions where public health infrastructures are considered well established and people have not suffered from such a widespread and life-changing infectious disease for almost a century. In addition to the utilitarian considerations, the concept of solidarity is one that has potential for defending policies tackling COVID-19.[15–17]

Grounded in the concept of solidarity, which is defined by Prainsack and Buyx as an enacted commitment to a relevant respect recognized by a group of individuals with equal moral status,[18] this article aims to evaluate the conditions under which a mandatory vaccination policy for the general public enforced by the state during the COVID-19 pandemic would be an ethically acceptable option. The general public refers to every person who lives under the state's jurisdiction, except those who should not be vaccinated as determined through legitimate medical reasons or the contraindications of vaccine products. This approach is complementary to utilitarian accounts and could better address other reasonable oppositions.

This issue has public health as well as clinical relevance in that, on one hand, any vaccination policy or program implemented by a government is essentially a public health intervention; on the other hand, it would affect frontline clinical practices with respect to COVID-19 patients and those who could potentially be infected by SARS-CoV-2. The proposed analysis also has potential applicability for pandemics of future emergent or resurgent (e.g., smallpox, polio) infectious diseases that have features similar to those of COVID-19. Note that the analysis focuses on solidarity within a sovereign state, given that a mandatory vaccination policy would be implemented by the national government. However, there is rising debate on and a call for global solidarity to address equitable global allocation of COVID-19 vaccines.[19,20]

For the simplicity of discussion, 2 assumptions are addressed. First, the analysis assumes that the vaccines currently available (or that will be available in the near future) for COVID-19 are generally safe and effective because, if there were no vaccines available at all, the discussion on mandates would be meaningless. In addition, the available vaccine products have different indications and contraindications for different populations such as children, youths, pregnant women, and individuals with an elevated risk of blood clots. This essay acknowledges these differences but must leave such details to clinical and epidemiological experts. However, as effectiveness is also an important factor in ethical evaluations of public health policies, this issue is still included in the analysis, with a focus on the effectiveness of mandates.

Second, the political settings of the mandatory vaccination policy are assumed to be democratic, where the people rule and are ruled in turn, and hence any legal obligations they impose on themselves are politically legitimate. In other words, the people are not ruled by an external entity such as a monarch, an elite class or party, or an authoritarian government.

A SOLIDARISTIC ACCOUNT OF MANDATORY VACCINATION

The concept of solidarity is notoriously ill defined and has various meanings.[21–23] In this article, the concise definition of solidarity proposed by Prainsack and Buyx is adopted as it is one of the most dominant and practical versions that have been developed in the field of bioethics and applied to related policies. Solidarity is understood as a descriptive concept with normative dimensions. It refers to the practices within which a group of individuals with equal moral status and membership in a community recognize similar risks in a relevant respect and therefore are willing to carry costs to assist each other.[18] Different from values, feelings, or obligations—which could be internal sentiments or thoughts—solidarity is enacted in the sense that it requires some forms of external expression or manifestation, which are actions engaging with the real world.[18] It is "symmetry between people in the moment of enacting mutual support."[15(p126)]

In terms of formalization, there are 3 tiers of solidarity. At tier 1, solidaristic practices are expressed informally at an interpersonal level. At tier 2, some group practices appear as informal customs or social atmosphere. At tier 3, the practices are institutionalized in the forms of contract, policy, law, or other solidaristic insitutions.[15,18] For Prainsack and Buyx, solidarity is not a purely deontic concept that directs what people should do but rather a more axiological one that depends on what people are really practicing under particular contexts. Policy decisions grounded in solidaristic practices are ethically preferable because they better reflect what people value, support, and commit to and would hence lead to a more flourishing society.[18]

In a recent analysis, Prainsack demonstrated that a more strengthened tier 3 solidaristic institution is an important factor that explains the resilience of a society to tackle the COVID-19 pandemic.[15] Although she was primarily referring to publicly funded health care systems that provide accessible and affordable services for all, other types of public institutions could also be grounded in a similar account of solidarity. In this article, the mandatory vaccination policy for everyone is considered as one example of a solidaristic public institution.

In the case of a mandatory vaccination policy for COVID-19, the relevant respect that people recognize is to end the COVID-19 pandemic as soon as possible. Then, with a group of individuals with equal moral status—for instance, fellow citizens of a state who are willing to carry costs to assist each other in this respect—a mandatory vaccination policy could be viewed as institutionalized mutual assistance. The costs to be carried here include not only the financial costs of purchasing the vaccine products and administering the national-wide vaccination program but also the health costs due to potential adverse events of vaccines (even a mature vaccine product has a normal expectation of adverse events; they just might be less frequent and less severe), scientific uncertainties, and the financial and emotional costs of compensating and mourning for those who unfortunately suffer from these health costs. This inclusion of scientific uncertainties could be a complement to the usual utilitarian accounts on mandatory vaccination, which often require that the intervention be effective and safe.

Hence, the solidaristic account is specifically suitable to situations such as COVID-19 wherein many uncertainties about the nature of the disease as well as the vaccine products remain because the standard calculation of the utilitarian account might find these uncertainties unmanageable and make more conservative estimations (i.e., underestimate the benefits and overestimate the risks). This more conservative evaluation could result in policy recommendations against mandatory vaccination. People's enacted solidarity in mutual assistance to combat COVID-19 could provide the necessary sentiments supporting the policy, allowing for a more inclusive acceptance of the uncertainties.

Beyond fellow citizens, the scope of the mutually recognized community might be broader, including those noncitizen residents who have lived, worked, studied, and engaged in other forms of social cooperation within a boundary of the state's jurisdiction and social members' living experience. The similar status of everyone in the face of COVID-19 gives rise to a similar recognition of common risks that they should tackle together, despite their differences in nationality, citizenship, or other factors.

The risks of COVID-19 are more than well recognized; they are very genuine and significant in scale, and no reasonable citizen will dispute this fact. With the solidaristic account, by recognizing these similar risks, citizens and other fellow dwellers have therefore self-imposed a moral obligation to assist each other. This self-imposed obligation could be considered a preexisting moral obligation for a mandatory vaccination policy. This moral obligation of ordinary citizens is probably not as strong as the professional code of ethics demanded for health care workers[4]; however, by the nature of the representation of the self-imposition and the recognition of each other's equal status, it carries greater weight than normally found among ordinary individuals who are not otherwise connected with each other under institutionalized solidaristic practices.

THE SOCIAL HEALTH INSURANCE SIMILARITY TEST

One issue to be considered is the extent to which this solidaristic mandatory vaccination could be coercive, in the sense that the government enforces different degrees of limitation on one's rights and behaviors against one's will. Drawing on the "intervention ladder" proposed by the Nuffield Council on Bioethics, Bradfield and Giubilini illustrated strategies with different degrees of coercion and their corresponding consequences if one refuses to take vaccines, from the most coercive "forced vaccination" (e.g., being physically captured and injected) to the least coercive "persuasion" (e.g., conducting campaigns, building infrastructures for public health activities).[4] The selection of these options depends on the particular context of the policy. The question, then, is under what degree of coercion would a solidaristic mandatory vaccination policy be justifiable?

Once solidarity practices to end the pandemic become institutionalized, they transform from moral obligations to legal ones. As a social contract to be honored and realized, mandatory vaccination acquires a degree of legality that warrants some legal enforcement. However, this does not answer the question regarding the boundaries of state coercive interventions. The answers to this question are largely subject to each state's judicial and even constitutional reviews, and each has very different contexts (for instance, consider the differences between a legal system of common law and one of civil law).

Despite this contextual limitation, a common ethical consideration is the principle of proportionality, balancing the harms and benefits that might be brought by a policy.[12,24] Here, a social health insurance (SHI) similarity test is proposed for policymakers to determine the proportionate distribution of harms and benefits and hence the acceptable degree of coercion of a mandatory vaccination policy. An SHI is a type of health system often considered to be grounded in the solidarity of mutual assistance to meet financial needs derived from health needs. This old notion of solidarity, which dates back to late–19th-century Europe, has been constantly revived in different forms such as social citizenship and later the ideal of universal health coverage.[25,26]

Based on the solid presumption of solidarity, participation in SHI is mostly mandatory and there are few or no opt-out options. Taking this analogy, an SHI similarity test implies that the acceptable degree of coercion on mandatory vaccination, which is also grounded on solidarity, should be roughly the same as the coercion on those who are not willing to participate in the SHI and contribute the social premiums of a specific state.

For instance, in the health system in Taiwan—an SHI called National Health Insurance—those who refuse to pay the premium are subject to a daily overdue charge of 0.1% of the amount payable, with a ceiling of 5% of the payment; if it becomes overdue for more than 150 days, the case may be subject to enforcement by court order.[27] According to the SHI similarity test, if a solidaristic mandatory vaccination policy were adopted in Taiwan, those who refused to be vaccinated would not be physically captured and administered the vaccine by a public health agency, but they could be subject to a daily financial penalty and (if they persisted in refusing to pay the penalty and receive the vaccination) an eventual enforcement action until the end of the pandemic.

As to how this process should be enforced and the noncompliant be sanctioned, it would depend on each state's administrative and judicial structures. To give a possible scenario here, the public health department could work with household registration departments or social security offices to establish the name list for vaccination and then identify those unwilling to take vaccines without any legitimate medical reasons. The public health department could then charge the penalty for refusal and, if necessary, move the case to court for further enforcement. Those who could prove that they are experiencing temporary financial hardship or qualify as being in poverty (as determined via a means-tested process) could apply for loans or subsidies from the government's welfare sector.[28] According to the SHI similarity test, the penalties are only financial in the illustrative case of Taiwan. There might be other possible forms of penalty with different degrees of coercion according to the test in other states.

With this penalty, those who refuse to take vaccines without legitimate medical reasons or reasons fitting the contraindications of vaccine products, although having their desires respected, will be held accountable proportionately and will not have an easy way to buy out of their responsibility.[12] The collected penalty fund could then be used to pay for the treatment of COVID-19 patients, the administration necessary for vaccination and disease control, and compensations for those who unfortunately suffer from adverse events associated with the vaccines.

The SHI is just one type of health system; there are many other types of designs that contain a mandatory element in their financing mechanisms, as demanded by the ideal of universal health coverage, which is grounded in the human right to health on one hand and a notion of solidarity on the other. Furthermore, health systems are just one of the solidaristic institutions of a state; there might be other institutions in other policy areas that are of a coercive nature. Other tests for a proportionate coercion of mandatory vaccination could derive from the SHI similarity test, depending on each state's specific context. Therefore, the solidaristic account of mandatory vaccination is applicable to states with different social norms and cultural patterns; the degree of coercion simply may vary according to the result of the similarity test.

RESPONSES TO REASONABLE OPPOSITIONS

There are 3 major oppositions to a solidaristic mandatory vaccination policy: the direct challenge of the ethical legitimacy of the solidaristic account, the challenge of respect for autonomy, and the challenge of proportionality between harms and benefits of the policies.

First, some might argue that solidarity, according to its definition, should consist of voluntary citizen practices and hence cannot warrant mandatory and coercive state intervention against individuals' will. This argument might be valid in tier 1 and tier 2 solidarity, in which the practices exist in informal forms such as daily interactions, local customs, or social atmosphere. However, once the solidarity practices have been institutionalized in the form of a public health policy, as in tier 3, they acquire a strong political authority that could act coercively, by mandate of the group of individuals who recognize the relevant respect, to pursue the goal of mutual assistance in that respect. In other words, tier 3 solidarity practices have a retrospective ethical legitimacy that could justify the imposition of a policy that is not necessarily desired by all individuals in the group.

In addition, some might further argue that they do not recognize the relevant respect in the first place, that is, ending the COVID-19 pandemic as soon as possible; therefore, the solidarity practices imposed on them are unwarranted. In this case, the solidaristic account is weighed against the respect for autonomy. The question then would be whether and to what extent autonomous decisions of not recognizing the merit of tackling a pandemic such as COVID-19, one that took and is still taking millions of lives, are reasonable[29] and should be respected.[30]

Second, others might draw on the respect for autonomy from other perspectives; for instance, they might argue that there should be some room for individuals to suspect the scientific uncertainties of the vaccines or that individuals should enjoy certain human or civil rights and be protected against state coercion. Scientific uncertainties and normal anomalies are common in any medical technology, including vaccines. Whether to accept or suspect a product is a matter of risk perception. The solidaristic mandatory vaccination policy would allow room for reasonable suspicion (e.g., on the part of antivaxxers), as the policy would not coercively capture a person and enforce vaccination. According to the SHI similarity test, the policy would at most be as coercive as another institutionalized (tier 3) solidarity practice.

In Taiwan's case, those who refuse to be vaccinated could choose to pay the penalty to compensate for the higher risk of transmission they would cause among their fellow neighbors: in a sense, their coercion of their neighbors' autonomy.[4] This degree of coercion based on another existing solidaristic policy is ethically and politically acceptable in that particular context. A solidaristic mandatory vaccination policy in a democratic state cannot persuade everyone (not to mention some of the antivaxxers upholding unreasonable conspiracy theories) to accept the vaccines, but it offers better justification for the pursuit of protection through vaccination while in the meantime allowing for some exceptions (although with penalties), thus respecting autonomous decisions in a minimal sense.

Third, still others might argue that there are other less restrictive alternatives to mandatory vaccination. Hence, even if they are grounded on a solidaristic account with a commonly recognized aim of ending the pandemic, not all vaccination policies necessarily have to be as restrictive as a mandatory policy under the consideration of proportionality. What measures to end pandemics are most effective and at the same time least restrictive is a question subject to empirical investigation. However, in the case of COVID-19, preliminary evidence has shown that vaccine coverage is negatively associated with the SARS-CoV-2 delta variant's mutation frequency,[31] and simulations have predicted that more equitable and rapid vaccination would lead to lowered transmission rates and mitigated antigenic evolution,[32] suggesting that universal vaccination is an effective and necessary measure against transmission. This necessity could be achieved only through a massive vaccination policy that is either supported by a majority of the population or universally mandated.

Considering the complexity of the issue and the surging vaccine hesitancy, a government could consider adopting other measures to promote willingness to be vaccinated. These seemingly less restrictive strategies might be preferable at first glance,[13,33,34] but they would also require a much longer time and resource investment (e.g., campaigns to convince partisan, conspiracy-driven, and populist antivaxxers; communicative countermeasures against misinformation and fake news; education to raise the public's scientific and health literacy; investment in public health infrastructures). Admittedly, these promotive long-term strategies are indeed necessary for public health, and it is not necessary to endorse a debate focusing on the "binary distinctions" between voluntary and mandatory vaccination.[33] However, neither these strategies nor the voluntary vaccination policy could pursue massive vaccination with the prompt timing and universal coverage that the mandatory policy could deliver, and they might eventually delay the end of the pandemic, causing larger health and social losses and even further undermining the effectiveness of other disease control measures.

In summary, although the vaccine products developed by different companies have different effects among different populations with different limitations, in general a government should consider implementing a solidaristic mandatory vaccination policy. Such a policy concurs with the utilitarian account of maximizing health, social, and economic benefits; is complementary to the utilitarian account with more inclusive consideration of uncertainties in terms of the effectiveness and safety of vaccines; and pursues universal vaccine coverage as much and as soon as possible while allowing for minimal unwillingness and autonomous decisions regarding individual vaccine refusal.

CONCLUSIONS

This article has assessed whether the state could implement a mandatory vaccination policy and extended the discussion from specific groups of people to the general population. Grounded in a solidaristic account, the article defends a mandatory vaccination policy for the general public to address the COVID-19 pandemic. Ending the pandemic is a common goal that no reasonable citizens will dispute. Given this recognition, citizens would be willing to carry the costs to take joint actions to achieve this goal. A mandatory vaccination policy as a form of tier 3 solidarity practice is hence ethically justified. The SHI similarity test is proposed for policymakers to determine the degree of coercion the policy should undertake in each state's specific context.

The tensions and tradeoffs between individual interests and public interests (or, in some senses, the common good) are part of a constant debate in the field of public health ethics, and they certainly influence practices on the frontlines. In times of pandemics, it is imperative to stop massive transmission and casualties as soon as possible, and hence it is necessary and ethically preferable to implement the solidaristic account of a mandatory vaccination policy when the volume of vaccines makes them available for all.

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CONFLICTS OF INTEREST

The author declares no conflicts of interest.

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No protocol approval was needed for this research because no human participants were involved.

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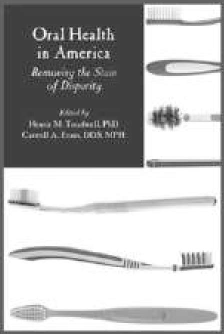

West Oakland's Experience in Building Community Power to Confront Environmental Injustice Through California's Assembly Bill 617

Lily MacIver, MCP, Jonathan London, PhD, Natalie Sampson, PhD, Margaret Gordon, Richard Grow, and Veronica Eady, JD

We explored how air quality management processes associated with Assembly Bill 617 (AB 617) in West Oakland, California, represent a shift in power relationships between government agencies and communities toward the goal of addressing legacies of environmental injustice.

We drew from a statewide assessment of community engagement in AB 617's first year, and an analysis of the West Oakland AB 617 process. The first comprised 2 statewide surveys (n = 102 and n = 106), 70 key informant interviews, observation of all AB 617 first-year sites, and analysis of related planning documents. The second comprised 2 rounds of interviews (n = 22 and n = 23, with a total of 19 individuals) and extensive participant observation.

Several factors are necessary for pursuing environmental justice: (1) invest in community partnerships and collaborations, (2) honor community knowledge and data, (3) ensure that community constituents share power in environmental governance, and (4) adopt explicit racial justice frameworks. Although still a work in progress, AB 617 offers important lessons for community and policy organizations nationwide engaged in environmental justice. (*Am J Public Health*. 2022;112(2):262–270. https://doi.org/10.2105/AJPH.2021.306592)

> "AB 617 will achieve historical remedies that West Oakland communities have never had before. . . . The solution is that the community is given power to make decisions."
>
> —*Margaret Gordon, West Oakland Environmental Indicators Project*

California's Assembly Bill 617 (AB 617), passed in 2017, has launched a bold and controversial experiment to transform state, regional, and local air quality management in ways that prioritize the well-being of communities experiencing the worst air quality in the state.[1] This vision entails a statewide strategy based on locally scaled plans for air pollution monitoring and management in communities affected by a high cumulative exposure burden and legacies of environmental racism. The pathway toward these goals has produced some notable successes and has also been challenging and conflictual.[2] Although many communities and regional environmental justice organizations have become active—if still critical—leaders in the AB 617 Community Steering Committees (CSCs), some statewide organizations have attacked the law's origins and its implementation.[3] Critics from inside and outside the process have questioned the degree of community power in decision-making, the significance of its impacts on air pollution reductions, and the mismatch between AB 617's goals and the time and resources needed to achieve them.[3] Examining this process and its outcomes are crucial to understanding the perils and potentials for redesigning public participation through community power building to achieve environmental justice.

The structure and process of AB 617 implementation are complex. Upon passage of the bill through the legislature and its signature by the governor, the California Air Resources Board (CARB) became the lead agency

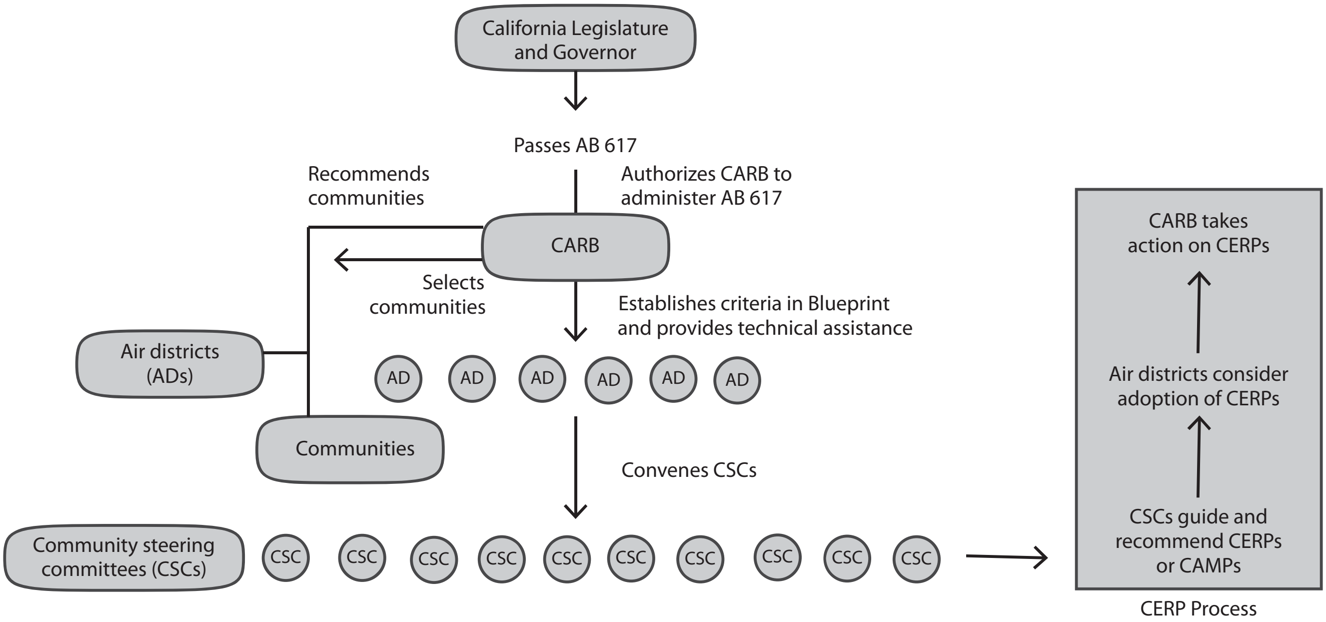

FIGURE 1— **Assembly Bill 617 Community Emissions Reduction Program (CERP) and Community Air Monitoring Plan (CAMP) Policy Development Process: California**

Note. CARB = California Air Resources Board.
Source. London et al.[2]

on the law's implementation. Part of this leadership is enacted through CARB's AB 617 Blueprint, which provides specific implementation guidance.[4] Through AB 617, regional air districts nominated, and CARB selected, communities to develop Community Air Monitoring Plans (CAMPs), Community Emissions Reduction Programs (CERPs), or both to guide air quality improvement strategies. The CAMPs set up systems of air quality monitoring focused on the sources and types of pollution in the designated communities, whereas CERPs consist of strategies to achieve reductions in emissions and exposures. The CAMPs and CERPs are intended to be guided by CSCs (composed of neighborhood residents, community organizations, academics, local governments, and businesses) and produced by air districts.[4] In practice, there is often conflict between air districts and CSCs over which body is driving the process. Ultimately, air districts adopt their CERPs, and CARB then reviews them, recommends enhancements, and has the final approval authority. (Figure 1).

Between 2017 and 2021, CARB provided $177 million to air districts for AB 617 implementation (including managing CSCs, developing CAMPs and CERPs, enforcement, reporting, and related activities).[5] CARB also directed $25 million into grants for community-based organizations to develop local education, organization, and planning activities to improve air quality and, in some cases, to build their capacity to be selected as future sites to develop a CAMP, a CERP, or both.[6] CARB itself is allocated $15 million per year to manage AB 617 implementation. Beyond funding AB 617 communities, since 2017, CARB has allocated $704 million in incentive funds to air districts to address air emissions hot spots from mobile sources throughout California.[7] Much of this funding comes from the state's Greenhouse Gas Reduction Fund. This connection to the state's market-based climate change policies was a reason for the opposition of some environmental justice organizations.

We examined the potential of AB 617 to address environmental health disparities by highlighting 1 of the first-year sites, West Oakland, which has been recognized as an exemplar of success and yet also struggles to meet its lofty goals. West Oakland's CERP, entitled "Owning Our Air," highlights the community power that guides its work.[8] We sought to answer the following questions: To what extent and in what ways has West Oakland's AB 617 process represented a shift in power relationships between government agencies and communities? Can lessons from this policy experiment be gleaned for adaptation in other policy contexts?

In addition to critical reflections from a diverse coauthorship including academics, community leaders, and agency staff, this study is based on 2 evaluations of AB 617: London et al.[2] and MacIver.[9] Lily MacIver is an environmental planner and the current article's first author, and Jonathan London is an environmental justice scholar and the article's second author. The third author, Natalie Sampson, is an environmental justice scholar; the fourth, Margaret Gordon, is a local environmental justice leader; the fifth, Richard Grow, is a member of the West Oakland CSC and retired from the US Environmental Protection Agency; the sixth, Veronica Eady, is a staff member with the Bay Area Air Quality Management District associated with the West Oakland AB 617 process and formerly of CARB.

London et al.[2] provide a statewide assessment, under contract with CARB, of community engagement in AB 617's implementation in the 10 first-year communities. MacIver[9] provides an analysis of the West Oakland AB 617 process. London et al.[2] conducted 2 statewide surveys, the first in fall 2018 (n = 102) and the second in winter 2020 (n = 106). The study also drew from 70 key informant interviews (5 associated with West Oakland), observation of all 10 first-year AB 617 sites, and analysis of the planning documents from all 10 sites and CARB. The study by MacIver[9] began as a master's thesis and was submitted to the Bay Area Air Quality Management District (BAAQMD) as a policy report. Survey respondents and interview participants in MacIver[9] included CSC members, and BAAQMD and CARB staff associated with the West Oakland site. MacIver[9] conducted 2 rounds of interviews (spring 2019: n = 22; fall 2019: n = 23). Some individuals were interviewed twice. This study also included extensive participant observation of CSC meetings.

GROUNDING AB 617 IN ENVIRONMENTAL JUSTICE STUDIES

For over 40 years, historically marginalized and overburdened communities have advocated for healthy environments in the places where they live, work, play, and learn as part of the larger environmental justice movement in the United States and other countries.[10] The environmental justice movement seeks to confront discriminatory legacies that have located low-wealth people, people of color, and indigenous peoples in disadvantaged physical, economic, political, and social positions.[11] Such legacies include placement and expansion of hazardous facilities near disadvantaged communities, destruction of existing communities through urban redevelopment and gentrification, and restriction of investments in infrastructure for thriving communities through redlining.[12] Environmental justice organizers also seek to disrupt racist governance systems that marginalize the voices and agency of low-income people and people of color in determining the fate of their communities.[13] Overall, the environmental justice movement works to address the systems implicated in the production and reproduction of racialized health disparities.[14–18]

Recent scholarship in critical environmental justice studies—helpfully synthesized by David Pellow into "four pillars"—has highlighted several themes relevant to our case study.[19] The first pillar concerns the intersectional quality of environmental injustice and the need to consider the impacts of dividing lines of race, ethnicity, class, caste, gender, sexuality, ability, immigration status, species, and others. Second, such studies must be multiscalar. To capture the complex ways in which environmental injustices are produced, there must be an analysis of how social, political–economic, and ecological systems intersect at multiple spatial scales. An expanded temporal scale is also needed to capture what Nixon calls the "slow violence" of chronic and often invisible sources and impacts of toxicity.[20] Third, critical environmental justice demands a reconsideration of the state's role as a presumed ally for communities confronting the depredations of capitalism and, instead, to view it as a perpetrator of such injustices integral to the functions of racial capitalism.[21] The critical task here is to imagine environmental justice beyond the state and to advocate for nonstate modes of self-governance. Fourth and finally, critical environmental justice brings into focus the value of "racial indispensability" as a counter to the dominant view of Black and Brown bodies as disposable and the demand that "all communities are seen as interconnected, interdependent, but also sovereign and requiring the solidarity of others."[19(p27)]

This approach to critical environmental justice engages with scholarship on environmental health inequities in several ways.[16] First, it highlights the dynamics of structural racism as a driving force in the production of environmental health injustices—for example, how the historical legacies of redlining in places like West Oakland create disparities in patterns of asthma, urban heat islands, and psycho-social stress.[22–24] Second, it describes how contemporary state practices continue to relegate low-income people and people of color to unhealthy neighborhoods through zoning, land use, housing, economic development, and policing policies and practices.[25] Third, it provokes crucial conversations about how improvements in health equity must be a metric by which all public policies are assessed.[16,26]

By focusing on the 4 pillars of critical environmental justice, we offer a framework to understand the successes and challenges of AB 617 to address air pollution and related health disparities in historically marginalized, disadvantaged communities such as West Oakland.

COMMUNITY LEADERSHIP FOR ENVIRONMENTAL INJUSTICE

West Oakland residents' health and well-being have suffered from the disproportionate siting of transportation infrastructure, industrial businesses, and the Port of Oakland's freight logistics activities in or near residential areas (Figure A, available as a supplement to the online version of this article at http://www.ajph.org).[27] These developments often serve whiter, wealthier communities elsewhere in the San Francisco Bay Area and beyond while burdening the local West Oaklanders with poor health. Despite significant investment in emission reduction technologies and stricter environmental regulations over past decades, West Oaklanders suffer higher rates of asthma emergency room visits and air pollution–related disease morbidity (stroke, heart attack, cancer, and chronic lower respiratory diseases) than the City of Oakland population.[28,29]

Residents and nonprofit organizations of West Oakland have actively confronted legacies of structural racism for decades (Figures A and B, available as supplements to the online version of this article at http://www.ajph.org).[3,27] One respected community leader, Margaret Gordon, cofounded the West Oakland Environmental Indicators Project (WOEIP) in 2000. WOEIP has worked collaboratively with neighborhood organizations, physicians, researchers, and public officials for the last 20 years to ensure environmental and economic justice for West Oaklanders. WOEIP's community science projects produce data to support pollution reduction advocacy.[30–32] WOEIP is also a member of the Ditching Dirty Diesel Collaborative—a coalition working to reduce diesel pollution in Bay Area low-income communities.[33,34] WOEIP attests that its work has built trusting relationships with residents and agencies, paving the way for a collaborative AB 617 process.

WOEIP calls its engagement and partnership building method Collaborative Problem Solving (CPS). CPS uplifts community members as primary decision-makers in policy and planning processes, while agency staff are considered technical assistance. CPS is now a term used by public agencies, many of which were developed after WOEIP started using this term in the early 2000s.[35] WOEIP's CPS model emerged from the West Oakland Toxic Reduction Collaborative (WOTRC), an effort driven by WOEIP and US EPA Region 9.[36] The WOTRC's partnering agreement, developed between 2003 and 2005, shared power between community and government stakeholders in a new way, clarifying the rules of collaboration for all parties involved. The WOEIP CPS method aims to insert democratic participation into bureaucratic functions that typically lack community agency. The WOEIP CPS method requires resident coleadership, the reconciliation of conflicting agendas through consensus-based decision-making, neutral facilitation, and partnership agreements that outline power-sharing via roles, expectations, and responsibilities. CPS ensures equitable participation by requiring food, child care, translation services at all meetings, and stipends for community members. The WOEIP staff describes the CPS process as most successful when government agency leadership fully endorses power-sharing with communities, as was the case for the WOTRC and, currently, West Oakland AB 617 efforts.

THE AB 617 WEST OAKLAND COMMUNITY ACTION PLAN

Because of its collaborative partnerships with local regional, state, and federal agencies, deep ties in the community, and expertise with citizen science, BAAQMD invited WOEIP to be the primary partner community organization for AB 617 in West Oakland.[9] Additionally, because of the wealth of existing air quality monitoring data collected by BAAQMD, WOEIP, and their research partners, the West Oakland AB 617 process skipped the step of developing a CAMP and jumped directly into developing a CERP.[9] West Oakland was the only AB 617 community out of the initial first-year sites to forego the CAMP step.[2]

To develop the CERP, WOEIP and BAAQMD formed a "colead team" that shared responsibility for providing data and direction to the West Oakland CSC. The CSC was composed of community stakeholders (i.e., residents, community organizations, small business owners, government staff with West Oakland jurisdiction). Using consensus-style decision-making and the CPS method, the CSC created plan content and served as the final decision-making body for CERP strategy development.[37]

We now turn to analyzing this case study and ask to what extent, and in what ways, this vision was achieved.

THE AB 617 PROCESS AND COMMUNITY POWER

In the West Oakland CERP process, the CPS method helped disrupt patterns of community exclusion from environmental governance by centering community leadership and increasing agency and informed participation.[9] It also built trusting relationships between stakeholders historically in conflict over environmental issues. MacIver[9] measured perceived trust between CSC members and BAAQMD staff through survey research and found that trust increased. As a BAAQMD leader said,

> The community co-leadership model is revolutionizing the way we do business and has changed our outlook and approach to community outreach . . . . It shifts the conversation from what we do with our technical work, graphs, and models, to what the community thinks should happen with their air.[9(p26)]

One example of power-sharing was WOEIP's corecruitment of the CSC. In most other AB 617 communities, the air districts recruited and selected the committee members.[2] Margaret Gordon described their process differently:

> Developing the Steering Committee was based on relationships we built with organizations and individuals on different projects, initiatives, and programs in the last 20 years. We have set the criteria to prioritize who would be on it.[9(p27)]

The formation of the CSC by a community-based organization placed power in local hands. WOEIP received $100 000 through a BAAQMD contract to support their colead role, separate from AB 617 funding sources. This funding was an extra investment from BAAQMD to support local capacity for coleadership and offers an example that other CSCs and air districts can adopt.[9]

The West Oakland case involves a shift in the distribution of power into community hands. West Oakland's approach diverged from the traditional model of air quality governance (Figure 1), which places CARB as the agency authority to approve plans from the air districts, which in turn have delegated power to create plans with varying degrees of community input. In this case, the West Oakland CSC maintained significant control over the development of the CERP, with BAAQMD providing technical assistance.[9] Thus, the CERP submitted to the BAAQMD Board for adoption directly represented CSC work. This differed from most other AB 617 first-year sites, where the air districts exerted much more control over final CERPs and CAMPs.[2]

The West Oakland AB 617 process represents a shift in power relationships between regional government and communities and downscales planning to a neighborhood level. Past air plans and initiatives in West Oakland, as in many other low-income communities and communities of color, have not shared planning and decision-making power with local stakeholders on coequal terms, nor did they provide technical training to residents to support informed participation. As a BAAQMD staff person attested,

> This is the first time we have partnered explicitly with the community; it's the first time we have had to take their input as equals. Previous plans were all regional. There was outreach, but it was only at the county level.[9(p24)]

The West Oakland CERP process was not without challenges. For example, residents made up the smallest share of the CSC; government and community organization staff far outnumbered them.[9] WOEIP, as a small organization with limited capacity, was not able to continuously do outreach to boost community participation. Community residents on the CSC were not paid for their participation in the planning process; they are now paid in the implementation phase.[9] Lastly, youth CSC members did not feel that engagement was appropriate or inclusive, and their participation fell over time.[9]

The West Oakland CERP strategies require agencies to respond meaningfully to community concerns that are complex, long-term, and often rooted in legacies of racist policy. One CERP strategy requires the City of Oakland to address gentrification resulting from the CERP's success. The CSC worries that improved environmental conditions will raise housing prices, replicating processes of structural racism and exclusion by displacing residents. However, this CERP strategy, like many others in the plan, does not provide details on how to accomplish it or metrics to measure success. This ambiguity was a common complaint from government staff charged with carrying out the ambitious strategies prioritized and written by community residents. As an agency staff member said, "The weak link is that if those strategies are not well written, they reduce feasibility and therefore the probability of a successful implementation."[9(p37)]

To successfully improve the air while channeling the cobenefits to the most vulnerable residents, AB 617 requires public agencies to work outside of their silos. For example, the CERP calls for the Alameda County Public Health Department to track changes in long-term health outcomes as an indicator of success.[8] The West Oakland CERP also requires sustained multiyear action (spanning plan writing to implementation). Implementation continues to require cross-sector collaboration between government, the private sector, and the community, while maintaining the CSC's central decision-making role. This reveals a weak point: local governments like cities and county health departments are not legally required to participate in AB 617, receive no extra funding or staff to do this work, and, in the case of West Oakland, often struggle to include it in their work plans.[9]

Another major challenge in linking AB 617 and environmental justice was racial equity's lack of integration into the planning process, strategies, and targets.[9] For example, the composition of the CSC did not represent all ethnic groups in West Oakland (in particular, not including the large and growing Latinx population).[9] In addition, targets for air pollution reduction and health outcomes were not disaggregated by race. To address these gaps, the CSC and the air district have committed that CERP implementation will use a methodology from the City of Oakland's Department of Race and Equity to operationalize equity.[38]

The outlook for this process is positive. Using the Department of Race and Equity's Racial Equity Implementation Guide, MacIver found that the West Oakland CERP process realizes equity-based practices in 3 ways that were distinct from those of most other AB 617 communities.[9] First, the CPS structure gave residents and local environmental justice organizations a high degree of decision-making power.[9] Second, the CERP's analysis of the community acknowledges that the population of West Oakland is majority low-income and people of color, with poor health outcomes related to air pollution.[9] Third, the CERP aims to reduce health disparities and air pollution exposure disparities between West Oakland's individual neighborhoods.[8] Among the first-year AB 617 implementation sites in California, several CERPs refer to health disparities (e.g., San Bernardino–Muscoy, East Los Angeles–Boyle Heights–West Commerce); however, only West Oakland and Wilmington–Carson–West Long Beach explicitly include health disparities in their CERP metrics of success.[2]

MacIver found that to meet its goal of achieving racial equity, CERP implementation will need to define racial groups most vulnerable and proximal to air pollution within West Oakland's neighborhoods and include equity-based evaluation and accountability metrics for strategies that can measure progress toward CERP goals.[9] Lastly, racial equity gaps in BAAQMD and CARB's current air pollution regulation and programming in West Oakland need to be identified and concrete steps to ameliorate such gaps defined.[9]

In summary, the West Oakland CSC, using WOEIP's CPS method, was able to navigate—skillfully, but not completely—issues that many other AB 617 communities struggled with, in particular the ownership of the process and conflict mediation between air districts and communities.[2] At times it struggled with maintaining high resident participation, integrating race equity into the core of its strategies and goals, and engaging youth CSC members appropriately. Nonetheless, there were many successful elements to the process and outcomes. As a BAAQMD staff member reflected, "There is a lot of wisdom in the community, and it needs space to come out. This process is creating that space."[9(p46)] The West Oakland AB 617 process is an example of a power-sharing partnership between governments and communities that aims to dismantle historic racial inequities and health disparities through participatory planning. The process drew on WOEIP's history of building community knowledge through participatory research and popular education, as well as partnerships with diverse stakeholders, to empower residents to write a CERP that will guide government work and investment in West Oakland for years to come.[9]

LESSONS FROM AB 617 AND THE WEST OAKLAND EXPERIENCE

The West Oakland CSC has struggled with some of the structural tensions inherent in AB 617. These tensions derive from a combination of the limited direction of the authorizing legislation, the challenge for CARB to develop a comprehensive implementation framework (the AB 617 Blueprint) able to guide diverse communities across the state, and the need for air districts to navigate between the legislation, the Blueprint, and their own strategies while balancing their existing responsibilities on a very short timeline and with what many districts consider inadequate resources.[2] One challenge related to environmental justice is that the authorizing legislation, the Blueprint, and most CERPs fail to explicitly refer to racial injustice, even though the bill was intended to address these structural issues, according to the bill's author.[2] However, a second version of the Blueprint, "the People's Blueprint" (in process of review at this writing), expands social equity and environmental justice and is currently being written by community and environmental justice leaders.[39] Another challenge is the significant variation between how individual air districts have opted to carry out the state mandates, including the kind and extent of consultation with CSCs and the types of measures in their CAMPs and CERPs. This variation causes conflict with the CSCs, who generally push for greater decision-making power to compel CARB and air districts to adopt more ambitious strategies.[2] In the case of the West Oakland CSC, the residents' and community organizations' drive for greater local power was met with a degree of support from BAAQMD not present in most of the state's other AB 617 sites.

To reflect on the challenges faced by California in meeting the potential of AB 617, we return to Pellow's 4 pillars.[19] The implementation of AB 617 addresses the intersectional nature of environmental justice by focusing on communities disadvantaged by the ravages of racial capitalism (first pillar).[21] Even here, though, it does not explicitly call out the multiple dimensions of environmental injustice nor substantively focus on racial indispensability (fourth pillar).[21] Nor is AB 617 (or any single piece of legislation) able to address structural racism on its own. Addressing structural racism is challenging and requires great sensitivity and skills to do so effectively—capacities that are limited in many air districts and represent a growing edge for CARB. AB 617 places local communities in a multiscalar network with cities, regional air districts, and state agencies needed to implement the strategies in the CERPs (second pillar). To fully meet the goals of improved air quality and, ultimately, health in focus communities, air districts must forge extensive collaborations with entities such as cities, counties, transportation systems, school districts, public health agencies, and other state agencies outside of their typical partnerships. This means evolving into a much more complex and well-managed planning and public health ecosystem.

AB 617's implementation particularly focuses on the relationships between the visions of communities and the mandates of state governance (third pillar). Their vehement critiques of CARB and the air districts notwithstanding, in contrast with Pellow's[19] and Pulido's[21] encouragement of environmental justice movements to move beyond pushing the state to better support their agendas, most of the participants in AB 617 still seek to use the policy to reshape, not transcend, state-based governance.[3,40] Thus, questions remain about whether public participation truly leads to increased community power or if it reproduces historical patterns of control by regional and state agencies. Even as air districts such as BAAQMD make great strides in changing their partnership models toward collaboration and coleadership communities, much work remains to be done to fully meet the demands of the environmental justice movement.[2,3]

Healing the wounds inflicted by decades of conflict between public agencies, residents, and community organizations will take substantial time and skill. Although the challenges to implementing AB 617 throughout California are significant, the innovations and lessons from West Oakland's "Owning Our Air" have great potential for achieving environmental justice and health equity across the state and country. AJPH

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The authors have no conflicts of interest to declare.

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Fetal Protection Policies and Corporate Liability of the US Vinyl Chloride Industry, 1974–1991

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In the late 20th century, fetal protection policies barred women from hundreds of thousands of industrial jobs on the pretext that if women became pregnant, their fetuses might be harmed by workplace exposure to toxic chemicals. Beginning in the 1970s, these policies set off a decades-long contest between the chemical industry, government agencies, and the judicial system over how to balance the uncertain reproductive health risks against sex discrimination. This article revives the subject of reproductive health and workplace protections through a historical case study of fetal protection policies at Firestone Plastics, a leader in the postwar vinyl chloride industry. I use formerly secret industry documents to argue that Firestone used scientific uncertainty and gender essentialism to skirt new regulatory pressures and minimize corporate liability. Ultimately, fetal protection policies stymied innovative regulatory efforts to protect all workers—not just women—from reproductive hazards in the workplace. (*Am J Public Health*. 2022;112(2):271–276. https://doi.org/10.2105/AJPH.2021.306539)

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With numbing regularity, evidence emerges about the dangerous reproductive health effects of environmental chemical exposures. Scientific findings often trickle down into popular consciousness in the form of eye-catching headlines about plummeting global sperm counts or endocrine disruptors in shampoo. Recent iterations of this phenomenon have reminded the public that men, too, are vulnerable to environmental reproductive risks. Even when they note the weak toxic chemical regulations in the United States, articles often end by recommending that people protect themselves and their families by changing their own consumption habits. Discussions of reproductive health risks from chemical exposures appear fixed in an individualistic and gendered paradigm of consumption and choice.[1] Yet this discourse fails to address the continued presence of unregulated toxic chemicals that workers of all genders encounter every day.

This article revives a discussion of reproductive health and workplace protections through a historical case study of fetal protection policies at Firestone Plastics, a leader in the postwar vinyl chloride industry. In 1974, Firestone announced that women would no longer be eligible for certain jobs because of alleged risks to fetal development from exposure to vinyl chloride monomer, or vinyl chloride. Vinyl chloride is a synthetic chemical used primarily to make polyvinyl chloride (PVC), the ubiquitous plastic found in products from pipes to waterproof clothing. Policies such as Firestone's were implemented voluntarily by companies in rubber, chemical, plastics, paint, and battery industries for a variety of chemicals. By 1979, women had been barred from approximately 100 000 positions.[2] Historians of workplace fetal protection have focused on its two most public incidents: the 1978 case of American Cyanamid, a company where five women underwent sterilization only to have their plant close, and the 1991 Supreme Court case *United Auto Workers v Johnson Controls*, which book-ended the history of workplace fetal protection by ruling it a form of sex discrimination.

Formerly secret industry documents now available on ToxicDocs, a publicly accessible digital archive, unveil the process of crafting and implementing these policies before they were challenged on the national stage. The primary sources in this article reveal the perspective of the chemical industry, but the workers whose lives and livelihoods were altered by fetal protection policies are conspicuously absent. Future historical inquiry should examine how everyday workers understood and experienced fetal protection policies.

In this article, I argue that behind early fetal protection policies lay years of uncoordinated, inconsistent, and unprincipled efforts to skirt new regulatory pressures and minimize corporate liability. The records of Firestone Plastics, a subsidiary of Firestone Tire and Rubber Co., offer an exemplary case study of this juggling act. I analyze the company's internal discussions as early iterations of industry tactics that would become central to later debates over fetal protection. First, Firestone protected its corporate interests by leveraging the persistent scientific uncertainty around the health risks and safe exposure levels of vinyl chloride. Second, it minimized liability by invoking gender essentialism, conflating women with their reproductive capacities. When acting in tandem to protect corporate interests, these two tactics reproduced long-standing gender disparities in American industry and stymied innovative regulatory efforts to protect all workers—not just women—from reproductive hazards in the workplace.

WHY FETAL PROTECTION?

Vinyl chloride was first synthesized for commercial use in 1939. By 1974, more than 5 billion pounds of vinyl chloride were produced annually.[3] At high levels of exposure, vinyl chloride is a human carcinogen; however, as with many synthetic chemicals from the postwar industrial boom, the health effects of vinyl chloride were unknown in the first several decades of its use. In 1970, the newly formed Occupational Safety and Health Administration (OSHA) and its research arm, the National Institute for Occupational Safety and Health (NIOSH), were tasked with setting standards for workplace exposure to industrial chemicals. Formal accountability, along with the parallel actions of environmental, labor, and consumer protection groups, prompted a "toxicity crisis" for the plastics and chemicals industries.[4]

In 1974, NIOSH issued a recommendation regarding occupational exposure to vinyl chloride: "it is recommended that no woman who is pregnant or expects to become pregnant should be employed directly in vinyl chloride monomer operations."[5] By singling out women's heightened susceptibility, the agency waded into what would become a decades-long contest over how to weigh the uncertain risk of toxic exposure against another federal regulatory project, Title VII of the 1964 Civil Rights Act, which outlawed employment discrimination on the basis of sex.

In response to the NIOSH recommendation, Firestone released a fetal protection policy that banned fertile women from jobs involving vinyl chloride exposure.[6] This policy reflected an ethos of precaution that the industry routinely dismissed when it came to other occupational health concerns. For instance, that same year, news that several vinyl chloride workers had died from a rare cancer prompted OSHA to propose drastically reducing the permissible exposure limit for vinyl chloride. In response, the president of Firestone Plastics argued that although the company was "gravely concerned about the potential health hazard" of vinyl chloride, "present medical and scientific data" did not justify the standard.[7] This exemplifies American industry's long-standing position on toxic chemical regulation: casting doubt about the risks of its products and resisting regulation by asserting that chemicals should be considered safe until definitively proven otherwise.

In its official 1976 standard, OSHA found insufficient evidence to support the NIOSH recommendation that fertile women be barred from vinyl chloride operations.[8] Although some vinyl chloride and PVC production companies rescinded their policies in response, Firestone and several of its peer companies elected to keep fetal protection in place. This decision reinforced the existing gendered structure of American industry (that is, a majority male workforce) amid the pressures of new occupational health and civil rights regulations.

Firestone's fetal protection policy was implemented at the same time as public perception of the fetus as a discretely vulnerable entity emerged. Just a decade earlier, thalidomide, a drug prescribed to thousands of women for nausea, had turned out to cause serious birth defects in infants. The episode heightened public awareness about hidden threats to the fetus and was followed closely by an early 1960s epidemic of rubella. It was in this context that national newspapers reported on research indicating that twice the expected rate of infants born with central nervous system defects had been found in areas surrounding PVC production plants.[9]

Unlike thalidomide and rubella, environmental chemical exposure lacked a clear causal pathway and raised questions about who would be responsible for mitigating risk. One possibility was responsibility falling on industry's shoulders. Although workers' compensation protected Firestone from employee lawsuits, companies were theoretically vulnerable to suits on behalf of an employee's child. In the eyes of

Firestone's leadership, the best way to avoid this liability was to preemptively eliminate the possibility of exposing a pregnant woman to vinyl chloride.

THE "CATCH 22"

The legal principle of gender-based workplace protection extends back to 1908, when the Supreme Court ruled in *Muller v Oregon* that limits on women's work hours were constitutional because, "as healthy mothers are essential for vigorous offspring, the physical well-being of women becomes an object of public interest and care in order to preserve the strength of the race."[10] Decades before the chemical industry's fetal protection policies, Progressive Era settlement house worker and industrial toxicologist Alice Hamilton argued that women should not work around reproductive hazards such as lead. Unlike chemical companies, however, Hamilton supported such protectionist policies as a strategic step toward broader workplace safety standards and argued that the principle of gendered protection reflected the social reality of a woman's "double shift" at work and at home.[11]

State protective laws persisted until Title VII of the 1964 Civil Rights Act outlawed sex-based employment discrimination and established the Equal Employment Opportunities Commission (EEOC) to field discrimination claims and encourage male-dominated fields to hire women. In 1973, women made up just 11% of the industrial chemicals sector. A 1976 EEOC audit of a Pennsylvania Firestone plant showed that 94% of the 140 workers were White men and that out of 25 female job applicants (all of whom were White), the plant hired just one.[12]

One interpretation of Firestone's fetal protection policy is that the precautionary approach of barring a few fertile women from certain jobs was a cost–benefit calculation that companies made to avoid costly lawsuits and maintain stability amid unprecedented regulatory intervention. Women workers, rather than the companies, would bear the cost of vinyl chloride's risks. They would miss opportunities, be fired, be forced into lower-paying positions, or keep their jobs only by undergoing sterilization. It is telling that majority-female workplaces in the 1970s with similarly concerning chemical exposures, including hospitals, electronics manufacturers, and dry cleaners, did not implement fetal protection policies, as the costs of doing so would have been very high.

Firestone did recognize that its fetal protection policy would likely hinder the industry's EEOC imperative to "increas[e] the number of women we have on 'blue collar' type jobs."[13] As such, a plant manager recommended not informing "female recruitment sources and the State Employment Commission" of the policy, as it would "focus unnecessary attention on our policy and create a new set of problems."[14] By the mid-1970s, the vinyl chloride industry found itself weighing competing prerogatives: to increase female hiring in traditionally male positions and to respond to evidence suggesting that this practice would place fertile women and their potential fetuses at risk. Companies believed that they had been placed in a "catch 22."[15] In 1975, T.C. Walker wrote to the company's hiring department about the fetal protection policy, predicting that it was "merely a matter of time" before it was challenged.[16] However, as a medical director at Exxon put it, companies would "rather face the EEOC than a deformed baby."[17]

TACTIC 1: LEVERAGING SCIENTIFIC UNCERTAINTY

The vinyl chloride industry of the 1970s was a tightly knit network of companies that endeavored to align their outward-facing positions and "speak with one voice" through trade organizations.[18] Yet, implementation of fetal protection among vinyl chloride producers was reactive, ad hoc, and frequently contradictory. Companies adopted policies and then abandoned them when new evidence emerged, disagreed over their terms, or did not implement them at all. At a 1977 "Vinyl Chloride Safety Committee" meeting attended by representatives from Firestone and other vinyl chloride producers, a summary report admitted that "exposure of women of child-bearing ability is of much concern" and "is still an unsettled topic."[19] In a 1978 survey distributed by Shell, 23 companies responded. Of those, nine reported either a formal policy or an "established practice" of fetal protection. Shell found that company policies "range from 'no problem, use females in any job' to a strict policy."[20]

This discord reflected genuine ambiguity surrounding chemical hazards in the mid-1970s. Research was almost always suggestive and provisional, especially for a relatively new synthetic chemical such as vinyl chloride whose adverse health effects might take decades to emerge. Methodological complexities contributed to persistent uncertainty surrounding reproductive hazards. For example, there were questions about how animal toxicology should be applied to humans and concerns that epidemiological studies did not account for confounding variables. The very meaning of "safe exposure level" has changed over time, shifting in response to new evidence, new research methods, and new disciplines such as risk assessment and cost–benefit analysis. Firestone leveraged this multilayered uncertainty to meet its immediate interests.

In 1976, months before Firestone's first appeal to the EEOC, provisional results were released from an epidemiological study carried out jointly by Firestone, NIOSH, the Centers for Disease Control and Prevention, and the University of North Carolina. The study had revealed excess miscarriages and stillbirths among the wives of male vinyl chloride workers at a Firestone plant. This finding suggested that men might incur genetic damage that could be passed on to a fetus.

Press coverage and concern within the local union prompted Firestone to assure employees that the company was monitoring the situation and that there was no cause for concern given the new standard for vinyl chloride exposure that was to be implemented that year.[21] Yet, Firestone's emphatic message that male workers should not worry about vinyl chloride exposure harming their future children was at odds with the company's contention to the EEOC that its fetal protection policy was justified because of recent findings indicating that vinyl chloride exposure had "mutagenic and teratogenetic effects," meaning that it could cause birth defects through both DNA mutations in male sperm and fetal exposure.[22]

TACTIC 2: GENDER ESSENTIALISM

In the 1970s, the idea that the health of a fetus could be considered apart from the health of the woman who carried it was only beginning to be articulated in scientific, legal, and popular discourse. Occupational health proved to be one of the arenas in which broader, less strictly gendered understandings of fetal susceptibility developed. At a 1975 conference on women in the workplace, Sylvia Krikel of the Oil, Chemical & Atomic Workers Union argued that "health standards should be set at levels low enough to protect everyone in the workplace, including the fetus." She saw in "the clamor over women workers in high-risk occupations" not a genuine concern for the safety of women or fetuses but, rather, "little more than a smokescreen to conceal industry's reluctance to place a priority on people rather than profit."[23]

Under the leadership of Eula Bingham, OSHA began in 1977 to move beyond gender essentialism in its approach to occupational health. In a speech, Bingham explained that "reproductive hazards have been seen as a 'women's problem'—as if there were no male contribution to the continuation of the species."[24] In May of 1978, Bingham penned a letter to corporate medical directors, including Firestone's, that summarized OSHA's position on fetal protection. Bingham wrote that although genuine concern for women and their fetuses was "praiseworthy," similar attention needed to be paid to male reproductive hazards, and exclusion was not a replacement for dealing with the exposures themselves.[25]

Firestone moved in the opposite direction of OSHA's emerging consensus around reproductive hazards. The company increasingly leaned on gender essentialism by limiting its understanding of fetal harm to the nine months in a woman's womb. In 1977 and 1978, the company took advantage of the uncertainty surrounding the effects of vinyl exposure and abandoned its previous references to male genetic damage. Firestone then sidestepped the question of male reproductive risks entirely by focusing narrowly on the susceptibility of the fetus to chemical exposure in the womb.[26] Some scholars of fetal protection point out that industry concern with fetal health reflected a conservative shift in the 1980s toward embracing fetal rights in opposition to women's.[27] But Firestone's arguments reveal continuity with an older view of women's and fetal health as inextricable. Whereas Firestone's policy was concerned with pregnant women, policies crafted after 1980 (e.g., that of Johnson Controls) seem to have placed more emphasis on "unborn children." Slippage between mother and fetus in industry discussions reflects evolving understandings of the fetus in the popular, medical, and legal discourse of the 1970s.

A REGULATORY SOLUTION

In 1980, Firestone Plastics was absorbed by Occidental Petroleum, abruptly ending one chapter in an ongoing story.[28] That same year, the EEOC and OSHA released joint guidelines that narrowly defined the situations in which employment restrictions were warranted. If a reproductive hazard was "known to affect the fetus through either parent," excluding only women from employment would be considered sex discrimination.[29] In a public response, the Chemical Manufacturer's Association (of which Firestone had been a member before its sale) criticized the guidelines by echoing and extending Firestone's essentialist logic, asserting that transplacental exposures posed an exceptional risk that threatened fetal rights. In spite of inconsistent policies within the vinyl chloride industry, the Chemical Manufacturer's Association had reached an internal consensus that fetal protection policies buttressed industry interests. The association ended its response with a warning: "the proposed Guidelines ... will probably result in greater numbers of birth defects in children of mothers who would be exposed to certain hazardous substances."[30]

The response of the Chemical Manufacturer's Association was expected, but women's health and labor advocates also opposed the guidelines. These groups, which usually supported industry regulation, worried that regulations based on limited scientific evidence could chip away at civil rights. As Ronald Bayer pointed out in a 1982 analysis, fetal protection caused both sides of the debate to reverse "their characteristic positions on risk assessment and its implications for industrial policy."[31] Facing opposition from all sides and the incoming Ronald Reagan administration, which was hostile toward regulatory oversight, the guidelines were withdrawn. With that, any hope of a federal regulatory solution to the "catch 22" between protection and civil rights was quashed. Those opposed to fetal protection policies turned to the courts.

In 1982, Johnson Controls, a car battery manufacturer, instituted a fetal protection policy for lead exposure. In response, the United Auto Workers filed a sex discrimination suit on behalf of seven workers that made its way to the Supreme Court. In 1991, the court ruled fetal protection policies unconstitutional, arguing that women should be able to choose whether to take a job that exposed them to possible reproductive hazards.[32] From a strictly civil rights perspective, the Johnson Controls decision was a victory. But judging fetal protection policies only in terms of sex discrimination ignored intersecting concerns about men's reproductive health and workers' rights. In debates that weigh individual rights against collective well-being, solutions that would satisfy both imperatives are often foreclosed. This is not because they are ethically incompatible but because of the fragmented structure of US regulatory bodies and the outsized influence of industry and corporate lobbying.

Fifty years after the Occupational Health and Safety Act was passed, workers from cosmetologists to surgeons and firefighters are exposed to chemicals for which the long-term reproductive health effects are uncertain.[33] As the United States continues to grapple with the COVID-19 pandemic, the nation's eyes have been reopened to the importance of workplace health and safety. Indeed, the outsized impact of COVID-19 on people of color is explained in part by their disproportionate employment as low-income but "essential" workers.[34] This moment should be seized upon as a policy window for the new presidential administration to improve OSHA's standard-setting process, invest in reproductive toxicology research, and embrace a precautionary approach to occupational chemical exposure regulation that protects the long-term reproductive health of all workers.[35] AJPH

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CONFLICTS OF INTEREST

The author declares no conflicts of interest.

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Projecting Quarantine Utilization During a Pandemic

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Objectives. To develop an approach to project quarantine needs during an outbreak, particularly for communally housed individuals who interact with outside individuals.

Methods. We developed a method that uses basic surveillance data to do short-term projections of future quarantine needs. The development of this method was rigorous, but it is conceptually simple and easy to implement and allows one to anticipate potential superspreading events. We demonstrate how this method can be used with data from the fall 2020 semester of a large urban university in Boston, Massachusetts, that provided quarantine housing for students living on campus in response to the COVID-19 pandemic. Our approach accounted for potentially infectious interactions between individuals living in university housing and those who did not.

Results. Our approach was able to accurately project 10-day-ahead quarantine utilization for on-campus students in a large urban university. Our projections were most accurate when we anticipated weekend superspreading events around holidays.

Conclusions. We provide an easy-to-use software tool to project quarantine utilization for institutions that can account for mixing with outside populations. This software tool has potential application for universities, corrections facilities, and the military. (*Am J Public Health*. 2022;112(2):277–283. https://doi.org/10.2105/AJPH.2021.306573)

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Contact tracing along with rapid isolation of infected individuals and quarantine of their exposed close contacts are a cornerstone of infection control for severe acute respiratory syndrome coronavirus 1 (SARS-CoV-1) and SARS-CoV-2.[1,2] Building quarantine capacity is important for congregate settings where individuals do not have a space for isolating themselves; these include university students, incarcerated populations,[3,4] and individuals in military housing.[5–7] It can be challenging, but important, to ensure that sufficient quarantine housing is available and to project short-term needs.

In this article, we describe and demonstrate a conceptually simple but statistically rigorous approach to project quarantine utilization over a 10-day window in real time. Our choice of the 10-day window depends in part on COVID-19 quarantine lengths, and modification of our approach to other time lengths is straightforward. We model the number of people who will need space provided by the institution. The logistics of providing that space will vary by institution. How to make capacity (i.e., logistics) is beyond the scope of this article.

We are motivated by our experience working at a large urban university that provides quarantine housing for students living on campus. With limited resources and a strong need to control infections, it is important to forecast utilization of this expensive and essential resource. Our approach allows for mixing between populations that require quarantine capacity (e.g., students living on campus) and those that do not (e.g., students living off campus). We demonstrate how this can be used in our setting and describe other potential applications. Our software is available and easy to implement.

METHODS

We present our methods for a 10-day-ahead, real-time quarantine projection and clarify the data needed for our methods. Institutions will likely have different strategies for allocating space, but our approach will project the number of individuals needing space.

Details on the statistical development and justification of the methods are in the Appendix (available as a supplement to the online version of this article at http://www.ajph.org). The code to implement the method can be found at https://github.com/KolaczykResearch/SimpleQuarantinePrediction.

Statistical Methods

We describe our methods using terminology for a university setting, where "on-campus students" are those requiring quarantine housing and "off-campus students" mix with on-campus students but do not require housing. We also performed 10-day-ahead projections consistent with the quarantine length for COVID-19 and institutional interest in having 10 days to increase capacity, if required. Our method performs the following steps, assuming a 10-day-ahead projection (Figure 1):

1. Estimate the expected number of on-campus students quarantined per diagnosed on-campus and off-campus student to create 2 multipliers: m_1 and m_2.
2. Project case counts for the next 10 days for on-campus and off-campus students.
3. Using the multipliers and projected case counts, calculate the quarantine utilization in 10 days.

In step 1, we use historical contact tracing data to estimate m_1 and m_2; these can be updated over time. The methods to estimate m_1 and m_2 depend on the data availability. If we have the information on the corresponding index cases for quarantined students, then we can directly compute 2 multipliers. Using data up to time t, we define the estimate $\hat{m}_1$ as the average number of on-campus students quarantined per diagnosed on-campus student in the period $[0, t]$, and $\hat{m}_2$ as the average number of on-campus students quarantined per diagnosed off-campus student in the period $[0, t]$. If the data for direct computation are unavailable, we can estimate the multipliers by minimizing the following quadratic loss:

$$\sum_{s=0}^{t}(\textit{The number of newly quarantined on-campus students at time } s - m_1 * \textit{The number of newly diagnosed on-campus students at time } s - m_2 * \textit{The number of newly diagnosed off-campus students at time } s)^2. \tag{1}$$

In step 2, we can assume as a baseline scenario that there will be the same number of cases in the next 10 days as in the prior 10 days, which reflects assumptions that contact network structure and exogenous rates are stable at these time scales.

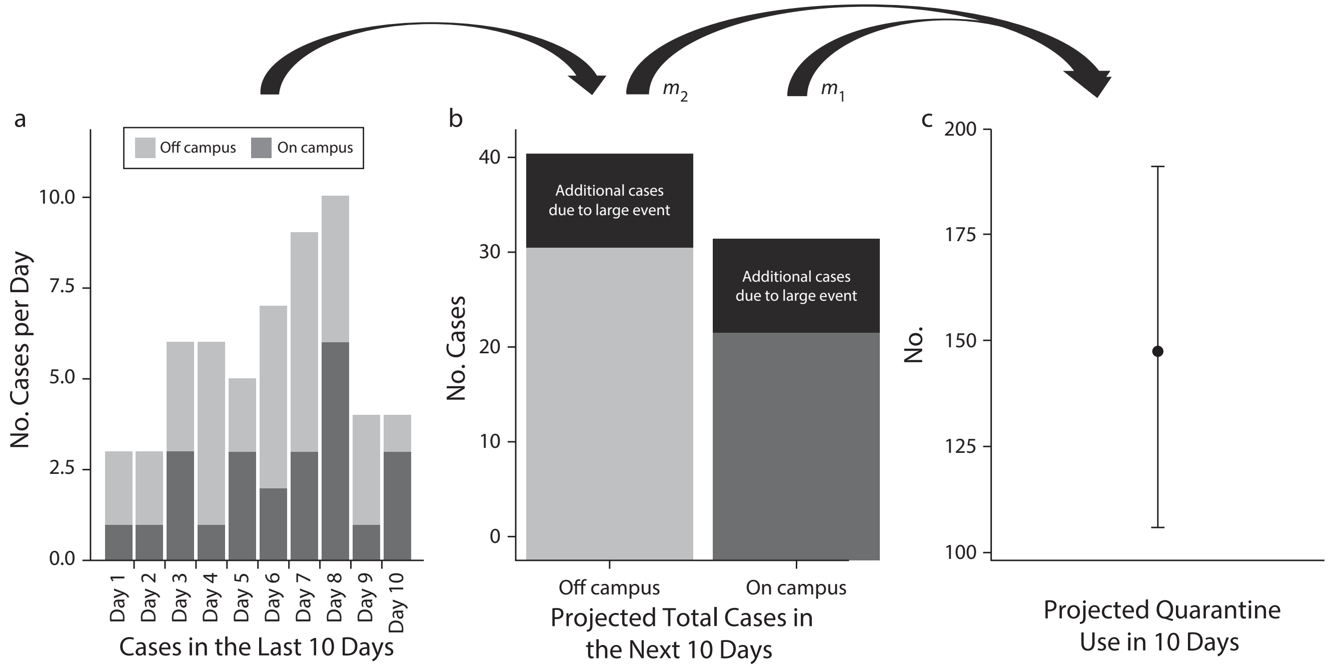

FIGURE 1— **Schematic of Our Method to Project Quarantine Needs: Boston University, Boston, MA**

Note. We first projected case counts for the next 10 days for on-campus and off-campus students, and then used 2 multipliers (i.e., m_1 and m_2) and projected case counts to calculate the quarantine utilization in 10 days.

Alternatively, we might consider a scenario in which the diagnosed counts in the next 10 days will be higher than in the past 10 days to account for superspreading events. Specifically, we assume that (1) there is a superspreading event on day t causing x_1 on-campus students and x_2 off-campus students to be infected and diagnosed; (2) the effect of the infectious event on diagnosed cases lasts for 2 weeks (i.e., a 14-day period where cases due to the infectious event might be diagnosed); (3) the peak of the diagnosed case count is 1 week after the infectious event; and (4) the rate of increase–decrease of diagnosed cases is constant. Under these assumptions, we can project the number of daily diagnosed cases due to the infectious event in time period $[t+1, t+14]$, which is a portion of $x_1 + x_2$. Then, the number of on-campus diagnosed students in the period $[i+1, i+10]$ can be approximated by (1) the number of on-campus diagnosed students in the period $[i-9, i]$ + the projected number of on-campus diagnosed students due to the infectious event in the period $[t+1, i+10]$, for $t-10 < i \leq t-1$; (2) the number of on-campus diagnosed students in the period $[t-9, t]$ + the projected number of on-campus diagnosed students due to the infectious event in the period $[i+1, min(i+10, t+14)]$, for $t-1 < i \leq t+13$; and (3) the number of on-campus diagnosed students in the period $[i-9, i]$ − the projected number of on-campus diagnosed students due to the infectious event in the period $[i-9, t+14]$, for $t+13 < i \leq t+22$. Similarly, we can project the number of off-campus diagnosed students in the period $[i+1, i+10]$, where $t-10 < i \leq t+22$. In our application (Figure 2), we anticipated isolated superspreading events around holiday weekends (Indigenous People's Day and the following weekend and Halloween). In discussions with the dean of students and the head of student health services, we identified holiday weekends as times when there might be superspreading events. Thus, as we evaluated the method, we considered superspreading events on these weekends, and these did in fact provide the best fit to the data.

In step 3, the projected quarantine utilization in 10 days is the sum of $\hat{m}_1 *$projected case counts for the next 10 days for on−campus students and $\hat{m}_2 *$projected case counts for the next 10 days for off−campus students. We provide details on confidence intervals for our estimates in the online Appendix.

Simulation

We conducted a small simulation study to illustrate the expected behavior of our quarantine projections. In this simulation study, we used a stochastic agent-based model for transmission of SARS-CoV-2, implemented with the software tool for the Boston University (BU) COVID prediction exercise,[8] to simulate an epidemic for the fall 2020 semester in a synthetic population of 2100 on-campus people and 1650 off-campus people. Software details are available on GitHub.[9] We implemented 2 scenarios: (1) no superspreading events and (2) 1 infectious event involving about 20 people spreading between on-campus and off-campus students on October 31. Then we used our proposed method to project quarantine utilization over a 10-day window. Code for the simulation study can be found at https://github.com/KolaczykResearch/SimpleQuarantinePrediction.

Data

We applied our method to fall 2020 semester data from BU. Our intent was to provide a projection of the number of individuals who would require quarantine space. BU is a large urban university with a population of more than 40 000 students, staff, and faculty. In the fall 2020 semester, BU implemented a vigorous testing, contact tracing, and quarantine–isolation strategy to bring students back to campus and offer in-person instruction for those who desired it.[8] There were 7134 students living on campus, and these students were tested twice a week; faculty, staff, and off-campus students had variable testing cadences, depending on their engagement with on-campus activities. Individuals who tested positive were immediately moved to isolation housing if they lived on campus or were instructed to isolate in their homes if they did not live on campus. Their close contacts were identified and instructed to quarantine. Close contacts who were BU students living on campus were moved to special quarantine housing. There was a strong interest in ensuring that there was sufficient quarantine housing, making accurate projections of quarantine demand valuable.

In our projections, we used the daily counts of the newly quarantined on-campus students and an indication of whether the diagnosed close contact(s) was living on campus, off campus, or both (if there was more than 1 close contact). We also made use of the daily counts of newly diagnosed on-campus and off-campus individuals. Note that the indication of residential status of index cases is not a requirement for our method.

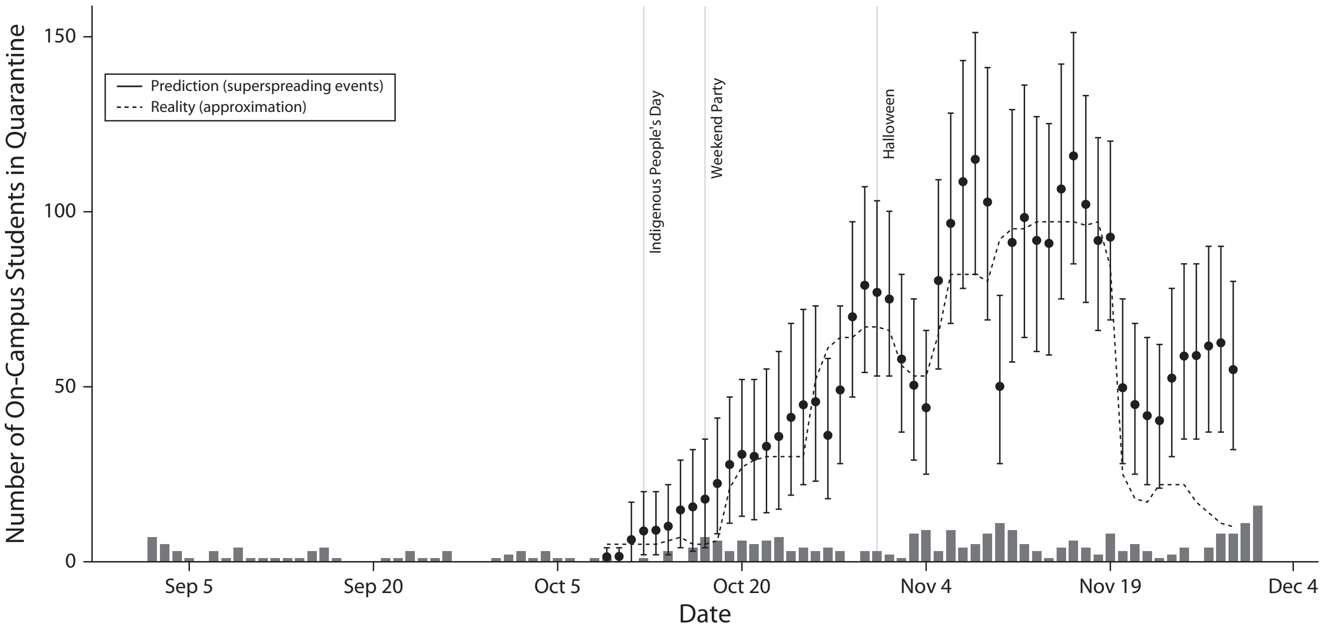

FIGURE 2— **Ten-Day-Ahead Projections of On-Campus Quarantine Counts When We Assumed There Were Parties on Indigenous People's Day, October 17 (the Following Weekend), and Halloween: Boston University, Boston, MA**

Note. Error bars are estimated 90% confidence intervals. Black bars are daily number of diagnosed students. Black curve is the best approximation of the real number of on-campus students in quarantine based on available Boston University data.

RESULTS

Figure 3a shows the average projections of on-campus quarantine counts under scenario 1 (no superspreading events) over 1000 trials. Note that we assumed that all people in quarantine never tested positive over the next 10 days and remained in quarantine. This assumption led to a conservative projection of quarantine counts because quarantined people might of course test positive and move to isolation.

Figure 3b illustrates the projections of on-campus quarantine counts under scenario 2 (superspreading event). In our simulation, we assumed that there was a superspreading event on October 31 causing 20 on-campus students and 20 off-campus students to be diagnosed; the effect of the infectious event on diagnosed cases lasted 2 weeks, the peak of the diagnosed case count was 1 week after the infectious event, and the increasing–decreasing rate was constant. Under these assumptions, we could project the diagnosed case counts in the next 10 days. Then, we calculated quarantine counts using our proposed method. As shown in Figure 3b, we got relatively accurate projections of quarantine counts.

Figure 2 shows the results of using this method with BU data from the fall 2020 semester. We analyzed the data as though we were using it in real time to evaluate how it would have performed if we had had it in fall 2020. Our approach was not a calibration, as we were not fitting to observed data. We estimated m_1 and m_2 to be 3.92 and 0.33, respectively (i.e., the average numbers of on-campus students quarantined per diagnosed on campus and off campus student were 3.92 and 0.33). We assumed that there were large gatherings on Indigenous People's Day, October 17 (the following weekend), and Halloween, and that the parties on those 3 days caused 10 (5 on-campus, 5 off-campus), 10 (5 on-campus, 5 off-campus), and 20 (10 on-campus, 10 off-campus) diagnosed cases, respectively. The dates of the superspreading events were informed by holiday dates and BU staff's experience of student behavior in previous years, and having superspreading events on these weekends provides the most accurate projections. Thus, our information from the university was fairly accurate for anticipating problem time periods. In reality, we would be continuously updating the model. We will eventually know if we missed a big event, and then we can update accordingly, even if we do not get it in real time (so the impact of missing a big event is not going to reverberate forward). Note that we assumed that all people in quarantine never tested positive over the next 10 days

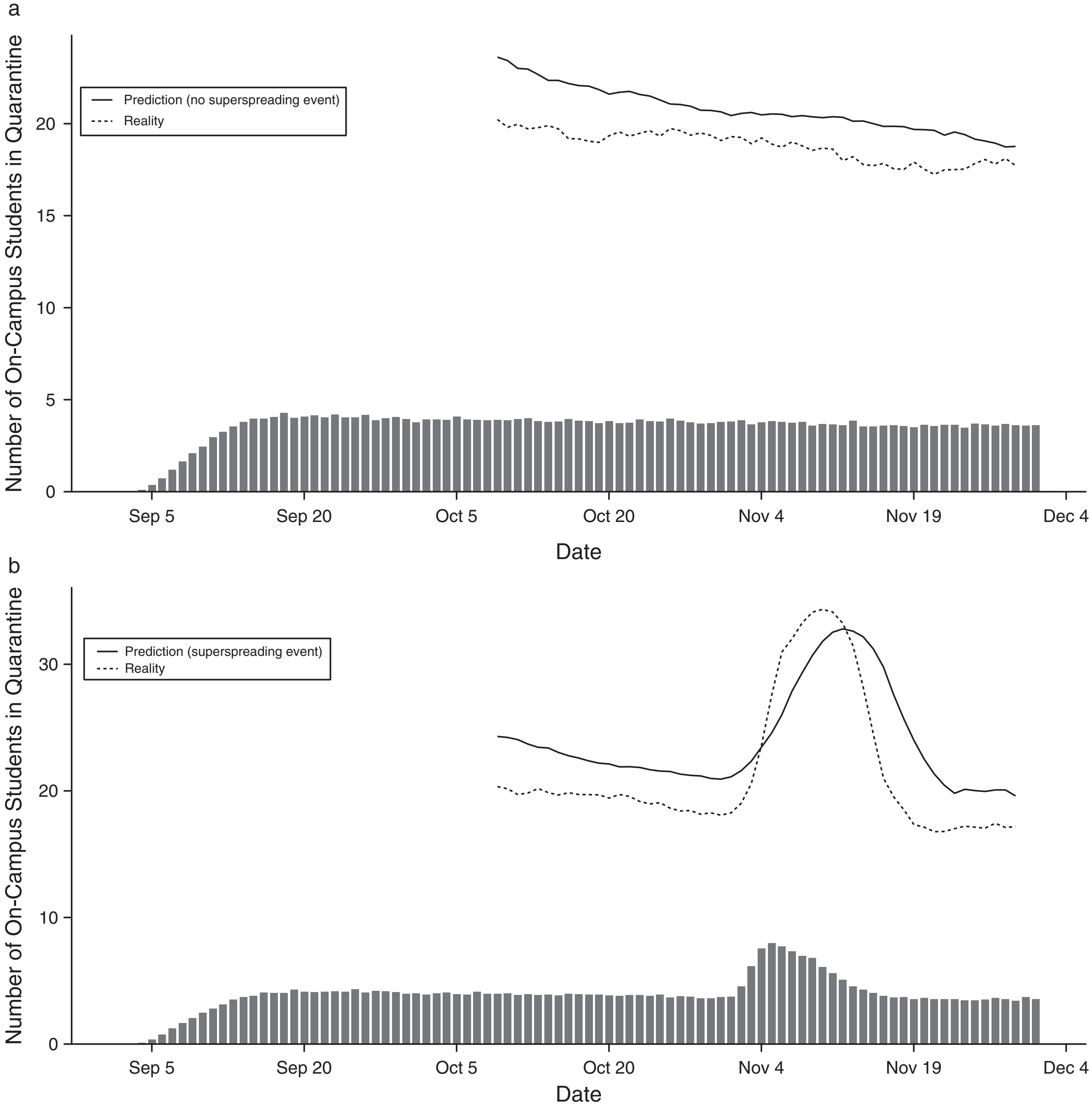

FIGURE 3— Means of 10-Day-Ahead Projections of On-Campus Quarantine Count in 1000 Simulation Trials for (a) No Superspreading Event and (b) Superspreading Event

Note. Black bars are the average daily number of diagnosed people over 1000 trials.

and remained in quarantine. This assumption led to a conservative projection of quarantine counts because quarantined people might test positive and move to isolation, freeing up space in quarantine. Some students went home before Thanksgiving, which led to fewer diagnosed cases and less contacts than usual. We did not take into account this effect of Thanksgiving, which caused the overestimation starting almost 1 week before the holiday. The overestimation in late November is due to the fact that students who left town for Thanksgiving were encouraged to remain off campus the rest of the semester, and hence only a few on-campus students entered quarantine around Thanksgiving.

DISCUSSION

COVID-19 has shown us yet again that contact tracing coupled with quarantine and isolation are very important parts of infection control. However, provision of quarantine housing is a large cost for institutions, making it necessary that they have an accurate sense of how much housing is appropriate to allocate. In addition to the residential university setting that we describe, this problem is also relevant to corrections facilities, which have experienced substantial COVID-19 outbreaks[4,10–12] and have employees who enter and exit the facility potentially infected but do not require quarantine housing. For example, in the prison setting, incarcerated individuals are comparable to on-campus students who require quarantine housing, whereas employees are more similar to off-campus students who are exposed but for whom the institution does not need to provide quarantine space. Military installations—where personnel housed by the military require quarantine housing—could also benefit from this approach.

We have described a framework for projecting quarantine utilization when there is mixing with an outside population not requiring quarantine housing. The strength of our method is that it is straightforward to implement, mathematically sound, and requires relatively simple data. At a minimum, the data needed are (1) daily case counts separated by location of the case (requiring quarantine or not) and (2) information on the extent to which those who require quarantine housing interact with those who do not, potentially from contact-tracing data. We show that this method performs well retrospectively in our university setting.

We made a few assumptions about contact networks in the statistical development and justification of the methods. Briefly, we assumed that the number of contacts and types of contacts were relatively stable over time, and that people in the same compartment had similar levels of connectivity. Details on the assumptions are in the online Appendix. These assumptions can be assessed by looking at contact-tracing data. For instance, to assess the assumption that on-campus students have similar levels of connectivity in our BU example, we could count the number of on-campus and off-campus contacts for each on-campus student by evaluating their contact networks. If almost all on-campus students have similar numbers of on-campus and off-campus contacts, then our assumption is reasonable.

We chose a 10-day window for quarantine projections in this article, but the method can be easily modified to other time periods. Ideally, the length of the projection would be based on the quarantine lengths and the time needed to increase quarantine capacity. Our choice of a 10-day window was based on COVID-19 quarantine lengths and the time BU needed to increase quarantine capacity. If the number of contacts and types of contacts change a lot over time, our estimated multipliers $\hat{m}_1$ and $\hat{m}_2$ (i.e., the estimated number of on-campus students quarantined per diagnosed on-campus and off-campus student) might not be good estimates for m_1 and m_2 during the projected period. Therefore, longer periods will make the assumptions in our methods more likely to be violated and might lead to less accurate projections.

In addition to quarantine projections, we provide confidence intervals for our projections. The length of confidence intervals depends on the confidence level, projected case counts, and the 2 estimated multipliers $\hat{m}_1$ and $\hat{m}_2$. Although we show results based on using the mean projection of quarantine utilization, the confidence interval could provide useful information for planning purposes. For instance, the upper bound of confidence levels represents a conservative projection, which could be considered for planning quarantine space. But this is only useful if the confidence interval is relatively narrow.

Because this is a simple forecasting approach that leverages the recent history of the outbreak, it will be affected by abrupt changes in disease patterns. To anticipate this, it is wise to run multiple potential scenarios, including potential superspreading events that might disproportionately affect those requiring quarantine housing. Given other information, appropriate weights could be given to the projections from those scenarios for planning purposes.

PUBLIC HEALTH IMPLICATIONS

COVID-19 has presented an opportunity to learn and prepare for future pandemics and outbreaks. This pandemic has demonstrated, yet again, the utility of contact tracing followed by quarantining as an effective infection control measure. We present a valuable software tool to assist in projecting quarantine utilization, which can be rapidly deployed using basic data as inputs. AJPH

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CONTRIBUTORS

All authors conceptualized the article, devised the statistical methodology, and wrote and approved the article. W. Li conducted the simulations and data analysis.

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CONFLICTS OF INTEREST

None of the authors have any potential or actual conflicts of interest.

HUMAN PARTICIPANT PROTECTION

The Boston University institutional review board determined that this work was non–human participant research.

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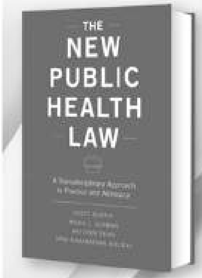

Self-Reported Treatment Need and Barriers to Care for Adults With Opioid Use Disorder: The US National Survey on Drug Use and Health, 2015 to 2019

Jannat Saini, PharmD, MPH, Breah Johnson, BS, and Danya M. Qato, PharmD, PhD, MPH

See also Nesoff et al., p. 199.

Objectives. To explore barriers to care and characteristics associated with respondent-reported perceived need for opioid use disorder (OUD) treatment and National Survey on Drug Use and Health (NSDUH)–defined OUD treatment gap.

Methods. We performed a cross-sectional study using descriptive and multivariable logistic regression analyses to examine 2015–2019 NSDUH data. We included respondents aged 18 years or older with past-year OUD.

Results. Of 1 987 961 adults, 10.5% reported a perceived OUD treatment need, and 71% had a NSDUH-defined treatment gap. There were significant differences in age distribution, health insurance coverage, and past-year mental illness between those with and without a perceived OUD treatment need. Older adults (aged ≥ 50 years) and non-White adults were more likely to have a treatment gap compared with younger adults (aged 18–49 years) and White adults, respectively.

Conclusions. Fewer than 30% of adults with OUD receive treatment, and only 1 in 10 report a need for treatment, reflecting persistent structural barriers to care and differences in perceived care needs between patients with OUD and the NSDUH-defined treatment gap measure.

Public Health Implications. Public health efforts aimed at broadening access to all forms of OUD treatment and harm reduction should be proactively undertaken. (*Am J Public Health*. 2022;112(2):284–295. https://doi.org/10.2105/AJPH.2021.306577)

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More than 2 million US adults have opioid use disorder (OUD), and nearly 90 000 adults are killed by an opioid overdose every year.[1,2] Numerous treatment and harm-reduction modalities, including pharmacotherapy, behavioral therapy, safer syringe supplies, and broad access to naloxone, exist for the treatment of OUD and mitigation of harm associated with opioid dependence. Medications for opioid use disorder (MOUD) include buprenorphine, methadone, and naltrexone. Despite the increased availability of MOUD treatment and number of US residents who are insured, evidence suggests a minority (31%) of patients in need of treatment actively seek out or receive it.[3,4] Barriers to access include lack of affordability (regardless of insurance status),[5] stigma associated with OUD, and lack of access to an OUD treatment program.[6]

By contrast with the enhanced mobilization for OUD pharmacotherapy and behavioral therapy, considerably fewer resources have been leveraged in support of harm-reduction programs. Furthermore, while our understanding of the etiology of OUD has improved, criminalization of "illicit" opioid use and punitive approaches to such use continue to be meted against low-income communities and communities of color.[7] In addition, previous research has found that nearly half of patients with OUD may go into remission without treatment and "recover naturally."[8] This population is often excluded or ignored from formal study that has largely centered OUD treatment paradigms that see pharmacotherapy and behavioral therapy initiation as singular metrics for success.

As a reflection of this epistemic problem, the extant literature on OUD treatment access has often conflated 2 distinct phenomena: (1) treatment gap as defined by providers and (2) perceived treatment need as defined by people with OUD. Using these terms interchangeably has led to inconsistent conclusions and has precluded comparisons across studies and populations.[9]

To illuminate this discordance and elaborate on the implications for OUD treatment more broadly, we used the most currently available National Survey on Drug Use and Health (NSDUH) data from 2015 to 2019 to quantify, describe, and contrast the prevalence and sociodemographic and clinical characteristics associated with respondent-reported perceived need for OUD treatment and NSDUH-defined treatment gap, considering the latter 2 measures distinctly.

We focused this analysis on NSDUH because of the pivotal role it plays in shaping federal and state policy priorities regarding OUD. NSDUH is directed by the Substance Abuse and Mental Health Services Administration (SAMHSA), and information derived from the annual survey is used to "support prevention and treatment programs, monitor substance use trends, estimate the need for treatment and inform public health policy."[10] Despite many vulnerable populations with high rates of OUD being specifically excluded from study, NSDUH remains central to scaffolding approaches to OUD and opioid use in the United States.

METHODS

We analyzed publicly available NSDUH data from 2015 to 2019 to provide the most current estimates. NSDUH is a cross-sectional household survey of annual self-reported estimates on alcohol, tobacco, and prescription and nonprescription drug use and other health-related domains. The survey is administered online or in person to noninstitutionalized civilians aged 12 years or older living in the United States.[11] Because of survey redesign beginning in 2015, NSDUH does not recommend pooling data after 2015 with earlier survey years.

Study Population

All respondents aged 18 years and older classified by NSDUH as having past-year OUD were included in our study. Respondents were classified as having a past-year OUD if they had a past-year prescription pain reliever use disorder or heroin use disorder. We defined past-year prescription pain reliever use disorder (or heroin use disorder) as having past-year dependence or abuse of pain relievers (or heroin).

Study Measures

Using OUD-specific variables (NDTXYRHER, NDTXYRPNR, NDMORTHER, and NDMORTPNR) that define feeling a need, or additional need, for treatment of heroin use and pain reliever use, we created a new variable that designated those with a perceived need for OUD-specific treatment (*OUD_need* = *1*), as having a perceived OUD treatment need.[6,12]

We categorized past-year treatment gap (i.e., classified as having past-year OUD but not receiving treatment) by using NSDUH variables TXYRNDILL ("needed treatment for illicit drug use") and TXYRILL ("received treatment at any location for illicit drug use"). We used these measures to create a new variable, *tx_gap*, with a value of 0 if the individual received treatment for OUD and 1 if the individual needed but did not receive treatment.

Among those with perceived OUD treatment need, NSDUH further asks respondents to report reasons for not receiving treatment or receiving inadequate treatment. Using methods proposed by Novak et al.,[6] we collapsed the original list of 14 categories into 6—affordability, treatment access, perceived stigma, treatment not a priority, lack of readiness to stop using, and lack of trust in treatment. We quantified barriers in the overall study sample and further describe barriers by OUD type (prescription OUD only or OUD with heroin use) and by treatment gap status. Respondents can report more than 1 barrier to treatment. In addition, respondents are asked whether they sought treatment or additional treatment in the past year for their OUD treatment need. Further details are included in the Appendix, under "Detailed information regarding treatment barriers" (available as a supplement to the online version of this article at http://www.ajph.org).

Covariates

We included variables in our analysis based on a review of the previous literature[6,13,14] and based on an understanding that it is necessary to identify particularly vulnerable subgroups of the population as well as points for clinical and policy interventions.

Sociodemographic and administrative characteristics of interest in our sample were age, sex, highest education level, insurance, and annual income level. We collapsed race/ethnicity into 4 categories because of sample size. We used the variable COUTYP4 to characterize geographic place of residence as "nonmetro" or "metro."[15] In addition, we included survey year in the regression analysis.

Clinical characteristics of interest in our sample included self-reported health and a past-year history of mental health illness. We defined the latter as the presence of serious psychological distress, a major depressive episode, or both in the past year. For self-reported health, we created 2 categories: "good to excellent" ("good," "very good," and "excellent") and "poor to fair" ("poor" and "fair").

Statistical Analysis

We used weighted proportions and corresponding 95% confidence intervals (CIs) to describe the distribution of population characteristics overall and by perceived OUD treatment need and NSDUH-defined treatment gap. We assessed differences in the distribution of characteristics between groups by using the Rao–Scott χ^2 test. We used multivariable logistic regression to assess the association between population characteristics and a treatment gap. Weighted proportions and corresponding standard errors are reported to describe the distribution of barriers to treatment in respondents with perceived OUD treatment need. To account for the complex survey design of NSDUH, we conducted weighted analyses using PROC SURVEYFREQ or PROC SURVEYLOGISTIC in SAS version 9.4 (SAS Institute Inc, Cary, NC). For the supplementary analysis, we characterized clinical and sociodemographic differences between those with and without a perceived OUD treatment need subset to those with a NSDUH-defined treatment gap. Notably, we ran a multivariable logistic regression model to assess the association between population characteristics and perceived OUD treatment need. However, because of low frequencies in certain predictor variable categories, we were unable to report the results of that analysis.

RESULTS

Of a weighted sample of 1 987 961 (unweighted n = 2183) adults with past-year OUD, 10.5% reported a perceived OUD treatment need (weighted n = 208 793) and 71.1% were defined by NSDUH as having a treatment gap (weighted n = 1 413 870). Table 1 reflects the sample characteristics. The majority of adults were aged 50 years or older (weighted proportion = 54.1%; 95% CI = 51.1%, 57.2%), male (weighted proportion = 58.4%; 95% CI = 55.5%, 61.2%), and non-Hispanic White (weighted proportion = 72.7%; 95% CI = 69.4%, 76.0%). Furthermore, most of the respondents were publicly insured (weighted proportion = 45.6%; 95% CI = 42.5%, 48.7%), lived in a large or small metropolitan area (weighted proportion = 84.7%; 95% CI = 82.6%, 86.9%), reported good to excellent health (weighted proportion = 69.8%; 95% CI = 66.8%, 72.9%), and reported a past-year history of mental illness (weighted proportion = 55.8%; 95% CI = 53.2%, 58.4%). Table A (available as a supplement to the online version of this article at http://www.ajph.org) provides row estimates within each category of interest. Notably, 11.3% (95% CI = 9.3%, 13.3%) of White and 7.4% (95% CI = 3.2%, 11.6%) of Black adults reported a perceived need for OUD treatment.

Table 1 further shows that there were significant differences in the distribution of age, health insurance, and past-year mental health illness between those with and without a perceived OUD treatment need. A majority of those reporting a perceived need were adults aged 18 to 49 years (58.9%; 95% CI = 49.3%, 68.4%), whereas, among those without a perceived need, the majority were adults aged 50 years or older (55.6%; 95% CI = 52.4%, 58.9%). Those with no perceived OUD treatment need had a higher proportion of individuals with private insurance (32.8%; 95% CI = 29.9%, 35.7%), whereas those with a perceived need had a higher proportion of individuals with no insurance coverage (34.8%; 95% CI = 27.7%, 41.9%). Among those with a perceived need, a higher proportion reported a past-year mental health illness (72.3%; 95% CI = 64.7%, 79.9%) compared with the proportion reporting mental health illness in the group without a perceived need (53.9%; 95% CI = 51.2%, 56.6%).

Those with a treatment gap had a higher proportion of respondents with private insurance (34.4%; 95% CI = 31.3%, 37.5%) compared with the proportion reporting private insurance in the group without a treatment gap (25.2%; 95% CI = 20.8%, 29.6%). Table A shows that 68.5% (95% CI = 65.3%, 71.7%) of White adults and 77.9% (95% CI = 69.5%, 86.4%) of Black adults had a treatment gap. More than 65% (65.2%; 95% CI = 61.0%, 69.4%) of those with public insurance, 77.1% (95% CI = 72.9%, 81.3%) with private insurance, and 74.6% (95% CI = 69.0%,

TABLE 1— Sociodemographic and Clinical Characteristics of US Adults With Past-Year Opioid Use Disorder (OUD), With and Without a Perceived Need for OUD Treatment and With and Without a Treatment Gap: National Survey on Drug Use and Health (NSDUH) 2015–2019

Characteristics	Overall OUD (Weighted n = 1 987 961[a]), Weighted % (95% CI)	Persons With Perceived Need for OUD Treatment (Weighted n = 208 793), Weighted % (95% CI)	Persons Without Perceived Need for OUD Treatment (Weighted n = 1 779 168), Weighted % (95% CI)	Persons With a NSDUH-Defined Treatment Gap (Weighted n = 1 413 870), Weighted % (95% CI)	Persons Without a NSDUH-Defined Treatment Gap (Weighted n = 574 091), Weighted % (95% CI)
Age category, y[b,c]					
18–49	45.9 (42.8, 48.9)	58.9 (49.3, 68.4)	44.4 (41.1, 47.7)	43.3 (40.0, 46.7)	52.1 (47.4, 56.9)
≥ 50	54.1 (51.1, 57.2)	41.1 (31.6, 50.7)	55.6 (52.4, 58.9)	56.7 (53.3, 60.0)	47.9 (43.1, 52.6)
Sex					
Female	41.6 (38.8, 44.5)	46.6 (38.2, 55.1)	41.0 (38.0, 44.1)	41.6 (38.2, 44.9)	41.7 (37.2, 46.3)
Male	58.4 (55.5, 61.2)	53.4 (44.9, 61.8)	59.0 (55.9, 62.0)	58.4 (55.1, 61.8)	58.3 (53.7, 62.8)
Race/ethnicity[c]					
Non-Hispanic White	72.7 (69.4, 76.0)	78.3 (71.9, 84.6)	72.1 (68.4, 75.7)	70.0 (65.7, 74.4)	79.3 (75.2, 83.5)
Non-Hispanic Black	10.4 (7.7, 13.1)	7.3 (3.2, 11.4)	10.8 (7.8, 13.7)	11.4 (7.8, 15.0)	7.9 (4.9, 11.0)
Hispanic	11.3 (8.8, 13.9)	10.2 (4.7, 15.7)	11.5 (8.7, 14.3)	12.3 (9.0, 15.5)	9.0 (5.8, 12.2)
Other	5.6 (4.3, 6.9)	4.2 (1.7, 6.7)	5.7 (4.4, 7.1)	6.3 (4.5, 8.1)	3.7 (2.2, 5.2)
Education[c]					
< high school	17.9 (15.8, 20.0)	15.9 (9.9, 21.9)	18.2 (16.0, 20.4)	18.0 (15.4, 20.6)	17.7 (14.3, 21.1)
High school graduate	32.5 (29.5, 35.6)	37.1 (28.6, 45.6)	32.0 (28.8, 35.1)	31.5 (28.0, 34.9)	35.0 (29.4, 40.7)
Some college	35.2 (31.6, 38.8)	35.9 (27.8, 44.0)	35.1 (31.3, 38.9)	34.2 (30.1, 38.3)	37.7 (32.4, 43.0)
≥ college graduate	14.4 (11.7, 17.0)	11.1 (4.8, 17.4)	14.7 (11.8, 17.7)	16.3 (12.7, 19.9)	9.6 (7.0, 12.1)
Household income,[c] $					
< 20 000	31.2 (27.9, 34.5)	33.0 (25.0, 41.1)	31.0 (27.4, 34.6)	27.9 (23.8, 32.0)	39.4 (34.5, 44.2)
20 000–49 999	31.8 (28.8, 34.8)	35.0 (27.7, 42.3)	31.4 (28.1, 34.7)	33.1 (29.5, 36.8)	28.5 (23.9, 33.0)
50 000–74 999	14.0 (12.0, 16.0)	10.7 (5.1, 16.4)	14.4 (12.3, 16.5)	14.3 (11.9, 16.8)	13.3 (10.1, 16.5)
≥ 75 000	23.0 (19.8, 26.1)	21.2 (14.6, 27.9)	23.2 (19.7, 26.6)	24.6 (21.0, 28.2)	18.9 (15.0, 22.8)
Health insurance[b,c]					
Public insurance[d]	45.6 (42.5, 48.7)	42.7 (35.6, 49.9)	46.0 (42.5, 49.4)	41.8 (38.2, 45.5)	54.9 (49.4, 60.4)
Private insurance	31.7 (29.2, 34.2)	22.5 (16.1, 28.9)	32.8 (29.9, 35.7)	34.4 (31.3, 37.5)	25.2 (20.8, 29.6)
No insurance coverage	22.7 (19.9, 25.4)	34.8 (27.7, 41.9)	21.3 (18.3, 24.2)	23.8 (20.6, 27.0)	19.9 (15.0, 24.8)
Self-reported health[e]					
Good to excellent	69.8 (66.8, 72.9)	68.6 (58.7, 78.5)	70.0 (66.8, 73.2)	69.7 (66.2, 73.1)	70.4 (64.4, 76.4)
Poor to fair	30.1 (27.1, 33.1)	31.4 (21.5, 41.3)	30.0 (26.8, 33.1)	30.3 (26.9, 33.8)	29.6 (23.6, 35.6)
Past-year mental illness[b,c]					
Yes	55.8 (53.2, 58.4)	72.3 (64.7, 79.9)	53.9 (51.2, 56.6)	53.4 (49.6, 57.2)	61.9 (56.9, 66.8)
No	44.2 (41.6, 46.8)	27.7 (20.1, 35.3)	46.1 (43.4, 48.8)	46.6 (42.8, 50.4)	38.1 (33.2, 43.1)
Residence					
Metro	84.7 (82.6, 86.9)	83.5 (78.4, 88.5)	84.9 (82.8, 87.0)	84.7 (82.1, 87.2)	84.9 (81.4, 88.4)
Nonmetro	15.3 (13.1, 17.4)	16.5 (11.5, 21.6)	15.1 (13.0, 17.2)	15.3 (12.8, 17.8)	15.1 (11.6, 18.6)

Note. CI = confidence interval; OUD = opioid use disorder.

[a] Unweighted no., overall OUD = 2183.

[b] $P < .05$ from Rao–Scott χ^2 test for comparison between both perceived need groups for each categorical variable.

[c] $P < .05$ from Rao–Scott χ^2 test for comparison between both treatment gap groups for each categorical variable.

[d] Public insurance was defined as covered by Medicare, Medicaid, Champus, ChampVA, VA, or military insurance.

[e] Columns do not add up to 100% because of missing values reported for self-reported health status.

80.3%) without insurance had a treatment gap. Among those with a perceived OUD treatment need, 84.5% had a NSDUH-defined treatment gap, compared with 69.6% of those without a perceived OUD treatment need (Table B, available as a supplement to the online version of this article at http://www.ajph.org).

Table 2 presents both the crude and adjusted odds ratios (ORs and AORs, respectively) and 95% CIs of logistic models assessing the association between population characteristics and presence of a NSDUH-defined treatment gap. In the multivariable adjusted analysis, we found that respondents aged 50 years and older had 1.5 times the odds (AOR = 1.5; 95% CI = 1.2, 2.0) of having a treatment gap compared with those aged 18 to 49 years. Hispanic and other race/ethnicity subgroups had higher odds of a treatment gap (AOR = 1.7; 95% CI = 1.0, 2.9 and AOR = 2.3; 95% CI = 1.3, 3.9, respectively) compared with White adults. We also found that Black adults with OUD had higher rates of treatment gap compared with White adults, though this difference was not statistically significant. Characteristics associated with lower odds of a treatment gap included public insurance versus private insurance (AOR = 0.6; 95% CI = 0.4, 0.8) and annual income less than \$20 000 versus \$50 000 to \$74 999 (AOR = 0.7; 95% CI = 0.4, 1.0; $P = .04$).

Table 3 describes barriers to OUD treatment overall and by OUD type among those who reported a perceived OUD treatment need. Affordability (49.3%) was the most commonly reported barrier to treatment, followed by access (42.1%), lack of readiness to quit (31.9%), and stigma (29.5%). Both the prescription OUD only and OUD with heroin use groups had a similar

TABLE 2— Sociodemographic and Clinical Factors Associated With the Presence of a Past-Year Treatment Gap in Adults With Opioid Use Disorder: National Survey on Drug Use and Health, United States, 2015–2019

	Treatment Gap Vs No Treatment Gap (Ref)	
Characteristics	**Crude OR (95% CI)**	**AOR (95% CI)**
Age, y		
18–49 (Ref)	1	1
≥ 50	1.4 (1.2, 1.8)[a]	1.5 (1.2, 2.0)[a]
Sex		
Male	1.0 (0.8, 1.3)	0.9 (0.7, 1.1)
Female (Ref)	1	1
Race/ethnicity		
Non-Hispanic White (Ref)	1	1
Non-Hispanic Black	1.6 (0.9, 2.8)	1.7 (1.0, 2.9)
Hispanic	1.5 (0.9, 2.5)	1.7 (1.0, 2.9)[a,b]
Other	1.9 (1.1, 3.4)[a]	2.3 (1.3, 3.9)[a]
Highest education level		
< high school	1.0 (0.8, 1.4)	1.1 (0.8, 1.5)
≥ high school (Ref)	1	1
Annual income category, $		
< 20 000	0.7 (0.4, 1.0)[a,c]	0.7 (0.4, 1.0)[a,c]
20 000–49 999	1.1 (0.7, 1.6)	1.1 (0.7, 1.6)
50 000–74 999 (Ref)	1	1
≥ 75 000	1.2 (0.9, 1.7)	1.1 (0.8, 1.6)
Self-reported health		
Good to excellent (Ref)	1	1
Poor to fair	1.0 (0.8, 1.4)	1.1 (0.8, 1.6)
Health insurance		
Public insurance	0.6 (0.4, 0.8)[a]	0.6 (0.4, 0.8)[a]
Private insurance (Ref)	1	1
No insurance coverage	0.9 (0.6, 1.3)	1.0 (0.7, 1.5)
Past-year mental illness		
Yes	0.7 (0.5, 1.0)[a,c]	0.8 (0.6, 1.0)
No (Ref)	1	1
Residence		
Metro (Ref)	1	1
Nonmetro	1.0 (0.7, 1.4)	1.2 (0.9, 1.6)
Survey year		
2015 (Ref)	1	1
2016	0.9 (0.7, 1.4)	1.0 (0.7, 1.5)
2017	0.7 (0.5, 1.0)[a,c]	0.7 (0.5, 1.1)
2018	0.9 (0.6, 1.4)	0.9 (0.6, 1.4)
2019	1.0 (0.6, 1.5)	1.0 (0.7, 1.6)

Note. AOR = adjusted odds ratio; OR = odds ratio. AOR > 1 indicates greater odds of treatment gap versus no gap compared with reference group; AOR < 1 indicates lower odds of treatment gap versus no gap compared with reference group; $df = 50$.

[a] CI does not include the null value.
[b] Before rounding to 1 decimal place, lower limit of CI was above 1.0.
[c] Before rounding to 1 decimal place, upper limit of CI was below 1.0.

TABLE 3— Barriers to Opioid Use Disorder (OUD) Treatment Overall and by OUD Type Among Individuals With Past-Year OUD and Perceived Treatment Need Who Did Not Receive Treatment at Any Location: National Survey on Drug Use and Health (NSDUH), United States, 2015–2019

	Perceived Barrier to OUD Treatment, Weighted Row % (SE)					
	Affordability	Access	Lack of Readiness	Stigma	Treatment Not a Priority	Lack of Trust in Treatment
Overall OUD[a]	49.3 (4.1)	42.1 (4.0)	31.9 (3.9)	29.5 (4.0)	8.5 (1.8)	. . .
Prescription OUD only	46.7 (4.9)	38.6 (4.7)	24.2 (3.9)	33.2 (5.8)	9.9 (2.6)	. . .
OUD with heroin use	51.8 (4.1)	45.3 (4.3)	39.1 (4.9)	26.0 (4.1)	7.1 (1.9)	. . .
Barriers among those with a perceived need for OUD treatment and NSDUH-defined treatment gap (weighted n = 176 353): overall OUD[b]	53.8 (9.4)	48.2 (7.2)	29.5 (8.0)	24.8 (3.6)	10.1 (4.5)	. . .
Barriers among those with a perceived need for OUD treatment without NSDUH-defined treatment gap (weighted n = 32 440): overall OUD[c]	48.5 (4.1)	40.9 (4.1)	32.3 (4.0)	30.4 (4.0)	8.1 (1.8)	. . .

Note. Weighted n = 208 793. We do not report results from “lack of trust” barrier because of low count per NSDUH cell suppression rules.

[a] Sample for those with OUD treatment barriers includes only individuals with perceived need for OUD treatment (unweighted n = 252).
[b] Sample for those with OUD treatment barriers includes only individuals with perceived need and NSDUH-defined treatment gap (unweighted n = 205).
[c] Sample for those with OUD treatment barriers includes only individuals with perceived need and without NSDUH-defined treatment gap (unweighted n = 47).

pattern of reported barriers. Table 3 further shows barriers among those with an OUD treatment need with and without a NSDUH-defined treatment gap, with similar most commonly reported barriers.

Figure 1 provides an overview of the study sample. Notably, 12.5% of individuals with a treatment gap reported a treatment need, and more than half (53.4%) of the adults with a treatment need reported trying to obtain treatment.

DISCUSSION

We found that, in a weighted sample of 1 987 961 adults with OUD, only 3 in 10 received treatment as defined by NSDUH in the past year. While nearly three quarters of the sample were classified as having an OUD treatment gap, only 10.5% reported a perceived need for treatment.

There were differences in the distribution of characteristics of persons reporting a need for OUD treatment and those with a NSDUH-defined treatment gap, illuminating both inadequate access to MOUD and the distinctions between the view of treatment vis-à-vis the NSDUH survey and the potentially more expansive view held by persons with OUD. Given the inherent NSDUH study design limitations, it is difficult to draw conclusions about the source and causal relationship between these associations. The NSDUH-based estimate of a treatment gap adheres to a strict treatment definition that ignores natural processes of recovery, economic and carceral consequences to access, and the value of harm-reduction programs. By doing so, more expansive treatment plans, such as those necessitating safe syringe supplies, housing, holistic health care, and other forms of social and economic support, are simply not “counted.” This is despite evidence suggesting that they, too, are effective and critical to improving health outcomes and preventing morbidity and mortality.[7] Persons with OUD may thus perceive their care needs as distinct and broader than those offered through pharmacotherapy and behavioral therapy alone, with some not considering resources as “treatment” needs at all but rather as services and social supports necessary for survival.[16] While one may propose that the necessary policy intervention to bridge this divide is simply enhanced education and enhanced treatment access, a more critical approach might be to broaden and make more available both treatment and social and economic supports required for improving health outcomes and quality of life. This constellation of resources may include singular or combinations of MOUD, behavioral therapy, and care rooted in principles of harm reduction and health equity.

In addition to highlighting the discordant assessments of care needs, our study updates national estimates of NSDUH-defined OUD treatment

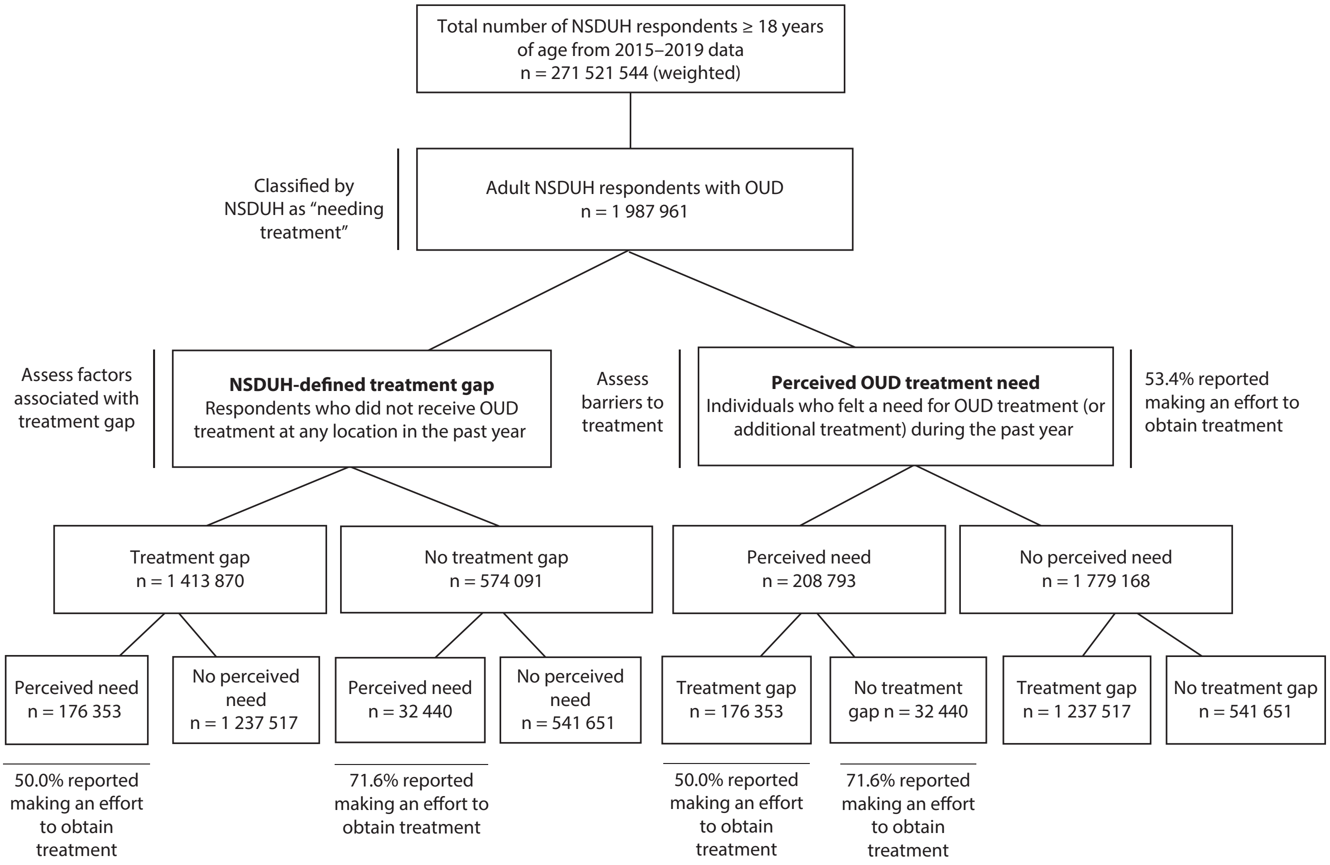

FIGURE 1— **Flow Chart of Study Sample Selection: National Survey on Drug Use and Health (NSDUH), United States, 2015–2019**

Note. OUD = opioid use disorder. Weighted frequencies reported in figure; total number of NSDUH respondents, 2015–2019, unweighted n = 282 768; adults with past-year OUD, unweighted n = 2183; adults with OUD and past-year treatment gap, unweighted n = 1497; adults with OUD and no past-year treatment gap, unweighted n = 686; adults with OUD and past-year treatment need, unweighted n = 252; adults with OUD and no past-year treatment need, unweighted n = 1931; adults with past-year treatment gap and treatment need, unweighted n = 205; adults with past-year treatment gap and no treatment need, unweighted n = 1292; adults with no past-year treatment gap and with treatment need, unweighted n = 47; adults with no past-year treatment gap and no treatment need, unweighted n = 639; all adults classified as having OUD by NSDUH are also classified as needing treatment.

access given the multiple policy changes ushered in during the past decade. We found that disparities in OUD treatment by race and class persist with differences underscoring the persistent inequities in care despite purported advancements in insurance attainment as well as treatment availability.

In our analysis, older adults had higher odds of a treatment gap. This finding is consonant with other research[13] and can partly be explained by the fact that, among Medicare recipients, the prevalence of OUD has increased by 377% in the past 10 years, outpacing the increased prevalence among younger adults.[17,18] However, while the number of Medicare beneficiaries receiving OUD treatment has increased,[19] many remain outside the fold of care. Treatment is further complicated by the increasing comorbidities and broader care needs of older adults.[18] Until January 2020, Medicare did not reimburse for methadone treatment.[20] To enhance coverage, the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act required Medicare to cover OUD treatment, including methadone and behavioral health services at opioid treatment programs (OTPs) beginning in 2020.[21] Other research has found that while two thirds of eligible outpatient buprenorphine prescribers for Medicare beneficiaries are family medicine and internal medicine practitioners, they constitute the lowest proportion of active buprenorphine prescribers.[22] This demonstrates the unfulfilled capacity for primary care and geriatric care expansion in MOUD prescribing and other forms of care for older adults with OUD.[23]

We found significantly lower odds of a treatment gap among adults with public insurance compared with those with private insurance. Previous research has also found that adults with Medicaid had more than twice the odds of OUD treatment receipt compared with those with private or other insurance.[4,13,24] Despite improvements enabled by the Mental Health Parity Act of 2008 and provisions of the Affordable Care Act (ACA)—including listing substance use disorder treatment as an essential health benefit—challenges to accessing OUD treatment among those privately insured and with no insurance persist.[25,26] Recent studies have found that health plans on the ACA Marketplace were more likely to require prior authorization for MOUD than for short-acting prescription opioids.[27] Payers also deny SUD treatment claims at higher rates than other medical claims.[26] While evidence suggests that Medicaid expansions under the ACA resulted in increased utilization and availability of OUD treatment,[28] there continues to be heterogeneity in methadone coverage even in expansion states.[29] Other survey-based research has also shown that because of the increasing costs of medications, patients who self-pay are prescribed buprenorphine 12.3 times more than those with private insurance.[30] Beneficiaries with private insurance may also elect to self-pay for their MOUD prescriptions, fearing loss of employment if MOUD therapies are adjudicated through their employer-sponsored insurance.[31] This is evidenced by our finding that 29.5% of our sample noted “stigma,” related, in part, to the fear that their OUD would have “a negative effect on their job,” as a barrier to treatment.

Our study found that adults from Hispanic and “other” race/ethnicity groups were more likely to have a NSDUH-defined treatment gap compared with White adults but that a lower proportion of Black, Hispanic, and “other” adults had a perceived need for OUD treatment than White adults with OUD. Previous research has shown that non-White adults had lower odds of treatment receipt and that access to OUD treatment is often informed by race.[13,29,30,32] We add to this literature by suggesting that potential differences in perceived need by race also reflect different assessment of care needs above and beyond MOUD. Despite federal and regional initiatives to increase the number of eligible prescribers to improve treatment access, the increase in receipt of MOUD has primarily been seen in wealthier and predominantly White counties.[33,34] Buprenorphine-providing facilities are more likely to be located in highly segregated, predominantly White counties, and methadone-providing facilities are more likely to be located in highly segregated, predominantly Black and Hispanic/Latino counties.[35]

Qualitative research has found that persons with OUD prefer buprenorphine to methadone, not only because it is accessible outside of OTPs but also because its use is less “stigmatizing.”[36] Furthermore, Black, Brown, and Indigenous communities and low-income communities more broadly are also more likely to be criminalized for their use of opioids under the laws and policies ushered in by the so-called War on Drugs. Nearly 15% of those in prison have an OUD, and Black people are incarcerated at a significantly higher rate than White people for similar drug-related “offenses.”[37] These realities, and medical racism more broadly, shape individual perceptions and strategies when engaging with the health care system.[4,38] From a critical public health perspective, our findings suggest that access to more flexible, less institutionalized, and less surveilled forms of medical treatment of OUD (unlike methadone, buprenorphine can be picked up at a community pharmacy) should be prioritized, especially in deliberately neglected communities of color.

Although it was not within the scope of this analysis, it is important to acknowledge the role of law enforcement, including that of the Drug Enforcement Agency and the Department of Justice, in shaping punitive responses to OUD. Qualitative research has shown that persons with opioid dependence and OUD treatment needs may be less likely to initiate the care cascade specifically because of fears of law enforcement involvement and coercive involuntary treatment.[7,39–41]

More than half of the adults with a perceived need for OUD treatment reported making an effort to obtain treatment, underlying the fact that barriers to treatment are informed primarily by structural barriers to care.[42–44] Overall, affordability was reported as a barrier by half of those with a perceived need. Even among those with insurance coverage, cost-sharing and frequent pharmacy visits for filling of buprenorphine prescriptions can be cost-prohibitive.[45] Factors such as limited methadone coverage within commercial health plans, scarcity of in-network methadone providers, rising costs of pharmaceuticals, and prior authorization requirements also increase patient out-of-pocket costs.[7,46]

Other barriers commonly reported included access, lack of readiness, and stigma. In our sample, access barriers included difficulty securing childcare, transportation, and treatment openings, or not knowing where to find care or the type of treatment desired. These barriers are interconnected and relate not only to travel times and distances to treatment facilities but also to making frequent visits to the pharmacy or treatment facility[47,48] and inequitable availability of buprenorphine at pharmacies. One study found that 1 in 5 pharmacies sampled were either unwilling or unable to fill a buprenorphine prescription entirely, and an additional 7% did not disclose controlled substance availability via phone and required patients to ask in person.[49] Importantly, travel burden is also linked to rurality, with patients in rural areas facing greater travel times to access treatment.[50] Our study did not find differences in treatment need by geography, but this could in part be because of the limited ability of the COUTYP4 variable in the publicly available NSDUH files to distinguish under-resourced rural areas from other geographies.

With respect to availability of treatment, there have been concerted local, state, and federal efforts to enhance treatment access through expanding scope of practice. Under the Drug Addiction Treatment Act of 2000, clinicians must receive an "X-waiver" to provide buprenorphine in outpatient settings. Though insufficient, the recent US Department of Health and Human Services prescribing guidelines exempting all eligible prescribers from federal certification requirements to treat up to 30 patients with buprenorphine was intended to support meeting OUD treatment needs.[51,52]

Although the number of office-based buprenorphine prescribers has increased, the number of OTPs providing methadone has remained relatively stagnant, partly because of state-level limits on establishing new facilities.[53] Because of the COVID-19 pandemic, SAMHSA issued guidance allowing states to request blanket exceptions for patients in OTPs—permitting methadone clinics to provide up to 4 weeks' supply of medication via telemedicine services instead of requiring burdensome daily visits and dispensing.[54] Maintaining these changes and further expanding methadone prescribing in settings beyond OTPs may narrow the gap in MOUD treatment access for those patients that want and seek it.

One third of respondents reported "lack of readiness to stop using" as a barrier to treatment. This finding underscores the importance of prioritizing harm reduction and patient-centered care needs. Relatedly, although prescribing injectable extended-release naltrexone does not require special credentialing by providers, it does require detoxification before starting treatment.[55] This abstinence requirement may be a significant barrier to the use of naltrexone, which is known to have lower rates of treatment initiation compared with other MOUD.[56,57]

Stigma, a complex and multifaceted phenomenon, was also cited as a barrier to OUD treatment by one third of respondents. Often with a racialized and class component, it includes not only how people with OUD perceive themselves but also how they imagine their providers may perceive them.[58] Perceived stigma against patients with OUD can lead to decreased likelihood of MOUD prescribing[59] and is known to be associated with greater support for punitive policies regarding substance use, denial of services, or reluctance toward MOUD.[26,60] Stigma informs the treatment landscape through misconceptions and biases directed at individuals with OUD and at a structural level—toward both OTPs and harm-reduction approaches (the "not-in-my-backyard" phenomenon).[58,61] Separation of treatment of addiction from "mainstream" medical issues has further created a feedback loop for stigma, wherein the separation originates from and contributes to stigma.[44,61] Normalizing language around OUD as a chronic condition, integrating clinical care with harm reduction, and early, targeted education for key health care providers and staff regularly interacting with persons with OUD is critical.[24,62–65]

Strengths and Limitations

Our study had several strengths. To address our research goals, we used the most recent data from a source that is used to derive national estimates of OUD treatment needs. We also unpacked the distinct phenomenon of treatment gap and perceived treatment need.[9] By quantifying and comparing both NSDUH-defined and patient-defined assessments of treatment need, we were able to illuminate the chasm between the two.

Our study had important limitations. First, NSDUH is based on self-reporting and, thus, is subject to recall bias and underreporting of substance use. Second, NSDUH excludes critical OUD populations (such as those institutionalized with serious mental illness, homeless persons not living in shelters, and incarcerated individuals, including those imprisoned for drug use). Third, NSDUH definitions of treatment are specifically centered around MOUD and behavioral therapy. This definition of treatment is restrictive and ignores the totality of the care needs of patients with OUD that may extend to harm reduction and other critical social supports. Finally, nonprescription fentanyl use is not incorporated in NSDUH variables that capture opioid use disorder.

Conclusions

Our work contributes the most current evidence on OUD treatment needs and illuminates the discordance between NSDUH-defined OUD treatment gaps and patient perceptions of need for OUD "treatment." By highlighting these differences, we sought to recenter patient agency and person-centered assessments of care and highlight the racial, structural, political, and economic factors that delimit care for low-income communities and communities of color. Furthermore, despite efforts to improve uptake of MOUD treatment, racism, lack of affordability, and stigma all continue to play a role in limiting treatment access. Public health programs and policies for eliminating barriers such as the "X-waiver" and investing in interventions above and beyond MOUD prescribing such as harm reduction should be proactively undertaken. Simultaneously, active disinvestment from carceral and punitive approaches to persons with OUD and persons using opioids should be prioritized to enable fulfillment of their self-described care needs.

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CONTRIBUTORS

D. M. Qato was responsible for supervision and funding of the research project. J. Saini and D. M. Qato conceptualized the study question, design, and analysis plan. J. Saini was primarily responsible for data analysis, under the mentorship of D. M. Qato. J. Saini and D. M. Qato wrote initial drafts of sections of the article, and all authors critically revised and edited the full article for important intellectual content. All authors have reviewed and approved the final manuscript.

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CONFLICTS OF INTEREST

All authors report no relationship or financial interest with any entity that would pose a conflict of interest with the subject matter of this article.

HUMAN PARTICIPANT PROTECTION

This was an analysis of publicly available data and was thus exempt from institutional review board review by the University of Maryland, Baltimore.

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Popularity of Delta-8 THC on the Internet Across US States, 2021

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Objectives. To assess the popularity of an emergent drug, delta-8 tetrahydrocannabinol (THC), and compare interest levels between US states with or without legalized recreational cannabis.

Methods. We used Google Trends to assess the growth of interest among delta-8 THC–related search terms from May 17, 2020, to May 9, 2021. We examined differences between states with or without legalized cannabis using state-level Google Trends data from February 13 to May 13, 2021, and policy data from the National Conference of State Legislatures.

Results. Interest in delta-8 THC increased starting in mid-June 2020, with search volumes for delta-8 THC queries currently at 35% of the "marijuana" query. States where recreational cannabis is illegal had higher relative queries than did states with legalized recreational cannabis (52.3 vs 14.8; $t = 40.9$; $P < .001$).

Conclusions. There has been rapid growth in interest in delta-8 THC. Findings between state policy contexts likely indicate delta-8 THC's role as a substitute good for delta-9 THC.

Public Health Implications. Digital signals such as search volumes may point to an emergent use trend in the substance delta-8 THC. Further studies are needed to assess potential harms and correlates of delta-8 THC use. (*Am J Public Health*. 2022;112(2):296–299. https://doi.org/10.2105/AJPH.2021.306586)

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Delta-8 tetrahydrocannabinol (THC) has risen in popularity, as evidenced by increased news[1] and social media[2] discussions. Delta-8 THC is a psychoactive drug, although it is less potent than the better known delta-9 THC.[3] Delta-8 THC is a naturally occurring cannabinoid found in concentrations too low in most cannabis plants to harvest. However, delta-8 THC can also be inexpensively synthesized from other cannabinoids through a process of isomerization.[4] With the rising popularity of cannabidiol (CBD) products, commercial enterprises have begun offering delta-8 THC products made with converted CBD as a cannabis alternative.[5] Little attention has been paid to delta-8 THC in the public health literature.[6] To our knowledge, there is currently no public health surveillance data tracking delta-8 THC use.

The legality of delta-8 THC is nuanced. The 2018 Farm Bill (Pub L No. 115-334) legalized cannabis and cannabis derivatives with extremely low concentrations of delta-9 THC (e.g., hemp). However, the lack of reference to delta-8 THC has created a legal "gray area" where some argue that delta-8 THC is legal under federal law. Although federal law may be ambiguous, some states have taken an active role in defining whether delta-8 THC is illegal under state law. Such regulations are currently present in only 12 states.[7] Given the vagueness of federal law and the inconsistency of state regulation and enforcement, delta-8 THC began being sold by online retailers in September 2019.[8] It is plausible that delta-8 THC may be acting as a substitute in places where typical cannabis products are illegal—effectively circumventing cannabis laws. Given the lack of available data, we provide initial reports from Google Trends (Google LLC, Mountain View, CA) that may be used to gauge the increasing interest in delta-8 THC over time, as well as the relationship between interest in delta-8 THC, and the legal status of cannabis at the state level.

METHODS

To investigate the popularity of delta-8 THC, we examined the weekly volume of Google searches related to delta-8 THC in the United States using Google Trends from May 2020 through May

2021. Before this period, the search volumes for delta-8 THC were effectively zero. Google Trends automatically normalizes search volume into a relative search index (RSI) that scales from 0 to 100, where 100 represents the peak popularity for the term. As a result, the absolute number of searches is not available. To put the RSI for delta-8 THC into context, we compared the delta-8 THC RSI to common search terms for cannabis. When making comparisons across terms, Google Trends again normalizes the search volumes between 0 and 100, with 100 representing the peak search volume of the most popular term.

Because of the relative newness of delta-8 THC, we combined a series of delta-8 THC–related searches into a single Google Trends query. Specifically, we evaluated the delta-8 THC search activity by combining the following search terms: “delta 8,” “delta-8,” “delta 8 gummies,” and “delta 8 thc.” We selected these terms by searching for “delta 8” and adding relevant search terms as suggested by Google Trends. We compared these with individual search queries for the terms “marijuana,” “cannabis,” and “THC.” We accessed all Google Trends data on May 13, 2021.

To examine whether mean search popularity varied by state recreational cannabis legalization, we evaluated the state-specific search activity for delta-8 THC alone in the 90 days before data access: February 13 through May 13, 2021. In search volume comparisons across states, Google Trends further standardizes by the total number of searches in each state to account for differences in overall search volume. We derived a binary variable measuring whether state law allows recreational cannabis use from the National Conference of State Legislatures.[9] We assessed the difference in the relative search volume for delta-8 THC by recreational cannabis’s legal status using the Welch *t* test.

RESULTS

Over the course of the study period, the search term “marijuana” remained the most popular, peaking at an RSI of 100 in early November 2020. This peak is likely an artifact of increased interest in ballot initiatives involving cannabis leading up to the 2020 election. Subsequent comparisons between delta-8 THC searches and searches for marijuana are thus based on the average relative search index for the query “marijuana” over the study period (RSI = 75). Before June 2020, there was little evidence of interest in delta-8 THC according to Google search traffic (RSI < 1). By early August 2020, the RSI for our delta-8 THC query had risen to 4 (approximately 5% as popular as “marijuana”). By the beginning of May 2021, the RSI for our delta-8 THC query had risen to 26 (approximately 35% as popular as “marijuana”; Figure 1). The mean state-specific RSI for delta-8 THC was higher in states where cannabis was not legal for recreational use (n = 34) than in states where cannabis was legalized (n = 17; 52.3 vs 14.8; $t = 40.9$; $P < .001$; mean difference = 37.6; 95% confidence interval = 27.8, 47.3; Figure A [available as a supplement to the online version of this article at http://www.ajph.org]).

DISCUSSION

Our findings demonstrate a rapid increase in the popularity of searches for an emergent drug, delta-8 THC. In less than a year, delta-8 THC went from only 5% of the relative search popularity of marijuana to more than one third the popularity of marijuana, nearly a 7-fold increase. Our finding that search volumes for delta-8 THC varied by state policy context has important implications. As more states continue to

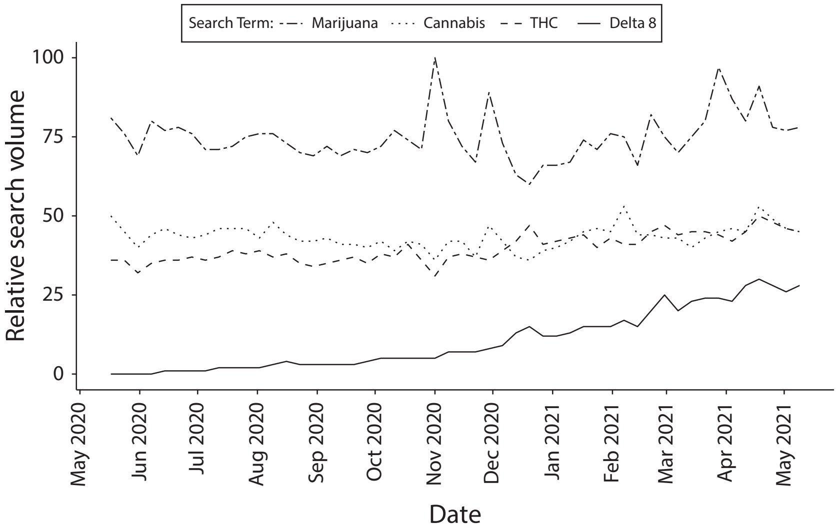

FIGURE 1— The Relative Search Volume of Delta-8 THC Compared With Common Cannabis-Related Search Terms: United States, May 17, 2020–May 9, 2021

Note. Before May 2020, the relative search volumes for delta-8 THC were consistently < 1.

legalize recreational cannabis use, this may create increased demand for cannabis alternatives in states where recreational cannabis remains illegal or diversion from states with legal markets.

Although legalization of recreational marijuana brings its own public health challenges, the current patchwork system of cannabis regulation is contributing to a growing "gray market" of unregulated cannabis alternatives of which we know little. However, what has been well documented is the racialized enforcement of laws for the underground market sales of delta-9 THC, resulting in the disproportionate incarceration of people of color. This contrasts with the open sales of delta-8 THC, a nearly identical isomer. As the country plans its response to the growing popularity of this emerging drug, it is critical that we do so in a way that does not further perpetuate racial disparities in drug enforcement.

Limitations

Our findings are not without limitations. Internet search volumes are a crude proxy for actual substance use and may not translate to behaviors or intentions. The normalized nature of Google Trends results further complicates interpretation of our findings, necessitating comparisons to other cannabis-related search terms to understand the magnitude of delta-8 THC's growing popularity.

Despite these clear limitations, results from Google Trends have been shown to be correlated with substance use from the Monitoring the Future study and noncigarette tobacco use from the Youth Risk Factor Behavior Survey.[9] Additionally, our measure of recreational cannabis ignored the heterogeneity in both the timing of legalization in recreational markets and state policies allowing medical use of cannabis.

Public Health Implications

Digital signals such as search volumes and social media reports may point to emergent substance use trends but lack the precision and rigor of designed research studies capable of estimating behavior prevalence and correlates. Although designed studies are needed to reliably evaluate emergent substance use, potential emerging topics must first be identified. There is a need for consistent integration of complementary approaches using search data,[10] social media chatter,[11] and signal detection methods[12] to rapidly identify emergent substance use. We have identified a rapid increase in search activities for the novel cannabis product delta-8 THC. Future studies should investigate the health impacts of delta-8 THC use and seek to understand delta-8 THC use across varied policy contexts. AJPH

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CONTRIBUTORS

M. D. Livingston conceptualized the study and drafted the initial version of the article. A. Walker, M. B. Cannell, and M. E. Rossheim aided in the drafting and editing of the article. M. B. Cannell aided in the conceptualization of the article and the analysis. All authors approved the final version of the article.

CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

HUMAN PARTICIPANT PROTECTION

No institutional review board review was necessary because no human participants were involved in this study.

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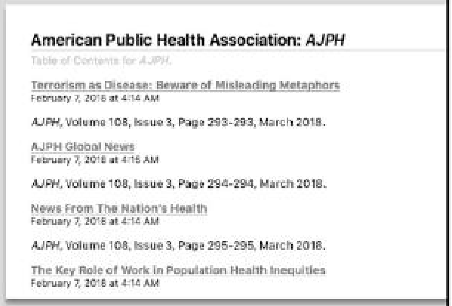

Opioid Overdose Deaths Among Formerly Incarcerated Persons and the General Population: North Carolina, 2000–2018

Shabbar I. Ranapurwala, PhD, Mary C. Figgatt, MPH, Molly Remch, MSPH, Carrie Brown, MD, Lauren Brinkley-Rubinstein, PhD, David L. Rosen, MD, PhD, Mary E. Cox, MPH, and Scott K. Proescholdbell, MPH

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Objectives. To compare opioid overdose death (OOD) rates among formerly incarcerated persons (FIPs) from 2016 to 2018 with the North Carolina population and with OOD rates from 2000 to 2015.

Methods. We performed a retrospective cohort study of 259 861 North Carolina FIPs from 2000 to 2018 linked with North Carolina death records. We used indirectly standardized OOD mortality rates and ratios and present 95% confidence intervals (CIs).

Results. From 2017 to 2018, the OOD rates in the North Carolina general population decreased by 10.1% but increased by 32% among FIPs. During 2016 to 2018, the highest substance-specific OOD rate among FIPs was attributable to synthetic narcotics (mainly fentanyl and its analogs), while OOD rates for other opioids were half or less than that from synthetic narcotics. During 2016 to 2018, the OOD risk for FIPs from synthetic narcotics was 50.3 (95% CI = 30.9, 69.6), 20.2 (95% CI = 17.3, 23.2), and 18.2 (95% CI = 15.9, 20.5) times as high as that for the North Carolina population at 2-week, 1-year, and complete follow-up after release, respectively.

Conclusions. While nationwide OOD rates declined from 2017 to 2018, OOD rates among North Carolina FIPs increased by about a third, largely from fentanyl and its analogs. (*Am J Public Health*. 2022;112(2):300–303. https://doi.org/10.2105/AJPH.2021.306621)

Formerly incarcerated persons (FIPs) have high prevalence of substance use and mental health disorders[1-3] and are at high risk of opioid overdose death (OOD) after release from incarceration.[4,5] In a previous North Carolina study, we found that from 2000 to 2015 the OOD rate among FIPs at 2 weeks and 1 year after release was 40 and 10.5 times that in the North Carolina general population, respectively.[4] Because of the dynamic OOD epidemic from commonly prescribed opioids (2011) to heroin (2014) and now to fentanyl and its analogs, it is unclear how the OOD rates have changed among FIPs.[6] This analysis adds 2016–2018 North Carolina incarceration release data to compare OOD rates among FIPs with the general population and examines effect measure modification by race, sex, and age.

METHODS

We conducted a retrospective cohort study among North Carolina FIPs released from incarceration from 2000 to 2018 to estimate postrelease OOD rates relative to the North Carolina general population OOD rates[4] and examined modification by age, sex, and race.

Data Sources

We linked the North Carolina Department of Public Safety's incarceration release data from January 1, 2000, to December 31, 2018, with North Carolina death records from the same period, using a deterministic algorithm including exact matches of Soundex for last and first names, date of birth, and sex.[4] The North Carolina Department of Public Safety data included dates of prison entry and exit and demographics. The death records included death date and cause documented with *International Classification of Diseases, 10th Revision,* codes (*ICD-10*; Geneva, Switzerland: World Health Organization; 1992). We used the National Vital Statistics System's bridged-race intercensal population estimates from 2000 to 2018 for annual North Carolina demographic and population estimates.

FIPs, aged 18 years or older at release, contributed person-time to OOD rates from their release date until reincarceration, death, or end of study, whichever occurred first.[4] For the general population, each North Carolina resident contributed 1 person-year (PY) per calendar year. Between 2000 and 2018, there were 451 453 releases from North Carolina prisons among 259 861 unique individuals. Those released accrued 2 458 639 PYs. During this time, 17 422 individuals suffered out-of-prison deaths.

We defined OOD using underlying and contributing causes of death with an *ICD-10* code of X40–X44, T40.0 (opium), T40.1 (heroin), T40.2 (other opioids), T40.3 (methadone), and T40.4 (other synthetic narcotics, commonly fentanyl or its analogs).[7] Upon recent Centers for Disease Control and Prevention (CDC) guidance, *ICD-10* code T40.6 (unspecified narcotics) was also added. We examined all OODs combined and for specific opioids, including heroin, methadone, prescription opioids, and fentanyl. Covariates included age (18–24, 25–34, 35–44, 45–54, 55–64, and ≥ 65 years), sex (female or male), race (White or non-White), and calendar year of incarceration release among FIPs.

Statistical Analysis

We calculated FIPs' OOD rates by dividing the number of OODs by the PYs contributed at 2-week, 1-year, and complete follow-up after incarceration release, and for North Carolina general population by dividing total OODs among North Carolina residents by the state population for each calendar year. Complete follow-up indicates all available postrelease person-time.

Using indirect standardization, we calculated standardized mortality ratios (SMRs) and 95% confidence intervals (CIs) at 2-week, 1-year, and complete follow-up after incarceration release, by comparing observed OODs among FIPs with expected OODs, had they had the same age–race–sex distribution as the North Carolina general population. We also calculated SMRs and 95% CIs comparing FIPs' observed versus expected OODs from heroin, commonly prescribed opioids (T40.2+T40.3), and other synthetic narcotics and measured effect measure modification by age, sex, and race. We also present directly standardized rates.

RESULTS

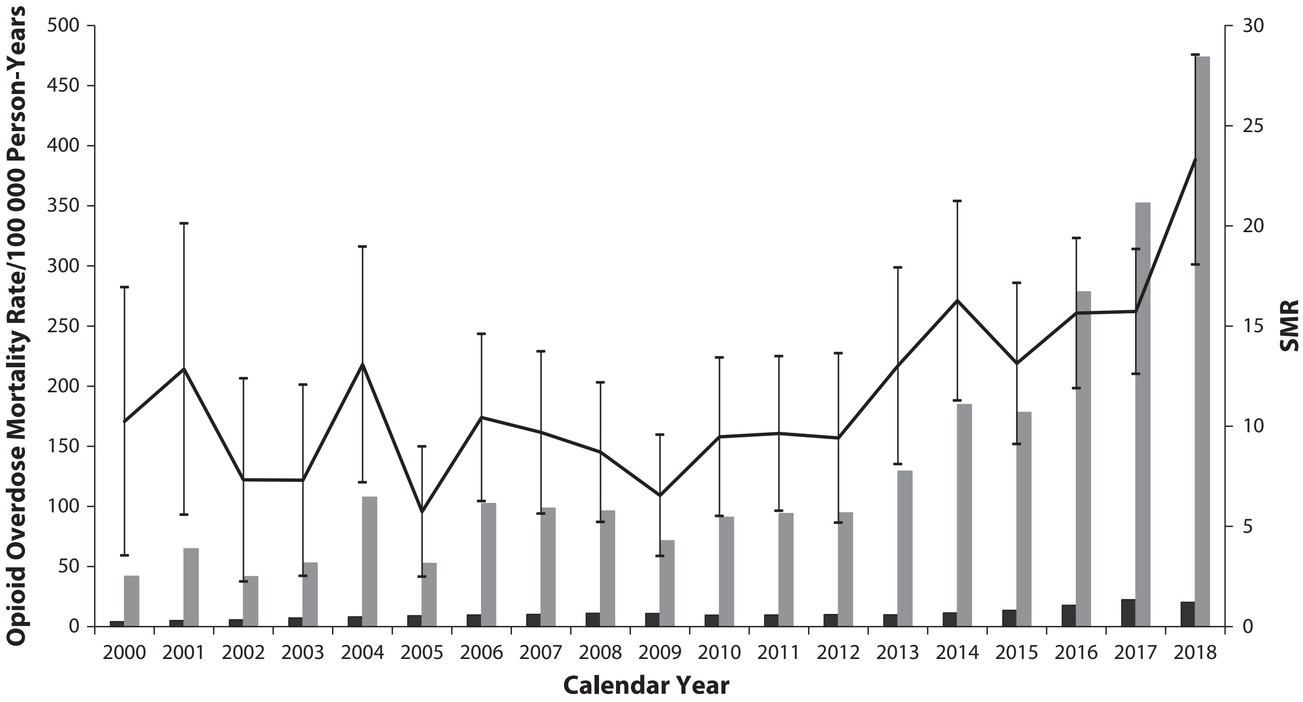
Of the 17 422 out-of-prison deaths among FIPs released between 2000 and 2018 in North Carolina, 2078 (11.1%) were OODs. The OOD rate in the North Carolina general population decreased from 22.8 per 100 000 PYs in 2017 to 20.7 per 100 000 PYs in 2018 (10.1% decline). However, the OOD rate among FIPs increased by 32% from 362 per 100 000 PYs in 2017 to 479 per 100 000 PYs in 2018 (Figure 1), largely attributable to other synthetic narcotics, mostly fentanyl (Table A, available as a supplement to the online version of this article at http://www.ajph.org). As a result, whereas the SMR remained stable from 2014 to 2017, it increased significantly in 2018 (Figure 1).

The overall age-, sex-, race-, and calendar year–standardized postrelease OOD rate among FIPs from 2016 to 2018 was 960 per 100 000 PYs (95% CI = 646, 1274) at 2 weeks after release, 359 per 100 000 PYs (95% CI = 314, 404) at 1 year after release, and 302 per 100 000 PYs (95% CI = 268, 335) at complete follow-up after release (Table A). The highest substance-specific OOD mortality rate at 2-week, 1-year, and complete follow-up after release during 2016 to 2018 was attributable to synthetic narcotics, followed by heroin and commonly prescribed opioids (Table A).

Similarly, the 2016–2018 SMRs comparing observed and expected OOD rates from FIPs were highest for synthetic narcotics. Compared to the general population, FIPs were 50.3 times (95% CI = 30.9, 69.6), 20.2 times (95% CI = 17.3, 23.2), and 18.2 times (95% CI = 15.9, 20.5) more likely to die from a synthetic narcotic overdose by 2-week, 1-year, and complete follow-up after release, respectively (Figure A, available as a supplement to the online version of this article at http://www.ajph.org). This is a large increase compared with 2000 to 2015 that is congruent with decreases for heroin and commonly prescribed OODs.[4] Hence, the majority of the 2018 SMR increase is attributable to synthetic narcotics, commonly involving fentanyl.

Overall, compared with general North Carolina population, from 2016 to 2018, FIPs were 46.6 times (95% CI = 31.4, 61.8), 17.4 times (95% CI = 15.2, 19.6), and 14.6 times (95% CI = 13.0, 16.6) as likely to die from OODs by 2-week, 1-year, and complete follow-up after release from incarceration, respectively (Figure A).

While there was no substantial effect measure modification by age, the 1-year postrelease SMR for female FIPs (42.6; 95% CI = 31.7, 53.4) was higher than for



	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
■ NC GP	4.09	5.04	5.68	7.24	8.23	9.17	9.81	10.16	11.06	10.92	9.60	9.76	10.06	9.94	11.36	13.58	17.80	22.40	20.33
▨ FIPS	41.94	64.76	41.59	52.85	107.70	52.63	102.40	98.51	96.29	71.51	90.98	94.11	94.69	129.30	184.0	178.30	278.60	352.30	473.80
— SMR	10.25	12.85	7.32	7.30	12.08	5.74	10.44	9.69	8.71	6.55	9.47	9.64	9.42	13.02	16.26	13.14	15.65	15.73	23.31
- SMR L95	3.55	5.58	2.25	2.53	7.20	2.49	6.26	5.64	5.22	3.52	5.52	5.78	5.18	8.11	11.29	9.12	11.90	12.62	18.07
- SMR U95	16.94	20.13	12.40	12.08	18.96	8.99	14.61	13.74	12.19	9.58	13.43	13.50	13.65	17.93	21.24	17.16	19.39	18.85	28.55

FIGURE 1— Standardized Annual Opioid Overdose Death Rates and Standardized Mortality Ratio Comparing Formerly Incarcerated Persons With North Carolina Residents: 2000–2018

Note. FIPS = formerly incarcerated persons; NC GP = North Carolina general population; SMR = standardized mortality ratios calculated using indirect standardization for age, sex, race, and calendar year; SMR L95 = lower 95% confidence interval for SMR; SMR U95 = upper 95% confidence interval for SMR.

male FIPs (14.7; 95% CI = 12.6, 16.8), and the SMR for White FIPs (20.9; 95% CI = 18.0, 23.8) was higher than for non-White FIPs (9.8; 95% CI = 6.9, 12.7).

DISCUSSION

While nationally and in North Carolina the OOD rates declined from 2017 to 2018,[8] OOD rates among FIPs increased by 32%, largely attributable to synthetic narcotics like fentanyl and its analogs. While the risk of OODs from heroin and commonly prescribed opioids among FIPs decreased during 2016 to 2018, the risk of OOD from synthetic narcotics increased substantively.[4] Compared with the 2000–2015 estimates,[4] the 1-year and complete follow-up SMRs for OODs comparing FIPs to North Carolina residents have increased substantially, even after excluding unspecified narcotics. Although there is effect measure modification by sex and race, all FIP subgroup SMRs are 10 times or more higher than the general population.

The North Carolina correctional system began successfully piloting programs to link FIPs to medications for opioid use disorders in community correction in 2017.[9] In addition, the North Carolina opioid action plan has increased naloxone access for everyone including community corrections officers.[10] Despite these interventions, FIPs continue to be vulnerable to OODs,[1] likely because our data predate these interventions; the 3-year period between 2016 and 2018 coincides with the 2017 peak of the synthetic opioid overdose epidemic in the United States,[8] and FIPs face barriers to medication for opioid use disorders initiation and retention upon re-entry including lack of health insurance, housing, and employment, and stigma around drug use and incarceration.[11] Furthermore, the North Carolina prison-based medication for opioid use disorders implementation has experienced COVID-19–related delays.

A potential limitation is the lack of death data for FIPs who move out of state. However, most incarcerated people are released on probation or parole, so the 1-year postrelease OOD rates should not be underestimated. A CDC health alert from December 2020 shows an increase in OOD beyond the 2017 highs.[12] Future research will need to examine how the drug overdose epidemic under the shadow of the COVID-19 pandemic affects the health of FIPs.

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CONTRIBUTORS

S. K. Proescholdbell, D. L. Rosen, S. I. Ranapurwala, and L. Brinkley-Rubinstein contributed to conceptualization and obtaining funding. S. I. Ranapurwala, S. K. Proescholdbell, and D. L. Rosen participated in study design. S. I. Ranapurwala, M. C. Figgatt, and M. Remch performed the analyses. All authors participated in interpretation, writing, and final approval.

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CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

HUMAN PARTICIPANT PROTECTION

This study was approved by the University of North Carolina at Chapel Hill’s institutional review board.

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Rural–Urban Differences in Influenza Vaccination Among Adults in the United States, 2018–2019

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See also Kapadia, p. 202.

Objectives. To provide adjusted rates of self-reported receipt of the influenza vaccine in the 2018–2019 flu season among adults in large metropolitan, medium and small metropolitan, and nonmetropolitan areas of the United States by age group, gender, and race.

Methods. We queried the 2019 National Health Interview Survey for respondents aged 18 years and older. To provide national estimates of influenza vaccination coverage, we performed sample-weighted multivariable logistic regressions and predicted marginal modeling while adjusting for age, gender, race/ethnicity, and urban–rural household designation.

Results. After weighting, 48.1%, 46.2%, and 43.6% of adults from large metropolitan, small and medium metropolitan, and nonmetropolitan areas, respectively, received the influenza vaccine. Additionally, there was a trend toward declining influenza vaccination status from large metropolitan to rural areas in all age groups, both genders, and multiple racial/ethnic groups.

Conclusions. Self-reported influenza vaccination rates were lower in rural than in urban areas among adults of all age groups and both genders. Using community leaders for health promotion, augmentation of the community health care workforce, and provision of incentives for providers to integrate influenza vaccination in regular visits may expand influenza vaccine coverage. (*Am J Public Health*. 2022;112(2):304–307. https://doi.org/10.2105/AJPH.2021.306575)

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There is extensive medical literature on racial/ethnic disparities in vaccination rates and outcomes in vaccine-preventable diseases. However, the urban–rural disparities of these parameters remain unclear despite considerable structural, economic, and social differences in the respective public health enterprises. Differences in patient demographics, income, educational attainment, literacy levels, environmental exposures, access to health services, and other social determinants of health are possible mechanisms behind the urban–rural divide.[1]

In 2019, higher age-adjusted mortality rates from influenza in both genders were noted in rural counties compared with urban counties.[2] Furthermore, there has been a widening gap in overall mortality between urban and rural areas since 1999.[3] Although urban–rural disparities in influenza vaccination uptake among children and pregnant women and immunizations against COVID-19, human papillomavirus, and meningococcus have been described, influenza vaccination rates among adults across urban–rural county levels and related sociodemographic characteristics have been studied less in the United States.[4]

We aimed to provide adjusted rates of self-reported receipt of the influenza vaccine in the 2018–2019 flu season among adults in large metropolitan, medium and small metropolitan, and nonmetropolitan areas by age group, gender, and race.

METHODS

We queried the National Health Interview Survey (NHIS), a continuous, cross-sectional national household survey of noninstitutionalized US civilians administered by the US Census Bureau, for respondents aged 18 years and older in

2019, when information on household urban–rural classification was made publicly available for the first time.[5] The outcome of interest was self-reported receipt of the influenza vaccine in the past 12 months based on respondents answering "yes" to the question, "During the past 12 months, have you had a flu vaccination? A flu vaccination is usually given in the fall and protects against influenza for the flu season."

To provide national estimates of influenza vaccination coverage, we performed sample-weighted multivariable logistic regressions and predicted marginal modeling using the average values of any unfixed covariates while adjusting for age, gender (male and female), race/ethnicity (White, Black, Hispanic, Asian, American Indian/Alaska Native, and any other group, and non-Hispanic other single or multiple races), and urban–rural household designation. We used the 2013 National Center for Health Statistics classification scheme and classified counties based on the population size as follows: large metropolitan (≥ 1 million population), medium and small metropolitan (50 000–999 999), and rural (< 50 000).[6] We predicted point estimates and 95% confidence intervals (CIs) of adjusted influenza vaccination rates across urban–rural household designation for all respondents and stratified them by age (18–49, 50–64, and ≥ 65 years), gender, and racial/ethnic group. We performed analyses in Stata/SE version 16.1 (StataCorp, College Station, TX).

RESULTS

In survey year 2019, 31 997 (90.5%) of 35 365 eligible adults from households included in the survey roster completed the interview. Data on vaccination receipt and relevant covariates were available for 31 539 (98.6%) respondents aged 18 years and older in 2019. The study included unweighted data from 16 466 (52.2%) large central and fringe metropolitan residents, 10 047 (31.9%) medium and small metropolitan residents, and 5028 (15.9%) nonmetropolitan residents.

Sample-weighted age, gender, race, and urban–rural household designation–adjusted estimates of influenza vaccination rates by patient group are presented in Figure 1. After weighting, 48.1% (95% CI = 47.1, 49.1), 46.2% (95% CI = 45.0, 47.5), and 43.6% (95% CI = 41.8, 45.4) of adults from large metropolitan, small and medium metropolitan, and nonmetropolitan areas, respectively, received the influenza vaccine. In large metropolitan and rural areas, respectively, 38.5% (95% CI = 37.3, 39.6) and 34.3% (95% CI = 32.5, 36.1) of adults aged 18 to 49 years, 48.9% (95% CI = 47.5, 50.4) and 44.4% (95% CI = 42.4, 46.5) of adults aged 50 to 64 years, and 71.0% (95% CI = 69.7, 72.3) and 67.2% (95% CI = 65.3, 69.0) of adults aged 65 years and older received the influenza vaccine.

Of men from large metropolitan and rural areas, 44.2% (95% CI = 43.0, 45.4) and 39.8% (95% CI = 37.9, 41.7), respectively, received the influenza vaccine. Among women, 51.8% (95% CI = 50.6, 53.0) and 47.3% (95% CI = 45.3, 49.2) of those living in large metropolitan areas and rural areas, respectively, received the influenza vaccine. Of White adults from large metropolitan and rural areas, 50.0% (95% CI = 48.8, 51.1) and 45.4% (95% CI = 43.7, 47.2), respectively, received the influenza vaccine. Although point estimates among Black, Hispanic, Asian, American Indian/Alaska Native individuals and other single/multiple races demonstrated declining vaccination status from large metropolitan to rural areas, the corresponding CIs overlapped (Figure 1).

DISCUSSION

We present evidence that self-reported influenza vaccination rates were lower in rural than in urban areas among adults of all age groups and in both genders. Furthermore, there was a trend toward lower vaccination rates among racial and ethnic minority groups from rural areas than from more urban areas; however, the wide CIs of these point estimates may be attributable to a small sample size, particularly among Black, Hispanic, Asian, and American Indian/Alaska Native individuals. Well-known racial disparities in vaccination coverage, in which Black and Hispanic adults had lower influenza vaccination rates than did White and Asian individuals, were replicated in this study.[7]

Urban–rural differences provide another dimension to analyzing existing disparities in vaccination coverage and may contribute to higher mortality in influenza among adults from rural counties.[2] Poorer health care access and delivery, along with differences in beliefs and vaccination acceptance, may be mechanisms behind this disparity. Indeed, the rural public health enterprise faces a longstanding "double disparity" of worse health outcomes and behaviors, in addition to inadequate investment in primary care and health departments compared with urban health care systems.[8] We suggest that future work link urban–rural influenza vaccination rates with clinical outcomes. The limitations of this study include its single-year and cross-sectional design; the small sample sizes among racial and ethnic minority groups; unmodeled factors such as socioeconomic status, comorbidities, or those unavailable in the NHIS; and the self-reported nature of vaccination status.

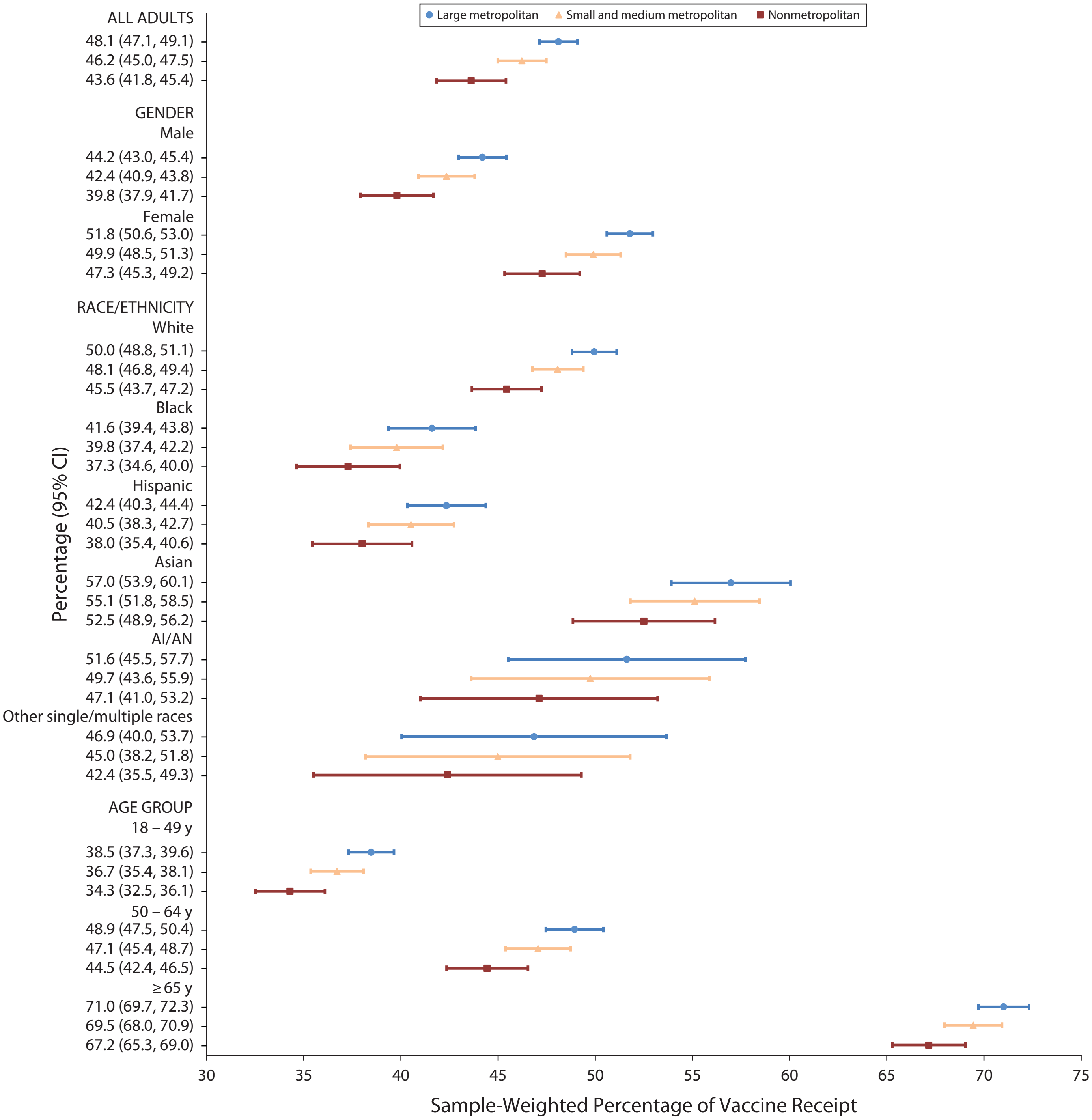

FIGURE 1— **Sample-Weighted Percentage of Influenza Vaccine Receipt: United States, 2018–2019**

PUBLIC HEALTH IMPLICATIONS

Although much of the discussion regarding urban–rural disparities has focused on higher mortality rates and hospital closures in rural areas,[2,9,10] our findings support the implementation of interventions that will improve broader access to the influenza vaccine, particularly in the realm of outpatient and primary care. The COVID-19 pandemic has heightened the public's awareness of the importance of vaccination and provides the public health community with the opportunity to reexamine the gaps in and its strategies for the rollout of routine vaccines in the postpandemic era.[11] With influenza vaccination coverage in the United States falling well below the Healthy People 2020 goal of 80% to 90%, efforts are needed to identify groups with lower coverage.

Our findings corroborate well-established literature indicating that adults living in rural areas constitute one of the groups that may benefit from efforts to improve vaccination uptake.[4] Using community leaders for health promotion, augmentation of the community health care workforce, and provision of incentives for providers to integrate influenza vaccination in regular visits are possible interventions, given that physician recommendation of influenza vaccination is significantly correlated with vaccine receipt.[12] Future efforts to promote influenza vaccination may also leverage the strategies used in the COVID-19 vaccine rollout, such as house-to-house, school-based, and work-based vaccinations; the creation of short-term community-based vaccination centers; and the use of an electronic vaccination registry.[11]

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CONTRIBUTORS

B. Jain and J. A. Paguio conceptualized the study, performed the formal analysis, and drafted the article. B. Jain, J. A. Paguio, J. S. Yao, and E. C. Dee had full access to and curated the data. U. Jain contributed to the data presentation and summarization. L. A. Celi and B. Ojikutu supervised the project and provided important intellectual content. All authors read, critically reviewed, and approved the final version of the article.

CONFLICT OF INTEREST

The authors have no conflicts of interest to declare.

HUMAN PARTICIPANT PROTECTION

The data were publicly available and de-identified and therefore institutional review was not sought per US Department of Health and Human Services regulation 45 CFR 46.101(c).

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Science Translation During the COVID-19 Pandemic: An Academic-Public Health Partnership to Assess Capacity Limits in California

Peter Maldonado, Angie Peng, BA, Derek Ouyang, MS, Jenny Suckale, PhD, and Daniel E. Ho, JD, PhD

See also Giannouchos, p. 197.

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On the basis of an extensive academic–public health partnership around COVID-19 response, we illustrate the challenge of science-policy translation by examining one of the most common nonpharmaceutical interventions: capacity limits. We study the implementation of a 20% capacity limit in retail facilities in the California Bay Area.

Through a difference-in-differences analysis, we show that the intervention caused no material reduction in visits, using the same large-scale mobile device data on human movements (mobility data) originally used in the academic literature to support such limits. We show that the lack of effectiveness stems from a mismatch between the academic metric of capacity relative to peak visits and the policy metric of capacity relative to building code.

The disconnect in metrics is amplified by mobility data losing predictive power after the early months of the pandemic, weakening the policy relevance of mobility-based interventions. Nonetheless, the data suggest that a better-grounded rationale for capacity limits is to reduce risk specifically during peak hours. To enhance the connection between science, policy, and public health in future times of crisis, we spell out 3 strategies: living models, coproduction, and shared metrics. (*Am J Public Health*. 2022;112(2): 308–315. https://doi.org/10.2105/AJPH.2021.306576)

Public health responses to COVID-19 have faced serious challenges in light of rapid changes in the scientific understanding of both the virus and the effectiveness of policy responses. This article discusses lessons from an academic–public health partnership around COVID-19 response. We present findings based on a collaboration with the Public Health Department of Santa Clara County, California, one of the largest counties in the United States. In conjunction with 5 other Bay Area counties, Santa Clara was the first jurisdiction in the country to issue a shelter-in-place order in response to COVID-19.[1] We illustrate challenges that can arise for evidence-based policy during times of crisis using a case study of a prominent nonpharmaceutical intervention—namely, the implementation of capacity limits on businesses (i.e., restricting businesses to some percent of capacity).

A main contribution of our work is to identify 3 tangible strategies for mutually enhancing science, policy, and public health, based on this partnership. We illustrate the gains to such a model in studying the implementation of a 20% capacity limit starting December 6, 2020, on the main affected sectors—namely, grocery stores, pharmacies, and general merchandise stores. (Indoor restaurant dining was already prohibited at this time.) Using data on human movements (mobility data) from mobile devices in a difference-in-differences framework,[2,3] we show that the 20% capacity limit had no significant impact on decreasing the number of visits or peak hour visits, or the length of visits to businesses in those sectors compared with prepandemic time periods. These are the same measures and data employed in the scientific literature to support capacity limits. The puzzle then is how to reconcile the existing scientific literature, which appears to support such limits, with an intervention that proved ineffective in practice.

To resolve this puzzle, we show that capacity limits were ineffective because of disparate definitions of maximum occupancy adopted by researchers as opposed to policymakers. Although scientists used measures available in retrospective data (e.g., 20% of peak capacity reported after a week from mobility data), policymakers require definitions that can be implemented and enforced on the ground in real time. The result was a limit that did not bind: most businesses were already below the enforced limit at baseline.

This disconnect highlights how profoundly human behavior had already shifted prior to the implementation of the capacity limit. Consistent with other evidence,[4,5] we show that mobility loses predictive power of case spread as public health orders are put into place. Scientific studies that anchored capacity limits in associations between human mobility and COVID-19 case rates from the first few months of the pandemic may therefore lose their policy relevance over time.

The effort to reduce the spread of COVID-19 through capacity limits holds valuable lessons for future policy responses to crises. Through our collaboration with public-sector partners, we identified 3 specific strategies for improvement: ensuring that models used to inform policy are dynamic (living) rather than static, improving collaboration between scientists and policymakers through coproduction (not merely science translation), and shifting to more targeted and enforceable metrics in science.

This article assesses the impact of capacity limits and explains how the limits were mistranslated from academic literature, and then reflects on broader lessons for academic–public health collaborations to improve crisis response.

IMPACT OF CAPACITY LIMITS

Capacity limits were motivated by scientific studies showing that restricting visits could decrease the transmission rate of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the novel coronavirus that can cause COVID-19. One such study estimated the impact of reducing visits for 10 different metropolitan areas and found that, for instance, a reduction to 20% of maximum visits in Chicago, Illinois, could reduce new infections by more than 80% while cutting total visits by only 42%.[6] The popular press framed this finding around 20% as a "magic number" for implementing capacity limits,[7] without articulating what 20% of maximum visits refers to, leaving room for misinterpretation.

A majority of US states have maintained capacity limits in place on various types of businesses (see section A.1 of Appendix, available as a supplement to the online version of this article at http://www.ajph.org). Substantial litigation, up to the US Supreme Court, has involved capacity limits. There is hence urgency to rigorously ground policy in science. We note that our evidence here is limited to retail locations and does not speak to the effect of capacity limits on "assemblies."[8] Such facilities, for instance, have different methods of calculating capacity limits (e.g., using fixed seating layouts or means of egress) and activities with distinct health risks. The analysis here is hence inapplicable to "assembly" uses.

Assessment Using Mobility Data

Policymakers and researchers have shifted much effort to extracting insights from mobility data.[9] Indeed, we are able to detect the drastic drop in visits from the March 2020 shelter-in-place order, demonstrating the ability of such (SafeGraph) data to pick up on mobility shifts. Figure 1 shows the year-over-year weekly average visits trends for restaurants in Santa Clara County, including both limited- and full-service restaurants.

In December 2020, restaurants had been closed by the County, and we focused our assessment of capacity limits on the primary affected sectors when the county implemented a 20% capacity limit on grocery stores, pharmacies, and general merchandise stores. Figure 2a shows visits for one of these sectors (general merchandise stores) before and after the limit was implemented in December. We defined our sector groups by excluding locations that were not consistently open throughout the entire 2019 and 2020 time period (Appendix, section A.2.1). Figure 2b compares Santa Clara County (magenta) against San Mateo County (green), which did not implement capacity limits until mandated by the state 2 weeks later. We focused on San Mateo County because it lies just north of Santa Clara County, exhibits similar economic activity, and had comparable pretreatment visit time series, yet adopted a starkly different approach to capacity limits. San Mateo's health

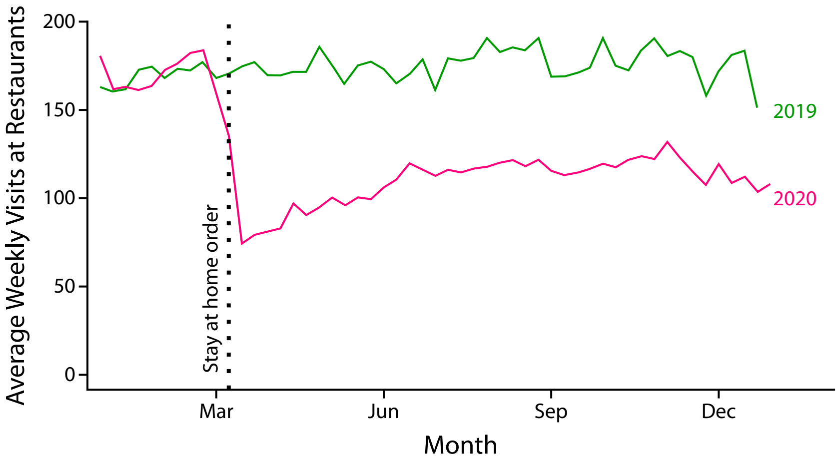

FIGURE 1— **The Weekly Average Visits for Restaurants: Santa Clara County, CA, 2019–2020**

Note. The green line shows the 2019 weekly average visit trend, and the magenta line shows the 2020 weekly average trend.

officer, for instance, expressed "grave concerns about the unintended consequences of reducing [the county's] grocery store capacity to 20%."[10]

To formally evaluate the impact, we created 2 comparisons. First, we compared the change in visits before and after the December 2020 order[11] to the same period 1 year earlier in 2019 for a difference-in-differences analysis. We used October 26 to December 6 as the preperiod when the capacity threshold was at 50%[12] and established a postperiod of December 7 to January 17. The same group of stores in 2019 formed the comparison group. (We note that the period between November 29 and December 6 was subject to an interim announcement of different capacity limits, which was quickly revised in favor of the 20% order, and our results are substantively identical when omitting this period.) Second, we compared the change in visits before and after the December 2020 order with the contemporaneous period in neighboring San Mateo County. Here, we used the same preperiod and an adjusted postperiod of December 7 to December 17, the day

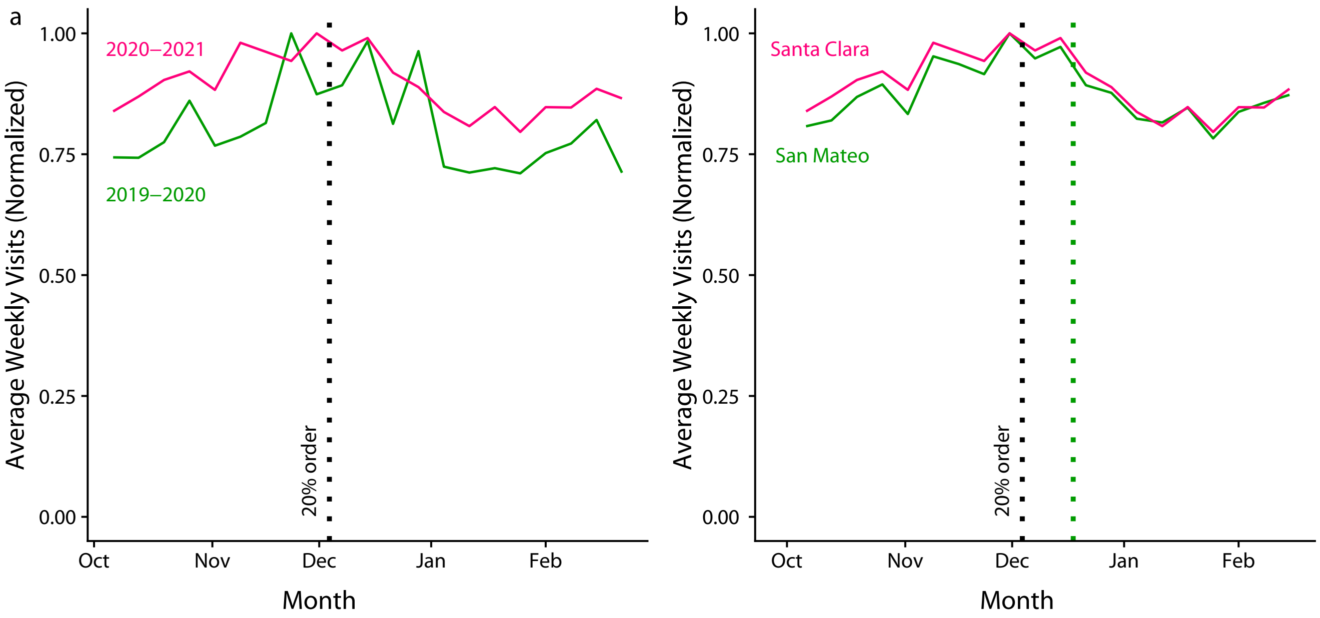

FIGURE 2— **Normalized Weekly Average Visits for General Merchandise Stores for (a) Santa Clara County Locations in 2019–2020 vs 2020–2021, and (b) San Mateo County vs Santa Clara County Locations: California**

Note. Panel a shows the normalized weekly average visits by sector for Santa Clara County locations for general merchandise stores affected by the December 20% order. The green line shows the 2019–2020 weekly average visit trend, and the magenta line shows the 2020–2021 weekly average trend. The black dotted vertical line shows the implementation of the 20% capacity order on December 6. Panel b shows the normalized weekly average visits for general merchandise stores for San Mateo County (green line) and Santa Clara County (magenta line). The black dotted vertical line shows the implementation of the 20% capacity order on December 6 in Santa Clara, and the green dotted line shows when San Mateo County adopted the same order.

when all Bay Area counties became subject to the 20% capacity limit for these sectors (Appendix, section A.4). We note that the intent of the capacity limits was to have immediate effect, given the surge in cases.

If capacity limits curbed behavior, we would expect to see a drop in daily visits or daily peak hour visits following the implementation of the limit: the 20% capacity limit was originally supported by scientific literature utilizing the same SafeGraph mobility data set.[6] However, we found no clear reduction in overall daily visits, the daily peak hourly visits, or the median number of minutes spent in store per visit, in either the 2020 versus 2019 comparison or the Santa Clara and San Mateo County comparison (Appendix, section A.4).

When comparing Santa Clara County visits in 2020 with the comparable time period in 2019, we did not see a significant decrease in daily visits, peak hour visits, or median visit time for pharmacies or groceries after the 20% capacity was implemented relative to the control group. We observed a slight decrease in daily visits and peak hour visits to general merchandise stores, but when we conducted a series of lead tests to test the parallel trends assumption, we saw that this effect was detected ahead of the December 6 order (Appendix, section A.6 for full analysis), suggesting that this comparative drop in visits between the 2 years predated the order.

When comparing neighboring Santa Clara County with San Mateo County under differing policies, we did not observe statistically significant decreases (at $\alpha = .05$) in daily visits, peak hour visits, or visit times. We observed 1 decrease in daily visits to groceries ($P = .06$). This effect was not corroborated by the first difference-in-differences design and may be an artifact from 9 tests conducted across 3 outcomes and 3 types of facilities. We also showed that there was no evidence of spillover effects (i.e., individuals visiting San Mateo because of the Santa Clara capacity limit; Appendix, section A.8). Comparing early versus late adopting counties across the Bay Area, we also observed no substantial decrease in visits upon the enactment of capacity limits (Appendix, section A.11).

Explanation of Effects

Why were the effects so negligible? We showed that the lack of effectiveness stemmed from differences in the definitions of occupancy and capacity between academic research and government. Government implementation focuses on the enforceable measures, such as 20% of the posted maximum occupancy by the fire code. The presence of the posted sign enabled inspectors to quickly check whether a facility violated the capacity limit (Appendix, section A.12). By contrast, academia may use convenience measures of maximum occupancy. One study, for instance, used the highest single number of hourly visits for each location.[6,7] This definition is convenient for measuring in historical mobility data, but would be difficult to enforce. Store managers and inspectors would need to know the maximum number of visits to each location over specific periods of time.

To illustrate the significance of this deviation, Figure 3 compares the academic capacity limit on the x-axis against California's enacted capacity limit on the y-axis for all stores (see Appendix, section A.2.4 for details). If definitions were comparable, the limits should line up on the dashed 45-degree line, but 77% of stores had a higher enacted capacity limit compared with the academic notion. The policy limit was, on average, at least 203% greater than the academic limit (see Appendix, section A.12 for additional comparisons). Put another way, although this was dependent on the baseline, a 5% capacity limit based on building square footage would have capped maximum occupancy at 20% of maximum mobility during the baseline time period used to compute the academic limit (Appendix, section A.2.4).

We then compared the enacted limit against baseline visits and showed that the vast majority of retail activity already complied with the 20% limit prior to the December restriction (both before and during the pandemic). We used estimated hourly occupancy from SafeGraph's visits, dwell time, and square footage data for each location (Appendix, section A.2.5). We then compared the distribution of the average hourly occupancy of 744 grocery stores, pharmacies, and general merchandise stores before and after the Santa Clara County 20% capacity order went into effect with the same time periods during the prior year (Appendix, section A.14). When we compared the 6 weeks before and after December 6, 2020 (when the 20% capacity limit was in effect) to the same weeks in the previous year, locations were rarely above the capacity limits set by the Santa Clara County order, with or without the 20% order in place. There was also no notable decrease in occupancy when the capacity limit was in place. Even for locations that had experienced occupancy greater than 20% before the Santa Clara County order, there were only a few "peak hours" when occupancy was above 20% (Appendix, section A.15).

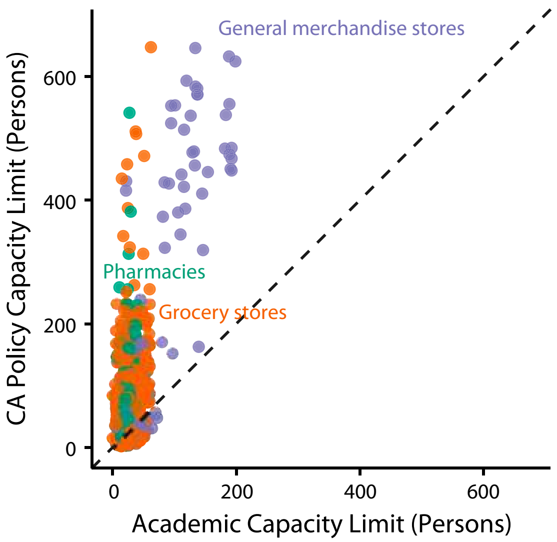

FIGURE 3— Academic Capacity Limit Relative to Baseline Peak Visits and the California Policy Capacity Limit Relative to Building Code Requirements Plotted for Grocery Stores, Pharmacies, and General Merchandise Stores: Santa Clara County, CA, 2020

Note. The black line marks equal capacity limits. Color corresponds to store sector. Three outliers were clipped by the y-axis limit. We excluded 33 locations that did not have square footage data available from SafeGraph.

Across all 4 time periods, each sector displayed similar distributions of average hourly occupancy. Notably, the gap in number of nonzero occupancy hours across sectors was larger between 2019 and 2020 compared with the gap before and after the December 6 order in 2020. This finding suggests that there were already significant behavior changes before the December capacity limit, lessening its impact.

The analysis presented in this section illustrates the potential for mistranslating scientific findings into policy based on metric definitions and static models that fail to capture evolving human behavior. California's implementation of the 20% capacity limit fell seriously short of what was warranted by the underlying science. The peak hour finding, however, does suggest an alternative rationale—distinct from prior accounts—for the capacity limits: reducing spread during the few (peak) hours of high risk, while minimizing disruption to business.

This case study also illustrates both challenges and opportunities to improving the science–policy nexus.

A MORE MEANINGFUL PARTNERSHIP BETWEEN SCIENCE AND POLICY

We identified 3 practical strategies for creating a partnership between science and policy that enhances science, policy, and public health: ensuring that models used to inform policy are dynamic rather than static, improving collaboration between scientists and policymakers through a model of coproduction, and shifting to the use of scientific metrics that are implementable as a policy matter.

Living Rather Than Static Models

The COVID-19 pandemic can be considered a classic "wicked problem" in that it is novel, unique, complex, and evolving, with incomplete, contradictory, and changing requirements.[13,14] Early public health orders were based on general scientific findings about communicable disease,[15–17] with less tailoring to COVID-19 circumstances.

There is great need for dynamic models to ensure that predictive models are continually updated using the latest monitoring data.[18] Recommendations from static models quickly become stale as current conditions diverge from modeling assumptions, as shown here for the specific case of capacity limits. Static models are hence in clear contrast with the dynamics of human behavior and risk perceptions, which changed rapidly and significantly, even over the first week of the pandemic.[19] Given how rapidly human behavior evolves, dynamic models are particularly important in light of evidence that health-risk messaging is most effective when it includes information about the effectiveness of the adopted measures.[20,21]

Figure 4 shows how the correlation between human mobility and COVID-19 case growth aggregated across the 9 Bay Area counties changed over the course of the pandemic (see Appendix, section A.16 for details). Notably, mobility was highly correlated with case growth at the beginning of the pandemic across counties, before the correlation coefficient fluctuated around zero over the summer months. This coincides with the observation for early peer-reviewed work (outlined in the gray rectangle). But the predictive power of mobility for case growth rapidly dwindled as the pandemic moved on. Such changes may be attributable to public health orders and related behavior changes such as mask wearing, time spent outdoors, and increased ventilation in indoor spaces. Without such a

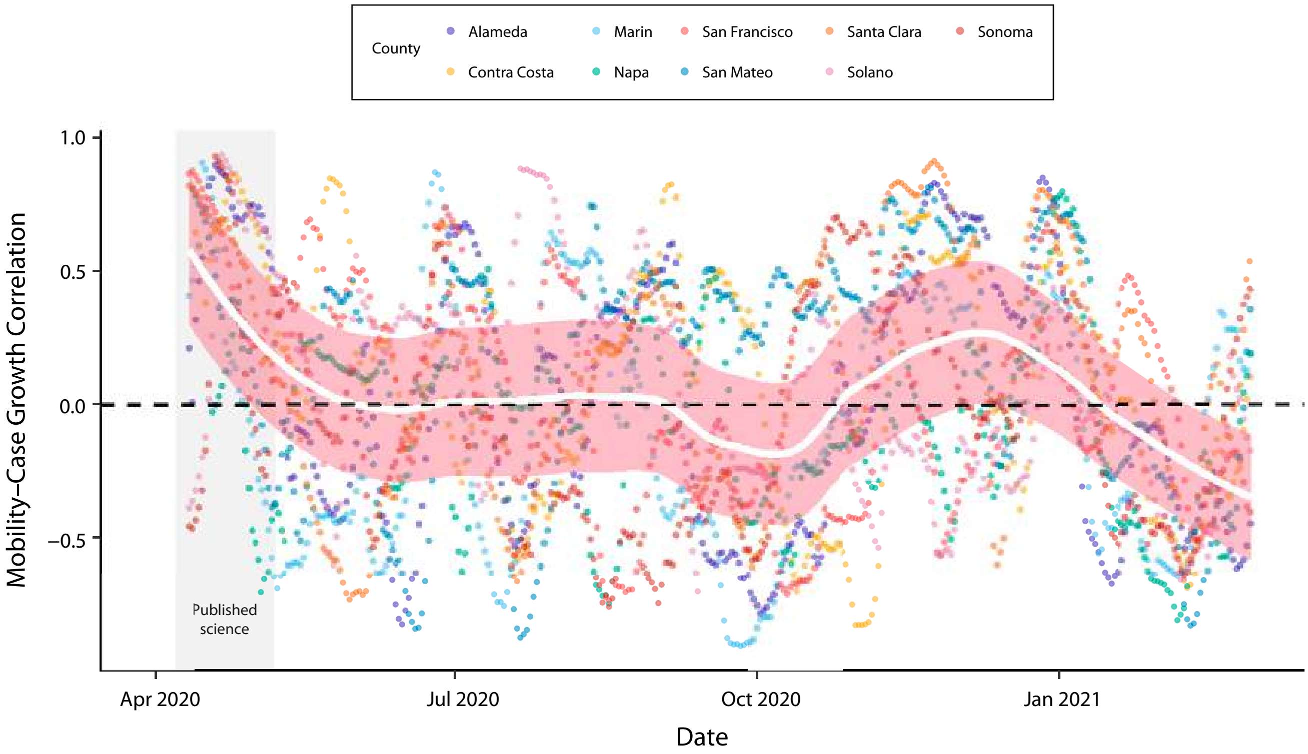

FIGURE 4— **Correlation Between COVID-19 Case Growth and 11-Day Lagged Mobility Over 1 Year During the Pandemic Aggregated Across Bay Area Counties: CA, 2020–2021**

Note. Each point represents the mean correlation between the case growth rate and 11-day lagged 7-day rolling average of mobility over the previous 28 days for a particular county (for more details on derivation, see Appendix, section A.16, available as a supplement to the online version of this article at http://www.ajph.org). The solid curve presents the LOESS curve aggregated across all counties, with a smoothing parameter of 0.4 and 50% prediction interval within the red ribbon. The rectangle spanning April 7, 2020, through May 7, 2020, highlights the consistent positive correlation between mobility and case growth at the beginning of the pandemic.

relationship, policy measures based on mobility patterns may impose hardship without affecting case growth.

The 2 largest deviations occurred in the fall and winter of 2020, when mobility–case growth correlation became positive and negative, respectively (Appendix, section A.16.3–4). These dynamics illustrate that mobility is not created equally: notwithstanding county nonpharmaceutical interventions, holiday travel, for instance, may be associated with greater risk of exposure than ordinary commuting, hence generating the positive association between mobility and case growth in winter 2020.

The pattern of strong-then-weakening correlation is significant because it suggests that mobility-based models developed at the beginning of the pandemic lose the ability to predict after the first few months. Because scientific findings around mobility and case growth were disproportionately based n the early months of the pandemic, they are less applicable for policy in later months, when the mobility–case growth relationship is weaker. Continuous (living) models that capture behavioral changes are critical for strengthening the evidence base in a rapidly evolving crisis.

Living models are also important when those performing data analysis are separate from data producers. During the research process, for instance, we identified real-time changes in SafeGraph's data schema that, left unaddressed, could potentially confound intertemporal comparisons. When data are released (and modified) in real time, living models can more easily account for such changes.

Coproduction Instead of Science Translation

The traditional view of science translation is based on a linear model of knowledge production, which entails a unidirectional flow of information from researchers to policymakers.[22] However, the rapidly evolving nature of the pandemic and human behavior during this unusually disruptive time means that policy priorities shift over time. We argue that the gap between scientific research and policy can be substantially shrunk through coproduction of solutions. Coproduction acknowledges that researchers and decision-makers hold "complementary and overlapping knowledge and skills that are essential for problem-solving."[23(p722)] In particular, policymakers often have insight into novel problems and constraints not yet considered by science. Thus, these types of partnerships are not merely translational, but rather reframe and redefine the nature of the questions posed. Our assessment of the effects of the public health order in Santa Clara County was only possible because of a direct partnership on implementation details. Such partnerships can enable real-time evaluations of the impact of policy implementation[24] and can also strengthen and solidify the feedback loop, especially for health policy.[25,26] Particularly, monitoring that includes up-to-date "best guess" estimates regarding the impact of ongoing policy interventions also allows for quicker diagnoses and adaptation of policy measures. Although conventional academic incentives are not well suited for this form of coproduction (e.g., publication timelines, negotiation of data sharing agreements), the ability of scientists and policymakers to coproduce strengthens both research and policy.

Syncing Science and Policy Metrics

Although the pandemic has transformed policy, it is a growth opportunity for impact-oriented science as well. Studies using convenience measures that are infeasible to implement are not useful for crisis response. Instead, scientists should work to incorporate such policy constraints into their models. Defining a capacity limit through aggregated mobility data reveals little about the spatial density of individuals within a store and does not necessarily equate to a direct reduction in physical or social contact.[27] If we were to use hourly store visits as a proxy for social distancing, though, there are generally only a few hours of the day when managing capacity is most important (Appendix, section A.15). A more targeted approach to improving safety measures and enforcing capacity limits during these hours could be more effective than a blanket "magic number" capacity across all locations and hours. This also focuses the intervention on a more measurable and enforceable metric, namely, total number of visits during specific store hours.

During times of crisis, effective public health policy is rarely achieved by a one-size-fits-all approach, as human behavior evolves rapidly, informed by both health risk and economic hardship. Through the combination of living models, academic–public policy coproduction, and incorporation of policy constraints into science, there is a greater opportunity for policy interventions to be strengthened by research. AJPH

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P. Maldonado and A. Peng contributed equally as co-first authors. D. Ouyang, J. Suckale, and D. E. Ho conceptualized the ideas. P. Maldonado and A. Peng carried out the statistical analysis. All authors contributed to the writing of the article.

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Data availability: the replication code used for the current study is available in the GitHub repository at https://github.com/reglab/capacity-limits.

CONFLICTS OF INTEREST

The authors declare that there are no conflicts of interest.

HUMAN PARTICIPANT PROTECTION

Institutional board review was not needed as no human participants were involved.

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Respiratory Syncytial Virus Bronchiolitis Hospitalizations in Young Infants After the Introduction of Paid Family Leave in New York State, 2015–2019

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See also Goodman, p. 194.

Objectives. To determine if the introduction of New York State's 8-week paid family leave policy on January 1, 2018, reduced rates of hospitalizations with respiratory syncytial virus (RSV) bronchiolitis or any acute lower respiratory tract infection among young infants.

Methods. We conducted an interrupted time series analysis using New York State population-based, all-payer hospital discharge records, October 2015 to December 2019. We estimated the change in monthly hospitalization rates for RSV bronchiolitis and for any acute lower respiratory tract infection among infants aged 8 weeks or younger after the introduction of paid family leave while controlling for temporal trends and RSV seasonality. We modeled RSV hospitalization rates in infants aged 1 year as a control.

Results. Hospitalization rates for RSV bronchiolitis and any acute lower respiratory tract infection decreased by 30% after the introduction of paid family leave (rate ratio [RR] = 0.71; 95% confidence interval [CI] = 0.54, 0.94; and RR = 0.72; 95% CI = 0.59, 0.88, respectively). There were no such reductions in infants aged 1 year (RR = 0.98; 95% CI = 0.72, 1.33; and RR = 1.17; 95% CI = 1.03, 1.32, respectively).

Conclusions. State paid family leave was associated with fewer RSV-associated hospitalizations in young infants. (*Am J Public Health*. 2022;112(2):316–324. https://doi.org/10.2105/AJPH.2021.306559)

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Respiratory syncytial virus (RSV) infection is one of the most common reasons for hospitalization among young children in the United States.[1,2] The first 3 months after birth are the highest risk period, with a cumulative seasonal risk of hospitalization for RSV among infants aged 2 months or younger (i.e., aged 0, 1, or 2 months) twice as high as that among infants aged 3 to 5 months (17.9 vs 8.0 per 1000, respectively), and 4.5 times that among infants aged 6 to 11 months (3.9 per 1000).[3] There is no approved vaccine for RSV, and immunoprophylaxis is only recommended in high-risk infants.[4]

Attendance at an out-of-home childcare facility is a well-established risk factor for lower respiratory tract infections such as RSV.[5–9] The increased risk associated with out-of-home childcare is most pronounced in the youngest infants. In a population-based study from Denmark, infants aged younger than 6 months attending out-of-home childcare were 79% more likely (95% confidence interval [CI] = 71%, 88%) to be hospitalized with an acute respiratory infection than children receiving childcare at home, while among children starting out-of-home childcare at age 3 years or older, no excess risk was present.[8] Thus, delaying the start of out-of-home childcare could be one strategy to reduce RSV hospitalizations in very young infants.

Paid family leave enables families to care for their newborn infants at home as part of family bonding. In January 2018, New York State introduced the most comprehensive paid family leave program in the United States (at that time) in terms of duration (8 weeks of paid leave), job protection, and eligibility.[10] In its first year, there were more than 86 500 claims to care for approximately 81 000 infants, representing nearly 40% of the annual births in the state.[11] We speculated that the introduction of this program could potentially reduce RSV-associated hospitalizations in young infants by delaying the start of out-of-home childcare. Although previous literature has generally found that paid family leave is associated with improved maternal and child health (particularly maternal mental health) and health behaviors (such as breastfeeding), this evidence is largely based on observational comparisons of women who did versus did not take paid leave,[12,13] which are less useful to US policymakers because they do not estimate the impact of state paid leave policies as implemented in the real-world setting. Of the limited number of studies evaluating the impact of US state paid family leave policies on infant health,[14–17] none, to our knowledge, have examined RSV hospitalizations.

The objective of this study was to determine if the introduction of paid family leave in New York State on January 1, 2018, was associated with a decrease in hospitalizations for RSV bronchiolitis and other acute lower respiratory tract infections in infants aged 8 weeks or younger.

METHODS

We obtained records of New York state hospitalizations (including New York City) from the New York SPARCS (Statewide Planning and Research Cooperative System) data set, a comprehensive all-payer reporting system that contains hospital discharge summaries for all inpatient hospitalizations in the state, including those paid by private insurance, government insurance (e.g., Medicaid), and self-pay. These data are available through a data use agreement with NY SPARCS and contain patient-level information on patient characteristics, treatment, diagnoses, and services. Zip codes were used to link with external data on neighborhood-level characteristics. We included admissions from October 1, 2015, to December 31, 2019. Our start date was chosen to coincide with the date when *International Classification of Diseases Clinical Modification* coding switched from version 9 to version 10 in the United States, ensuring a consistent coding system throughout our study period.

Paid Parental Leave Policy

On January 1, 2018, New York State introduced a paid family leave policy providing most private and certain public employees who work in New York State with up to 8 weeks of paid leave for parents of a newborn within the first 12 months of the child's birth.[18] In its first year, family bonding leave was claimed for 81 000 babies,[12] corresponding to approximately half the women who were employed during pregnancy that year.[19] Benefits of the policy were phased in over 4 years, increasing to 12 weeks of paid leave in January 2021, but for the purpose of consistency within the study period, we restricted our focus to the first 8 weeks of paid leave.

Respiratory Syncytial Virus Hospitalizations

We identified acute lower respiratory tract hospitalizations among infants aged 56 days (8 weeks) or younger at a nondelivery hospital admission using *International Classification of Diseases, Tenth Revision, Clinical Modification* (*ICD-10-CM*; Atlanta, GA: Centers for Disease Control and Prevention, National Center for Health Statistics; 2015) diagnosis codes. We defined our outcome using both a narrow and a broader definition. Our narrow definition used the specific *ICD-10-CM* code for RSV bronchiolitis (J21.0). Our broader definition included diagnosis codes for other and unspecified acute lower respiratory tract infections (J20 [acute bronchitis], J21 [acute bronchiolitis], J12–J18 [pneumonia], and J10–J11 [influenza]). We used this latter definition because previous research has found that the virus responsible for an acute lower respiratory tract infection is often unknown or unspecified at discharge, and RSV infection can also be misattributed to a different disease agent.[20,21]

Our denominator was the number of deliveries in New York State per month, identified in SPARCS hospitalization records by using a previously published strategy modified to remove stillbirths.[22]

Statistical Analysis

We used loess smoothers (nonparametric locally weighted smoothers) to visualize temporal trends in RSV hospitalizations. We used descriptive statistics (frequencies with percentages) to examine characteristics of deliveries throughout the study period.

We used an interrupted time series design to estimate the effect of paid family leave on lower respiratory tract infections in young infants.[23] This approach helped us to isolate the program's effect from any underlying time trends. Specifically, we modelled

$$E(Y_t) = exp(b_0+b_1 * t+b_2 * post+b_3 * timepost+b_4 * Jan...+b_{14} * Dec) \quad (1)$$

where t = time in months (from 1 to 50, for each month from November 2015 to December 2019); b_1 captures any underlying longer-term temporal trends (independent of RSV seasonality); b_2 is the primary coefficient, an indicator variable estimating the difference in rates postimplementation of the policy in January 2018 versus preimplementation; b_3 is the change in the underlying postpolicy trend from the prepolicy trend, adjusting for calendar month; and b_4 to b_{14} are indicator variables for each calendar month (with July as the reference category) to account for seasonality of RSV hospitalizations. We used marginal estimates from our model to calculate absolute rate differences, for both the rate difference averaged over the calendar year and at the peak of RSV season (January). As not all eligible families opted to use the program, our study estimates are analogous to intention-to-treat effects, reflecting the overall impact of the program as implemented in practice.

We used negative binomial regression to implement the design. This approach is similar to Poisson regression, but helped to account for potential overdispersion in our count data. Our outcome was the count of RSV bronchiolitis or acute lower respiratory tract infection hospitalizations each month, offset by the estimated number of infants aged 8 weeks or younger in a given month (calculated as the sum of live deliveries in the current and previous month). We used robust standard errors to account for residual autocorrelation of error terms among consecutive observations. We accounted for the strong seasonality of lower respiratory tract infections in our models by using indicator variables for calendar month, which proved a better fit than the use of harmonic functions (sine and cosine)[24,25] prespecified in our study plan (Figure A in the Supplemental Material, available as a supplement to the online version of this article at http://www.ajph.org). We plotted changes in study population characteristics over time to ensure that there were no abrupt changes in characteristics coinciding with the introduction of the new family leave policy. Our statistical code and model output can be accessed at https://osf.io/97dfs.

Negative Control Analysis

We conducted a negative control analysis[26] to help rule out the possibility that our primary effect was caused by a factor other than the introduction of paid family leave. That is, we repeated our analyses in a population that should not have been as directly affected by paid family leave compared with newborns: infants aged 1 year. Any observed association in this population would be interpreted as evidence of residual confounding in our primary analysis. We selected infants aged 1 year (12 to $<$ 24 months) because their parents were no longer eligible to take paid parental leave for newborn bonding (which must be taken within the first 12 months after birth), and they were also less likely to be indirect beneficiaries of paid family leave through the birth of a younger sibling compared with children aged older than 24 months (as 85% of interpregnancy intervals in the United States are $>$ 12 months[27]; i.e., most siblings are more than 21 months apart in age). In posthoc analyses, we repeated this analysis in infants whose ages ranged from older than 8 weeks to 52 weeks.

Subgroup Analyses

We conducted prespecified subgroup analyses stratified by race/ethnicity (non-Hispanic White, non-Hispanic Black, Hispanic, non-Hispanic Asian, and non-Hispanic other) and quartiles of zip code poverty rates among women with a birth in the previous 12 months (percentage in zip code $<$ 100% of federal poverty level), obtained from the 2018 American Community Survey 5-year estimates[28] and posthoc subgroups of insurance status (Medicaid, private, other) and rural or urban status (based on zip code rural–urban commuting area codes, with codes 1 to 3 classified as urban, and codes 4 to 10 as rural) with the goal of exploring whether the policy had differential effects across population subgroups.

RESULTS

There were 925 956 hospital deliveries in New York State between October 1, 2015, and December 31, 2019. As shown in Table 1, non-Hispanic White women accounted for just under half the deliveries (46%), and 44% were paid for using Medicaid insurance. Approximately 34% of deliveries were Caesarean, 9% were preterm, and 51% were among women residing in New York City. Importantly, there were no clinically

TABLE 1— Maternal Characteristics of 925 956 Live Birth Delivery Hospitalizations: New York State, 2015–2019

Characteristic	Before Paid Family Leave (Oct 1, 2015, to Dec 31, 2017), No. (%) or % ±SD	After Paid Family Leave (Jan 1, 2018, to Dec 31, 2019), No. (%) or % ±SD
No.	497 058	428 898
Discharge year		
2015	55 650 (11)	. . .
2016	223 897 (45)	. . .
2017	217 511 (44)	. . .
2018	. . .	218 495 (51)
2019	. . .	210 403 (49)
Age, y		
< 20	17 277 (3)	12 903 (3)
20–24	79 712 (16)	62 705 (15)
25–29	132 595 (27)	107 410 (25)
30–34	153 195 (31)	135 004 (31)
≥ 35	114 279 (23)	110 876 (26)
Race/ethnicity		
Non-Hispanic White	227 236 (46)	201 534 (47)
Non-Hispanic Black	69 777 (14)	58 526 (14)
Non-Hispanic Asian	49 257 (10)	40 724 (9)
Non-Hispanic other	65 455 (13)	52 153 (12)
Hispanic	85 333 (17)	75 961 (18)
Insurance		
Medicaid	221 105 (44)	185 310 (43)
Other	12 396 (2)	9 009 (2)
Private	263 557 (53)	234 579 (55)
Cesarean delivery	167 064 (34)	144 209 (34)
Preterm birth < 37 wk[a]	42 268 (9)	37 007 (9)
Women in residential zip code at < 100% of federal poverty level	23.6 ±18.9	23.4 ±19.1
Residence within state[b]		
New York City	242 141 (51)	213 742 (52)
Outside New York City	236 800 (49)	199 567 (48)

Source. New York State Statewide Planning and Research Cooperative System all-payer hospital claims records.

[a] Excludes deliveries with missing gestational age information (n = 17 410).
[b] Excludes deliveries among women whose county of residence was outside New York State (n = 33 956).

meaningful differences in population characteristics before versus after the introduction of paid family leave, and no abrupt changes in population characteristics at the time of the policy change, suggesting that confounding by these characteristics was unlikely.

There were 6809 hospitalizations for acute lower respiratory tract infection among infants aged 56 days (8 weeks) or younger, of which 4733 were for RSV bronchiolitis (Table A in the Supplementary Materials). Approximately 35% of hospitalized infants were non-Hispanic White, and 57% of the hospitalizations were paid for with Medicaid insurance. The average length of stay was approximately 5 days. There was a strong seasonality of lower respiratory tract infection hospitalizations, with rates approximately 16 times higher in January as compared with July (Figure 1). The crude average monthly rates of RSV bronchiolitis and acute lower respiratory tract infection hospitalization during RSV season (November to April of each year), inclusive, were 4.9 and 6.6

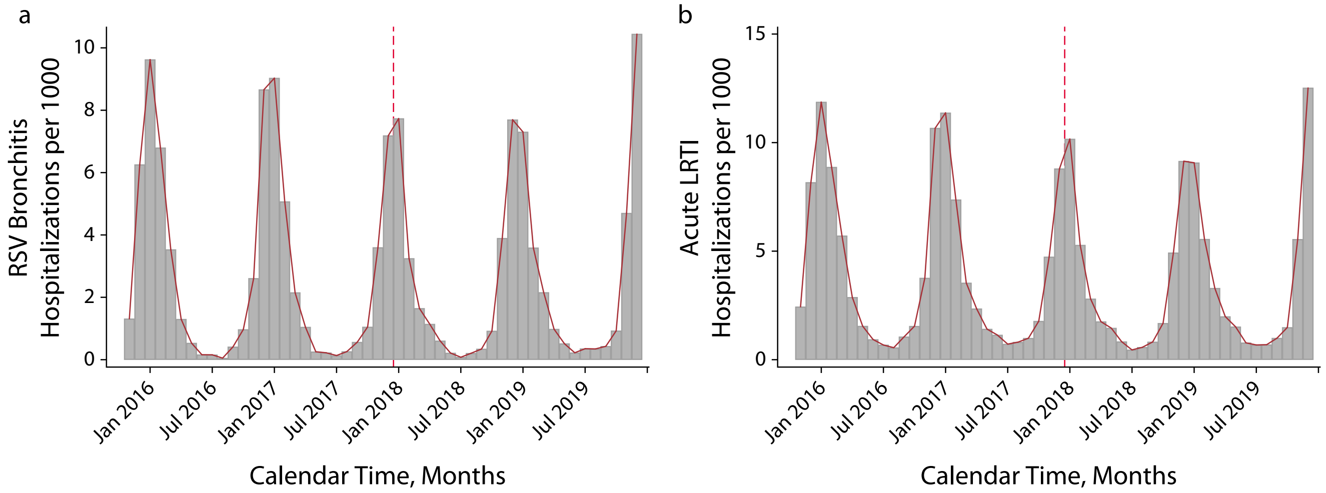

FIGURE 1— **Hospitalizations in Infants Aged 8 Weeks or Younger for (a) Respiratory Syncytial Virus (RSV) Bronchiolitis and (b) Acute Lower Respiratory Tract Infection (LRTI): New York State, 2015–2019**

Note. Bars indicate observed monthly rates; red line indicates smoothed monthly rates per 1000 infants.
Source. New York State Statewide Planning and Research Cooperative System all-payer hospital claims records.

per 1000 infants before the introduction of paid family leave, and 4.5 and 6.0 per 1000 afterward, respectively. Overall rates (i.e., including infants delivered in summer and other non-RSV season months) were 2.8 and 4.1 per 1000 infants before the introduction of paid family leave, and 2.5 and 3.5 per 1000 afterward, respectively.

Our interrupted time series model estimated that the introduction of the paid family leave program in New York State was associated with a 30% decrease in the rate of RSV bronchiolitis-associated hospitalizations (rate ratio [RR] = 0.71; 95% CI = 0.54, 0.94) and 30% decrease in the rate of acute lower respiratory tract infection hospitalizations (RR = 0.72; 95% CI = 0.59, 0.88) for infants aged 56 days (8 weeks) or younger (Table 2; Figure 2). The corresponding January rate differences per 1000 infants were −3.1 (95% CI = −6.0, −0.2) and −3.8 (95% CI = −6.2, −1.3), respectively. The introduction of paid family leave in New York State was not associated with a decrease in hospitalizations for lower respiratory tract infection among infants aged 1 year (RSV bronchiolitis: RR = 0.98 [95% CI = 0.72, 1.33]; any acute lower respiratory infection: RR = 1.17 [95% CI = 1.03, 1.32]; Table 2), nor in infants whose ages ranged from older than 8 weeks to 52 weeks (Table B in the Supplementary Materials).

In subgroup analyses, RRs were suggestive of beneficial effects of the policy in all zip code poverty quartiles (ranging from 0.58 for infants in neighborhoods with the lowest household poverty rates to 0.79 for infants in neighborhoods with highest household poverty rates for RSV bronchiolitis), but CIs overlapped for all estimates, precluding any conclusions about differential effects (Table C in the Supplemental Materials). By contrast, RRs suggested that policy benefits were greater among newborns covered by Medicaid compared with private insurance, although CIs were also overlapping. Policy effects were similar by race/ethnicity group, with the exception of a null effect estimated for non-Hispanic Asian infants, and there was a trend toward more pronounced effects in rural infants compared with urban infants.

DISCUSSION

Using an interrupted time series analysis, we estimated that RSV bronchiolitis and acute lower respiratory tract infection–associated hospitalizations among young infants in New York State decreased by nearly 30% after the introduction of the state's paid family leave program in January 2018. No such reductions were observed among infants aged 1 year, supporting the conclusion that our estimates reflected a policy effect rather than decreases attributable to other underlying factors.

Comparison With the Literature

Although several studies have examined the impact of legislated paid family leave policies in the United States on other child health outcomes (such as low birth weight,[14–16] infant mortality,[14,15] and hospitalizations for causes

TABLE 2— Hospitalization Rates in Infants Aged 8 Weeks or Younger After the Introduction of Paid Family Leave: New York State, 2015–2019

	Estimated Effect of Paid Family Leave (vs No Leave)				
Outcome	**Predicted Monthly Rate per 1000,[a] Immediately Before Policy Change**	**Predicted Monthly Rate per 1000,[a] Immediately After Policy Change**	**RR (95% CI)**	**Monthly Rate Difference per 1000[a] (95% CI)**	**Monthly Rate Difference per 1000 in January[b] (95% CI)**
Infants aged ≤ 8 wk					
RSV bronchiolitis	3.1	2.2	0.71 (0.54, 0.94)	−0.9 (−1.7, −0.1)	−3.1 (−6.0, −0.2)
Any acute lower respiratory tract infection	4.4	3.1	0.72 (0.59, 0.88)	−1.3 (−2.0, −0.5)	−3.8 (−6.2, −1.3)
Negative control group: infants aged 1 y					
RSV bronchiolitis	0.3	0.3	0.98 (0.72, 1.33)	0.0 (−0.1, 0.1)	0.0 (−0.4, 0.3)
Any acute lower respiratory tract infection	1.3	1.5	1.17 (1.03, 1.32)	0.2 (0.0, 0.4)	0.4 (0.1, 0.6)

Note. CI = confidence interval; RR = rate ratio; RSV = respiratory syncytial virus.

Source. New York State Statewide Planning and Research Cooperative System all-payer hospital claims records.

[a] Interrupted time series controlling for RSV seasonality (i.e., after including an indicator variable for calendar month) and underlying time trends, averaged across all birth months.

[b] Interrupted time series controlling for RSV seasonality (i.e., after including an indicator variable for calendar month) and underlying time trends, estimated based on January hospitalization rates.

deemed “avoidable” through better preventive care[29]), only a single study has previously examined the impact of paid family leave policy in the United States on acute lower respiratory tract infections in young infants.[29] An evaluation of California’s 2004 paid family leave found no reduction in lower respiratory tract infection hospitalizations after the introduction of the program. However, the study examined hospitalizations among all infants aged younger than 1 year, whereas a protective effect derived from less exposure to out-of-home childcare would be

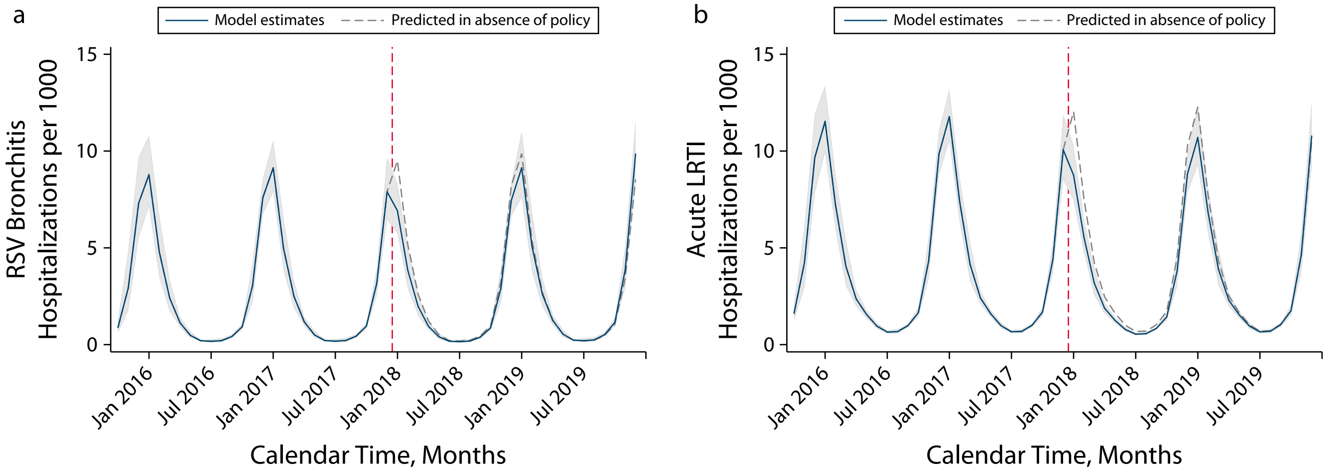

FIGURE 2— Monthly Hospitalization Rates in Infants Aged 8 Weeks or Younger Before and After the Introduction of Paid Family Leave for (a) Respiratory Syncytial Virus Bronchiolitis (RSV) and (b) Acute Lower Respiratory Tract Infections (LRTI): New York State, January 1, 2018

Note. Gray shaded area indicates 95% confidence band around interrupted time series estimates.
Source. New York State Statewide Planning and Research Cooperative System all-payer hospital claims records.

expected to be primarily experienced in the duration of the paid family leave (6 weeks in California). By contrast, our study limited its scope to acute lower respiratory tract infection hospitalizations that occurred during the time period in which infants were most likely to be experiencing the benefit of the policy under examination (8 weeks in New York State).

The magnitude of effect observed in our study is plausible given the primary mechanism through which we hypothesized that paid family leave might reduce RSV infections. Previous research has found that infants aged younger than 6 months who received childcare at home were nearly 80% less likely to be hospitalized with an acute respiratory infection than those receiving out-of-home childcare. Given that fewer than 40% of newborn parents in New York State took advantage of the paid family leave program in 2018, a population-level reduction in hospitalizations of 30% is therefore consistent with the effect size expected from only 40% of newborns potentially experiencing a benefit from at-home childcare. The magnitude of the observed decrease is notable given that a recent randomized trial found that maternal RSV vaccination reduces the risk of newborn hospitalization for RSV-associated lower respiratory tract infection by 44.4% (95% CI = 19.6, 61.5).[30] However, as uptake of maternal immunization for other diseases such as influenza is relatively low (50%–60%),[31,32] the real-world benefits achieved by paid family leave in reducing RSV-associated hospitalizations could potentially be greater than that achieved through maternal vaccination.

A second potential mechanism for the reported associations is breastfeeding. Breastfeeding has been associated with lower risks of respiratory tract infections in some,[33] but not all, studies,[34] and paid maternity leave has been linked with increases in breastfeeding rates.[35,36] However, as the largest breastfeeding promotion trial found no significant reduction in infant respiratory tract infection despite a 36.9-percentage-point increase in 3-month exclusive breastfeeding in the intervention arm,[34] and the estimated increases in breastfeeding associated with paid family leave policies in the United States are all much smaller than this,[35,36] the benefits derived through breastfeeding are likely smaller in magnitude.

Strengths and Limitations

Our use of a quasi-experimental interrupted time series design helped us to isolate policy effects from other underlying factors in a methodologically rigorous manner. We examined a child health outcome for which a strong, specific mechanism for a protective effect exists (as opposed to outcomes such as infant mortality or low birth weight, which can occur through multiple etiologies, often arising prenatally), and focused our analyses on the time period in which benefits were most likely to have been experienced.

We cannot definitively rule out that our findings are explained by factors other than the new policy. Specifically, it is possible that the RSV seasons after the introduction of paid family leave happened to be milder seasons than previous years. However, RSV surveillance data from the US Centers for Disease Control and Prevention (CDC), as well as a previously validated approach of using Internet search engine data to monitor RSV rates,[37] showed no evidence that the 2017–2018 and 2018–2019 seasons were milder than those of previous years (see Figures B and C in the Supplemental Materials). Furthermore, a report from US Department of Veterans Affairs found that, in their elderly population, RSV hospitalizations and RSV deaths were higher in both of the 2017–2018 and 2018–2019 seasons (after the policy change) than in any of the 2014–2015, 2015–2016, or 2016–2017 seasons (before the policy change).[38] We cannot explain an apparent spike in rates in December 2019 in our data, but speculate that this reflects a particularly severe RSV month, as similar spikes were observed in neighboring regions in CDC data (Figure B). Our use of a negative control, RSV hospitalizations among infants aged 1 year, further helps to rule out this potential alternative explanation. The winter during which paid family leave was introduced, the 2017–2018 season, had a higher-than-normal influenza burden.[39] This would have been expected to produce an increase in rates among young infants for our broad outcome definition (which included influenza and lower respiratory tract infections of unknown or unspecified etiology), rather than the decrease we observed, and likely explains the postpolicy increase we observed in our negative control group of infants aged 1 year.

Hospital discharge codes are imperfect measures of RSV-associated bronchiolitis hospitalizations as established by laboratory testing.[21] However, as long as the degree of measurement error in the hospital discharge codes was constant throughout our study period, this should not introduce bias to our estimates of the relative reduction in rates observed with the introduction of paid family leave. We observed a similar magnitude of decrease in our broader outcome definition of "hospitalization with any acute lower respiratory tract infection," which includes lower respiratory tract infections from unspecified and other organisms and is thus less likely to be affected by such misclassification in pathogen type. We had no data on out-of-home childcare utilization, so we were unable to test whether the decrease in RSV hospitalizations occurred through the hypothesized mechanism of reduced exposure to this setting, or the extent to which out-of-home childcare factors such as group size or number of hours influences risk.

Our study duration was limited by 2 fixed factors: the change from *ICD-9-CM* to *ICD-10-CM* coding at the beginning of the follow-up period, and the onset of the COVID-19 pandemic at the end. A longer follow-up time would have been ideal, but our study nevertheless included 50 months of observation and represents the best available evidence under the circumstances. Our findings reflect effects of paid leave above and beyond existing policies (including temporary disability and employer benefits). The effect of the policy may be greater in states where women have less access to other sources of paid leave (or lower in states where access is greater).

Finally, interrupted time series analyses can often be strengthened by the inclusion of contemporaneous data from control states. However, as eligibility for New York State's paid family leave policy is based on employment location, the parents of infants in neighboring states who would be best suited to serve as controls (e.g., New Jersey) might also be eligible for paid leave, limiting the value of these states as controls. Furthermore, 3 of the potential control states with close geographic proximity (which is important when one is examining an infectious disease outcome) either had or introduced paid family leave (Massachusetts, Rhode Island, New Jersey), making them poor indicators of the rates expected in New York State had paid family leave not been introduced. We therefore opted instead to use a within-state negative control.

Public Health Implications

Our findings suggest that paid family leave reduces hospitalizations with RSV bronchiolitis in young infants. The importance of paid family leave as a tool to promote health has previously been recognized by the US surgeon general in the context of breastfeeding support and promotion[40]; this work provides evidence of another avenue through which paid family leave may play an important role in improving child health through the prevention of respiratory infection in young infants. Our study findings can inform state policymakers in the 41 US states that currently have no paid family leave law and support the passage of currently proposed policies such as the federal government's American Families Plan. Furthermore, our findings may be useful in justifying the continuation of paid family leave in jurisdictions in which such policies are currently enacted. AJPH

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J. A. Hutcheon and K. A. Ahrens originated the study research question. All authors contributed to the design of the study and interpretation of findings. K. A. Ahrens obtained the study data and conducted statistical analyses. J. A. Hutcheon wrote the first draft of the article. K. A. Ahrens and T. Janevic provided critical review of the content of the article.

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CONFLICTS OF INTEREST

All authors report no conflicts of interest.

HUMAN PARTICIPANT PROTECTION

The study was approved by the University of Southern Maine institutional review board (protocol 20-01-1431). Our preanalysis plan is available at https://osf.io/fpvx9.

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US Food Industry Progress Toward Salt Reduction, 2009–2018

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See also Brown et al., p. 191.

Objectives. To determine the extent to which reductions in sodium during the National Salt Reduction Initiative (NSRI) target-setting period (2009–2014) continued after 2014.

Methods. We used the NSRI Packaged Food Database, which links products in the top 80% of US packaged food sales to nutrition information, to assess the proportion of products meeting the NSRI targets and the sales-weighted mean sodium density (mg/100 g) of 54 packaged food categories between 2009 and 2018.

Results. There was an 8.5% sales-weighted mean reduction in sodium between 2009 and 2018. Most change occurred between 2009 and 2012, with little change in subsequent years. The proportion of packaged foods meeting the 2012 and 2014 targets increased 48% and 45%, respectively, from 2009 to 2012, with no additional improvements through 2018.

Conclusions. Food manufacturers reduced sodium in the early years of the NSRI, but progress slowed after 2012.

Public Health Implications. The US Food and Drug Administration just released 2.5-year voluntary sodium targets for packaged and restaurant food. Continued assessment of industry progress and further target setting by the Food and Drug Administration is crucial to reducing sodium in the food supply. (*Am J Public Health*. 2022;112(2):325–333. https://doi.org/10.2105/AJPH.2021.306571)

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There is widespread agreement that the US population's sodium intake is too high. Between 1999–2000 and 2015–2016, median sodium intake among US adults increased slightly, and in 2015–2016, more than three quarters of adults exceeded the recommended daily upper limit for sodium.[1–7] High sodium intake increases the risk of hypertension, a major cause of heart disease and stroke.[5] In 2012, adults with sodium intake of more than 2 grams per day contributed to approximately 9.5% of cardiometabolic deaths and $3.8 billion in health care costs.[8,9] In 2010, it was estimated that a 40% reduction in sodium in the US population would reduce cardiovascular disease deaths by 20%, averting 1.2 million deaths from cardiovascular disease by 2020.[10]

Reducing sodium intake will require changes to the US food supply. The vast majority (71%) of sodium comes from salt added to packaged and restaurant foods rather than salt occurring naturally or added at the table.[11] Interventions targeting individual behavior change, such as dietary counseling, labeling, and educational campaigns, are more likely to reduce sodium intake when combined with structural interventions, such as concerted efforts by the food industry to reduce sodium added to their products.[12,13]

In 2005, to achieve a voluntary global target of less than 2 grams of sodium per day by 2025, the World Health Organization called on member states to engage food manufacturers in reducing sodium. To achieve that target, more than 75 countries have developed salt reduction strategies, some resulting in large reductions in population sodium intake.[13,14] For example, between 2003 and 2010, the United Kingdom reduced adult sodium intake by 15% by setting voluntary sodium reduction targets, launching a public awareness campaign, and implementing a voluntary front-of-package sodium-labeling program.[15,16] In 2021, the World Health Organization announced global sodium benchmarks for packaged food categories.[17]

Inspired by sodium reduction efforts in the United Kingdom, the US sodium reduction strategy has been led by the National Salt Reduction Initiative (NSRI), a coalition of more than 100 health organizations coordinated by the New York City Department of Health and Mental Hygiene ("Health Department"). The NSRI was launched in 2009 with the goal of achieving a 20% reduction in population sodium intake by 2014. Through analysis of national sales data, meetings with industry, and a public comment period, the Health Department set voluntary sodium reduction targets, which varied by category but amounted to an approximately 10% reduction in sodium by 2012 ("2012 targets") and 25% reduction by 2014 ("2014 targets") in 62 categories of packaged foods and 25 categories of restaurant foods.[18,19] By 2014, 26% of packaged food categories met the 2012 targets and 3% met the 2014 targets; between 2009 and 2014, a 7% decline in sales-weighted mean sodium in US packaged foods was observed.[20] Cogswell et al. estimated that if food companies had met the 2014 packaged and restaurant food targets, the usual mean daily sodium intake in the US population would have declined 20%—from 3417 milligrams to 2719 milligrams.[21]

The NSRI highlighted the opportunity for the Food and Drug Administration (FDA) to set short- and long-term targets, solicit further company commitments, and monitor sodium in the food supply through a publicly accessible database; however, the federal government was slow to act. In 2010, the Institute of Medicine urged the FDA to adopt mandatory sodium reduction targets for industry, citing the NSRI as a model framework.[18] In response, the FDA and the US Department of Agriculture (USDA) issued a request for comments on strategies to reduce sodium; approximately 1500 comments were submitted in response to this request.[22] A public meeting was held in November 2011, and in June 2016, the FDA released draft 2- and 10-year voluntary targets with opportunity for public comment.[23] In October 2021, the FDA announced voluntary 2.5-year sodium guidance (means and maxima) for packaged and restaurant food categories.[24]

Studies have evaluated the effects of government salt reduction strategies on changes to the food supply, but there are limited data on the sustainability of sodium reduction initiatives without continued industry engagement and government oversight. We used 2009 to 2018 NSRI food supply data to examine changes in sodium in US packaged foods during (2009–2012 and 2012–2014) and after the end of (2014–2018) the NSRI—when no targets for industry were set. We also examined the feasibility of continued sodium reduction through product reformulation and innovation. We provide recommendations for an effective sodium reduction strategy with strong federal government support.

METHODS

The Health Department created the NSRI Packaged Food Database ("the database") to monitor packaged food industry progress toward the 2012 and 2014 sodium reduction targets. The database linked products in the top 80% of national sales in 61 NSRI packaged food categories to nutrition information in 2009, 2012, 2014, and 2018. We acquired national sales data from Nielsen ScanTrack for the preceding 52-week period in each year and included weekly product-level sales from large grocery stores (i.e., grocery retailers with > $2 million in annual sales).

We calculated the total equivalized unit sales for each product by multiplying product size by units sold. We matched branded products in the top 80% of unit sales in each category to nutrition information by UPC (universal product code), a unique product identifier. We excluded private label products (20% of US food dollar sales in 2020).[25] Nutrition information came from Guiding Stars, a proprietary nutrition rating system that maintains a database of nutrition facts labels for more than 100 000 packaged foods, and Label Insight, an open data source of more than 400 000 products purchased in the United States. If no match was found in either database, we searched for product nutrition facts labels on manufacturer or grocery store Web sites.

Packaged Food Sample

Sodium reduction targets were set for 62 packaged food categories; 1 category lacked sales data so we did not include it in the database. We grouped the 61 remaining categories into 15 metacategories, which included all branded products in the top 80% of sales in each category with available sales, sodium, and serving size information (n = 6336 in 2009, n = 6898 in 2012, n = 7396 in 2014, n = 7381 in 2018). On average, products included in the 61 categories represented 87% of branded top-selling products (84% in 2009, 86% in 2012, 89% in 2014, and 89% in 2018; Table 1). When estimating changes in sales-weighted mean sodium density over time, we excluded 7 categories (1 metacategory) that

TABLE 1— Characteristics of US Packaged Foods in the National Salt Reduction Initiative Packaged Food Database: 2009–2018

Metacategory	2009, No. (%)[a]	2012, No. (%)[a]	2014, No. (%)[a]	2018, No. (%)[a]	Products Sold by Committed Companies in 2009, No. (%)	Market Share of Products Sold by Committed Companies in 2009, %
Overall	6336 (84)	6898 (86)	7396 (89)	7381 (89)	1568 (25)	18.0
Bakery	1333 (80)	1571 (80)	1556 (80)	1607 (81)	290 (22)	11.0
Canned fish	36 (59)	33 (97)	35 (97)	45 (100)	0 (0)	0.0
Cereal	200 (97)	230 (97)	260 (99)	269 (99)	1 (0.5)	0.2
Dairy	389 (90)	374 (89)	391 (88)	364 (90)	188 (48)	27.4
Fats and oils	326 (92)	266 (82)	298 (96)	326 (97)	197 (60)	40.6
Legumes	141 (81)	143 (87)	185 (93)	178 (95)	26 (18)	7.6
Meats	841 (75)	858 (73)	1001 (85)	924 (83)	134 (16)	15.0
Mixed dishes	1400 (88)	1571 (93)	1653 (94)	1616 (95)	238 (17)	12.0
Nut butters	32 (97)	34 (100)	55 (98)	43 (100)	11 (34)	13.6
Potatoes	108 (84)	127 (91)	143 (91)	133 (86)	51 (47)	37.1
Sauces	510 (86)	520 (84)	585 (86)	626 (90)	198 (39)	35.5
Seasoning mixes	49 (98)	34 (92)	45 (92)	44 (98)	2 (4)	6.0
Snacks	494 (91)	609 (93)	662 (93)	671 (92)	59 (12)	4.8
Soup	236 (89)	278 (99)	289 (91)	304 (98)	131 (56)	43.0
Vegetables	241 (85)	250 (99)	238 (96)	231 (95)	42 (17)	12.2

[a] Indicates no. (%) of products with sodium and serving size information available out of all branded products in the top 80% of sales.

reported serving sizes by volume or units rather than by weight and 1 category that reported sales in dollars rather than units.[20]

Measures

To assess industry progress toward the sodium reduction targets, we tabulated the number and percentage of products meeting the 2012 and 2014 targets in each year for all 61 categories and 15 metacategories. In the 54 categories with consistent unit sales by product weight, we also estimated changes in sales-weighted mean sodium density from 2009 to each subsequent year overall and by metacategory. To assess category turnover, we tracked products in the top 80% of sales in 2009 through 2018 and classified them into 4 mutually exclusive groups. Products in the top 80% of sales at all time points were "high market share" products. In high market share products, we considered items to be "reformulated" if sodium density changed from 1 time point to the next; otherwise, we labeled products "same." We labeled products "discontinued" if they no longer appeared in the sales data in 2018 and "low market share" if they fell out of the top 80% of sales at any time point after 2009 but were not discontinued. "New" products were those that were not in the sales data in 2009 but were in the top 80% of sales in any subsequent year.

Statistical Analysis

We ran generalized linear regressions with binomial family and identity link to estimate the percentage of products meeting the 2012 and 2014 NSRI targets in 2009, 2012, 2014, and 2018. The independent variable was an indicator for year, and the dependent variable was an indicator for whether the product met the target. We used postregression estimation to compare means in each year to those in the previous year. Next, we used generalized linear regressions with a normal distribution and identity link to assess whether sales-weighted mean sodium density changed significantly over time. The 3 indicator variables for years 2012, 2014, and 2018 were the independent variables (with 2009 as the reference year), and product sodium density (mg/100 g) was the dependent variable. We weighted regressions by each product's percentage unit sales in the sales category, and we used postregression estimation to compare means in each year to those in the previous year. We used a similar statistical analysis to assess product reformulation and innovation. To assess reformulation, we limited the analytic sample to high market share products (products in the top 80% of sales at each time point). To assess innovation, the analytic sample included all products in the top 80% of sales in 2009 (the reference group) and products newly introduced to the market and in the top 80% of sales in 2012, 2014, and 2018. For all analyses in which some products existed in multiple years, we applied generalized estimating equations to account for correlation among products in the database. We conducted all statistical analyses in SAS version 9.4 (SAS Institute, Cary, NC).

RESULTS

The number of branded products with sodium and serving size information in the top 80% of sales increased from 6336 in 2009 to 7381 in 2018 (Table 1). The proportion of products with complete sodium and serving size information was similar at each time point, ranging from 84% in 2009 to 89% in 2018.

By 2014, 23 companies had publicly committed to targets in at least 1 NSRI packaged food category. In 2009, products sold by committed companies accounted for 25% of products in the database and 18% of market share. Market share of products sold by committed companies at baseline ranged from 0.0% (canned fish) to 43.0% (soup). Products sold by committed companies accounted for more than one quarter of market share in the dairy (27.4%), potatoes (37.1%), sauces (35.5%), and fats and oils (40.6%) metacategories.

Changes in Sodium

Between 2009 and 2018, the sales-weighted mean sodium density of US packaged foods decreased 8.5%, from 591 milligrams per 100 grams in 2009 to 541 milligrams per 100 grams in 2018 (Figure 1). Most changes occurred between 2009 and 2012, during which time there was a 5.1% decrease in sodium (mean difference = −30 mg/100 g; 95% confidence interval [CI] = −20, −40; $P < .001$). There was less change between 2012 and 2014 (mean difference = −10 mg/100 g; 95% CI = −20, −1; $P = .037$) and between 2014 and 2018 (mean difference = −10 mg/100 g; 95% CI = −16, −4; $P = .002$).

Between 2009 and 2018, the proportion of US packaged foods meeting the 2012 NSRI targets increased 47.7%, from 27.7% in 2009 to 40.9% in 2018, and the proportion of US packaged foods meeting the 2014 targets increased 44.9%, from 13.6% in 2009 to 19.7% in 2018. All improvements took place between 2009 and 2012, during which time the proportion of US packaged foods meeting the 2012 targets increased 44.8% (mean difference = 12.4%; 95% CI = 10.2, 14.6; $P < .001$), and the proportion of US packaged foods meeting the 2014 targets increased 46.3% (mean difference = 6.3%; 95% CI = 4.7, 8.0; $P < .001$). There were no further changes between 2012 and 2014 or between 2014 and 2018 overall, although there was some variation by metacategory (Tables A and B [available as a supplement to the online version of this article at http://www.ajph.org]).

Product Reformulation and Innovation

Of the 6336 foods that were in the top 80% of sales in the NSRI database in 2009, 2407 (38%) were high market share products, meaning they were in the top 80% of sales in their category in 2009, 2012, 2014, and 2018 (Figure 2). Of these foods, 2013 (84%) were reformulated between 2009 and 2018, and 394 (16%) did not change. Discontinued products accounted for less than 1% (n = 29) of products, and 3900 (62%) products were low market share, meaning they were sold at all time points but not consistently in the top 80% of category sales. After 2009, 4921 new products were introduced and in the top 80% of category sales.

Among high market share products, sales-weighted mean sodium density declined 5.5% from 2009 to 2012 because of product reformulation (mean difference = −32 mg/100 g; 95% CI = −40, −23; $P < .001$; Table 2). There was a less than 1.5% decline in sodium from 2012 to 2014 (mean difference = −8 mg/100 g; 95% CI = −15, −1; $P = .029$) and no further reduction between 2014 and 2018 (mean difference = −4 mg/100 g; 95% CI = −9, 1; $P = .1$). Although this pattern was consistent across the majority of metacategories, there were some outliers. For example, sodium in nut butters decreased substantially between 2014 and 2018 (mean difference = −36 mg/100 g; 95% CI = −52, −21; $P < .001$), with no significant changes in previous years (Table D [available as a supplement to the online version of this article at http://www.ajph.org]).

Products new to the market in 2012 in the top 80% of sales were 4.1% lower in sodium than were products in the top 80% of sales in 2009 (mean difference = −24 mg/100 g; 95% CI = −46, −2; $P = .036$). There were no further reductions in sodium in newly introduced products in subsequent years overall, but again, there was some variation by metacategory. For example, mixed dishes (e.g., frozen, refrigerated, or canned entrées and side dishes)

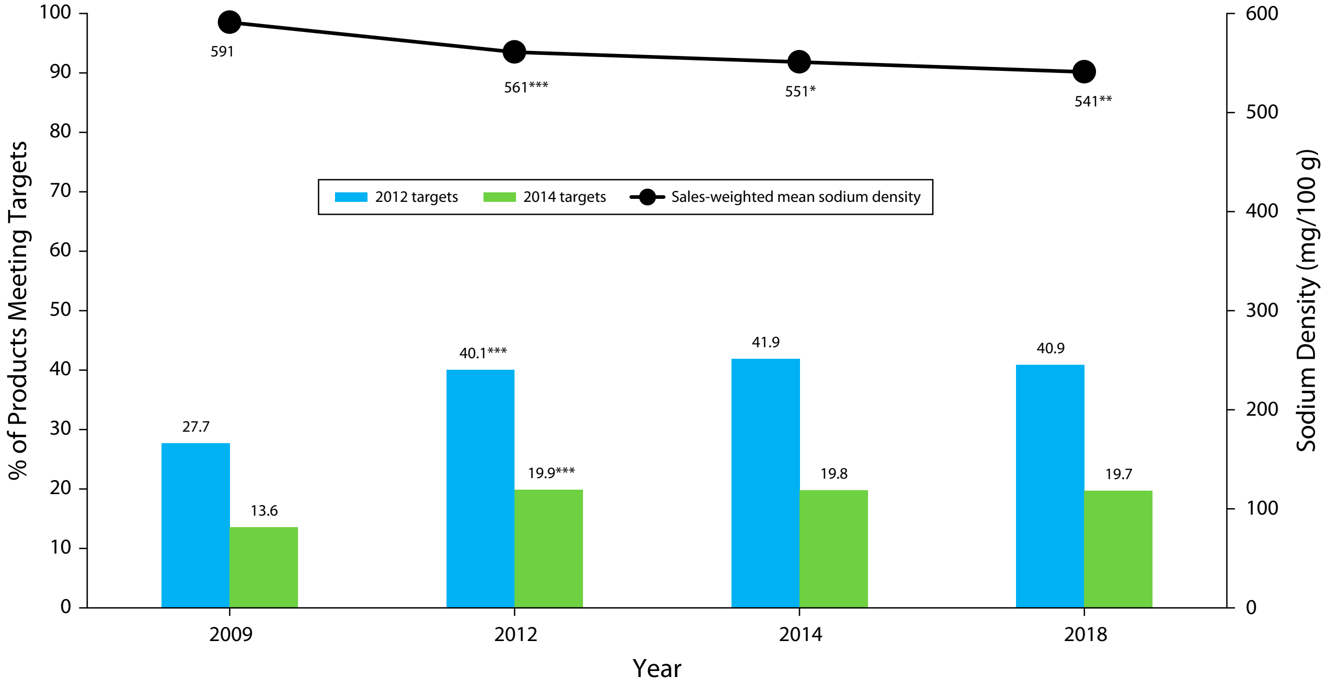

FIGURE 1— **Change in the Percentage of US Packaged Foods Meeting the National Salt Reduction Initiative (NSRI) 2012 and 2014 Targets, and Sales-Weighted Mean Sodium Density: 2009–2018**

Note. Results are from the authors' analysis of packaged foods in the NSRI Packaged Food Database, 2009–2018. Sales-weighted means were estimated in each year by regressing sodium density on year and weighting by market share. The percentage of products meeting targets in each year were estimated by regressing an indicator for whether the product met the target on year. Generalized estimating equations accounted for products appearing in multiple years.
$^{*}P<.05$; $^{**}P<.01$; $^{***}P<.001$.

introduced to the market between 2014 and 2018 were 14.5% lower in sodium than were new products in 2012 to 2014 (mean difference = −67 mg/100 g; 95% CI = −100, −34; $P<.001$; Table E [available as a supplement to the online version of this article at http://www.ajph.org]).

DISCUSSION

We found an 8.5% sales-weighted mean reduction in sodium in 54 packaged food categories sold at large grocers between 2009 and 2018, which manifested as a modest reduction in sodium between 2009 and 2012 (5.1%), and less change between 2012 and 2014 (1.8%) and 2014 and 2018 (1.8%). The proportion of packaged foods meeting the 2012 and 2014 targets increased by nearly 50% from 2009 to 2012, but there were no additional improvements through 2018. Among top-selling products, sales-weighted mean sodium density declined by 5.5% from 2009 to 2012, declined by 1.5% from 2012 to 2014, and plateaued in subsequent years. Products new to the marketplace in 2012 were 4.1% lower in sodium than were products in 2009, but we observed no further reductions in sodium among new products introduced in 2014 or 2018. These results suggest that food manufacturers reduced sodium in the early years of the NSRI, but progress slowed over time. On average, there was little progress toward sodium reduction after 2014, a time during which no formal targets were in place. Although there was some variation in the timing and magnitude of sodium reduction across food categories, few categories had a significant change in mean sodium content between 2014 and 2018 and no categories saw their largest reductions in sodium during this period.

Early industry changes in sodium from 2009 to 2012 may be explained by the launch of the NSRI, which received widespread media attention, and the broader political context in which the NSRI was initiated. This was a pivotal time in US sodium policy, marked by the Institute of Medicine's 2010 report recommending mandatory federal targets,[18] the FDA–USDA 2011 docket and public meeting, striving

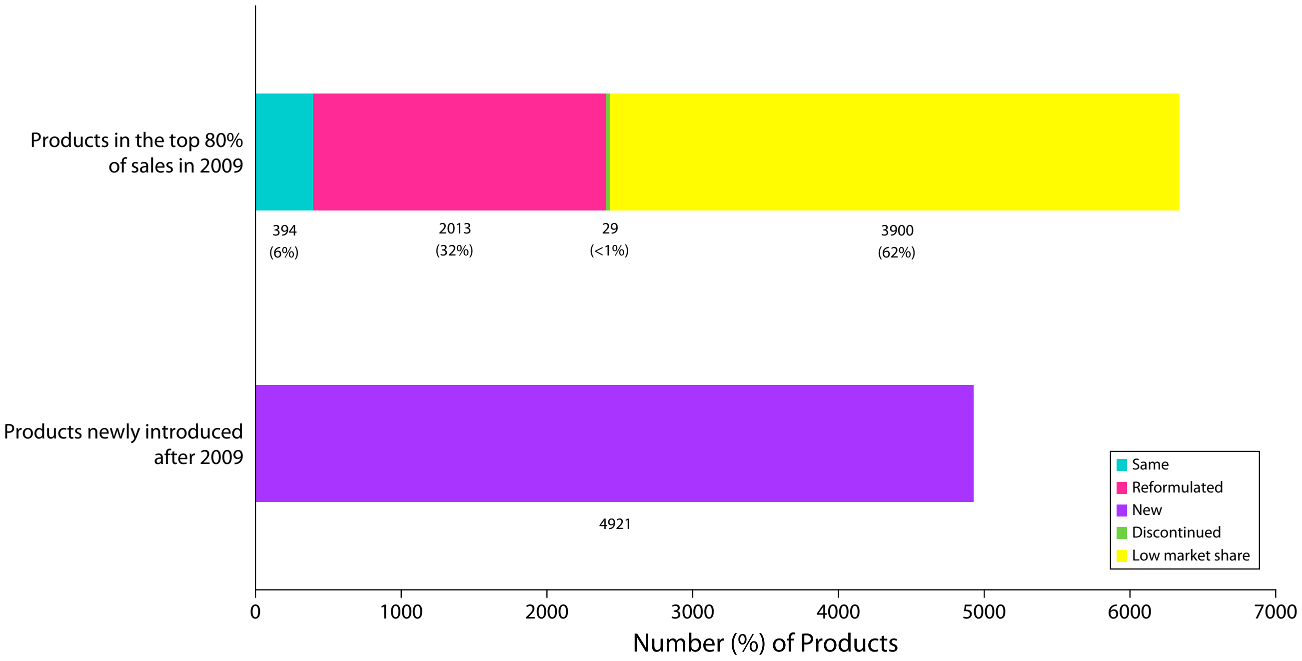

FIGURE 2— Reformulation, Innovation, and Discontinuation of US Packaged Foods in the National Salt Reduction Initiative (NSRI) Packaged Food Database: 2009–2018

Note. Results are from the authors' analysis of products in the NSRI Packaged Food Database, 2009–2018. The top bar represents all products in the database in 2009. Products in the top 80% of sales at all time points with 0%–1% change in sodium density are labeled "same." Products in the top 80% of sales at all time points with > 1% change in sodium density were labeled "reformulated." Products were labeled "discontinued" if they no longer appeared in the sales data in 2018. Products were labeled "low market share" if they fell out of the top 80% of sales at any time point after 2009 but were not discontinued. "New" products were not in the sales data in 2009 but in the top 80% of sales in any subsequent year.

toward a nationwide sodium reduction strategy,[22] and stricter sodium limits for the USDA National School Lunch Program.[26] The anticipation of regulatory oversight is a common cause of industry self-regulation. The attention from the FDA and the USDA leading up to 2012, in combination with voluntary commitments sought by the NSRI, may have motivated early industry efforts. In 2016, the FDA released draft sodium targets for industry with a

TABLE 2— Sales-Weighted Mean Sodium Density of US Packaged Foods in Top 80% of Sales (High Market Share Products) in 2009, 2012, 2014, and 2018 and Foods New to the Market (New Products): 2012, 2014, and 2018

	Sales-Weighted Mean (SE) Sodium Density (mg/100 g)			
	2009	2012	2014	2018
High market share products	580 (13.1)	548 (12.4)***	540 (11.8)*	536 (11.7)
New products	591 (3.9)	567 (10.6)*	566 (9.5)	571 (12.4)

Note. Results from authors' analysis of products in the National Salt Reduction Initiative (NSRI) Packaged Food Database, 2009–2018. For "high market share products," means were estimated from regressions of sodium density on an indicator for year, weighted by market share. The sample is all products in the top 80% of sales in 2009, 2012, 2014, and 2018 (n = 2214). For "new products," means were estimated from regressions of sodium density on an indicator for whether the product was in the top 80% of sales in 2009 (n = 5938), newly introduced in 2012 (n = 1166), newly introduced in 2014 (n = 1429), or newly introduced in 2018 (n = 1098), weighted by market share.

*$P < .05$; **$P < .01$; ***$P < .001$.

public comment period and some discussion on the release of final targets[23]; however, federal momentum toward sodium reduction targets slowed until the release of final targets in 2021. During the period before the 2021 release, the FDA broadened its focus to include added sugars,[27] and the USDA rolled back sodium standards for school meals.[28]

The NSRI was designed as a framework on which federal targets could be modeled, and our findings add to previous research showing that the initiative is a feasible approach to reducing sodium in the US food supply.[20] A wide and diverse group of companies publicly joined the initiative, ranging from large multinational food companies to small businesses, which included manufacturers, distributors, retailers, and foodservice providers. Most companies that joined the initiative met the targets in the categories to which they committed, using a range of strategies, including reformulation of popular foods and innovation of new, lower sodium products. Reductions in sodium occurred in categories with and without public commitments, suggesting that these benchmarks carried weight for the industry overall, not only for companies that were formally engaged. The NSRI approach relied on (1) providing feasible benchmarks that industry could use widely for reformulation and new product development, (2) monitoring progress toward the targets over time, and (3) seeking voluntary adoption of those targets. Although there were modest reductions in sodium during the NSRI period, there was virtually no change following 2014. National targets—if they are closely monitored and iteratively reduced—will encourage more sustained and larger scale shifts that will improve the public's health.

Limitations

Our study had a few limitations. First, this was an observational study, and we could not definitively attribute changes in sodium to the NSRI. Rather, as previously discussed, it is likely that progress during the initiative also resulted from the anticipation of federal action. Changes in sales-weighted mean sodium density may also be attributable to consumers selecting lower sodium products, a behavior change that may have resulted from labeling initiatives and mass media campaigns that ran concurrent with the NSRI.

Second, national sales data from mass merchandisers (e.g., Walmart), club stores (e.g., BJs), and small stores were not available, so we did not include them in the NSRI database. This may have led to the exclusion of products sold only in small grocers or mass merchandisers and may have led to overestimating the number of products defined as new if these products were previously sold in other store types and later expanded to large grocery stores. We do not, however, have reason to believe that the lack of mass merchandiser data would have a large impact on changes in sodium over time; in a sensitivity analysis, we purchased data from mass merchandisers for 3 categories of foods in 2018 and found no meaningful differences in sales-weighted mean nutrient values, top manufacturers in each category, or top products in each category by market share. In 2013, the mean sodium density of packaged food purchases from Walmart was very similar to that of food purchases from other retailers, although there was a slightly larger decline in the sodium density of Walmart purchases compared with other food retail purchases from 2009 to 2013, which may have biased our results toward the null, at least in the early years of the NSRI.[29]

Third, results could be affected by products missing sodium density information. Based on our analysis of missing data, products without sodium or serving size information tend to have less market share and potentially higher sodium density than do products with complete data. Fourth, the database excludes private label products, products in the bottom 20% of sales in each category, and products in non-NSRI categories. Lastly, we did not examine changes in sodium in restaurant foods, which made up an increasing share of food expenditures until 2020.[30] Other research has shown that, after 2012, there was a reduction in sodium in newly introduced menu items but no change in sodium in common or "core" menu items in the top US chain restaurants.[31]

Public Health Implications

Evidence from global initiatives shows that industry engagement in sodium reduction can improve public health, particularly when targets are mandated and efforts are multipronged.[13] At least 11 countries have implemented mandatory maximum levels of sodium in 1 or more food categories (mostly breads), and 2 countries—Argentina and South Africa—have implemented mandatory targets across a range of food categories.[32] In 2013, following a 2-year voluntary salt reduction program, the Argentinian government set maximum sodium levels in meats, farinaceous foods (cereals, cookies, pizza, pasta), and soups and dressings, with new regulations further lowering the targets in 2018 and 2019.[33,34] There are many benefits of a regulatory or legislative approach to sodium reduction; modeling studies show that sodium mandates with defined sodium maxima lead to better industry compliance, are more cost effective, and result in larger reductions in sodium intake than do voluntary targets.[13] However, if legislation or regulation takes considerable time to enact or is difficult to change once established,[35] voluntary targets may be appropriate. A voluntary approach may have a meaningful impact if there is strong and sustained central government leadership and pressure, public sector commitment to monitoring and surveillance, and a robust and active network of health organizations to hold industry accountable.

Next Steps

The FDA's recently announced 2.5-year targets and maxima are an important step forward, but alone they will not be enough. We urge the FDA to build on the release of these targets and develop a robust system to monitor industry progress and changes in population sodium intake over time as part of a broader federal strategy on sodium reduction. The creation of a branded, up-to-date, publicly accessible nutrition database that enables the monitoring of packaged and restaurant foods will be key to ensuring industry participation and to setting future targets. To this end, our findings suggest the need for both monitoring and continued government action to ensure ongoing progress in sodium reduction in the food supply. AJPH

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A. J. Moran drafted the article. J. Wang analyzed the data. A. L. Sharkey and E. A. Dowling assisted with data management and analysis. All authors conceptualized the research, contributed to data interpretation, critically revised the article, and approved the final version of the article.

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Note. The findings and conclusions in this article are those of the authors and do not necessarily represent the views of the CDC.

CONFLICTS OF INTEREST

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HUMAN PARTICIPANT PROTECTION

No protocol approval was necessary because this research did not involve human participants.

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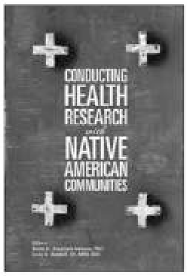

Balancing Risks and Benefits of E-Cigarettes in the Real World

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We appreciate the assessment by Balfour et al. of the use, risks, and potential of e-cigarettes.[1] Although in our view they downplayed the literature on use among youths and what is known about the risks of these products, they correctly qualified what can be concluded from the current science on the benefits of e-cigarettes with words such as "may" and "potential." Various scientists will prioritize different aspects of the body of literature, including what they see as notable strengths and weaknesses of specific studies as well as the totality of the evidence, particularly when a systematic review approach is not employed. Here we raise a few additional key points.

We challenge the public health and scientific community to move away from characterizing scientists as "opponents" or "supporters" of e-cigarettes for three primary reasons.

First, many investigators believe that e-cigarettes have potential benefits for smokers in theory; what matters is how these products perform at the individual and population levels in practice and their effects on reducing tobacco-related disparities. These effects depend in large part on how the products are regulated and marketed.

Second, e-cigarettes comprise a heterogeneous class of products, and thus their short- and long-term harms and benefits are likely to vary according to device characteristics (e.g., power, modifiability, manufacturing quality), composition of the liquid (e.g., nicotine concentration, nicotine salt or base, flavor chemicals), how people actually use them, and how individual companies advertise and promote them.

Third, the "opponents/supporters" terminology highlights division rather than the many areas in which there is agreement. Most scientists would agree that balancing the risks and benefits of e-cigarettes for the individual cigarette smoker is critically important. Most would also agree that tobacco-naive youths should not start using e-cigarettes, not only because of concerns about whether they will go on to use cigarettes but also because of the unknown short- and long-term effects of e-cigarettes on health.

We agree also that much more needs to be done in the United States and in countries around the world to reduce the burden of combustible products quickly and decisively and to help smokers quit. However, highlighting e-cigarettes and harm reduction as the only solution disregards the critical utility of proven, established, science-supported interventions. We strongly encourage the scientific community to consider how e-cigarettes (in all of their heterogeneity of design and use patterns) perform in the real world when making conclusions about their effects and move away from the opponents/supporters false dichotomy.

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J. E. Cohen and S. Krishnan-Sarin prepared the first draft of the letter. All of the authors reviewed the letter.

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CONFLICTS OF INTEREST

Suchitra Krishnan-Sarin has received free study medications from Astra Zeneca and Novartis to test treatments designed to reduce alcohol drinking behaviors. Thomas Eissenberg is a paid consultant in litigation against the tobacco industry and the electronic cigarette industry and is named on a patent for a device that measures the puffing behavior of electronic cigarette users, a patent application for a smartphone application that determines electronic cigarette device and liquid characteristics, and a patent app for a smoking cessation intervention. Eric Soule is named on a patent application for a smartphone app that determines electronic cigarette device and liquid characteristics.

REFERENCE

1. Balfour DJK, Benowitz NL, Colby SM, et al. Balancing consideration of the risks and benefits of e-cigarettes. *Am J Public Health*. 2021;111(9):1661–1672. https://doi.org/10.2105/AJPH.2021.306416

Editorial Note

Farzana Kapadia, PhD, MPH

ABOUT THE AUTHOR

Farzana Kapadia is with the Department of Epidemiology, New York University School of Global Public Health, New York, NY. She is also the Deputy Editor of AJPH.

This letter by Cohen et al. (p. XXX) caps a series of letters and letter responses regarding a previous publication by Balfour et al.[1] on the risks versus benefits of e-cigarette products. Cohen et al. offer thoughtful and judicious advice to the public health and scientific communities as well as advocates who approach this debate from all perspectives.

To be clear, there are many questions about e-cigarette products that are still unanswered. Undoubtedly, more empirical data from rigorously designed and conducted studies are warranted. Careful evaluation and, yes, reevaluation of the strengths and biases of these studies will be required as we move forward. A balanced consideration of the real-world impacts occurring in parallel among adults and adolescents will be warranted. Further reconsideration of all of these factors will be necessary as manufacturers continue to reformulate and remarket e-cigarette products. We can agree that the end goal is to inform and advance the correct policies on e-cigarette use: ones that minimize harms in all populations. We can respond to this call and advocate for the best policies by allowing constructive and collaborative dialogue that is guided by the totality of the evidence as it emerges.

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science-supported interventions. We strongly encourage the scientific community to consider how e-cigarettes (in all of their heterogeneity of design and use patterns) perform in the real world when making conclusions about their effects and move away from the opponents/supporters false dichotomy.

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Correspondence should be sent to Joanna E. Cohen, PhD, Institute for Global Tobacco Control, Department of Health, Behavior and Society, Johns Hopkins Bloomberg School of Public Health, 2213 McElderry St, 4th Floor, Baltimore, MD 21205 (e-mail: jcohen@jhu.edu). Reprints can be ordered at http://www.ajph.org by clicking the “Reprints” link.

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CONTRIBUTORS

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CONFLICTS OF INTEREST

The author has no conflict of interest to report.

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Erratum In: State-Level Sexism and Women’s Health Care Access in the United States: Differences by Race/Ethnicity, 2014–2019

In: Rapp KS, Volpe VV, Neukrug H. State-level sexism and women’s health care access in the United States: differences by race/ethnicity, 2014–2019. *Am J Public Health*. 2021; 111(10):1796–1805. https://doi.org/10.2105/AJPH.2021.306455

On page 1799, the rows with percentages for “Less than high school” and “High school degree or equivalent” were interchanged in Table 1. This portion of Table 1 should appear as follows:

TABLE 1— Descriptive Statistics, Consumer Survey of Health Care Access: United States, 2014–2019

	Non-Hispanic White (n=8756), Mean (SD) or %	Non-Hispanic Black (n=1060), Mean (SD) or %	Hispanic (n=1082), Mean (SD) or %	Racial/Ethnic Difference *P*
Education				.003
Less than high school	4.23	5.73	5.47	
High school degree or equivalent	33.8	30.33	28.31	
Some college	36.29	38.32	36.07	
College or more	25.68	25.63	30.15	

This correction does not affect the paper’s conclusions.

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